NORTH WEST

LABS

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LABS

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

(248) 301-6917

NORTH WEST LABS

CLIA ID: 23D2126347

Since 2017 , North West Labs has been dedicated to providing best-in-class patient care through our cutting-edge technologies, rigorous quality control measures, comprehensive data analytics and reliable, timely results. Our commitment to state-of-the-art technology and research has allowed us to enhance the accuracy, speed and range of our services strengthening our brand as the trusted laboratory partner in the medical community. North West offers a wide spectrum of clinical tests, anatomical pathology, and toxicology services.

Why our clients choose North West Labs:

- **Local, MI based company proudly serving providers nationwide.**
- **Highest quality diagnostic equipment with most accurate test results**
- **In-Network with EVERY MI based insurance carrier**
- **Low-cost billing for Uninsured patients**
- **EMR Integration with 100 different systems and counting**
- **Industry leading turnaround time**
- **Comprehensive Drug testing menu for both urine and oral fluids**
- **Innovative PCR testing covering a wide-range of specialties**
- **Most advanced client web-portal with customizable reporting and graphical data analysis**
- **Dedicated team of Pathologists covering every sub-specialty made available for consultation anytime**
- **4-hour STAT turnaround time**
- **Best-in-class customer service**

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

Toxicology

URINE AND ORAL FLUID DRUG TESTING

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

TOXICOLOGY TEST REQUISITION FORM

NORTH WEST

29580 Northwestern Hwy Suite 120, Southfield, MI 48034

(248) 301-6917 www.nwlabs.com

PATIENT INFORMATION

Patient Demo Attached ☐

Last Name:_____ First Name:_____

Middle Name:_____ Sex: ☐ Male ☐ Female

Address:_____

City:_____ State:_____ Zip:_____

DOB:___/___/___ Mobile:_____

Email:_____

PRIMARY INSURANCE

☐ Medicare ☐ Medicaid ☐ Commercial ☐ Auto ☐ Workers Comp ☐ Client ☐ Other Insurance

Insurance Name:_____ Subscriber Name:_____

Policy #:_____ DOB:___/___/___

Group #:_____ Relation to Patient: ☐ Self ☐ Spouse ☐ Guardian

Order Screen

☐ 11 Panel Drug Screen With Reflex Confirmation
6-Am, AMP, BZO, BUP, FEN, COC, MET, MTD, OPI, OXY, THC

☐ 10 Panel Drug Screen With Reflex Confirmation
6-Am, AMP, BZO, BUP, FEN, COC, MET, MTD, OPI, OXY

SPECIMEN INFORMATION

___/___/___ DATE COLLECTED | _____ INITIAL | _____:_____ TIME COLLECTED AM PM

URINE ONLY
Temperature read within 4 min. and is in range of 32.2 - 37.3°C (90 - 100°F)
☐ YES ☐ NO If NO: Actual Temp.:_____

Med List Attached ☐ Specimen Source: Urine ☐ Oral Fluid ☐ POC Performed in Office ☐

Reflex Confirmation Definition

1. Confirm all inconsistent results
2. Confirm positive illicit findings
3. Confirm all negative prescribed medications of interest
4. Tests for prescribed medications of interest not available on the presumptive test (example: Gabapentin, Muscle Relaxers, antidepressants, fentanyl etc)
5. Confirm all positive classes of drugs for specific analyte breakdown

OR ORDER CONFIRMATION by drug class or individual analyte

☐ Opiates & Opioids
- ☐ Buprenorphine (Suboxone) + Metabolite
- ☐ Carfentanil (Wildnil)
- ☐ Codeine (Tylenol III) + Metabolites
- ☐ Fentanyl (Actiq) + Metabolite
- ☐ Hydrocodone (Norco) + Metabolites
- ☐ Hydromorphone (Dilaudid)
- ☐ Meperidine (Demerol) + Metabolite
- ☐ Methadone (Dolophine) + Metabolite
- ☐ Mitragynine (Kratom) + Metabolite
- ☐ Morphine (MS Contin)
- ☐ Naloxone (Narcan)
- ☐ Naltrexone (Revia)
- ☐ Oxycodone (Percocet) +Metabolites
- ☐ Oxymorphone (Opana)
- ☐ Sufentanil (Dsuvia)
- ☐ Tapentadol (Nucynta) +Metabolite
- ☐ Tramadol (Ultram) +Metabolite

☐ Benzodiazepines
- ☐ Alprazolam (Xanax) + Metabolite
- ☐ Clonazepam (Klonopin) + Metabolite
- ☐ Diazepam (Valium) + Metabolite
- ☐ Lorazepam (Ativan)
- ☐ Oxazepam (Serax)
- ☐ Temazepam (Restoril) + Metabolite
- ☐ Triazolam (Halcion)

☐ Non-Benzodiazepines Hypnotics
- ☐ Zolpidem (Ambien)

☐ Neuropathic Analgesics
- ☐ Gabapentin (Neurontin)
- ☐ Pregabalin (Lyrica)

☐ Stimulants
- ☐ Amphetamines (Adderall)
- ☐ Lisdexamfetamine (Vyvanse)
- ☐ Methylphenidate (Ritalin/Concerta) + Metabolite
- ☐ Phentermine (Adipex)

☐ Antidepressants
- ☐ Bupropion (Wellbutrin) + Metabolite
- ☐ Buspirone (Buspar)
- ☐ Citalopram/Escitalopram (Celexa/Lexapro)
- ☐ Duloxetine (Cymbalta)
- ☐ Fluoxetine (Prozac)
- ☐ Ketamine (Special K)
- ☐ Mirtazapine (Remeron) + Metabolite
- ☐ Paroxetine (Paxil)
- ☐ Sertraline (Zoloft)
- ☐ Trazodone (Oleptro, Desyrel)
- ☐ Venlafaxine (Effexor) + Metabolite
- ☐ Vortioxetine (Trintellix)

☐ Tricyclic Antidepressants
- ☐ Amitriptyline (Elavil) + Metabolite
- ☐ Doxepin (Aponal)
- ☐ Imipramine (Tofranil)
- ☐ Nortriptyline (Pamelor)

☐ Antipsychotics
- ☐ Aripiprazole (Abilify)
- ☐ Asenapine (Saphris)
- ☐ Brexpiprazole (Rexulti)
- ☐ Cariprazine (Vraylar)
- ☐ Clozapine (Clozaril)
- ☐ Fluphenazine (Prolixin/Permitil)
- ☐ Haloperidol (Haldol)
- ☐ Lamotrigine (Lamictal)
- ☐ Lurasidone (Latuda)
- ☐ Olanzapine (Zyprexa)
- ☐ Quetiapine (Seroquel) + Metabolite
- ☐ Risperidone (Risperdal) + Metabolite
- ☐ Ziprasidone (Geodon, Zeldox)

☐ Anticonvulsants/Mood Stabilizers
- ☐ Carbamazepine (Tegretol) + Metabolite
- ☐ Oxcarbazepine (Trileptal)
- ☐ Paliperidone (Invega)

☐ Barbiturates
- ☐ Butalbital (Fioricet)
- ☐ Phenobarbital (Solfoton)

☐ Muscle Relaxants
- ☐ Carisoprodol (Soma) + Metabolite
- ☐ Cyclobenzaprine (Flexeril)
- ☐ Meprobamate (Equanil)
- ☐ Xylazine (Rompun) + Metabolite

☐ Illicits
- ☐ 6-MAM (Heroin) + Metabolite
- ☐ Cocaine + Metabolite
- ☐ MDMA (Ecstasy)
- ☐ Methamphetamine (Desoxyn) (Crystal Meth)
- ☐ THC-COOH (Marijuana Metabolite)

☐ Fentanyl Analogs
- ☐ Acetyl Fentanyl
- ☐ Acetyl Norfentanyl
- ☐ Acrylfentanyl
- ☐ Alfentanil
- ☐ Butyryl Fentanyl
- ☐ Cyclopropyl Fentanyl
- ☐ Furanyl Fentanyl
- ☐ Valeryl Fentanyl

Additional Analytes
- ☐ Acetaminophen (OTC Tylenol)
- ☐ Butabarbital (Butisol)
- ☐ Chlordiazepoxide (Librium)
- ☐ Clomipramine (Anafranil)
- ☐ Cotinine (Nicotine)
- ☐ Dextromethorphan (Robitussin)
- ☐ Diphenhydramine (Benadryl)
- ☐ JWH-018 (Spice, K2)
- ☐ JWH-250
- ☐ Lysergic Acid Diethylamide (LSD)
- ☐ MDEA (Eve)
- ☐ MDPV (Bath Salt)
- ☐ Mephedrone (White Magic)
- ☐ Methylone (bubbles, explosion)
- ☐ Midazolam (Versed)
- ☐ PCP (Phencyclidine) (Angel Dust)
- ☐ Pentazocine (Talwin)
- ☐ Propoxyphene (Darvocet)
- ☐ Secobarbital (Seconal and Tuinal)
- ☐ Topiramate (Topamax)
- ☐ Zaleplon (Sonata)

☐ ETG/ETS (Alcohol)

ICD List Disclaimer: It is the sole responsibility of the ordering clinician to diagnose the patient accurately and faithfully. The diagnosis codes provided below are published by the CMS for ease of ordering. Any diagnosis codes on the requisition MUST also be documented in the patients' clinical medical records. Please provide a copy of those records along with the order.

ICD List Disclaimer: It is the sole responsibility of the ordering clinician to diagnose the patient accurately and faithfully. The diagnosis codes provided below are published by the CMS for ease of ordering. Any diagnosis codes on the requisition MUST also be documented in the patients' clinical medical records. Please provide a copy of those records along with the order.

SUD Substance Use Disorder Patients

Primary ☐ Z03.89

SUD Secondary Codes

- ☐ F10.11 Alcohol abuse, in remission
- ☐ F10.130 Alcohol abuse with withdrawal, uncomplicated
- ☐ F10.131 Alcohol abuse with withdrawal delirium
- ☐ F10.132 Alcohol abuse with withdrawal with perceptual disturbance
- ☐ F10.20 Alcohol dependence, uncomplicated
- ☐ F10.930 Alcohol use, unspecified with withdrawal, uncomplicated
- ☐ F10.931 Alcohol use, unspecified with withdrawal delirium
- ☐ F10.932 Alcohol use, unspecified with withdrawal with perceptual disturbance
- ☐ F11.11 Opioid abuse, in remission
- ☐ F11.13 Opioid abuse with withdrawal
- ☐ F11.20 Opioid dependence, uncomplicated
- ☐ F11.220 Opioid dependence with intoxication, uncomplicated
- ☐ F11.221 Opioid dependence with intoxication delirium
- ☐ F11.222 Opioid dependence with intoxication with perceptual disturbance
- ☐ F11.229 Opioid dependence with intoxication, unspecified
- ☐ F11.23 Opioid dependence with withdrawal
- ☐ F11.24 Opioid dependence with opioid-induced mood disorder
- ☐ F11.250 Opioid dependence with opioid-induced psychotic disorder with delusions
- ☐ F11.251 Opioid dependence with opioid-induced psychotic disorder with hallucinations
- ☐ F11.259 Opioid dependence with opioid-induced psychotic disorder, unspecified
- ☐ F11.281 Opioid dependence with opioid-induced sexual dysfunction
- ☐ F11.282 Opioid dependence with opioid-induced sleep disorder
- ☐ F11.288 Opioid dependence with other opioid-induced disorder
- ☐ F11.29 Opioid dependence with unspecified opioid-induced disorder

SUD Secondary Codes

- ☐ F12.11 Cannabis abuse, in remission
- ☐ F12.13 Cannabis abuse with withdrawal
- ☐ F12.23 Cannabis dependence with withdrawal
- ☐ F12.93 Cannabis use, unspecified with withdrawal
- ☐ F13.11 Sedative, hypnotic or anxiolytic abuse, in remission
- ☐ F13.130 Sedative, hypnotic or anxiolytic abuse with withdrawal, uncomplicated
- ☐ F13.131 Sedative, hypnotic or anxiolytic abuse with withdrawal delirium
- ☐ F13.132 Sedative, hypnotic or anxiolytic abuse with withdrawal with perceptual disturbance
- ☐ F14.11 Cocaine abuse, in remission
- ☐ F14.13 Cocaine abuse, unspecified with withdrawal
- ☐ F14.93 Cocaine use, unspecified with withdrawal
- ☐ F15.11 Other stimulant abuse, in remission
- ☐ F15.13 Other stimulant abuse with withdrawal
- ☐ F16.11 Hallucinogen abuse, in remission
- ☐ F18.10 Inhalant abuse, uncomplicated
- ☐ F18.11 Inhalant abuse, in remission
- ☐ F18.120 Inhalant abuse with intoxication, uncomplicated
- ☐ F18.90 Inhalant use, unspecified, uncomplicated
- ☐ F19.11 Other psychoactive substance abuse, in remission
- ☐ F19.130 Other psychoactive substance abuse with withdrawal, uncomplicated
- ☐ F19.131 Other psychoactive substance abuse with withdrawal delirium
- ☐ F19.132 Other psychoactive substance abuse with withdrawal with perceptual disturbance
- ☐ F19.20 Other psychoactive substance dependence, uncomplicated

Provider Acknowledgement:

I acknowledge that documentation to support medical necessity for all tests ordered is recorded in the patients chart. If not signed, the authorized Healthcare Provider affirms that the test orders are placed in the patient file with Provider Signature and will be available upon request. The office of the inspector general requires documentation in patient medical chart including date of service, tests ordered, and documentation to support medical necessity. I have taken a risk assessment score and will send that along with the first order for the patient when the patient is a COT patient and I will follow the Medicare guidelines for COT or SUD patients frequency of testing.

Patient Consent:

Authorization to Release Information: I hereby authorize my treating provider NORTHWEST LABS to: (1) release any information necessary to insurance carriers and providers regarding my illness, treatments and results; (2) process insurance claims generated in the course of examination or treatment; and (3) allow a photocopy of my signature to be used to process insurance claims for the period of lifetime. This order will remain in effect until revoked by me in writing.

Provider Signature:
Signature Date:

Patient Signature:
Signature Date:

Version Control #	Issue Date:

NORTH WEST LABS
29580 Northwestern Hwy
Suite 120, Southfield, MI 48034
(248) 301-6917
nwlabs.com
LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

FINAL

Dr Test Test
123 Main St
Southfield, MI 48034
Organization: Example Test

Test, Test
Patient: #: 0000
DOB: 01/01/2001
MRN:
Sex: Female

Accession: xxxxx
Collected Date: 01/01/2001 1:00 PM LAB
Received Date: 01/01/2001 7:10 PM

Drug Adherence Assessment Report

Medications: *Clonazepam [Klonopin], Trazodone [Desyrel]*
Listed Medications Not Tested For: *None*

PRESCRIBED MEDICATIONS

REPORTED PRESCRIPTIONS	ANTICIPATED POSITIVES	MEASURED RESULTS	CUTOFF	TEST OUTCOME	COMMENTS	DETECTION WINDOW
Trazodone [Desyrel]	Trazodone		25	NEGATIVE	Inconsistent	
Clonazepam [Klonopin]	Clonazepam		20	NEGATIVE	Inconsistent	2-7
	7-aminoclonazepam		25	NEGATIVE	Inconsistent	2-7

INCONSISTENT RESULTS - ANALYTE DETECTED BUT NO CORRESPONDING PRESCRIPTION REPORTED

ANALYTE DETECTED	ILLICIT	MEASURED RESULT	CUTOFF	TEST OUTCOME	DETECTION WINDOW
Alpha-hydroxyalprazolam	No	282	25	POSITIVE	2-3
O-desmethyltramadol	No	>2500	25	POSITIVE	1-7
Tramadol	No	>2500	25	POSITIVE	2-4

SPECIMEN VALIDITY TESTING

TEST	MEASURED RESULT	TEST OUTCOME	REFERENCE RANGE
Creatinine	25.00	Normal	20.00 - 400.00
pH	7.30	Normal	4.50 - 9.00
Specific Gravity	1.005	Normal	1.002 - 1.030

HISTORICAL REPORT

Analyte	10/1/2025	3/13/2025	2/12/2025		
Alprazolam		64	71		
Alpha-hydroxyalprazolam		391	844		
Amphetamine		>5000	>5000		
Buprenorphine		55	92		
Norbuprenorphine		29	26		
7-aminoclonazepam	153	322			
Morphine	>2500				
Tramadol	>2500	105	46		
O-desmethyltramadol	>2500	484	136		
THC-COOH		79.8	181.1		

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FINAL

Dr Test Test
123 Main St
Southfield, MI 48034
Organization: Example Test

Test, Test
Patient: #: 0000
DOB: 01/01/2001
MRN:
Sex: Female

Accession: xxxxx
Collected Date: 01/01/2001 1:00 PM LAB
Received Date: 01/01/2001 7:10 PM

NWL Urine Confirmation

Test Name	Outcome	Measured Result	Cutoff	Units	Illicit?	Status
Trazodone						*Run by TE on 11/20/2025 4:32:49 PM at Locatio*
Trazodone	NEGATIVE		25	ng/ml	No	Inconsistent Result
OPIATES & OPIOIDS						*Run by TE on 11/20/2025 4:32:49 PM at Locatio*
Buprenorphine	NEGATIVE		10	ng/mL	No	Consistent Result
Norbuprenorphine	NEGATIVE		10	ng/mL	No	Consistent Result
Carfentanil	NEGATIVE		1	ng/mL	No	Consistent Result
Codeine	NEGATIVE		25	ng/mL	No	Consistent Result
Hydrocodone	NEGATIVE		25	ng/mL	No	Consistent Result
Norhydrocodone	NEGATIVE		25	ng/mL	No	Consistent Result
Morphine	NEGATIVE		25	ng/mL	No	Consistent Result
Hydromorphone	NEGATIVE		25	ng/mL	No	Consistent Result
Fentanyl	NEGATIVE		2.0	ng/mL	No	Consistent Result
Norfentanyl	NEGATIVE		10	ng/mL	No	Consistent Result
Meperidine	NEGATIVE		25	ng/mL	No	Consistent Result
Normeperidine	NEGATIVE		25	ng/mL	No	Consistent Result
Methadone	NEGATIVE		50	ng/mL	No	Consistent Result
EDDP	NEGATIVE		50	ng/mL	No	Consistent Result
Mitragynine	NEGATIVE		2.5	ng/ml	No	Consistent Result
7-Hydroxymitragynine	NEGATIVE		10	ng/ml	No	Consistent Result
Naloxone	NEGATIVE		25	ng/mL	No	Consistent Result
Naltrexone	NEGATIVE		25	ng/mL	No	Consistent Result
Oxycodone	NEGATIVE		25	ng/mL	No	Consistent Result
Noroxycodone	NEGATIVE		25	ng/mL	No	Consistent Result
Oxymorphone	NEGATIVE		25	ng/mL	No	Consistent Result
Sufentanil	NEGATIVE		10	ng/ml	No	Consistent Result
Tapentadol	NEGATIVE		25	ng/mL	No	Consistent Result
N-desmethyltapentadol	NEGATIVE		25	ng/mL	No	Consistent Result
Tramadol	POSITIVE	>2500	25	ng/mL	No	Inconsistent Result
O-desmethyltramadol	POSITIVE	>2500	25	ng/mL	No	Inconsistent Result

Clinical Laboratory SERVICES

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

BLOOD TEST REQUISITION FORM

NORTH WEST LABS
29580 Northwestern Hwy Suite 120, Southfield, MI 48034
(248) 301-6917 www.nwlabs.com

PATIENT INFORMATION Patient Demo Attached ☐

Last Name: _____ First Name: _____

Middle Name: _____ Sex: ☐ Male ☐ Female

Address: _____

City: _____ State: _____ Zip: _____

DOB: ____/____/_____ Mobile: _____

Email: _____

PROVIDER

OTHER INFORMATION

ALLERGIES ☐ Y ☐ N PREGNANT ☐ Y ☐ N PEDIATRIC ☐ Y ☐ N

Specimen Information

☐ Urine ☐ Blood ☐ Other

Date of Collection:____/____/_____ Time:_____ Collector Initials:_____

INSURANCE INFORMATION ☐ Commercial Insurance ☐ Medicare ☐ Medicaid ☐ Self-Pay ☐ Bill to Client

Relationship to Insured: ☐ Self ☐ Spouse ☐ Child ☐ Other: _____ Insurance Company: _____

Name of Insured: _____ Group Number: _____

Policy Number: _____ DOB of Insured: ____/____/_____ *Please attach copy of the insurance card & other demographics

PLEASE MARK THE DESIRED TEST (S) OR PANELS TO BE TESTED

PANELS

- ☐ Acute Hepatitis Screen [AHS]
- ☐ Alb/Creat Ratio, Urine [UACR]
- ☐ Amylase, 24 hrUrine [24HUAMY]
- ☐ Anemia Panel [ANEMIA]
- ☐ Basic Metabolic Panel [BMP]
- ☐ Calcium, 24 hr Urine [24HUCA]
- ☐ Calcium/Creatinine Ratio [CACRER]
- ☐ Cardiac Risk Panel [CARDIAC]
- ☐ Chloride, 24 hr Urine [24HUCL]
- ☐ Comprehensive Metabolic Panel [CMP]
- ☐ Creatinine Clearance [CC]
- ☐ Creatinine, UR Random [UCRE2]
- ☐ Depression Screen Panel [DSP]
- ☐ eGFR Panel [GFR]
- ☐ Electrolyte Panel [LYTES]
- ☐ Female Health Screen Panel [FHS]
- ☐ Female Hormone Panel [FHP]
- ☐ Female Weight Loss Panel [FWLP]
- ☐ General Health Panel [GHP]
- ☐ Gestational Glucose Tolerance Profile [GGTP]
- ☐ Glucose-1 hour [GLU1H]
- ☐ Glucose-2 hour [GLU2H]
- ☐ Glucose-3 hour [GLU3H]
- ☐ Glucose-Fasting [GLUF]
- ☐ Glucose 24hour [24HRUGLU]
- ☐ Iron Panel [FEP]
- ☐ Lipid Panel [LIPD]
- ☐ Liver Panel [LIVR]
- ☐ Magnesium, 24hr Urine [24HUMG]
- ☐ Male Health Screen Panel [MHS]
- ☐ Male Hormone Panel [MHP]
- ☐ Male Weight Loss Panel [MWLP]
- ☐ Obesity Panel [OP]
- ☐ Obstetric & HIV Panel [OB2]
- ☐ Obstetric Panel [OB1]
- ☐ Phosphorus, 24 hr Urine [24HUIPHOS]
- ☐ Potassium, 24 hr Urine [24HUK]
- ☐ Protein/Creatinine Ratio [PRCRR]
- ☐ Renal Panel [RENAL]
- ☐ Sodium, 24 hr Urine [24HRUNA]
- ☐ Testosterone Evaluation Profile [FTESTOE]
- ☐ Thyroid Panel [THYP]
- ☐ Urea Nitrogen, 24 hr Urine [24HUBUN]
- ☐ Uric Acid, 24 hr Urine [24HUURCA]

BLOOD BANK

- ☐ ABO Grouping and Rho(D) Typing [ABORH]
- ☐ Antibody Screen [ABSCRN]

CHEMISTRY

Chemistry/Immunoassay - Diabetes

- ☐ C-Peptide [CPS]
- ☐ Hemaglobin A1C [A1C]
- ☐ Insulin [IRI]

Chemistry - General Chemistry

- ☐ Alanine Aminotransferase (SGPT) [ALT]
- ☐ Aspartate Aminotransferase (SGOT) [AST]
- ☐ Albumin [ALBP]
- ☐ Alkaline Phospatase [ALP]
- ☐ Amylase [AMY]
- ☐ Bilirubin, Direct [DBIL]
- ☐ Bilirubin,Total [TBIL]
- ☐ Calcium [CA]
- ☐ Cholesterol [CHOL]
- ☐ Creatine Kinase [CK]
- ☐ Creatinine [CREA]
- ☐ Gamma Glutamyltransferase [GGT]
- ☐ Glucose [GLU]
- ☐ HDL Cholesterol [HDLC]
- ☐ Iron [IRON]
- ☐ Lactate [LAC]
- ☐ Lactate Dehydrogenase [LDLP]
- ☐ LDL Cholestrol [LDLC]
- ☐ Lipase [LIP]
- ☐ Magnesium [MG]
- ☐ Microalbumin, Urine [MALB]
- ☐ Inorganic Phosphorus [IPHOS]
- ☐ Potassium [K]
- ☐ Total Iron Binding Capacity + Iron [FETIBC]
- ☐ Total Protein [TP]
- ☐ Triglycerides [TRIG]
- ☐ Uric Acid [URCA]
- ☐ Urinary/Cerebrospinal Fluid Protein [UCFP]

Chemistry - Specific Proteins

- ☐ Complement C3 [C3]
- ☐ Complement C4 [C4]
- ☐ CRP Extended Range [RCRP]
- ☐ CRP High Sensitivity [CCRP]
- ☐ Immunoglobulin A [IGA]
- ☐ Immunoglobulin G [IGG]
- ☐ Immunoglobulin M [IGM]
- ☐ Lipoprotein(a) [LPA]
- ☐ Prealbumin [PALB]
- ☐ Transferrin [TRF]

Chemistry/Immunoassay - Theraputic Drug Monitoring

- ☐ Carbamazepine [CARB]
- ☐ Digoxin [DGN]
- ☐ Gentamicin [GENT]
- ☐ Lithium [LITH]
- ☐ Phenobarbital [PHNB]
- ☐ Phenytoin [PHNY]
- ☐ Valproic Acid [VALP]
- ☐ Vancomycin [VANC]

Immunoassay - Anemia

- ☐ Ferritin [FER]
- ☐ Folate [FOL]
- ☐ Vitamin B-12 [VB12]

Immunoassay - Autoimmune

- ☐ Anti-Cyclic Citrullinated Peptide IgG [ACCP]

Immunoassay - Bone Metabolism

- ☐ Intact Parathyroid Hormone [PTH]
- ☐ Vitamin D Total (25 OH) [VITD]

Immunoassay - Cardiac

- ☐ B-Type Natriuretic Peptide [BNP]
- ☐ Creatine Kinase MB [CKMB]

Immunoassay - Hepatitis

- ☐ Hepatitis A IgM Antibodies [AHAVM]
- ☐ Hepatitis A virus Total Antibodies [HAVT]
- ☐ Hepatitis B Core IgM Antibodies [AHBCM]
- ☐ Hepatitis B Core Total Antibodies [HBCT2]
- ☐ Hepatitis B Surface Antibodies [AHBS2]
- ☐ Hepatitis B Surface Antigen II [HBSAG]
- ☐ Hepatitis C Antibodies [AHCV]

Immunoassay - HIV

- ☐ HIV Ag/Ab Combo (US) [CHIV]

Immunoassay - Inflamation

- ☐ Total IgE [TIGE]

Immunoassay - Metabolic

- ☐ Cortisol [COR]
- ☐ Homocysteine [HCY]

Immunoassay - Oncology

- ☐ Alpha-Fetoprotein [AFP]
- ☐ CA 125II [CA125]
- ☐ CA 15-3 [CA153]
- ☐ CA 19-9 [CA199]
- ☐ Carcinoembryonic Antigen [CEA]
- ☐ Free Prostate Specific Antigen [FPSA]
- ☐ Hybritech p2PSA & phi [P2PSA]
- ☐ Prostate-Specific Antigen [PSA]

Immunoassay - Reproductive Endocrinology

- ☐ Dehydroepiandrosterone Sulfate [DHEAS]
- ☐ Enhanced Estradiol [E2]
- ☐ Follicle Stimulating Hormone [FSH]
- ☐ Total Human Chorionic Gonadotropin [THCG]
- ☐ Luteinizing Hormone [LH]
- ☐ Progesterone [PRGE]
- ☐ Prolactin [PRL]
- ☐ Sex Hormone Binding Globulin [SHBG]
- ☐ Testosterone II [TESTO]

Immunoassay - Special ID

- ☐ Syphilis [SYPH]

Immunoassay - Thyroid

- ☐ Antibody Thyroglobulin II [TGAB]
- ☐ Anti-Thyroid Peroxidase [aTPO]
- ☐ Free Triiodothyronine [FT3]
- ☐ Free Thyroxine [FT4]
- ☐ Thyroglobulin [TG]
- ☐ Total Triiodothyronine [T3]
- ☐ Total Thyroxine [T4]
- ☐ Thyroid-Stimulating Hormone3 Ultra II [TSH3UL]
- ☐ Thyroid Uptake [TUP]

Immunoassay - Torch

- ☐ Cytomegalovirus IgG Antibodies (CMV IgG) [CMVIGG]
- ☐ Herpes-1 IgG [HSV1]
- ☐ Herpes-2 IgG [HSV2]
- ☐ Rubella IgG [RUBG]
- ☐ Rubella IgM [RUBM]
- ☐ Toxoplasma G [TOXOG]
- ☐ Toxoplasma M [TOXOM]

COAGULATION

- ☐ D-Dimer [DDIMER]
- ☐ Prothrombin Time/INR [PTINR]
- ☐ Partial Thromboplastin Time [aPTT]

HEMATOLOGY

- ☐ CBC [CBC]
- ☐ CBC W/ Diff [CBCD]
- ☐ Hemoglobin/Hematocrit [HH]
- ☐ Manual Differential [DIFF]
- ☐ Plateletes [PLT]
- ☐ Retic [RETIC]
- ☐ Sed Rate [ESR]
- ☐ Sickle Cell Screen [SCS]

MICROBIOLOGY - MISCELLANOUS

- ☐ Helicobacter pylori breathing test [HP]
- ☐ Rapid Fecal Occult Blood Test [FOBT]
- ☐ Streptococcus group A [GAS]
- ☐ Urine Pregnancy Test [UHCG]

SEROLOGY

- ☐ Anti-Streptolysin-O [ASO]
- ☐ Mononucleosis Spot Test [MONO]
- ☐ RPR Screen w/Reflex to Titer [RPRRFLX]

URINALYSIS

- ☐ Urinalysis Macro Only [URMAC]
- ☐ Urine Microscopic [URMIC]
- ☐ Urinalysis, Routine with Reflex to Microscopic [UA]

Tube Color Key Code	
Sodium Fluoride Potassium	
RED TOP (NO GEL)	NO ADDITIVE URINE
LAVENDER TOP	LIGHT BLUE
SST	UA TIGER TOP

Other Tests:

DIAGNOSIS (ICD-10) INFORMATION

BASIC METABOLIC PANEL

- ☐ E11.9 - Diabetes Mellitus, Unspecified
- ☐ I50.9 - Heart Failure, Unspecified
- ☐ E78.5 - Hyperlipidemia, Unspecified
- ☐ I10 - Hypertension, Essential Unspecified
- ☐ E87.1 - Hyponatremia
- ☐ E87.6 - Hypokalemia
- ☐ E03.9 - Hypothyroidism, Unspecified
- ☐ E78.2 - Mixed Hyperlipidemia
- ☐ E66.9 - Obesity, Unspecified
- ☐ Z79.899 - Other Long-term Current Drug Therapy
- ☐ E03.8 - Other Specified Hypothyroidism
- ☐ R79.89 - Other Specified Abnormal Findings of Blood Chemistry
- ☐ N28.9 - Renal Insufficiency Acute
- ☐ E11.65 - Type 2 Diabetes Mellitus with Hyperglycemia
- ☐ E11.21 - Type 2 Diabetes Mellitus with Diabetic Nephropathy
- ☐ E11.69 - Type 2 Diabetes Mellitus with Other Specified Complications
- ☐ E11.9 - Type 2 Diabetes Mellitus Without Complications
- ☐ N39.0 - Urinary Tract Infection (UTI)

COMPLETE BLOOD COUNT

- ☐ R78.71 - Abnormal Lead Level in Blood
- ☐ R10.9 - Abdominal Pain, Unspecified
- ☐ R63.4 - Abnormal Weight Loss
- ☐ D50.9 - Anemia, Iron Deficiency, Unspecified
- ☐ D53.9 - Anemia, Nutritional, Unspecified
- ☐ D64.9 - Anemia, Unspecified
- ☐ I25.10 - Atherosclerotic Heart Disease of Native Coronary Artery Without Angina
- ☐ N18.3 - Chronic Kidney Disease Stage 3, Moderate
- ☐ R42 - Dizziness and Giddiness
- ☐ Z51.81 - Encounter for Therapeutic Drug Monitoring
- ☐ K21.9 - Gastro-Esophageal Reflux Disease Without Esophagitis
- ☐ I10 - Hypertension, Essential Unspecified
- ☐ E78.5 - Hyperlipidemia, Unspecified
- ☐ E03.9 - Hypothyroidism, Unspecified
- ☐ R73.01 - Impaired Fasting Glucose
- ☐ Z79.01 - Long-term Use of Anticoagulants
- ☐ Z79.899 - Long-term Use of Other Meds
- ☐ E78.2 - Mixed Hyperlipidemia
- ☐ R73.09 - Other Abnormal Glucose
- ☐ R53.83 - Other Fatigue
- ☐ R79.89 - Other Specified Abnormal Findings of Blood Chemistry
- ☐ E78.00 - Pure Hypercholesterolemia, Unspecified
- ☐ R55.9 - Syncope and Collapse
- ☐ E11.65 - Type 2 Diabetes Mellitus with Hyperglycemia
- ☐ E11.9 - Type 2 Diabetes Mellitus Without Complications
- ☐ N39.0 - Urinary Tract Infection
- ☐ E55.9 - Vitamin D Deficiency, Unspecified

HEPATIC FUNCTION PANEL

- ☐ R74.8 - Abnormal Levels of Other Serum Enzymes
- ☐ R94.5 - Abnormal Results of Liver Function Studies
- ☐ R10.9 - Abdominal Pain, Unspecified
- ☐ R63.4 - Abnormal Weight Loss
- ☐ R63.5 - Abnormal Weight Gain
- ☐ R74.0 - Abnormal Liver Enzymes
- ☐ K75.4 - Autoimmune Hepatitis
- ☐ I50.9 - Congestive Heart Failure, Unspecified
- ☐ R60.9 - Edema
- ☐ Z51.81 - Encounter for Therapeutic Drug Monitoring
- ☐ K76.0 - Fatty Change of Liver NOS
- ☐ R50.9 - Fever, Unspecified
- ☐ B16.9 - Hepatitis B, Acute NOS
- ☐ B17.10 - Hepatitis C, Acute Non
- ☐ Z79.01 - Long-term Use of Anticoagulants
- ☐ Z79.891 - Long-term Use of Opiate Analgesic
- ☐ R53.83 - Other Fatigue
- ☐ Z79.899 - Other Long-term Current Drug Therapy
- ☐ K76.89 - Other Specified Disease of Liver
- ☐ R53.81 - Malaise
- ☐ R53.1 - Weakness

ACUTE HEPATITIS PANEL

- ☐ R10.9 - Abdominal Pain, Unspecified
- ☐ R74.0 - Abnormal Liver Enzymes
- ☐ R63.4 - Abnormal Weight Loss
- ☐ B17.9 - Acute Viral Hepatitis, Unspecified
- ☐ K74.60 - Cirrhosis of Liver, Without Alcohol, NOS
- ☐ B18.2 - Chronic Viral Hepatitis C
- ☐ Z01.89 - Encounter for Other Specified Special Examinations
- ☐ R53.83 - Fatigue
- ☐ R10.84 - Generalized Abdominal Pain
- ☐ K75.9 - Hepatitis, Unspecified
- ☐ K75.9 - Inflammatory Liver Disease, Unspecified
- ☐ R11.0 - Nausea
- ☐ R11.2 - Nausea with Vomiting
- ☐ R53.81 - Other Malaise
- ☐ B19.9 - Viral Hepatitis, NOS

LIPID & CHOLESTEROL

- ☐ R79.9 - Abnormal Finding of Blood Chemistry, Unspecified
- ☐ N18.9 - Chronic Kidney Disease, Unspecified
- ☐ I50.9 - Congestive Heart Failure, Unspecified
- ☐ I25.10 - Coronary Atherosclerosis
- ☐ E11.9 - Diabetes Mellitus, Unspecified
- ☐ Z51.81 - Encounter for Therapeutic Drug Monitoring
- ☐ E78.5 - Hyperlipidemia, Unspecified
- ☐ I10 - Hypertension, Essential Unspecified
- ☐ E03.9 - Hypothyroidism, Unspecified
- ☐ E78.2 - Mixed Hyperlipidemia
- ☐ E66.9 - Obesity, Unspecified
- ☐ Z79.899 - Other Long-term Current Drug Therapy
- ☐ E03.8 - Other Specified Hypothyroidism
- ☐ R79.89 - Other Specified Abnormal Findings of Blood Chemistry
- ☐ E78.1 - Pure Hyperglyceridemia
- ☐ E78.00 - Pure Hypercholesterolemia, Unspecified
- ☐ E11.65 - Type 2 Diabetes Mellitus with Hyperglycemia
- ☐ E11.21 - Type 2 Diabetes Mellitus with Diabetic Nephropathy
- ☐ E11.69 - Type 2 Diabetes Mellitus with Other Specified Complications
- ☐ E11.9 - Type 2 Diabetes Mellitus Without Complications

THYROID PANEL

- ☐ R94.6 - Abnormal Results of Thyroid Function Studies
- ☐ R63.4 - Abnormal Weight Loss
- ☐ R63.5 - Abnormal Weight Gain
- ☐ G30.9 - Alzheimer's Disease, Unspecified
- ☐ D64.9 - Anemia, Unspecified
- ☐ F41.9 - Anxiety, Unspecified
- ☐ I48.91 - Atrial Fibrillation
- ☐ E06.3 - Autoimmune Thyroiditis
- ☐ I50.9 - Congestive Heart Failure, Unspecified
- ☐ K59.00 - Constipation, Unspecified
- ☐ F03.90 - Dementia, Unspecified
- ☐ F32.9 - Depression
- ☐ E11.9 - Diabetes Mellitus, Unspecified
- ☐ E07.9 - Disorder of Thyroid, Unspecified
- ☐ R60.9 - Edema
- ☐ R53.83 - Fatigue
- ☐ R50.9 - Fever, Unspecified
- ☐ E04.9 - Goiter, Unspecified
- ☐ E78.5 - Hyperlipidemia, Unspecified
- ☐ I10 - Hypertension, Essential Unspecified
- ☐ E05.90 - Hyperthyroidism, Unspecified
- ☐ E03.9 - Hypothyroidism, Unspecified
- ☐ R53.81 - Malaise
- ☐ R41.3 - Memory Loss
- ☐ R20.0 - Numbness, Skin
- ☐ R73.03 - Prediabetes
- ☐ Z79.899 - Other Long-term Current Drug Therapy
- ☐ E03.8 - Other Specified Hypothyroidism
- ☐ R00.2 - Palpitations
- ☐ F03.90 - Senile Dementia, Uncomplicated
- ☐ E11.65 - Type 2 Diabetes Mellitus with Hyperglycemia
- ☐ E11.9 - Type 2 Diabetes Mellitus Without Complications

URINALYSIS

- ☐ R10.9 - Abdominal Pain, Unspecified
- ☐ N18.9 - Chronic Kidney Disease, Unspecified
- ☐ I50.9 - Congestive Heart Failure, Unspecified
- ☐ E11.9 - Diabetes Mellitus, Unspecified
- ☐ R30.0 - Dysuria
- ☐ R53.83 - Fatigue
- ☐ R50.9 - Fever, Unspecified
- ☐ R31.9 - Hematuria, Unspecified
- ☐ I10 - Hypertension, Essential Unspecified
- ☐ R53.81 - Malaise
- ☐ C61 - Malignant Neoplasm of Prostate
- ☐ R35.1 - Nocturia
- ☐ R82.99 - Nonspecific Findings on Examination of Urine
- ☐ Z79.899 - Other Long-term Current Drug Therapy
- ☐ R39.9 - Other Symptoms of Urinary System
- ☐ M06.9 - Rheumatoid Arthritis, Unspecified
- ☐ N28.9 - Renal Insufficiency, Acute
- ☐ R33.9 - Retention of Urine, Unspecified
- ☐ R35.0 - Urinary Frequency
- ☐ R32 - Urinary Incontinence, Unspecified
- ☐ N39.0 - Urinary Tract Infection (UTI)

OTHER

PATIENT AUTHORIZATION

I understand that I am responsible for all co-pays and deductibles, and for amounts not covered by insurance, litigation, or third-party liability. By signing this authorization, I am authorizing to submit claims and acknowledging that payment(s) of authorized insurance benefits or attorney settlements, including but not limited to Medicaid, Medicare, other benefits, or payments shall be made on my behalf of [LAB NAME] for the services provided to pursuant to this Laboratory request and that I will pay for any amounts not covered by other sources. I request that payment of authorized benefits be made on my behalf to [LAB NAME] and/or its Affiliates. If my current policy prohibits direct payments to [LAB NAME] I agree to receive the funds and relinquish them to and/or its [LAB NAME] Affiliates. If my current policy prohibits direct payments to as payment towards charges for services rendered. This payment will not exceed my indebtedness to [LAB NAME], and I understand that I am to determine these benefits payable for related services.

Patient Signature: _____ DATE: _____

AUTHORIZED HEALTHCARE PROVIDER ACKNOWLEDGMENT

I acknowledge that documentation to support medical necessity for all tests ordered is recorded in the patient's chart. If not signed, the Authorized Healthcare Provider affirms that test orders are placed in patient file with provider signature and will be available upon request. The Office of the Inspector General requires documentation in patient medical charts including date of service, tests ordered, and documentation to support medical necessity.

Provider Signature: _____ DATE: _____

NORTH WEST LABS
29580 Northwestern Hwy
Suite 120, Southfield, MI 48034
(248) 301-6917
nwlabs.com
LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

PRELIMINARY

Dr Test Test
123 Main St.
Southfield, MI 48034

Test, Test
Patient: #: 0000
DOB: 01/01/2001
MRN:
Sex: Female

Accession: xxxxx
Collected Date: 01/01/2001 1:00 PM LAB
Received Date: 01/01/2001 7:10 PM

Organization: EXAMPLE TEST

Test Name	Result	Units	Flag	Reference Range/Cutoff
NWL Blood Profiles				
Comprehensive Metabolic Panel [CMP]				*Run by MJ on 11/18/2025 10:28:11 PM at Locati*
A/G Ratio	1.3			0.9 - 1.8
Alanine Aminotransferase (SGPT) [ALTI]	17	U/L		10 - 49
Albumin [ALBP]	3.9	g/dL		3.2 - 4.8
Alkaline Phosphatase [ALPI]	80	U/L		46 - 116
Aspartate Aminotransferase (SGOT) [AST]	29	U/L		<34
Calcium [CA]	8.9	mg/dL		8.7 - 10.4
Carbon Dioxide [ECO2]	26	mmol/L		20 - 31
Chloride [CL]	107	mmol/L		98 - 107
Creatinine [CRE2S]	0.80	mg/dL		0.55 - 1.02
Estimated GFR (eGFR)	102.2			>60.0
Globulin	3.0	g/dL		2.0 - 3.5
Glucose [GLUC]	98	mg/dL		74 - 106
Potassium [K]	3.8	mmol/L		3.5 - 5.1
Sodium [NA]	143	mmol/L		136 - 145
Total Bili [TBI]	0.2	mg/dL	LOW	0.3 - 1.2
Total Protein [TP]	6.9	g/dL		5.7 - 8.2
Urea Nitrogen [BUN]	13	mg/dL		9 - 23
THYROID PANEL [THYP]				*Run by MJ on 11/18/2025 10:28:11 PM at Locati*
Free T3 [FT3]	2.98	pg/mL		2.30 - 4.20
Free T4 [FT4]	1.04	ng/dL		0.89 - 1.76
Thyroxine [T4]	6.1	ug/dL		4.5 - 10.9
Triiodothyronine [T3]	0.91	ng/mL		0.60 - 1.81
TSH3-Ultra II [TSH3U]	1.514	uIU/mL		0.550 - 4.780

Location 1000B: NORTH WEST LABS 29580 Northwestern HWY Suite-120, Southfield, MI 48034 T: (248) 301-6917 www.nwlabs.com
Lab Director: Eugene Olsowka MD CLIA ID# 23D2126347

All tests are performed at Northwest Labs, 29580 Northwestern Hwy Suite 120, Southfield, MI 48034 except some are performed at LabCorp

NORTH WEST LABS
29580 Northwestern Hwy
Suite 120, Southfield, MI 48034
(248) 301-6917
nwlabs.com
LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

PRELIMINARY

Dr Test Test
123 Main St
Southfield, MI 48034

Test, Test
Patient: #: 0000
DOB: 01/01/2001
MRN:
Sex: Female

Accession: xxxxx
Collected Date: 01/01/2001 1:00 PM LAB
Received Date: 01/01/2001 7:10 PM

Organization: EXAMPLE TEST

Test Name	Result	Units	Flag	Reference Range/Cutoff
NWL Blood Profiles				
CBC W/ Diff [CBCD]				*Run by RS on 11/18/2025 9:59:01 PM at Locatio*
WBC Count	4.5	10*3 cells/uL		3.8 - 10.6
RBC Count	4.24	10*6 cells/uL		4.15 - 5.55
Hemoglobin	10.50	g/dL	LOW	12.00 - 15.00
***SPECIMEN CHECKED FOR CLOT. VERIFIED BY RERUN ANALYSIS.				
Calculated Hematocrit	32.6	%	LOW	36.0 - 46.0
MCV	77.0	fL	LOW	80.0 - 100.0
MCV-C1	Microcytosis 1+			
MCH	24.9	pg	LOW	26.0 - 34.0
MCHC	32.3	g/dL		31.0 - 37.0
MCH-C1	Hypochromia 1+			
RDW	14.3	%		11.5 - 15.0
Platelet Count	264	10*3 cells/uL		150 - 450
MPV	9.1	fL		7.3 - 11.4
Neutrophil,%	57	%		40 - 74
Neutrophil,Abs.	2.60	10*3 cells/uL		1.80 - 7.70
Lymphocyte,%	32	%		19 - 48
Lymphocyte,Abs.	1.40	10*3 cells/uL		1.10 - 4.00
Monocyte,%	8	%		3 - 9
Monocyte,Abs.	0.30	10*3 cells/uL		0.00 - 0.80
Eosinophil,%	3	%		0 - 7
Eosinophil,Abs.	0.10	10*3 cells/uL		0.00 - 0.70
Basophil,%	0.9	%		0.0 - 1.5
Basophil,Abs.	0.00	10*3 cells/uL		0.00 - 0.20
NRBC %	0	%		0 - 0
NRBC#	0			0 - 0

Specimen Collection Reference Guide

Questions? Call 248 301 6917

NORTH WEST LABS

Starswab II CTS
OR
BD BBL Culture Swab Plus

Ear, Eye, Nasal, Vaginal, Rectal, Skin, Throat, Tongue, Wound, and other Aerobic/Anaerobic Cultures
Gram Stain

Epredia Biopsy Container

All Sources – Formalin Container

ARX Viral Transport Media

COVID-19 PC
Respiratory Profile PCR
Influenza A & B
RSV

Nasopharyngeal Swab

Bordetella/ Pertussis

Oral Toxicology Swab

Any Confirmation Testing

BD Surepath Swab

Self- Swab HPV

BD Molecular Swab

Vaginal Panel
Vaginal Panel Comprehensive
Vaginal STI Panel

Stuart Media Swab

MRSA NAA

Clean Stool Vial

C-Diff
Fecal Fat
H. Pylori Stool
Lactoferrin, Stool

Stool Culture Vial

Stool Culture

O & P Stool Containers

Ova and Parasites

Fecal Occult Blood Test Kit

Fecal Occult Blood Test

Urine Culture Collection Kit

- Urine Culture & Sensitivity
- Urine UTI PCR

Urinalysis Tube

Urinalysis *ONLY* *(Preferred)*

E Swab

Wound PCR
Additional PCR tests

24 Hour Urine Jug

- Amylase
- Calcium
- Chloride
- Magnesium
- Phosphorus
- Potassium
- Sodium
- Urea Nitrogen
- Uric Acid
- Total Protein
- Protein Elect /IFE

Thin Prep

- PAP Smear
- HPV

Stool

Enteric Solutions Portfolio
- Enteric & Extended Enteric Bacterial Panel
- Enteric Parasite Panel
- Enteric Viral Panel

Healthcare-Associated Infections
- Clostridium Difficile Toxin Panel [CDIFF]

Breath ID Kit

H. Pylori Breath Test
(Blue & Grey bags only)

Viral Transport Media

Herpes Culture
Viral Culture
Varicella Zoaster PCR

Sterile Collection Container

All Urine Drug screen and confirmation testing

Urine
- Urinalysis *(optional)*
- Chlam/GC Urine
- Mycoplasma/Ureaplasma
- Trichomonas

Other
- Body Fluid
- Sputum Culture
- Kidney Stone (4788L)

Plastic Envelope

(nail bag)

Nail Fungal PCR

PGX Kit

PGX

Puritan Swab

Strep A

BD BBL Culture Swab

Group B Strep

Females Only

Mycoplasma & Ureaplasma

Females Only

NORTH WEST LABS

Blood Collection Reference Guide

Questions? Call 248 301 6917



OR


DON'T SPIN

Light Blue

Protime/INR

ALL TESTS BELOW ARE ALWAYS A STAT PICKUP

- D-Dimer
- Antithrombin AG
- Factor VIII
- Factor XI
- Fibrinogen
- Lupus Screen
- Protein C
- Protein S
- PTT
- Thrombine Time

Note: Tube must be filled to the designated line.

****LAB NEEDS TO BE NOTIFIED UPON COLLECTION****

ROYAL / NAVY BLUE

ONLY FOR:
LEAD
HEAVY METALS

SPIN

SST

- Alpha1 Antitryp
- ANTI - DNA
- ANTI - Thyroid Abs
- ASO Titer
- CA 125
- CA 15-3
- CA 19-9
- CCP, Ab, IgG
- CEA
- Ceruloplasmin
- CMP
- C3, C4
- CH50 (frozen)
- Cortisol
- DHEA-S
- Digoxin
- Dilantin
- Electrolytes
- Estradiol
- Ferritin
- Folate
- FSH
- Hep C
- Beta HCG
- Haptoglobin
- HSV-I IgG
- HSV-II IgG
- HIV - I/II
- Immunofixation
- Homocysteine
- IgA, IgE, IgG, IgM
- AFP (tumor marker)
- ANA Multiplex w/ Reflex
- Basic Metabolic Panel
- CRP (ultrasensitive)
- CMV IgG, CMV IgM
- EBV IgG, EBV IgM
- ENA Abs (SSA, SSB, SM, RNP)
- Free Kappa & Lambda
- Valproic Acid (depakote)
- Vitamin B-12
- Vitamin D 25 Hydroxy
- Hepatic Function Panel
- Hep A IgG, Hep A IgM
- Hep B AB Quant
- Hep BS Ag
- Hep B Core IgG
- Hep B Core IgM
- Lyme Disease Ab
- Toxo IgG, Toxo IgM
- Lipid Panel
- LH
- Prealbumin
- Progesterone
- Prolactin
- Protein Elect.
- PSA
- Free PSA
- RA
- RPR
- Syphilis Total AB
- Rubella IgG
- Sars-Cov 2 IgG
- TIBC/UIBC
- Transferrin
- T Uptake
- T3, T4 Free
- T3, T4 Total
- T7
- TSH
- Testosterone Free
- Testosterone Total

SPIN

Lavender

- CBC w/ Diff
- Hgb A1C
- Retic Count
- Sed Rate

ALL TESTS BELOW REQUIRE A DEDICATED TUBE. 1 PER TEST

- Hgb Electrophoresis
- PTH-Intact
- ABO Group & RH Type
- Antibody Scr. ID if Pos.
- BNP

Note: Tube must be full.

-*-AMMONIA -*-

Ammonia must be spun, separated, and frozen

Quantiferon TB Kit

Order of Draw:

1. Grey
2. Green
3. Yellow
4. Lavender

Do NOT use butterfly due to limited vacuum in tubes.

Grey

- Blood Alcohol
- Glucose
- Glucose Challenge - 1 Hr
- Glucose Tolerance - 2 Hr
- Glucose Tolerance - 3 Hr

Notes:

Tube must be minimum half full.

Tubes must have Time of Collection

STAT PICKUP

****LACTIC ACID****

Spin, Separate & Refrigerate

****LAB NEEDS TO BE NOTIFIED UPON COLLECTION****

Red Top

(Clot Activator)

- Lithium
- Phenobarbital
- Tegretol
- Theophylline

SPIN

Wait 20 minutes after collection
Centrifuge for 10 minutes at 3500 RPM

URINE CULTURES MUST BE TRANSFERRED INTO A C&S TUBE WITHIN 20 MINUTES OF COLLECTION

Genetic Testing

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

NORTH WEST LABS

| PREVENTEST™ | Hereditary Cancer Test Requisition Form

29580 Northwestern Hwy Suite 120 ♦ Southfield, MI ♦ ☎ 2483016917 ♦ FAX 2483016805 ♦ ✉ ♦ www.nwlabs.com

1. PATIENT INFORMATION *

Last Name: MI: First Name: Suffix:

Date of Birth: Gender: ◯ Female ◯ Male

Email: Phone:

Street Address:

City: State: Zip:

Race/Ethnicity:

- ◯ African American/Black
- ◯ Ashkenazi Jewish
- ◯ White (Non-Hispanic)
- ◯ Caucasian
- ◯ French Canadian
- ◯ Hispanic/Latin American
- ◯ East Asian
- ◯ South Asian
- ◯ Southeast Asian
- ◯ Mediterranean
- ◯ Middle Eastern
- ◯ Native American
- ◯ Native Hawaiian or other Pacific Islander
- ◯ Adopted
- ◯ Other_____

2. ORDERING PHYSICIAN *

Name: NPI #:

Facility Name:

Street Address:

City: State: Zip:

Phone: Fax:

3. TEST REQUESTED *

◯ **BRCA1 & BRCA2**
For patients meeting hereditary breast and ovarian cancer syndrome testing criteria

AND

◯ **Lynch Syndrome** *(MLH1,MSH2,MSH6,PMS2,EPCAM)*
For patients meeting colorectal cancer syndrome testing criteria

◯ **PREVENTEST™** *(GTR000567625.2) - APC, ATM, AXIN2, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, HOXB13, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, POLE, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RECQL4, RET, RINT1, SMAD4, STK11, TP53*

◯ **Custom** *(specify genes from PREVENTEST™ panel):*

4. PATIENT PERSONAL HISTORY *

◯ No Known Personal History or Current Diagnosis of Cancer
◯ Bone Marrow Transplant Recipient

Cancer				DX Age
◯ Breast	◯ DCIS ◯ Invasive	◯ Triple Negative ◯ Metastatic		
◯ Ovarian				
◯ Prostate	◯ Metastatic	◯ Intraductal		
◯ Pancreatic				
◯ Endometrial/Uterine				
◯ Colorectal/Colon				
◯ Gastric/Stomach				
◯ Kidney				
◯ Colon Polyps: # of Polyps:				

$PREMM_5$ Score:

5. PATIENT FAMILY HISTORY *

◯ No Known Family History
◯ Limited Family Structure: Adopted or < 2 1st/2nd degree relatives past age 45 years old

MS - metastatic cancer **MP** - multiple primaries **IN** - intraductal cancer
3x - triple negative **MT** - metachronous tumor **GS** - gleason score
ST - synchronous tumor **PM** - Premenopausal **HR** - high-risk ethnicity

Relationship	Side of Family	Cancer	Cancer Sub-Type	DX Age

Known Family Mutation: Gene: Variant:

Relationship:

6. ICD-10 CODES *

For Reference:

C18.9: Malignant neoplasm of colon, unspecified
C25.9: Malignant neoplasm of pancreas, unspecified
C50.919: Malignant neoplasm, breast (female), unspecified site
C55: Malignant neoplasm of the uterus, part unspecified
C56.9: Malignant neoplasm, ovary
C61: Malignant neoplasm of prostate

Z80.0: Family history of malignant neoplasm- colon or GI cancers
Z80.3: Family history of malignant neoplasm, breast
Z80.41: Family history of malignant neoplasm, ovary
Z80.42: Family history of prostate cancer
Z80.8: Family history of malignant neoplasm, other specified
Z85.3: Personal history of malignant neoplasm, breast
Z86.010: Personal history of colonic polyps

Selected ICD10 Codes:

◯ **Z01.89** Encounter for other specified special examinations
◯ **Z80.3** Family history of malignant neoplasm, breast
◯ Other ICD10 Codes: _____

7. STATEMENT OF MEDICAL NECESSITY *

TEST REQUESTS WITHOUT A SIGNATURE WILL NOT BE PROCESSED
I affirm that I am authorized under applicable federal and state laws to order genetic testing and have determined that the requested test(s) are medically necessary based on the patient's clinical presentation, personal and/or family history, or differential diagnosis. I certify that all diagnosis codes have been provided to the best of my clinical knowledge and that I have obtained and documented written informed consent from the patient or their legally authorized representative. This consent includes a clear explanation of the purpose, scope, risks, benefits, limitations, and potential outcomes of the testing, as well as the implications for the patient and their family. The patient has also consented to the release of results to a third-party genetic counselor for interpretation, counseling, and insurance-related purposes. I accept responsibility for interpreting and communicating the results to the patient, ensuring appropriate follow-up care, and retaining all related documentation, including the signed informed consent, in the patient's medical record. I confirm that the information submitted on this requisition form is accurate and complete to the best of my knowledge.

8. SAMPLE REQUIREMENTS *

◯ **Mouthwash Sample** OR ◯ **Buccal Swab**

Ordering Physician Signature | Test Ordered Date | Specimen Collected Date

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PATIENT		SPECIMEN		HEALTHCARE PROVIDER
Name: Date of Birth: Gender: Accession #: Test Type:		Specimen Type: Collection Date: Completion of Testing:	**Saliva**	

Ordering Physician:

Result: Positive – Pathogenic Variant Detected in the MSH6 Gene

Note: This variant is associated with Lynch syndrome. The patient may also be considered a carrier for constitutional MMR deficiency (CMMRD) syndrome. Please see section "Reproductive Recommendations."

Additional Findings: No other variants of clinical significance identified.

FINDING	CODON	PROTEIN	INTERPRETATION
MSH6. Frameshift Variant. Exon 6	**c.3514dupA**	**p.Arg1172LysfsTer5**	**PATHOGENIC**

PERSONAL/FAMILY HISTORY SUMMARY AND MANAGEMENT INFORMATION

FAMILY MEMBER	DIAGNOSIS/CANCER	AGE
Mother	Ovarian	57

FAMILY MEMBER	DIAGNOSIS/CANCER	AGE

Genes tested: APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, ELAC2, EPCAM, HOXB13, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, POLE, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RINT1, RET, RECQL4, SMAD4, STK11, TP53.

*Patient personal/family history was provided by the healthcare provider on the requisition form and may not have been verified by GeneID.

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Name:	Accession:	Ordering Physician:

OVERVIEW OF MSH6 PATHOGENIC VARIANTS

- Lynch syndrome is associated with a high risk of colon cancer, especially for those with a family history of colon cancer.[2]
- Lynch syndrome is also associated with elevated risks of gastric, small bowel, urothelial, and central nervous system cancers.[1,3] It has also been associated with an increased risk of breast and prostate cancer, but research is inconclusive, and no current screening or treatment guidelines exist.
- Females with an MSH6 pathogenic variants have a higher risk of endometrial and ovarian cancers than the general population.[3,4]

GENE INFORMATION

The MSH6 gene or mutS homolog 6 encodes for the DNA mismatch repair protein MSH6. Along with the MSH2 protein, the MSH6 protein identifies the location of mistakes made during DNA replication. Once the mistake is identified, other mismatch repair proteins can come in and fix the error. When a mutation occurs within MSH6, the MSH2-MSH6 complex cannot efficiently identify mistakes made in the DNA. Without the ability to identify mistakes the cell cannot repair the errors, leaving cells susceptible to uncontrolled growth. This uncontrolled growth can cause tumors to form, creating an increased risk of cancer.[5]

CANCER RISK

The statistics below refers to the patients with pathogenic variants in comparison to the general population. Having a pathogenic variant does not guarantee cancer, and there are many factors that can contribute to cancer risk.

CONDITION	CANCER	MEAN AGE OF ONSET	RISK WITH MUTATION	GENERAL POPULATION RISK
MSH6-Related Lynch Syndrome	Colon	42 - 69 years	10% - 44% †	4.2%
	Endometrial	53 - 55 years	16% - 49%	3.1%
	Prostate	63 years	11.6%	11.6%
	Ovary (Epithelial)	46 years	≤13*	1.3%
	Stomach	2 cases reported at age 45 and 81	1% - 7.9%	<1%
	Biliary Tract	Not reported	0.2% - 1%	<1%
	Bladder	71 years	1% - 8.2%	2.4%
	Small bowel	54 years	1% - 4%	<1%
	Brain/CNS	43 - 54 years	0.8% - 1.8%	<1%
	Renal Pelvis/Ureter	65 - 69 years	0.7% - 5.5%	<1%
	Breast (Female)	-	12.8%	12.8%
	Pancreas	Not reported	1.4% - 1.6%	<1%
	Skin	See ††		

* Strength of evidence: Mixed

Name:	Accession:	Ordering Physician:

† A meta-analysis has reported cumulative risk for colorectal cancer for MLH1 carriers through age 70 for males to be 43.9% and for females to be 37.3%
†† Frequency of malignant and benign skin tumors such as sebaceous adenocarcinomas, sebaceous adenomas, and keratoacanthomas have been reported to be increased among patients with Lynch syndrome.

RECOMMENDATIONS OVERVIEW

The overview on medical management is based on the genetic test results. The recommendations included below are only those issued by the National Comprehensive Cancer Network® (NCCN®) unless otherwise indicated. Recommendations may focus only on the most common cancers associated with the mutation identified. References are provided and should be relied upon for additional information. Some pathogenic variants may have implications for other conditions. Only cancer-related recommendations are included. Recommendations within this document are for informational purposes only. Specific recommendations and treatment plans should be developed by doctors and genetic counselors with expertise in the relevant syndromes and cancers. Strategies may warrant adjustment due to additional information such as patient medical history, family history, other treatments, or surgeries.

NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN) RECOMMENDATIONS

CANCER	PROTOCOL	SUMMARY	BEGIN	FREQUENCY
Colon[6]	Colonoscopy	Begin at age 30-35, or 2-5 years prior to the earliest incident of colon cancer in the family if the relative was diagnosed before the age of 30.	Age 30-35	Repeat every 1-2 years
	Aspirin	The panel recommends that all individuals with LS who have a risk for future colorectal cancer (i.e., excluding those with prior total proctocolectomy) consider using daily aspirin to reduce their future risk of colorectal cancer. The decision to use aspirin for reduction of colorectal cancer risk in LS and the dose chosen should be made on an individual basis, including discussion of individual risks, benefits, adverse events, and childbearing plans. In determining whether an individual with LS should take aspirin and in deciding on the appropriate dosing, the panel recommends that providers carefully review patient-specific factors that may increase the risk of aspirin therapy – including but not limited to increased age, prior allergy, concurrent use of antiplatelets/anticoagulants, and untreated H. pylori eradication – as well as patient-specific factors that indicate a comparably low future cumulative risk of colorectal cancer (i.e., increased age, history of prior colectomy) and who may thus be less likely to experience significant benefit.		
Endometrial[6,7]	Education	Because endometrial cancer can often be detected early based on symptoms, women should be educated regarding the importance of prompt reporting and evaluation of any abnormal uterine bleeding or postmenopausal bleeding. The evaluation of these symptoms should include an endometrial biopsy.	After diagnosis of LS genetic mutation	-
	Hysterectomy	Total hysterectomy has not been shown to reduce endometrial cancer mortality but can reduce the incidence of endometrial cancer. Hysterectomy is a risk-reducing option that can be considered. Timing of total hysterectomy can be individualized based on whether childbearing is complete, comorbidities, family history, and LS gene, as risks for endometrial cancer vary by pathogenic variant.	Individualized	-
	Screening and biopsy	Endometrial cancer screening does not have proven benefits in women with LS. However, endometrial biopsy is both highly sensitive and highly specific as a diagnostic procedure. Screening via endometrial biopsy can be considered.	Age 30-35, or after diagnosis of LS genetic mutation	Every 1-2 years for biopsy

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CANCER	PROTOCOL	SUMMARY	BEGIN	FREQUENCY
		Transvaginal ultrasound to screen for endometrial cancer in postmenopausal women has not been shown to be sufficiently sensitive or specific as to support a positive recommendation but may be considered at the clinician's discretion. Transvaginal ultrasound is not recommended as a screening tool in premenopausal women due to the wide range of endometrial stripe thickness throughout the normal menstrual cycle.		
Ovarian (Epithelial)[6, 7]	Bilateral Salpingo-oophorectomy	Insufficient evidence exists to make specific recommendations for risk-reducing salpingo-oophorectomy (RRSO) in MSH6 pathogenic variant carriers. Bilateral salpingo-oophorectomy (BSO) may reduce the incidence of ovarian cancer. The decision to have a BSO as a risk-reducing option should be individualized. Timing of BSO should be individualized based on whether childbearing is complete, menopause status, comorbidities, family history of ovarian cancer and Lynch syndrome associated pathogenic variant, as risks for ovarian cancer vary by pathogenic variant. Estrogen replacement after menopausal oophorectomy may be considered.		
	Education	Since there is no effective screening for ovarian cancer, women should be educated on the symptoms that might be associated with the development of ovarian cancer, such as pelvic or abdominal pain, bloating, increased abdominal girth, difficulty eating, early satiety, or urinary frequency or urgency. Symptoms that persist for several weeks and are a change from a woman's baseline should prompt her to seek evaluation by her physician.		
	Screening	Data do not support routine ovarian cancer screening for LS. Transvaginal ultrasound for ovarian cancer screening has not been shown to be sufficiently sensitive or specific as to support a routine recommendation but may be considered at the clinician's discretion. Serum CA-125 is an additional ovarian screening test with caveats similar to transvaginal ultrasound. Consider risk reduction agents for endometrial and ovarian cancers, including discussing risks and benefits.		
Urothelial (renal pelvis, ureter, and/or bladder)[6]	Screening	There is no clear evidence to support surveillance for urothelial cancers in LS. Surveillance may be considered in selected individuals such as those with a family history of urothelial cancer. Surveillance options may include annual urinalysis starting at age 30-35. However, there is insufficient evidence to recommend a particular surveillance strategy.		
Gastric and Small Bowel [6]	Upper Endoscopy	No clear data exist to support surveillance for gastric, duodenal, and more distal small bowel cancer for Lynch syndrome. Individuals with a family history of these tumors may have increased risk, but the benefit of surveillance is unknown. Regarding gastric cancer, risk factors include male sex, older age, MLH1 or MSH2 pathogenic variants, a first-degree relative with gastric cancer, Asian ethnicity, residing in, or immigrant from countries of high background incidence of gastric cancer, chronic autoimmune gastritis, gastric intestinal metaplasia, and gastric adenomas. Consider baseline EGD with random biopsy of the proximal and distal stomach at the time of colonoscopy.	Age 40	Surveillance EGD every 3-5 years in those with above risk factors
	H. pylori screening and treatment	Consider testing and treating H. pylori, if detected.	-	-

Name:	Accession:	Ordering Physician:

CANCER	PROTOCOL	SUMMARY	BEGIN	FREQUENCY
Brain[6]		Patients should be educated regarding signs and symptoms of neurologic cancer and the importance of prompt reporting of abnormal symptoms to their physicians.		
Pancreatic[6, 7]		There are limited data on pancreatic cancer risk among MSH6 pathogenic/likely pathogenic variant carriers. Consider pancreatic cancer screening beginning at age 50 years (or 10 years younger than the earliest exocrine pancreatic cancer diagnosis in the family, whichever is earlier) for individuals with exocrine pancreatic cancer in one or more first or second-degree relatives from the same side of the family as the patient. For individuals considering pancreatic cancer screening, the panel recommends that screening be performed in experienced high-volume centers, ideally under research conditions. The panel recommends that such screening only take place after an in-depth discussion about the potential limitations to the screening, including cost, the high incidence of benign or intermediate pancreatic abnormalities, and uncertainties about potential benefits of pancreatic cancer screening. The panel recommends that screening be considered using annual contrast – enhanced MRI/MRCP and/or EUS, with consideration of shorter screening intervals for individuals found to have worrisome abnormalities on screening. The panel emphasizes that most small cystic lesions found while screening will not warrant biopsy, surgical resection, or any other intervention.		
Breast[6]		There have been suggestions that there is an increased risk for breast cancer in LS patients; however, there is not enough evidence to support increased screening above average-risk breast cancer screening recommendations or those based on personal/family history of breast cancer.		
Skin Manifestations[6]		Frequency of malignant and benign skin tumors such as sebaceous adenocarcinomas, and keratoacanthomas, has been reported to be increased among patients with LS, but cumulative lifetime risk and median age of presentation are uncertain. Consider skin exam every 1-2 years with a health care provider skilled in identifying LS-associated skin manifestations. Age to start surveillance is uncertain and can be individualized.		

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REPRODUCTIVE RECOMMENDATIONS

There is a concern for patients with pathogenic variants in passing their risk onto their children. Patients of reproductive age should be advised about options for prenatal diagnosis and assisted reproduction including pre-implantation genetic diagnosis. Discussion should include known risks, limitations, and benefits of these technologies. Referral to a reproductive specialist and a genetic counselor is recommended.

Beyond the risk of passing the specific variant to their offspring, Lynch syndrome mutations are linked to a rare autosomal recessive condition called constitutional MMR deficiency syndrome (CMMRD syndrome). For this reason, it is recommended that individuals with pathogenic/likely pathogenic variants in the MSH6 gene have their partners tested to determine if they too have a deleterious variant. If both partners are a carrier of a pathogenic/likely pathogenic MSH6 variants, any pregnancy may carry a 25% risk of the child having constitutional MMR deficiency syndrome.

RISK TO FAMILY MEMBER

Blood relatives of pathogenic variant carriers are at an increased risk of having the variant.

- 1st degree relatives (Mother, Father, Sister, Brother, Daughter, Son) of an individual with a mutation have a 50% chance of having the mutation.
- 2nd degree relatives (Grandmother, Grandfather, Aunt, Uncle, Niece, Nephew, Granddaughter, Grandson, as well as Half-Brothers and Half-Sisters) of an individual with a mutation have a 25% chance of having the mutation.
- 3rd degree relatives (Great Grandmother, Great Grandfather, Great Aunt, Great Uncle, Cousins, etc.) of an individual with a mutation have a 12.5% chance of having the mutation.

HIPAA restrictions prevent a physician from sharing this information with family members without permission from the patient. The patient is recommended to share information about possible inherited cancer risk, options for risk assessment and management with family or friends. Recommend genetic counseling and consideration of genetic testing for at-risk relatives.

ADDITIONAL RESOURCES AND SUPPORT

National Society of Genetic Counselors	http://www.nsgc.org/
I Have Lynch Syndrome	http://www.ihavelynchsyndrome.com
Lynch Syndrome international	https://lynchcancers.com
Hereditary Colon Cancer *Takes Guts*	www.hcctakesguts.org/support-organizations
National Comprehensive Cancer Network	http://www.nccn.org/
Genetic Information Nondiscrimination Act	http://www.ginahelp.org/

Name:	Accession:	Ordering Physician:

TECHNICAL OVERVIEW OF MSH6 VARIANT

Finding	Codon	Protein	Interpretation
MSH6. Frameshift Variant. Exon 6	**c.3514dupA**	**p.Arg1172LysfsTer5**	**PATHOGENIC**

The outcomes of this analysis are consistent with a germline heterozygous MSH6 frameshift mutation at Exon 6, noted as c.3514dupA (rs63751327; Chr2: 47804985 on Assembly GRCh38 and Chr2: 48032124 on Assembly GRCh37), which results in an amino acid alteration, replacing an arginine (R) with a lysine (K) at position 1172, and creating a premature stop signal in the new reading frame noted as p.Arg1172LysfsTer5. The substitution is predicted to result in a non-functional protein, either through protein truncation or nonsense-mediated mRNA decay.

This mutation is considered a non-tolerated amino acid change based on “in silico” prediction algorithms (disease causing), and it has been reported as Pathogenic in the ClinVar Database (NCBI National Library of Medicine, NIH, Bethesda MD, 2013, 2014, 2015, 2018, 2019 and 2020). This variant has been previously described in patients with or suspected Lynch Syndrome (Nat Genet. 1999 Oct;23(2):142-4, Fam Cancer. 2009;8(1):75-83, J Med Genet. 2010 Sep;47(9):579-85, Nat Commun. 2017; 8: 14755)

Although the exact risk of cancer conferred by this specific variant has not been determined, studies of this type of mutations in Lynch Syndrome families indicate that pathogenic MSH6 variants may confer as much as a 44% risk of colon cancer, 46% of endometrial cancer and an increased risk of ovarian cancer (NCCN Guideless Version 3, December 2019). It is worth noting that rare MSH6 variants may also predispose to familial breast cancer (Breast Cancer Res Treat. 2010 Sep;123(2):315-20, J Clin Oncol. 2017 Aug 1;35(22):2568-2575) and have been identified in pancreatic cancer patients (Cancer Epidemiol Biomarkers Prev. 2016 Jan;25(1):207-11).

Cancer risks can be further modified by family history, reproductive choices, lifestyle and environmental factors and other genetic factors. Therefore, the contribution of this variant to the relative cancer risk cannot be established solely from this analysis.

ADDITIONAL FINDINGS

Other Variants: Variants of clinical significance are reported. Variants identified as benign or likely benign polymorphisms are not reported. Evidence indicates that these variants do not impact cancer risk.

Current medical opinion recommends against using findings of variants that are not clinically significant to modify patient medical management. Medical management decisions should be made based on personal and family history and any other clinically significant findings.

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PREVENTEST™ MOLECULAR REPORT
PHYSICIAN GUIDE

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Name:	Accession:	Ordering Physician:

SUMMARY & METHODOLOGY

TARGET GENES: 36 germline cancer genes

PREVENTEST® MOLECULAR PANEL is a full risk sequencing of germline mutations involved in familial cancer predisposition. The panel interrogates 36 germline key-cancer predisposition genes, targeting mutational hotspots associated with both common and rare familial cancer syndromes. All translated exons and immediately adjacent intronic regions are sequenced. Single nucleotide polymorphisms, duplications, insertions, deletions, and variants of uncertain significance can be detected. Sequencing analysis on the other genes included in the panel described above are consistent with intron variant and synonymous variant polymorphisms and are considered benign.[9-13]

Genomic DNA from **XXXXXXXXX** submitted specimen was enriched for the complete coding regions and splice site junctions of the genes described in the panel. The products were sequenced on two different massive parallel sequencing platforms; Miniseq Illumina platform (target enrichment) and Ion Torrent Platform (Ion sphere particles - Chef System/S5XL). The sequences were aligned to reference sequences based on Human Genome build GRCh37/UCSChg19. BRCA1/BRCA2, PTEN, APC, MLH1/MSH2, PMS2 (exons 1-11) and MSH6 concurrent deletion/duplication testing was performed by Multiple Ligation Probe Amplification (MLPA). Deletion/duplication analysis determines copy number at a single exon resolution at virtually all targeted exons. However, in sporadic situations, single exon copy number events may not be analyzed due to inherent sequence properties or isolated reduction in data quality. Fragment analysis and comparative analysis were performed by Coffalyser DB software, v.140701 (MRC-Holland). Sequencing bio-informatics pipelines were analyzed by Illumina VariantStudio v.3.0 and Torrent Suite Software v.4.0.2., respectively. Discrepancies between platforms, if any, were resolved by selective incorporation of chain-terminating dideoxynucleotides (Sanger Sequencing) targeting with specific FWD/REV primers, 5' M13 tailed and HPLC purified. All sequence alterations are described according to the Human Genome Variation Society (HGVS) nomenclature guidelines. Genetic data is stored under Variant call format (VCF).[14,15] AMD follows internal policies and ACMG recommendations for variants reporting.[16] Benign and likely benign variants, if present, are not included in this report, but are available upon request.

COMMENTS & CONCLUSION

Most human cancers are "sporadic" because there is no identifiable inherited gene mutation involved. Those cancers develop as a result of environmental factors such as carcinogenic cigarette smoke that randomly induces mutations in cells, leading to uncontrolled growth. Such factors are encountered throughout life and act over a long period of time.

Familial cancers, on the other hand, tend to occur because it is a specific gene with a defined inheritance pattern. Thus, one is born with a preexisting risk factor for cancer, acting as "one strike". Years later another event triggers the cancer growth. Most of the classical familial cancer syndromes involve a tumor suppressor gene with the "two-hit" hypothesis applying to that gene. A person inherits one copy of the mutated gene (first hit), but still has another functional copy of this gene on the other chromosome. Sometime later, a pathogenic variant wipes out the remaining normal copy (second hit), and the ability to regulate cellular growth is lost. This allows a clone of neoplastic cells to arise, and multiple organs can be affected. Thus, familial cancers often involve more than one organ, and affected individuals can have more than one cancer.

PREVENTEST® is a multiple gene panel that includes the most frequent tumor suppressor genes involved in the inheritance of genetic factors increasing cancer risk.

Conclusion: Up to date, the MSH6 variant detected in this patient meets the requirements to be considered pathogenic.

Dr. Daniel Cohen, M.D., Laboratory Director

This report was electronically signed.

Disclaimer: The accompanying Technical Specifications summary describes the analysis, method, performance characteristics, nomenclature, and interpretive criteria of this test. This test result does not exclude the possibility of other predisposing mutations that have been reported in individuals with increased risk. There are infrequent genetic abnormalities in long homopolymers or highly homologous regions that this test may not detect. This result rules out most abnormalities believed to be responsible for hereditary cancer susceptibility due to pathogenic variants on the gene panel described. The classification and interpretation of all variants identified in this assay reflects the current state of scientific understanding at the time this report was issued and may change as new scientific information becomes available. The interpretation of this test may be impacted if the patient has a hematologic malignancy or an allogeneic bone marrow transplant. This test may be considered investigational by some states. This test and its performance characteristics were determined by North West Labs. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Name:	Accession:	Ordering Physician:

ENDNOTES AND FURTHER RESEARCH INFORMATION

(1) Senter, Leigha, et al. "The clinical phenotype of Lynch syndrome due to germ-line PMS2 mutations." *Gastroenterology* 135.2 (2008): 419-428. (2) Peltomäki, Päivi. "Lynch syndrome genes." *Familial cancer* 4.3 (2005): 227-232. (3) Bonadona, Valérie, et al. "Cancer risks associated with germline mutations in MLH1, MSH2, and MSH6 genes in Lynch syndrome." *Jama* 305.22 (2011): 2304-2310. (4) Walsh, Tom, et al. "Mutations in 12 genes for inherited ovarian, fallopian tube, and peritoneal carcinoma identified by massively parallel sequencing." *Proceedings of the National Academy of Sciences* 108.44 (2011): 18032-18037. (5) MSH6: Genetics Home Reference – see https://ghr.nlm.nih.gov/gene/MSH6. (6) Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Genetic/Familial High-Risk Assessment: Colorectal V.2.2021. © National Comprehensive Cancer Network, Inc 2022. All rights reserved. Accessed May 16, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc. (7) Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic V.2.2022. © National Comprehensive Cancer Network, Inc 2022. All rights reserved. Accessed May 16, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc. (8) Flicek, P et al. Ensembl 2013. Nucleic Acids Research (2013) 41(D1):D48-D55 (9) Thorvaldsdóttir, JT et al. Integrative Genomics Viewer (IGV): high-performance genomics data visualization and exploration. Briefings in Bioinformatics (2013) 14(2):178-192. (10) Pruitt, KD et al. The consensus coding sequence (CCDS) project: Identifying a common protein-coding gene set for the human and mouse genomes. Genome Research (2009) 19(7):1316-23. (11) Sherry, ST et al. dbSNP: the NCBI database of genetic variation. Nucleic Acids Research (2001) 29(1):308-11. (12) Fokkema, IF et al. LOVD v.2.0: the next generation in gene variant databases. Human Mutation (2011) 32(5):557-63. (13) Davies, K. Powering Preventative Medicine. DNA Electronics is building the foundations for semiconductor sequencing. Bio-IT World (2011). (14) DNA Electronics Licenses IP to Ion Torrent. GenomeWeb (2010). (15) Richard, S et al. ACMG Laboratory Quality Assurance Laboratory. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genetics in Medicine (2015) 17(5): 405-24.

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A **PREVENTEST™ cancer-risk predisposition test** was ordered on your behalf in consult with your health care provider due to factors such as personal and/or family history of cancer which indicated that you may have a change in your DNA (called a "pathogenic variant") that increases your risk of one or more kinds of cancer.

Result: Positive – Risk-Increasing Variant Found in the MSH6 Gene
Note: This variant is associated with Lynch syndrome.

Additional Findings: All other findings not listed are considered benign and do not increase your risk of cancer.

Your DNA test revealed a pathogenic variant in the MSH6 gene. MSH6 pathogenic variants increase your risk for more than one form of cancer. There are medical interventions that your doctor and genetic counselor can recommend which may help to reduce your risk significantly. A genetic counselor is a genetics expert who is trained in counseling and providing guidance regarding genetics and genetic conditions. A positive result for a mutation does not mean that you will get cancer, but reflects an increased risk compared to the general population without the mutation.

RISK STATISTICS

MSH6 pathogenic variants have been shown to increase the risk of more than one type of cancer. Below are the statistics for the cancers that are most commonly found in patients who have the same pathogenic variant as you.

CONDITION	CANCER	MEAN AGE OF ONSET	RISK WITH MUTATION	GENERAL POPULATION RISK
MSH6-Related Lynch Syndrome	Colon	42 - 69 years	10% - 44%	4.2%
	Endometrial	53 - 55 years	16% - 49%	3.1%
	Prostate	63 years	2.5% - 11.6%	11.6%
	Ovary (Epithelial)	46 years	≤13	1.3%
	Stomach	49 - 63 years	1% - 7.9%	<1%
	Biliary Tract	Not reported	0.2% - 1%	<1%
	Bladder	71 years	1% - 8.2%	2.4%
	Small bowel	54 years	1% - 4%	<1%
	Brain/CNS	43 - 54 years	0.8% - 1.8%	<1%
	Renal Pelvis/Ureter	65 - 69 years	0.7% - 5.5%	<1%
	Breast (Female)	-	11.1% - 12.8%	12.8%
	Pancreas	Not reported	1.4% - 1.6%	<1%

PREVENTEST™ MOLECULAR REPORT
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Name:	Accession:	Ordering Physician:

CAN I REDUCE MY RISK OF CANCER?

Individuals with pathogenic variants in the MSH6 gene are at a higher risk of being diagnosed with cancer than the general population. Whether this will occur is based on many factors such as lifestyle, diet, and other influences. Ask your healthcare provider and genetic counselor about steps you can take to help reduce your risk of a future cancer diagnosis.

HOW DO MY RESULTS AFFECT MY FAMILY?

While this test may only include your specific risk for cancer, your family members are likely to have similar risks. If you have a positive result, your first-degree blood relatives (Mother, Father, Sister, Brother, Daughter, Son) have a 50% risk for the same pathogenic variant. Your second-degree blood relatives (Grandmother, Grandfather, Aunt, Uncle, Niece, Nephew, Granddaughter, Grandson, as well as Half-Brothers and Half-Sisters) will have a 25% risk for the same pathogenic variant, while your third-degree blood relatives (Great Grandmother, Great Grandfather, Great Aunt, Great Uncle, Cousins, etc.) are at a 12.5% risk for the same positive pathogenic variant, indicating a higher risk of cancer.

NEXT STEPS

- Communicate with your doctor to help determine your next steps.
- Speaking to a genetic counselor can help you better understand your risks and options. A genetic counselor can help you understand the impacts of a pathogenic variant, what your options are, and how to communicate with family members you may want to speak to about genetic cancer risks. They can also help you process the information and deal with any emotional ramifications. Your doctor can help you find a genetic counselor, or you can search at www.NSGC.org to find a counselor in your area, or one who provides counseling over the phone.
- If you are considering having children, discuss reproductive options with your doctor, and if needed, a reproductive specialist. When having children, there is a risk of passing the genetic change to them, but options exist to reduce or eliminate this risk.
- Learn about clinical studies that are being done on patients with your genetic conditions. Clinical studies can often provide higher levels of care and cutting-edge options while helping to further the scientific understanding of your condition.
- Connect to others who also have pathogenic variants - you are not alone! There are hundreds of thousands of others who also have pathogenic variants. Support groups and other resources (see below) can be a great source of support and information.

Although recommendations in this report are suggested, and many are recommended by authoritative organizations, the best course of action is to speak to your physician and relevant specialist to determine your next step. It is beneficial to find out as much as you can about your family history of cancer and bring that information with you for any discussions, as that information will play a role in identifying the best course of action.

ADDITIONAL RESOURCES AND SUPPORT

National Society of Genetic Counselors	http://www.nsgc.org/
I Have Lynch Syndrome	http://www.ihavelynchsyndrome.com
Lynch Syndrome international	https://lynchcancers.com
Hereditary Colon Cancer *Takes Guts*	www.hcctakesguts.org/support-organizations
National Comprehensive Cancer Network	http://www.nccn.org/
Genetic Information Nondiscrimination Act	http://www.ginahelp.org/

This document provides an overview of the results for your genetic test for cancer risk. Your doctor has received a more comprehensive report which he/she can share with you. You can also request a full report by sending a request in writing to support@nwlabs.com

North West Labs | 29580 Northwestern Hwy, Ste 120 | Southfield, MI 48034 | Phone: (248) 301-6917 | Fax: (248) 301-6785 | CLIA #23D2126347
NPI # 1568994879 | www.nwlabs.com

NORTH WEST LABS

| Pharmacogenomics Testing | Requisition Form

29580 Northwestern Hwy Suite 120 ♦ Southfield, MI ♦ ☎ 2483016917 ♦ FAX 2483016805 ♦ ✉ ♦ www.nwlabs.com

1. PATIENT INFORMATION *

Last Name: MI: First Name: Suffix:

Date of Birth: Gender: ◯ Female ◯ Male

Email: Phone:

Street Address:

City: State: Zip:

Race/Ethnicity:

- ◯ African American/Black
- ◯ Ashkenazi Jewish
- ◯ White (Non-Hispanic)
- ◯ Caucasian
- ◯ French Canadian
- ◯ Hispanic/Latin American
- ◯ East Asian
- ◯ South Asian
- ◯ Southeast Asian
- ◯ Mediterranean
- ◯ Middle Eastern
- ◯ Native American
- ◯ Native Hawaiian or other Pacific Islander
- ◯ Adopted
- ◯ Other_____

2. ORDERING PHYSICIAN *

Name: NPI #:

Facility Name:

Street Address:

City: State: Zip:

Phone: Fax:

3. TEST REQUESTED *

◯ **COMPREHENSIVE**
ABCB1, ABCG2, ADRA2A, ADRB2, ANKK1, APO-ε, COMT CYP1A2, CYP2B6, CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4 CYP3A5, CYP4F2, DPYD, Factor 2, Factor V, GRIK4, HTR1A HTR2A, HTR2C, ITGB3, MTHFR, NUDT15, OPRM1, SLC6A2 SLCO1B1, TPMT, UGT2B15, VKORC1

◯ **CARDIOVASCULAR**
ADRA2A, APO-ε, CYP1A2, CYP2C19, CYP2C9, CYP2D6 CYP3A4, CYP3A5, CYP4F2, Factor 2, Factor V, ITGB3 MTHFR, SLCO1B1, VKORC1

◯ **PSYCHIATRIC/MENTAL HEALTH**
ABCB1, ADRA2A, COMT, CYP1A2, CYP2B6, CYP2C19 CYP2C9, CYP2D6, CYP3A4, CYP3A5, HTR2A, HTR2C MTHFR, SLC6A2, UGT2B15

◯ **NEURO/PAIN**
ADRA2A, CYP2D6, CYP2C19, CYP3A4 CYP3A5, COMT, HTR2A, UGT2B15

4. LIST OF CURRENT AND PROSPECTIVE MEDICATION(S) *

5. ICD-10 CODES *

PSYCHIATRIC/MENTAL HEALTH

F20.89: Other schizophrenia
F31.62: Bipolar disorder, current episode mixed, moderate
F33.9: Major depressive disorder, recurrent, unspecified
F41.0: Panic disorder [episodic paroxysmal anxiety]
F41.1: Generalized anxiety disorder
F43.12: Post-traumatic stress disorder, chronic
F52.0: Hypoactive sexual desire disorder (HSSD)
F60.5: Obsessive-compulsive personality disorder
F90.8: Attention-deficit hyperactivity disorder, other type
G47.09: Other insomnia
G47.419: Narcolepsy without cataplexy
N95.8: Other specified menopausal and perimenopausal disorders

NEURO/PAIN

F11.23: Opioid dependence with withdrawal
F95.2: Tourettes Disorder
G10: Huntingtons Disease
G40.101: Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109: Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.401: Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.409: Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.811: Lennox-Gastaut syndrome, not intractable, with status epilepticus
M06.8A: Other specified rheumatoid arthritis, other specified site
M19.09: Primary osteoarthritis, other specified site
R52: Pain, unspecified
T75.3: Motion Sickness
T75.3XXA: Motion Sickness, Initial Encounter
T75.3XXS: Motion sickness, sequela
Z48.811: Encounter for surgical aftercare following surgery on the nervous system
Z48.89: Encounter for other specified surgical aftercare

CANCER

C16.9: Malignant neoplasm of stomach, unspecified
C18.9: Malignant neoplasm of colon, unspecified
C25.9: Malignant neoplasm of pancreas, unspecified
C34.9: Malignant neoplasm of unspecified part of unspecified bronchus or lung
C50.919: Malignant neoplasm of unspecified site of unspecified female breast
C91.00: Acute lymphoblastic leukemia not having achieved remission
C91.01: Acute lymphoblastic leukemia, in remission
Z17.0: Estrogen receptor positive status [ER+]
Z17.1: Estrogen receptor negative status [ER-]
Z51.0: Encounter for antineoplastic radiation therapy
Z92.21: Personal history of antineoplastic chemotherapy

OTHER

B20: Human immunodeficiency virus [HIV] disease
B37.8: Candidal esophagitis
B37.89: Other sites of candidiasis
B48.8: Other specified mycoses
E75.22: Gaucher's Disease
K21.9: Gastro-esophageal reflux disease without esophagitis
K25.9: Gastric ulcer, unspecified as acute or chronic, without hemorrhage or perforation
M35.00: Sjogren syndrome, unspecified
N32.81: Overactive Bladder
N39.46*: Mixed incontinence
R11.2: Nausea with vomiting, unspecified
Z16.32: Resistance to antifungal drug(s)
Z94.0: Kidney transplant status
Z94.1: Heart transplant status
Z94.4: Liver transplant status

CARDIOVASCULAR

E11.8*: Type 2 diabetes mellitus with unspecified complications
E66.9: Obesity Unspecified
E78.00: Pure hypercholesterolemia, unspecified
E78.2: Mixed hyperlipidemia
E78.49: Other hyperlipidemia
I10: Essential (primary) hypertension
I20.0: Unstable angina
I21.9: Acute myocardial infarction, unspecified
I21.A9: Other myocardial infarction type
I25.10: Atherosclerotic heart disease of native coronary artery without angina pectoris
I26.09: Other pulmonary embolism with acute cor pulmonale
I48.19: Other persistent atrial fibrillation
I50.9: Heart failure, unspecified
Z72.0: Tobacco use
Z79.01: Long term (current) use of anticoagulants
Z82.49: Family history of ischemic heart disease and other diseases of the circulatory system
Z86.718: Personal history of other venous thrombosis and embolism
Z86.73: Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
Z86.79: Personal history of other diseases of the circulatory system
Z95.4: Presence of other heart-valve replacement
Z98.61: Coronary angioplasty status
Z98.62: Peripheral vascular angioplasty status

SELECTED ICD10 CODES:

◯ Other ICD10 Codes: _____

6. STATEMENT OF MEDICAL NECESSITY *

TEST REQUESTS WITHOUT A SIGNATURE WILL NOT BE PROCESSED
I affirm that I am authorized under applicable federal and state laws to order genetic testing and have determined that the requested test(s) are medically necessary based on the patient's clinical presentation, personal and/or family history, or differential diagnosis. I certify that all diagnosis codes have been provided to the best of my clinical knowledge and that I have obtained and documented written informed consent from the patient or their legally authorized representative. This consent includes a clear explanation of the purpose, scope, risks, benefits, limitations, and potential outcomes of the testing, as well as the implications for the patient and their family. The patient has also consented to the release of results to a third-party genetic counselor for interpretation, counseling, and insurance-related purposes. I accept responsibility for interpreting and communicating the results to the patient, ensuring appropriate follow-up care, and retaining all related documentation, including the signed informed consent, in the patient's medical record. I confirm that the information submitted on this requisition form is accurate and complete to the best of my knowledge.

7. SAMPLE REQUIREMENTS *

◯ **Mouthwash Sample** OR ◯ **Buccal Swab**

Ordering Physician Signature | Test Ordered Date | Specimen Collected Date

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Pgx Comprehensive Report

Current Patient Medications

Atorvastatin, Citalopram, Losartan

Atorvastatin
Lipitor®

Increased Atorvastatin Exposure — ACTIONABLE

SLCO1B1: Decreased Function

The patient's genotype is associated with possible increased atorvastatin exposure. Patients may be at an increased myopathy risk.

Consider starting atorvastatin at doses ≤40 mg. If doses >40 mg are needed, consider combination therapy (e.g., atorvastatin plus a non-statin guideline directed therapy).

Cooper-DeHoff RM, Niemi M, Ramsey LB, Luzum JA, Tarkiainen EK, Straka RJ, Gong L, Tuteja S, Wilke RA, Wadelius M, Larson EA, Roden DM, Klein TE, Yee SW, Krauss RM, Turner RM, Palaniappan L, Gaedigk A, Giacomini KM, Caudle KE, Voora D. The Clinical Pharmacogenetics Implementation Consortium Guideline for SLCO1B1, ABCG2, and CYP2C9 genotypes and Statin-Associated Musculoskeletal Symptoms. Clin Pharmacol Ther 2022 May;111(5):1007-1021.

Lipitor [package insert]. New York, NY: Pfizer Inc.; 2020.

Citalopram
Celexa®

Decreased Citalopram Exposure — INFORMATIVE

CYP2C19: Rapid Metabolizer

The patient's genotype is associated with a decreased exposure to citalopram and may increase risk of therapeutic failure. Citalopram can be initiated at standard label-recommended dosage. If clinical response not achieved, consider a higher maintenance dose or an alternative medication not predominantly metabolized by CYP2C19.

Bousman CA, Stevenson JM, Ramsey LB, Sangkuhl K, Hicks JK, Strawn JR, Singh AB, Ruaño G, Mueller DJ, Tsermpini EE, Brown JT, Bell GC, Leeder JS, Gaedigk A, Scott SA, Klein TE, Caudle KE, Bishop JR. Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for CYP2D6, CYP2C19, CYP2B6, SLC6A4, and HTR2A Genotypes and Serotonin Reuptake Inhibitor Antidepressants. Clin Pharmacol Ther. 2023 Apr 9. doi: 10.1002/cpt.2903. Epub ahead of print. PMID: 37032427.

Losartan
Cozaar®, Hyzaar®

Normal Response to Losartan — INFORMATIVE

CYP2C9: Normal Metabolizer

Losartan is metabolized to its active metabolite by CYP2C9 and CYP3A4. The patient's genotype predicts a normal exposure to losartan and its active metabolite. Losartan can be prescribed at label-recommended dosage and administration.

Dorado P, Beltrán LJ, Machín E, Peñas-Lledó EM, Terán E, Llerena A, . Losartan hydroxylation phenotype in an Ecuadorian population: influence of CYP2C9 genetic polymorphism, habits and gender. Pharmacogenomics 2012 Nov;13(15):1711-7.

Joy MS, Dornbrook-Lavender K, Blaisdell J, Hilliard T, Boyette T, Hu Y, Hogan SL, Candiani C, Falk RJ, Goldstein JA. CYP2C9 genotype and pharmacodynamic responses to losartan in patients with primary and secondary kidney diseases. Eur J Clin Pharmacol 2009 Sep;65(9):947-53.

Bae JW, Choi CI, Lee HI, Lee YJ, Jang CG, Lee SY. Effects of CYP2C9*1/*3 and *1/*13 on the pharmacokinetics of losartan and its active metabolite E-3174. Int J Clin Pharmacol Ther 2012 Sep;50(9):683-9.

Unrecognized Medications: None
Outside of Scope Medications: Gabapentin, Mirtazapine

Risk Management

Hyperuricemia and Gout

Normal Risk of Gout

The patient carries two copies of ABCG2 rs2231142 C allele.

The ABCG2 rs2231142 C allele is associated with normal ABCG2 activity and subsequent normal renal elimination of uric acid. The patient's genotype is associated with a normal risk of hyperuricemia and gout.

No action is needed for this patient unless other genetic or non-genetic risk factors are present.

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Potentially Impacted Medications

Medications are binned according to their respective therapeutic class and specialty, as well as the predicted impact of the patient's genotypes. The drugs that appear in this table are based solely on the patient's genetic results. Please note that there are available alternative medications that do not have PGx guidance and are not included within this report.

CATEGORY	DRUG CLASS	STANDARD PRECAUTIONS	CAUTION	ALTERNATIVES RECOMMENDED
Anticancer Agents	Anti-Estrogens	Tamoxifen (Nolvadex®, Soltamox®)		
	Antifolates	Methotrexate (Trexall®)		
	Fluoropyrimidines	Capecitabine (Xeloda®) Fluorouracil (Adrucil® (IV); Carac® (topical); Efudex® (topical))		
	Protein Kinase Inhibitors	Erdafitinib (Balversa®) Gefitinib (Iressa®)		
	Taxanes	Paclitaxel (Taxol®, Abraxane®)		
	Thiopurines	Azathioprine (Azasan®, Imuran®) Mercaptopurine (Purinethol®, Purixan®) Thioguanine (Tabloid®)		
Antihistamines	Histamine (H1) Receptor Antagonists	Meclizine (Antivert®)		
Cardiovascular	Angiotensin II Receptor Antagonists	Azilsartan (Edarbi®, Edarbyclor®) Irbesartan (Avapro®) Losartan (Cozaar®, Hyzaar®)		
	Antianginal Agents	Ranolazine (Ranexa®)		
	Antiarrhythmics	Flecainide (Tambocor®) Mexiletine (Mexitil®) Propafenone (Rythmol®)		
	Anticoagulants		Warfarin (Coumadin®)	
	Antiplatelets	Clopidogrel (Plavix®)		
	Beta Blockers	Carvedilol (Coreg®) Metoprolol (Lopressor®) Nebivolol (Bystolic®) Propranolol (Inderal®) Timolol (Blocadren®)		

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CATEGORY	DRUG CLASS	STANDARD PRECAUTIONS	CAUTION	ALTERNATIVES RECOMMENDED
	Cardiac myosin inhibitor	Mavacamten (Camzyos®)		
	Diuretics	Torsemide (Demadex®)		
	Statins		Fluvastatin (Lescol®) Pravastatin (Pravachol®) Rosuvastatin (Crestor®)	Atorvastatin (Lipitor®) Lovastatin (Mevacor®, Altoprev®, Advicor®) Pitavastatin (Livalo®) Simvastatin (Zocor®)
Diabetes	Meglitinides	Nateglinide (Starlix®) Repaglinide (Prandin®, Prandimet®)		
	Thiazolidinediones	Pioglitazone (Actos®, Oseni®) Rosiglitazone (Avandia®)		
Gastrointestinal	Antiemetics	Dolasetron (Anzemet®) Dronabinol (Marinol®) Fosnetupitant / Palonosetron (Akynzeo-IV®) Metoclopramide (Reglan®) Netupitant / Palonosetron (Akynzeo-oral®) Palonosetron (Aloxi®)	Granisetron (Sancuso®, Sustol®) Ondansetron (Zofran®, Zuplenz®)	
	Proton Pump Inhibitors	Esomeprazole (Nexium®) Rabeprazole (Aciphex®)	Dexlansoprazole (Dexilant®, Kapidex®) Lansoprazole (Prevacid®) Omeprazole (Prilosec®) Pantoprazole (Protonix®)	
Gaucher Disease	Endocrine-Metabolic Agents	Eliglustat (Cerdelga®)		
Gynecology	Endometriosis Pain Agents	Elagolix (Orilissa®)		
Hematology	Hemostatic Agents	Avatrombopag (Doptelet®) Eltrombopag (Promacta®) Lusutrombopag (Mulpleta®)		
Infections	Anti-HIV Agents		Efavirenz (Sustiva®)	
	Antifungals	Flucytosine (Ancobon®)		Voriconazole (Vfend®)
Multiple Sclerosis	Disease-Modifying Agents	Siponimod (Mayzent®)		
Pain	Muscle Relaxants		Carisoprodol (Soma®) Tizanidine (Zanaflex®)	

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CATEGORY	DRUG CLASS	STANDARD PRECAUTIONS	CAUTION	ALTERNATIVES RECOMMENDED
	NSAIDs	Celecoxib (Celebrex®) Flurbiprofen (Ansaid®) Ibuprofen (Advil®, Motrin®) Meloxicam (Mobic®) Piroxicam (Feldene®)		
	Opioids	Benzhydrocodone (Apadaz®) Codeine (Codeine; Fioricet® with Codeine) Dihydrocodeine (Synalgos-DC®) Fentanyl (Actiq®) Hydrocodone (Vicodin®) Morphine (MS Contin®) Oliceridine (Olinvyk) Oxycodone (Percocet®, Oxycontin®) Tramadol (Ultram®)	Methadone (Dolophine®)	
Psychotropic	**Anti-ADHD Agents**	Amphetamine (Adderall®, Evekeo®) Dextroamphetamine (Dexedrine®) Lisdexamfetamine (Vyvanse®) Viloxazine (Qelbree®)	Atomoxetine (Strattera®) Dexmethylphenidate (Focalin®) Methylphenidate (Ritalin®, Aptensio XR®, Concerta®, Metadate ER®, Quillivant ER®)	
	Antiaddictives	Lofexidine (Lucemyra®)	Bupropion (Wellbutrin®, Zyban®, Aplenzin®, Contrave®) Naltrexone (Vivitrol®, Contrave®)	
	Anticonvulsants	Brivaracetam (Briviact®) Fosphenytoin (Cerebyx®) Phenobarbital (Luminal®) Phenytoin (Dilantin®) Primidone (Mysoline®) Zonisamide (Zonegran®)		
	Antidementia Agents	Donepezil (Aricept®) Galantamine (Razadyne®)		

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CATEGORY	DRUG CLASS	STANDARD PRECAUTIONS	CAUTION	ALTERNATIVES RECOMMENDED
	Antidepressants	Amoxapine (Amoxapine®) Desipramine (Norpramin®) Desvenlafaxine (Pristiq®) Fluoxetine (Prozac®, Sarafem®) Fluvoxamine (Luvox®) Maprotiline (Ludiomil®) Nefazodone (Serzone®) Nortriptyline (Pamelor®) Paroxetine (Paxil®, Brisdelle®) Protriptyline (Vivactil®) Sertraline (Zoloft®) Venlafaxine (Effexor®) Vortioxetine (Trintellix®)	Citalopram (Celexa®) Escitalopram (Lexapro®)	Amitriptyline (Elavil®) Clomipramine (Anafranil®) Doxepin (Silenor®) Imipramine (Tofranil®) Trimipramine (Surmontil®)
	Antipsychotics	Aripiprazole (Abilify®, Aristada®) Brexpiprazole (Rexulti®) Chlorpromazine (Thorazine®) Haloperidol (Haldol®) Iloperidone (Fanapt®) Paliperidone (Invega®) Perphenazine (Trilafon®) Pimozide (Orap®) Thioridazine (Mellaril®)	Clozapine (Clozaril®) Olanzapine (Zyprexa®) Risperidone (Risperdal®)	
	Benzodiazepines	Clobazam (Onfi®)	Diazepam (Valium®) Lorazepam (Ativan®) Oxazepam (Serax®)	
	Other Neurological Agents	Deutetrabenazine (Austedo®) Dextromethorphan / Quinidine (Nuedexta®) Flibanserin (Addyi®) Valbenazine (Ingrezza®)	Tetrabenazine (Xenazine®)	
Rheumatology	**Anti-Hyperuricemics and Anti-Gout Agents**	Allopurinol (Zyloprim®, Lopurin®, Aloprim®)		
	Immunomodulators	Leflunomide (Arava®)		
	Other Antirheumatic Agents		Sulfasalazine (Azulfidine®, Sulfazine®)	
Sjogren's Syndrome	**Cholinergic Agonists**	Cevimeline (Evoxac®)		
Sleep Disorder Agents	**Narcoleptic Agents**	Pitolisant (Wakix®)		
Transplantation	**Immunosuppressants**		Tacrolimus (Prograf®)	

RE:

I have reviewed the medical records for , **81 (Years) Female**, including available diagnostics, medications, and allergies. Listed below for your review are my treatment/diagnostic recommendations.

Allergy/Medication Reactions: Sulfa, Lisinopril, Sulfasalazine

Recommended treatment considerations:
• Pharmacogenomic Recommendations:
CYP2C19 Normal Metabolizer
CYP2B6 Intermediate Metabolizer
SLCO1B1 Decreased Function
APOE ε3/ε3
CYP3A4 Normal Metabolizer
CYP2D6 Normal Metabolizer

• Sertraline (CYP2B6 IM; CYP2C19 NM)
This patient may display some increased sensitivity and response to sertraline (Zoloft®) at the recommended dosage in the package insert. Consider starting with the recommended dose and a slower titration schedule, and possibly a lower maintenance dose, adjusting based on the tolerance of side effects and clinical efficacy. Monitor closely for side effects (including dry mouth, diarrhea, sexual dysfunction, sleepiness, unusual thoughts or behaviors, loss of appetite). Consider an alternative SSRI from the personalized Alternative Medication Guide selection tables in this report if the patient does not tolerate the medication well.

• Atorvastatin and the ε3/ε3 APOE Patient Diplotype (with decreased SLCO1B1 function)
The patient’s APOE genotype, ε3/ε3 (to copies of the most common genotype), is associated with normal metabolism and processing of lipids compared to the ε2/ε2, ε2/ε3, ε2/ε4, and ε4-related diplotypes. However, the SLCO1B1 functional issues discussed below may lead to elevated plasma levels of atorvastatin and recommendations are based on that information.
The ε3/ε3 diplotype is associated with lower LDL-cholesterol reduction when the patients are treated with atorvastatin compared to the ε2/ε2, ε2/ε3, and ε2/ε4 diplotypes. Statin treatment and dietary changes to reduce lipid levels are recommended to reduce the risk of cardiovascular disease. In the context of the SLCO1B1 genetic issues, an alternative statin should be considered.

• Patient has history of falls, but also history of abuse which may have contributed to fall occurrences - continue to monitor as patient is now in SNF setting instead of at home.

• Recommend use of ARB therapy as patient shows allergy to ACEi

• Assess need for continued use of Flecainide if AFIB has been ruled out for the patient

• Recommend routine EKG checks as Sertraline, Flecainide and Quetiapine can cause QT prolongation

• Use caution while patient is taking Quetiapine due to the increased risk of side effects and mortality when antipsychotics are used in older adults

• Monitor for an increased risk of bleeding due to interaction between Aspirin and Sertraline

• Patient due for yearly CBC, TSH, Lipid Panel and CMP draws

• Recommend HbA1c to establish baseline

• Recommend serum vitamin D, iron, B12, Mg, folate levels

• Recommend obtaining an updated DEXA scan as most recent found on file is from 2018

• External labs pulled from LabCorp and Centers. External medical history pulled from health information exchange (HIE) Vivlio. Medications were reviewed from the patient's medical record, as well as external medical history pulled from health information exchange if available (HIE - Vivlio). The medications were reviewed for interactions, applicability to diagnosis/indication, and duplicate therapy.

Laboratory findings:

- 10-17-2024 Additional Labs obtained from: [Practice: WellSpan; Obtained from Health Information Exchange],
  RBC 3.43, MCV 101.2, MCH 34.1, SCR 0.74, BUN 28

  Rest of CBC and BMP WNL

- 10-08-2024 EKG obtained from: [Practice: WellSpan; Obtained from Health Information Exchange],
  QTC 423, sinus rhythm with occasional ectopic premature complexes, 66bpm

- 06-27-2024 Lipids obtained from: [Practice: WellSpan; Obtained from Health Information Exchange],
  total cholesterol 172, TG 86, HDL 71, LDL 84

- 10-08-2024 CMP obtained from: [Practice: WellSpan; Obtained from Health Information Exchange],

Glucose 107, SCR 0.76

rest of CMP WNL

- 10-21-2024 Labs obtained from: [Practice: WellSpan; Obtained from Health Information Exchange],
  Folate, Vitamin B12, TSH WNL

Medication Review:
• Renal Function Adjustments: GFR 81; CrCl 43
• Flecainide CrCl 36-59 dosing recommendation: No dosage adjustment necessary; consider obtaining serum trough concentrations to guide dosage adjustments in addition to the anticipated clinical response; dose increases should be made cautiously and at intervals of ~7 days

• Hepatic Function Adjustments: None

• BEER's Recommendations:
• Selective Serotonin Reuptake Inhibitors (Sertraline) are identified in the Beers Criteria as potentially inappropriate medications to be used with caution in patients 65 years and older due to the potential to cause or exacerbate syndrome of inappropriate antidiuretic hormone secretion (SIADH) or hyponatremia; monitor sodium concentration closely when initiating or adjusting the dose in older adults

• Antipsychotics (Quetiapine) are identified in the Beers Criteria as a potentially inappropriate medication to be avoided in patients 65 years and older due to an increased risk of cerebrovascular accidents (stroke) and a greater rate of cognitive decline and mortality in patients with dementia. Antipsychotics may be appropriate for schizophrenia, bipolar disorder, other mental health conditions or short-term use as antiemetic during chemotherapy but should be given in the lowest effective dose for the shortest duration possible. In addition, antipsychotics should be used with caution in older adults due to their potential to cause or exacerbate syndrome of inappropriate antidiuretic hormone secretion (SIADH) or hyponatremia; monitor sodium closely with initiation or dosage adjustments in older adults

Drug Interactions:
- Flecainide/Quetiapine
  Additive QT interval prolongation may occur during coadministration of flecainide, a moderate-risk QT-prolonging agent, and QUEtiapine Fumarate Oral.

- Aspirin/Sertraline
  The risk of upper gastrointestinal bleeding may be increased with concurrent administration of aspirin and selective serotonin reuptake inhibitors (eg, Sertraline HCl Oral).

- Quetiapine/Sertraline

Additive QT interval prolongation may occur during coadministration of Sertraline HCl Oral and QUEtiapine Fumarate Oral.

Recommended diagnostics:
• Repeat CBC, CMP, Lipid panel, Thyroid Panel, HbA1C, Vitamin D, B12, Mg at clinically appropriate intervals

Diagnoses: E46: Unspecified protein-calorie malnutrition, E78.49: Other hyperlipidemia, F33.9: Major depressive disorder, recurrent, unspecified, F41.1: Generalized anxiety disorder, G30.9: Alzheimer's disease, unspecified, I10: Essential (primary) hypertension, I25.10: Atherosclerotic heart disease of native coronary artery without angina pectoris, I25.2: Old myocardial infarction, R29.6: Repeated falls, R62.7: Adult failure to thrive, R73.03: Prediabetes

Thank you for including us in the care of this patient. Please, contact Jake Hickerson, at jhickerson@aegishealthservices.com should you have questions or need additional information.

Respectfully,

Jake Hickerson, Pharm D
Kevin Rosenblatt, MD, PhD

Date: 11-17-2025

References:
The results and recommendations provided by these clinicians are intended to inform but do not replace clinical judgment. Therapeutic options should be individualized and determined after discussion between the patient and their care provider.
Source: [Micromedex]. Greenwood Village (CO): IBM Corporation; [2022]. Available from: www.micromedexsolutions.com.
Source: [Lexicomp, UpToDate]. Hudson (OH): Wolters Kluwer [2023]. Available from www.factsandcomparisons.com, www.uptodate.com
Source: [YouScript]. San Francisco (CA): Invitae; [2020]. Available from: www.youscript.net
Source: [Pharmacist's letter/Prescriber's Letter] PL Detail-Documents, TRC Healthcare [2022] Available from www.pharmacist.therapeuticresearch.com
Source: [American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults] Published: 04 May 2023 https://doi.org/10.1111/jgs.18372

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Pharmacogenomics (PGX) Drug Response Testing

What are the Benefits of PGX Drug Response Testing?

- Your DNA doesn't change, so a one-time test is all you'll ever need
- Reduce overall prescriptions
- No more trial-and-error means getting the right medication the first time
- Avoid costly hospitalizations by decreasing patient falls and adverse drug reactions

Pharmacogenomics (PGX) = Drug Response Testing

Traditional Method of Prescribing Medicine | A standard dose that works for most people

Standard Dose

This is the correct dose for many patients | This medication may not work at all for some patients | This dose is too high for some patients | This dose is too low for some patients

Prescribing Medicine While Incorporating PGX (Drug Response Testing) | Identifying the best medication at the optimal dose

Identifying at the optiomal dose

Standard Dose | Different Medication | Lower Dose | Higher Dose

Drug response testing tells your doctor how **YOU** will respond to a certain medication. → Then your doctor can use that information to prescribe the right dose or an alternative medication based on your DNA.

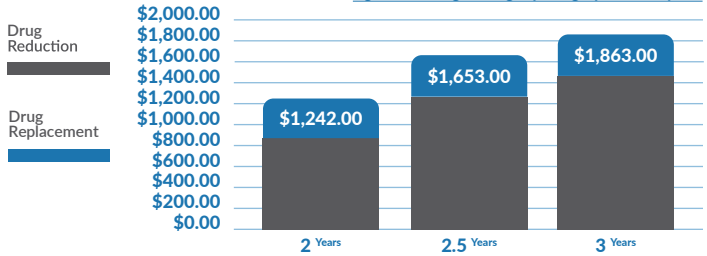
WHAT IS Drug Response Testing?

Pharmacogenomic (PGX), or drug response testing, is a simple, non-invasive cheek swab that tests to see how you will personally respond to medications based on your genetic makeup/DNA.

Cost Savings

- The potential savings over time outweigh the cost of Drug Response testing by more than two-fold.
- On average, residents saved $1,863 after utilizing PGX results to guide treatment.

Figure 1: Average savings by category over 2–3 years



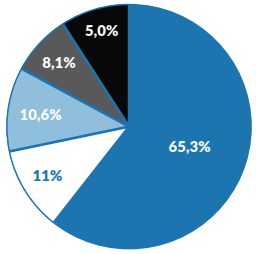


Figure 2: Savings by drug class

Psychotropic | Urology | Neurology | Other | Cardiovascula

Saldivar J, Taylor D, Sugarman E, Cullors A, Garces J, Oades K, Centeno J. Initial assessment of the benefits of implementing pharmacogenetics into the medical management of patients in a long-term care facility. Pharmacogenomics Pers Med. 2016;9:1–6 https://doi.org/10.2147/PGPM.S91480

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Postpartum PGx Benefits

Pharmacogenomic (PGx) testing for postpartum depression (PPD) can improve treatment outcomes by reducing the trial-and-error approach to medication selection. By analyzing how a person's genes affect their response to medication, PGx tests can help providers choose a more effective medication and dosage with fewer side effects.

HOW PGx Testing Helps with Postpartum Depression

For new mothers, PGx testing can address several key clinical and emotional concerns:

Reduced Trial & Error

Many psychiatric medications, particularly antidepressants, have a low initial success rate. PGx testing can shorten the time it takes to find an effective treatment, which is critical for new mothers experiencing the severe and time-sensitive symptoms of PPD.

Personalized Treatment Plan

PGx testing can inform medication choices for mood disorders like PPD. By revealing how a patient's unique genetic profile affects medication response, it helps to create a more personalized and effective treatment plan.

Durable Effects

Studies have suggested that PGx-guided treatment for depression can lead to more lasting symptom improvement and higher remission rates compared to traditional prescribing methods.

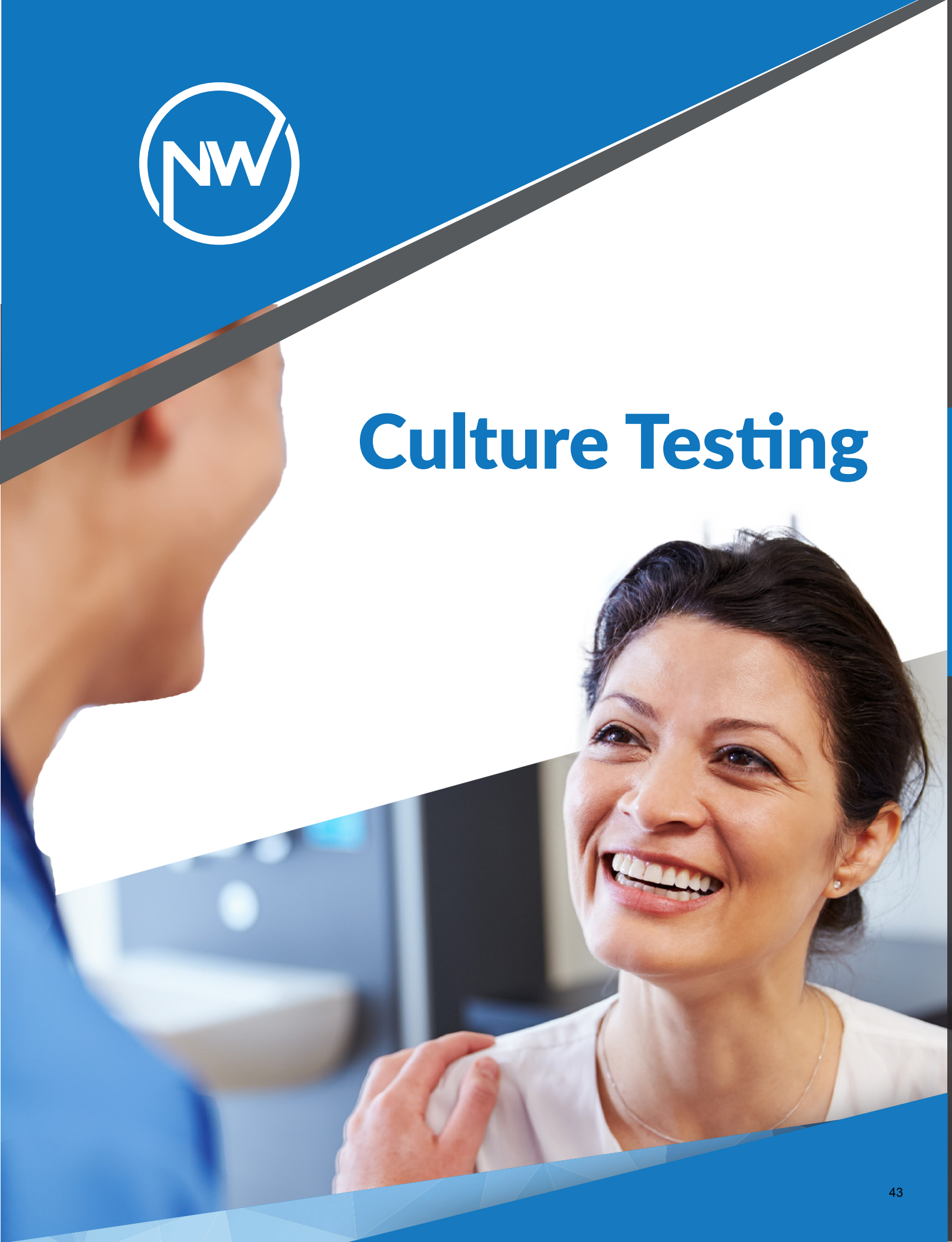
Informed Decision-making for breastfeeding

Test results can help alleviate a mother's anxiety about drug metabolites passing into breast milk and potentially harming her infant. With genetic information, a provider can select a medication and dose that is less likely to cause uncommon but severe drug toxicity in the infant, supporting the mother's confidence in breastfeeding.

Reduced Adverse Effects

The test can identify gene variants that cause a person to metabolize certain medications too slowly or too quickly, which can lead to adverse drug reactions (ADRs) or ineffective treatment. For a new mother, avoiding these negative side effects can increase compliance and confidence in her treatment plan.

Culture Testing



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CLIA ID# 23D2126347

FINAL

Dr Test Test		TEST, TEST		**Accession:**	XXXXX
123 Main St.	**Patient #:**	0000	**MRN:**	**Collected Date:**	01/01/2001 10:20 AM OFC
Southfield, MI 48034	**DOB:**	01/01/2001	**Sex:** Female	**Received Date:**	01/01/2001 9:50 PM

Urine Culture

Run by XX on 7/14/2025 11:53:57 AM at Locatio

Specimen Description: Urine (Clean Catch).

Site: URINE

Result 1: Escherichia coli. Culture shows 10,000-100,000 CFU/ml of bacteria.

Result 2: Culture shows <10,000 CFU/ml of Catalase-negative Gram-positive cocci, indicating the presence of streptococc with Beta-hemolysis negative (Not Strep group B). This colony count is not generally considered to be clinically significant.

ORGANISM 1: **Escherichia coli**

Sensitivity	Escherichia coli
Amp/Sulbactam	S, <=8/4
Ampicillin	S, <=8
Amox/K Clav	S, <=8/4
Ceftriaxone	S, <=1
Ceftazidime	S, <=1
Ceftazidime/Avibactam	S, <=4
Cefazolin	S, <=2
Ciprofloxacin	S, <=0.25
Cefepime	S, <=2
Ertapenem	S, <=0.5
Nitrofurantoin	S, <=32
Gentamicin	S, <=4
Imipenem	S, <=1
Levofloxacin	S, <=0.5
Meropenem	S, <=1
Meropenem/Vaborbactam	S, <=2
Piperacillin/Tazobactam	S, <=16
Trimethoprim/Sulfa	S, <=2/38
Tobramycin	S, <=4

Notes:
S = Susceptible
I = Intermediate
R = Resistant
MIC = mcg/ml (mg/L)
N/R = Not Reported
--- = Not Tested
POS = Positive
NEG = Negative
Blank = Data not available, or drug not advisable or tested
ESBL = Extended spectrum beta•lactamase
Blac = Beta-lactamase positive
TFG = Thymidine-dependent strain
S* = Predicted susceptible interpretation
R* = Predicted resistant interpretation
EBL? = Suspected ESBL Confirmatory tests needed to differentiate ESBL from other bela-.!actamases.
IB = Inducible Beta.Jacta!119se, Appears In place of MSusceptlble" with species known to possess Inducible bela-lactamases; potentially they may become resistant to all beta-lactam drugs. Monitoring of patients duringfafter therapy Is recommended. Avoid other/combined beta-lactam drugs. ^ = Reported interpretation changed For blood and CSF Isolates, a bela-1actamase test Is recommended for Enterococcus species.

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Infectious Diseases

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Get her vaginitis diagnosis right the first time with the BD Vaginal Panel.[1-5]

Demand a new standard of care for you and your patients.

BD

The BD Vaginal Panel for use with the BD MAX™ System and the BD COR™ System:
A clear vaginitis diagnosis in one test

By identifying the root cause of your patient's vaginitis symptoms, you can help avoid recurrence.

Clear diagnosis of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and *Trichomonas vaginalis* (TV) is critical to:

Ensure
- Informed treatment decisions[2]
- Appropriate patient management[2]

Decrease
- The risk of complications[5]
- The risk of contracting STIs[5]
- The risk of resistance to treatment[2]
- Health resource utilization[5]

The BD Vaginal Panel provides precision and clarity.

In the diagnosis of vaginitis:

- **Distinct diagnosis** of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC) and *Trichomonas vaginalis* (TV)[1]
- The only FDA-cleared test on the market to provide **separate results for *C. glabrata* and *C. krusei*,** two *Candida* species that are clinically indistinguishable and can be hard to treat as they have inherent and/or acquired resistance to azoles.[1,12-14]

In the identification of vaginitis and STI co-infection:

- The same sample can also be tested for ***Chlamydia trachomatis*** **and** ***Neisseria gonorrhoeae*** by using the BD CTGCTV2 assay.[16]

What if you could get her vaginitis diagnosis right, from the start?

Only a clear diagnosis can stop the cycle of repeat visits.
Traditional diagnostic techniques are often subjective, and their sensitivity is low.[5-7]

4/10 1

4 out of 10 women with vaginitis symptoms **don't receive appropriate diagnosis and treatment.**[4]

42% 2

As a result, up to **42% of women with vaginitis go back to their doctors** for persistent symptoms.[4]

1/4 3

More than **1 out of 4 women with vaginitis symptoms have multiple infections,** which makes accurate diagnosis and treatment challenging.[7]

7/10 4

Almost 7 out of 10 women report depression or anxiety during acute vaginitis episodes.[8,9]

Vaginitis is complex and has considerable impact on a woman's quality of life. You want **a diagnostic tool that provides actionable and objective results** to make informed clinical decisions.[2-5,10,11]

Two points that differentiate the BD Vaginal Panel: it provides clinical information that other assays don't.

1. BD Vaginal Panel **is the only FDA-cleared test on the market to provide separate results for *C. glabrata* and *C. krusei,* two *Candida* species that are clinically indistinguishable,** require different treatments and can be hard to treat as they have inherent and/or acquired resistance to azoles.[1,12-14]

2. BD Vaginal Panel is **the first FDA-cleared microbiome-based, PCR assay that directly detects bacterial vaginosis, vulvovaginal candidiasis and *Trichomonas vaginalis*,** the 3 most common infectious causes of vaginitis, in one test, with one swab.[1,7,10]

What precision does BD Vaginal Panel provide that traditional methods can't?

BD Vaginal Panel vs traditional methods:

A significantly higher sensitivity and comparable specificity to traditional tests.[10]

Condition	Diagnostic method	Sensitivity	Specificity
BV*	**BD Vaginal Panel**	**92.7%**	**91.5%**
	Clinician diagnosis	77.3% [a]	92.3% [b]
	Amsel's criteria	75.6% [a]	94.1% [b]
VVC*	**BD Vaginal Panel**	**90.7%**	**93.6%**
	Clinician diagnosis	56.8% [a]	89.2% [c]
	Potassium hydroxide wet mount	57.5% [a]	89.4% [c]
TV	**BD Vaginal Panel**	**96.7%**	**99.1%**
	Clinician diagnosis	68.9% [a]	99.1% [b]
	Wet mount	69.7% [a]	99.5% [b]

* Note: All methods compared to Nugent 0–3 and 7–10 sub-populations as part of study. [a] P<0.0001 compared to the investigational test. [b] P>0.05 compared to the investigational test. [c] P<0.0005 compared to the investigational test.

The greater sensitivity you require to detect co-infections.[10]

Diagnostic method	BV + VVC	BV + TV	VVC + TV	BV + VVC + TV
BD Vaginal Panel	**73.5%**	**92.4%**	**72.0%**	**80.0%**
Clinician diagnosis	17.8% [a]	21.2% [a]	20.0% [b]	10.0% [b]

[a] P<0.0001 compared to the investigational test. [b] P<0.0005 compared to the investigational test.

The BD Vaginal Panel provides a more accurate vaginitis diagnosis as compared to traditional methods, including an improved detection of co-infections which occur in 1 out of 4 women.[6,7,10]

A more accurate diagnosis means improved patient management and informed downstream treatment recommendations.[10]

The BD Vaginal Panel detects a broader range of pathogens responsible for vaginitis.[1,13-15]

BD Vaginal Panel vs other molecular tests on the market:

		BD Vaginal Panel	Hologic Aptima® BV and CT/TV Assays[13,15]	Cepheid Xpert® Xpress MVP[14]
Bacterial vaginosis (BV)	*Gardnerella vaginalis*	✓	✓	✗
	Lactobacillus spp.	✓ *L. crispatus* and *L. jensenii*	✓ *L. crispatus, L. jensenii, L. gasseri*	✗
	Atopobium vaginae	✓	✓	✓
	BVAB-2	✓	✗	✓
	Megasphaera-1	✓	✗	✓
	Reported as	BV	BV	BV
	Reportable results	POS NEG	POS NEG	POS NEG
Vulvovaginal candidiasis (VVC) / *Trichomonas vaginalis* (TV)	*Candida albicans*	✓	✓	✓
	Candida tropicalis	✓	✓	✓
	Candida parapsilosis	✓	✓	✓
	Candida dubliniensis	✓	✓	✓
	Candida glabrata	✓	✓	✓
	Candida krusei	✓	✗	✓
	Trichomonas vaginalis	✓	✓	✓
	Reported as	*Candida* group *C. glabrata* *C. krusei* *T. vaginalis*	*Candida* species group *C. glabrata* *T. vaginalis*	*Candida* spp. *C. glabrata / C. krusei* *T. vaginalis*
	Reportable results	POS NEG	POS NEG	DETECTED NOT DETECTED
Recommended CPT® Code 81514†		✓	✗	✗

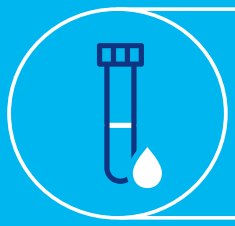
* *Atopobium* spp. (*Atopobium vaginae*, *Atopobium* novel species CCUG 55226)

With the BD Vaginal Panel, achieve a clear vaginitis diagnosis in a single test.[1,7]

†Disclaimer: Health economic and reimbursement information provided by BD is gathered from third-party sources and is subject to change without notice. The information contained in this reference is presented for information purposes only and does not constitute reimbursement or legal advice. It is always the provider's responsibility to determine medical necessity and to submit appropriate codes and changes for services that are rendered. BD recommends that you consult with your payers, reimbursement specialist and/or legal counsel regarding coverage, coding, and payment matters. CPT five-digit codes, description, two-digit modifiers and other data are copyright © 2022 American Medical Association. All rights reserved. The codes referenced here are not all-inclusive and are not intended to represent all coding options options.

The right treatment starts with the right diagnosis: **Ask for the BD Vaginal Panel**

- **FDA-cleared to detect** DNA from organisms associated with **BV, VVC and TV from a single swab.**[1]
- Designed with a proprietary, microbiome-based algorithm for BV that **determines a definitive positive or negative BV result for each patient.**
- Provides **separate results for *C. glabrata* and *C. krusei*,** two *Candida* species that may not respond to traditional therapeutics.[1,12]
- Utilizes the **highly sensitive** and CDC-recommended diagnostic technology, **NAAT, for TV detection**.[10,17]
- Approved for **clinician-collected and patient-collected samples**.*[1]
- Available on the BD MAX™ System for low to mid volume laboratories and the BD COR™ System for high volume laboratories.



Did you know?

You can use the same sample to test for vaginitis and the 3 most prevalent non-viral STIs in symptomatic women if you use the BD Vaginal Panel together with the BD CTGCTV2 assay.[1,16,18]

Ask your BD Representative for more information.

Let's shape the future of women's health. Together and now.

BD Vaginal Panel - BD CTGCTV2 Assay -
BD Onclarity™ HPV Assay - BD MAX™ GBS Assay
For more information about the BD comprehensive diagnostic Women's Health portfolio, please scan the QR code.

*Patient collection takes place in a healthcare setting.

BV, bacterial vaginosis; FDA, Food and Drug Administration; NAAT, nucleic acid amplification test; NEG, negative; POS, positive; TV, Trichomonas vaginalis; VVC, vulvovaginal candidiasis.

References: 1. BD MAX™ Vaginal Panel Package Insert (P0258) and BD Vaginal Panel for use with the BD COR™ System (L012454). **2.** Broache M et al. *Obstet Gynecol.* 2021;138(6):853–9. **3.** Miller JM et al. *Clin Infect Dis.* 2018;67(6):e1–e94. **4.** Hillier SL et al. *Clin Infect Dis.* 2021;72(9):1538–43. **5.** Brown H and Drexler M. *Popul Health Manag.* 2020;23(S1):S3–S12. **6.** Schwebke JR et al. *J Clin Microbiol.* 2020;58(2):e01643–19. **7.** Gaydos CA et al. *Obstet Gynecol.* 2017;130(1):181–9. **8.** Bilardi JE et al. *PLoS One.* 2013;8(9):e74378. **9.** Aballéa et al. *Health and Quality of Life Outcomes.* 2013;11:169–81. **10.** Schwebke JR et al. *J Clin Microbiol.* 2018;56(6):e00252–18. **11.** Van Der Pol B et al. *Sex Transm Dis.* 2021;48(2):134–40. **12.** Thompson A et al. *Eur J Clin Microbiol Infect Dis.* 2020;39(1):39–44. **13.** Hologic Aptima® CV/TV Assay Package Insert. **14.** Cepheid Xpert® Xpress MVP Instructions for Use. **15.** Hologic Aptima® BV Assay Package Insert. **16.** BD CTGCTV2 for BD MAX™ System Package Insert (P0237). **17.** Workowski KA et al. *MMWR Recomm Rep.* 2021;70(4):1–187. **18.** Center for Disease Control and Prevention. *Sexually Transmitted Infections Prevalence, Incidence, and Cost Estimates in the United States,* CDC. https://www.cdc.gov/std/statistics/prevalence-2020-at-a-glance.htm. Accessed Dec 20, 2022.

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The right treatment begins with **the right diagnosis.**

Test your patient with both the **BD MAX™ Vaginal Panel** and the **BD CTGCTV2** assay to diagnose vaginitis and the most prevalent non-viral STIs with one swab.[1-7]

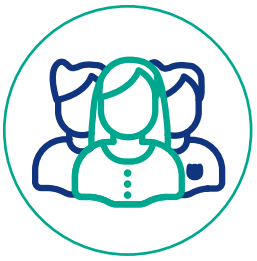
BD

BD MAX™ Vaginal Panel: Get her vaginitis diagnosis right the first time.[1,4-7]

Help stop the cycle of repeat visits

Traditional diagnostic techniques are often subjective, and their **sensitivity is low.**[3,5,8]

with vaginitis are misdiagnosed.[4,6]



Women who receive empiric treatment are more likely to have a **recurrent visit** within 90 days.[6]

Due to the complex etiology of vaginitis, you need a diagnostic tool that provides **actionable and objective results to make informed clinical decisions.**[9-12]

Get a clear vaginitis diagnosis in one test

BD MAX™ Vaginal Panel is **the first FDA-cleared microbiome-based, PCR assay that directly detects bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and *Trichomonas vaginalis* (TV)**, the 3 most common infectious causes of vaginitis, in one test, with one swab.[12,13]

01100
10110
11110

Designed with a proprietary, microbiome-based algorithm for BV.[1]

Determines a definitive positive or negative BV result for each patient.[1]

Provides **separate results for candida species** *C. glabrata* and *C. krusei* that may not respond to traditional therapeutics.[1,14]

Utilizes the **highly sensitive** diagnostic technology, NAAT, for TV detection.[13,17]

Identify vaginitis and STI co-infection
from visit one, with one patient collection

Vaginitis and STI co-infection is common

25%

One study found that **approximately 25% of women with BV or VVC also had an STI.**[18]

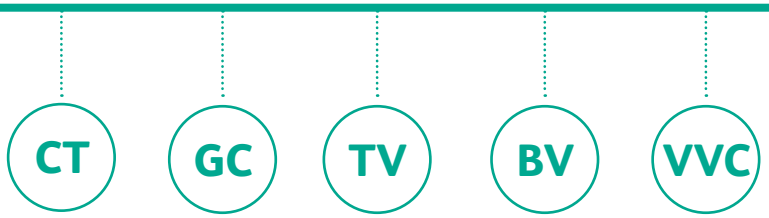
Most people with CT, GC and TV do not develop symptoms, but each has been associated with downstream consequences including pelvic inflammatory disease, tubal factor infertility, and adverse pregnancy outcomes.[3,15,19,20]

60%-80%

TV often coexists with BV pathogens, with co-infection rates of 60%-80%.[13,15-17]

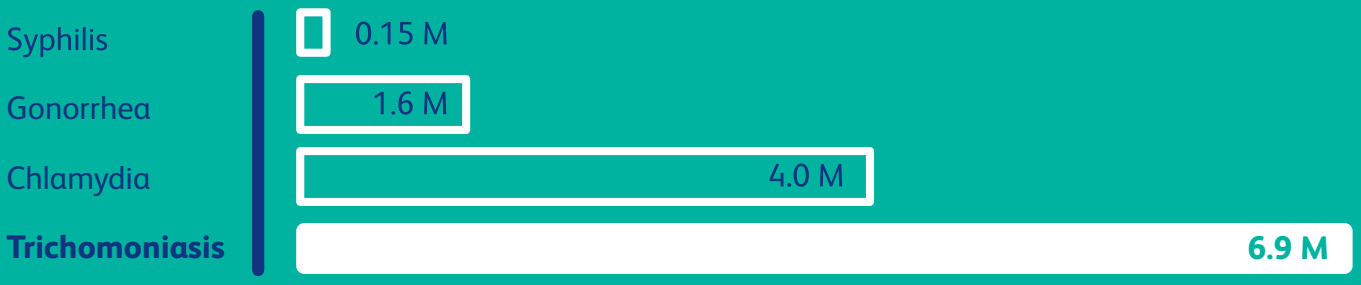
1 sample: 5 results.
Get a comprehensive diagnosis from the start[1-7,12,13,18]

With the BD CTGCTV2 assay and the BD MAX™ Vaginal Panel, you can use the same sample to test for vaginitis and the 3 most prevalent non-viral STIs in symptomatic women.[1-3,17,18,21]



BD CTGCTV2 assay: Go one step further in testing for STIs by detecting TV - in addition to CT and GC.[2,3,21]

TV likely causes more STIs than CT and GC combined in many populations.[21]



The rates of **all STIs continue to increase.**[18]

70%

Approximately **70% of TV infections** are asymptomatic.[15]

To protect women against the potentially serious adverse outcomes associated with STIs, **you need results you can trust.**[17]

Get an accurate diagnosis with advanced detection

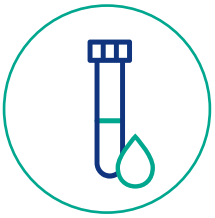
The BD CTGCTV2 FDA-cleared assay is designed to detect *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC) and *Trichomonas vaginalis* (TV), the 3 most prevalent non-viral STIs, with a single test.[2,3,21]

Includes dual gene targets for GC, which **maximizes the assay specificity:** both GC gene targets are required for a positive GC result.[2,3]

Utilizes the **highly sensitive CDC-recommended** diagnostic technology, NAAT for both CT and TV detection.[2,17]

Adapt to your patients' needs with flexible testing from a wide variety of sample types.[1,2]

test up to five different conditions



The BD Molecular Swab Collection Kit can be used to test for **up to five different women's health and STI conditions,** including CT, GC, TV, BV, and VVC, from one sample.[1,2,23]

With the possibility to use patient-collected samples*, you can **spend more time with your patients** and focus on more critical tasks.[1,2]

spend more time with your patients

include men in testing

The ability to detect CT, GC and TV in urine samples allows you to **include men in testing.[2]**

	Male		Female	
	Symptomatic	Asymptomatic	Symptomatic	Asymptomatic
Urine	CT GC TV	CT GC TV	CT GC TV	CT GC TV
Endocervical Swab			CT GC	CT GC
Vaginal Swab - Self Collected*			CT GC TV BV VVC	CT GC TV
Vaginal Swab - Clinician Collected			CT GC TV BV VVC	CT GC TV
PreservCyt® LBC			CT GC	CT GC

With the BD MAX™ Vaginal Panel and the BD CTGCTV2 assay, you can use the same sample to test for vaginitis and the 3 most prevalent non-viral STIs.[1-3,17,18,21]

- Help decrease the number of recurrent visits, incorrect treatments, and risk of negative sequelae.[4,6]
- Include TV when you screen for STIs and vaginitis.
- Detect the major causes of vaginitis and the 3 most prevalent non-viral STIs with just one swab.[1-3,12,13,21]
- Adapt to your patients' needs with a wide variety of compatible sample types.[1,2]

Let's shape the future of women's health. Together and now.

BD CTGCTV2 assay - BD MAX™ Vaginal Panel - BD Onclarity™ HPV Assay - BD MAX™ GBS

For more information about BD's comprehensive diagnostic Women's Health portfolio, please visit **womens-health-solutions.bd.com**

*patient-collection takes place in a healthcare setting

BV, bacterial vaginosis; CT, *Chlamydia trachomatis*; FDA, Food and Drug Administration; GC, *Neisseria gonorrhoeae*; LBC, liquid-based cytology; NAAT, nucleic acid amplification test; PCR, polymerase chain reaction; STI, sexually transmitted infection; TV, *Trichomonas vaginalis*; US, United-States; VVC, vulvovaginal candidiasis.

References: 1. BD MAX™ Vaginal Panel Package Insert (P0258). 2. BD CTGCTV2 for BD MAX™ System Package Insert (P0237). 3. Van Der Pol B et al. Sex Transm Dis. 2021;48(2):134–40. 4. Broache M et al. Obstet Gynecol. 2021;138(6):853–9. 5. Brown H and Drexler M. Popul Health Manag. 2020;23(S1):S3–S12. 6. Hillier SL et al. Clin Infect Dis. 2021;72(9):1538–43. 7. Miller JM et al. Clin Infect Dis. 2018;67(6):e1–e94. 8. Menard JP et al. Clin Infect Dis. 2008;47(1):33–43. 9. Hainer BL and Gibson MV. Am Fam Physician. 2011;83(7):807–15. 10. Anderson MR et al. JAMA. 2004;291(11):1368–79. 11. Paladine HL and Desai UA. Am Fam Physician. 2018;97(5)321–29. 12. Gaydos CA et al. Obstet Gynecol. 2017;130(1):181–9. 13. Schwebke JR et al. J Clin Microbiol. 2018;56(6):e00252–18. 14. Pfaller MA et al. J Clin Microbiol. 2010;48(4):1366–77. 15. Trichomoniasis – CDC Fact Sheet, CDC. Available at: https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm. Last updated July 22, 2021. Accessed April 10, 2022. 16. Sobel JD et al. Curr Infect Dis Rep. 2013;15(2):104–8. 17. Workowski KA et al. MMWR Recomm Rep. 2021;70(4):1–187. 18. Van Der Pol B et al. Clin Infect Dis. 2019;68(3):375–81. 19. Chlamydia – CDC Fact Sheet, CDC. Available at: https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm. Last updated December 31, 2021. Accessed February 16, 2022. 20. Gonorrhea – CDC Fact Sheet, CDC. Available at: https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm. Last updated July 22, 2021. Accessed February 16, 2022. 21. Sexually Transmitted Infections Prevalence, Incidence, and Cost Estimates in the United States, CDC. Available at: https://www.cdc.gov/std/statistics/prevalence-2020-at-a-glance.htm. Last updated January 25, 2021. Accessed February 18, 2022. 22. Kissinger P. BMC Infect Dis. 2015;15:307. 23. BD Molecular Swab Collection Kit Package Insert (P0246).

bd.com

BD Life Sciences
7 Loveton Circle, Sparks, MD 21152-0999, USA
Tel: 1.800.638.8663

Elevate the standard of cervical cancer screening

HPV extended genotyping is an innovative screening tool to enhance clinical management.

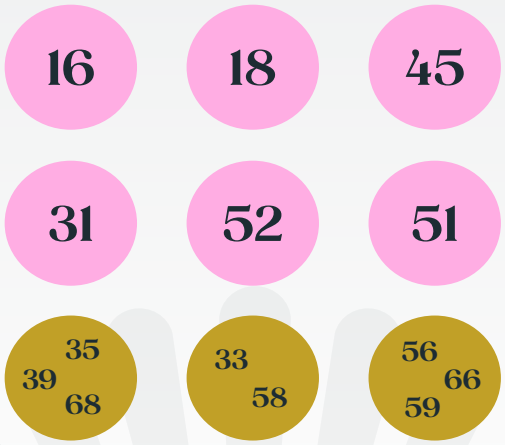
Individual identification of high-risk genotypes is essential to reveal the true risk of CIN3+ disease*,[1]

Partial genotyping:

Only 2 high-risk HPV types individually identified

Extended genotyping with BD Onclarity™ HPV Assay:

6 high-risk HPV types individually identified

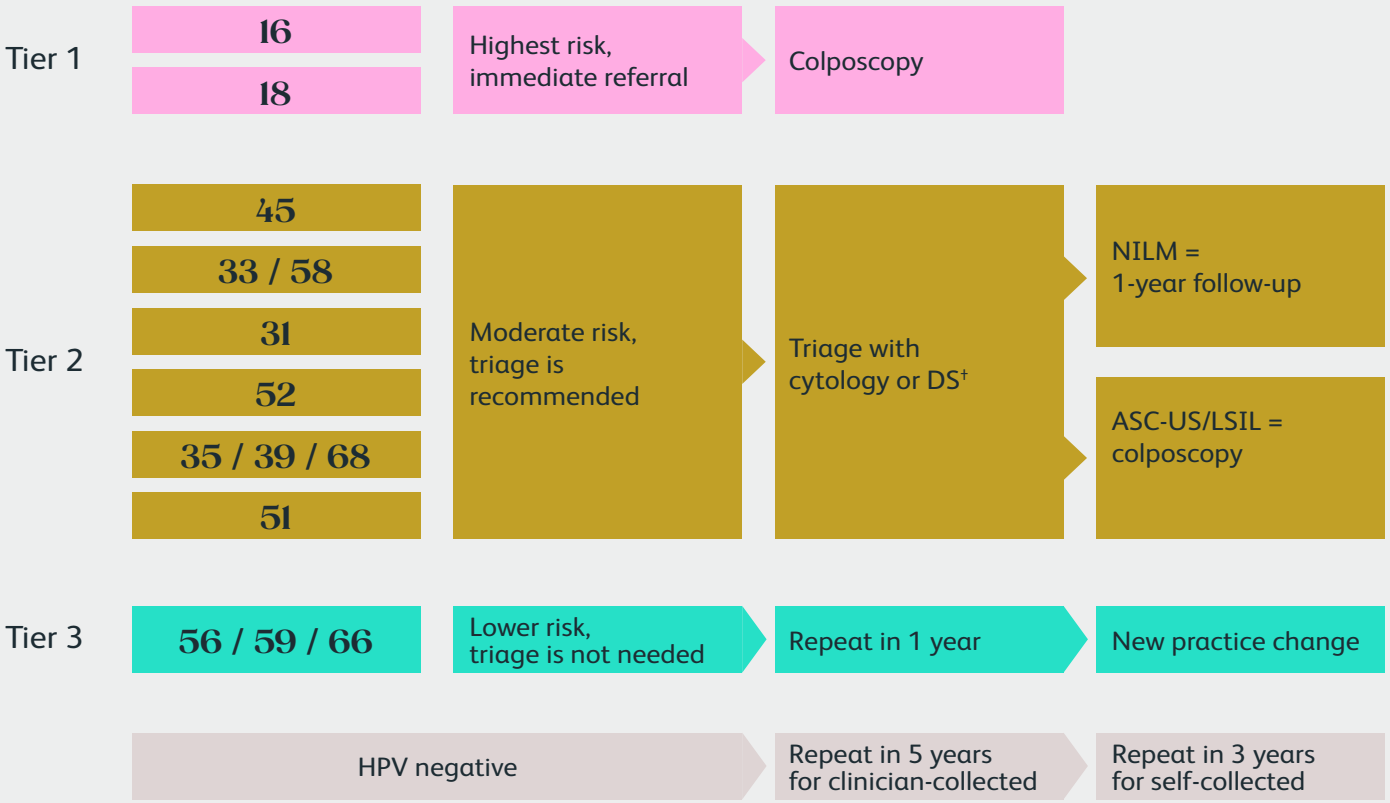


Individual results Pooled results

BD Onclarity™ HPV Assay has officially been added to the ASCCP guidelines

The American Society for Colposcopy and Cervical Pathology (ASCCP) has separated the BD Onclarity™ HPV Assay channels into three different risk-based tiers, which inform new clinical recommendations.[2]

Patient management with BD Onclarity™ HPV Assay (Co-Testing / HPV Primary)



It's time to redefine screening and make powerful progress towards **eliminating cervical cancer**

Learn more at bd.com/onclarity

*CIN, cervical intraepithelial neoplasia.
†Note: Dual Stain is not FDA approved for use as a triage with BD Onclarity™ HPV Assay

References: 1. Bonde JH et al. *J Low Genit Tract Dis*. 2020;24(1):1–13. **2.** ASCCP. *Management Guidelines and the Enduring Guidelines Process*. Accessed February 2025.

NORTH WEST LABS

BD

BD, Sparks, MD, 21152, U.S. **bd.com**

NORTH WEST LABS

INFECTIOUS DISEASES REQUISITION

29580 Northwestern Hwy Suite 120, Southfield, MI 48034

(248) 301-6917 www.nwlabs.com

PATIENT INFORMATION

Patient Demo Attached ☐

Last Name: _____ First Name: _____

Middle Name: _____ Sex: ☐ Male ☐ Female

Address: _____

City: _____ State: _____ Zip: _____

DOB: _____ Mobile: _____

Email: _____

Provider Information:

PRIMARY INSURANCE

☐ Medicare ☐ Medicaid ☐ Commercial ☐ Auto ☐ Workers Comp ☐ Client ☐ Other Insurance

Insurance Name: _____ Subscriber Name: _____

Policy #: _____ DOB: _____

Group #: _____ Relation to Patient: ☐ Self ☐ Spouse ☐ Guradian

SPECIMEN INFORMATION

__/__/__ (DATE COLLECTED) _____ (INITIALS) _____:_____ (TIME COLLECTED)

ICD 10 CODES: (ENTER ALL THAT APPLY)

TESTING ORDERS:
PAP SMEAR (CERVICAL CYTOLOGY)

Collection Type: Clinician-collected cervical sample

Select Collection Device: ☐ Hologic ThinPrep

Screening Purpose: ☐ Routine screening ☐ Follow-up to abnormal results ☐ High-risk surveillance

HPV-BD ONCLARITY
(EXTENDED GENOTYPING)

Collection Type (must select one): ☐ ThinPrep ☐ Clinician/Patient collected vaginal swab (FLOQSwab)

Ordering Type (select one): ☐ Primary HPV screening (age ÷25) ☐ PAP W/ Reflex to HPV (ASCUS only)
☐ PAP + HPV
☐ PAP W/ reflex to HPV

Genotype Reporting: Individually Reported: HPV 16, 18, 31, 45, 51, 52 Grouped Genotypes: HPV 33/58, HPV 56/59/66, HPV 35/39/68

BD MAX VAGINAL PANEL / STI Panel

Collection Type: ☐ Clinician/Patient collected vaginal swab (BD Molecular Swab)
☐ Urine

Ordering Options (select one or more): ☐ Comprehensive Vaginal Panel ☐ STI Panel (Urine)
☐ Vaginal Panel ☐ Group B Strep
☐ STI Panel (BD Molecular Swab)

MYCOPLASMA / UREAPLASMA / UTI / URINE CULTURE

Collection Type: Patient-collected first-catch urine sample

Ordering Options (select one or more): ☐ Mycoplasma ☐ Ureaplasma ☐ UTI W/ ABR Panel ☐ Urine Culture

Purpose: ☐ Urogenital pathogen evaluation

PATHOLOGY - BIOPSY

	Type of Procedure	Site of Specimen	Time of Collection
1			
2			
3			
4			

BLOOD

☐ BLD-aHAVM = Hepatitis A IgM
☐ BLD-HAVT = Hepatitis A Total
☐ BLD-aHBcM = Hepatitis B core Antigen
☐ BLD-HBcT2 = HBc Total 2
☐ BLD-HBsII = Hepatitis B surface Antigen II
☐ BLD-aHBs2 =Anti-Hepatits B surface Antigen 2
☐ BLD-aHCV = Hepatitis C
☐ BLD-HSV1 = Herpes - 1 IgG
☐ BLD-HSV2 = Herpes - 2 IgG
☐ BLD-Rub G = Rubella IgG
☐ BLD-Syph = Syphilis
☐ BLD-Toxo G = Toxoplasma IgG
☐ BLD-Toxo M = Toxoplasma IgM
☐ BLD-CHIV = HIV Ag/Ab Combo (US)

INFECTIOUS DISEASES REQUISITION

NORTH WEST LABS

29580 Northwestern Hwy Suite 120, Southfield, MI 48034

(248) 301-6917 www.nwlabs.com

PATIENT HISTORY

Last Pap Date:	Last HPV Test Date:	Prior abnormal Pap or HPV? ☐ Yes ☐ No ☐ Unknown
History of CIN2+ or HSIL? ☐ Yes ☐ No		Hysterectomy: ☐ None ☐ Partial ☐ Total ☐ Cervix Removed
Currently Pregnant: ☐ Yes ☐ No	Immunocompromised (e.g., HIV): ☐ Yes ☐ No	DES Exposure in Utero: ☐ Yes ☐ No

TEST REFERENCE GUIDE

Test	Sample Source	Collection Method	Approved Collection Device	Notes
Pap Smear (Cytology)	Cervical, Endocervical, Vaginal	Clinician collected	Hologic ThinPrep	Image Guided
BD Onclarity HPV - Clinician	Cervical, Endocervical, Vaginal	Clinician collected	Hologic ThinPrep	HPV Screen / PAP + HPV PAP w/ reflex to HPV or ASCUS
BD Onclarity HPV - Self	Vaginal	Patient self-collected	FLOQ Swab in transport tube	FDA-cleared for self-collection
BD MAX Vaginal Panel BD MAX STI Panel	Vaginal Urine	Clinician- or self-collected	BD Molecular Swab Sterile urine cup	BV, yeast, trichomonas, CT/GC/TV
Mycoplasma / Ureaplasma	Urine (first-catch)	Patient-collected	Sterile urine cup	Urogenital pathogen detection
UTI PCR & Culture	Urine (first-catch)	Patient-collected	Urine C&S tube	Transfer from Cup to Tube within 20 minutes

SCREENING GUIDELINES SUMMARY: CERVICAL CANCER SCREENING (ACOG, USPSTF, ASCCP)

- Age <21: No screening
- Age 21-29: Cytology every 3 years
- Age 30-65: HPV primary q5 yrs, Co-testing q5 yrs, or Cytology q3 yrs
- Age >65: Stop if adequate negative history and no high-risk history
- Post-Hysterectomy (cervix removed): Stop unless history of CIN2+ or cancer

RISK-BASED EXCEPTIONS

Continue or intensify screening if:

- Immunocompromised (e.g., HIV)
- History of CIN2+ or cervical cancer
- In utero DES exposure
- Inadequate prior screening

STI & VAGINAL INFECTION SCREENING

Group	Recommendation	Suggested Test
Women <25, sexually active	Annual screening	BD MAX Vaginal Panel (STI)
Women ÷25, at risk	Same as above	BD MAX Vaginal Panel
Vaginal complaints	Discharge, odor, irritation	BD MAX BV and/or STI Panel
Suspected recurrent BV	Confirm with molecular testing	BD MAX Vaginal Panel
Non-vaginal urogenital symptoms	Consider urine-based testing	Mycoplasma / Ureaplasma

Physician Authorization:

1. Any pathology, cytology, and thin prep specimens will be forwarded to KC Pathology Laboratory 44400 Van Dyke Ave, Ste 102, Sterling Heights, MI 48314; Phone:(586) 262-4243.
2. I understand that while the initial order is placed with North West Labs, the actual testing may be performed by their partner laboratories as specified above.
3. I acknowledge that this referral process may affect billing procedures and timeline for results, and accept this as part of the standard operating procedure for these specific test types.
4. I confirm that I have informed my patients about this testing arrangements appropriate and in accordance with applicable regulations.

Physician Signature: _____ **Date:** _____

Patient Consent and Authorization:

I authorize North West Labs and KC Pathology Laboratory to perform the tests ordered and release results to my provider. I understand my sample will be tested only as authorized and I may withdraw consent prior to processing. I authorize the release of my medical information including test results for submission of personalized reports to my healthcare providers and insurance carrier(s). I request that payment of benefits be made to North West Labs, Inc. on my behalf. If my policy does not allow for direct payment, I agree to relinquish allocated funds to North West Labs, Inc as compensation for services rendered. I also acknowledge that I will be liable for payments of deductibles, co payments and/or co insurance as detailed by my healthcare insurer. I understand that I am liable for charges not covered by my healthcare insurer. I also authorize North West Labs, Inc to appeal insurance claims on my behalf. I acknowledge the benefits, risk and limitations of this testing as described to me by a qualified healthcare provider. My insurance may not cover or pay full amount for testing; I may be responsible for full or part of amount charged due to out of network benefits, deductible and co pays. North West Labs, Inc has my permission to bill my insurance carrier(s), this notice gives me the option to proceed with the procedure or decline. By signing this I have read all of the above and understand it. Medicare Advance Beneficiary Notice: Medicare will only pay for services that it determines to be reasonably and necessary under section 1882 (a) (1) of the Medicare Law. If Medicare determines that a particular service, although it would otherwise be covered, is not reasonable and necessary under the Medicare Program standards, Medicare will deny payment for that service. Medicare usually does not pay for these tests for the reported diagnosis. By signing the Patient/Responsible Party Signature on this requisition, you are confirming your agreement to assume financial responsibility for the payment of these tests.

Patient Signature: _____ **Date:** _____

NORTH WEST LABS

29580 Northwestern Hwy
Suite 120, Southfield, MI 48034
(248) 301-6917
nwlabs.com

LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

FINAL

OLSOWKA, EUGENE MD		**TEST, TEST**		**Accession:**	**xxxxxx**
29580 NORTHWESTERN HWY	**Patient: #:**	xxxxx	**MRN:**	**Collected Date:**	5/22/2025 10:13 AM
Southfield, MI48034	**DOB:**	01/01/2001	**Sex:** Female	**Received Date:**	5/22/2025 10:13 AM
Organization: NORTHWEST LABS					

Test Name	Result	Units	Flag	Reference Range/Cutoff
Molecular				
URINE STI Panel [USTI]				*Run by LG on 5/22/2025 5:53:31 PM at Location*
URIN Chlamydia Trachomatis [UCT]	POSITIVE		**POSITIVE**	NEGATIVE
URIN Neisseria Gonorrhoeae [UNG]	POSITIVE		**POSITIVE**	NEGATIVE
URIN Trichomonas vaginalis [UTV]	POSITIVE		**POSITIVE**	NEGATIVE

Location 1000B: NORTH WEST LABS 29580 Northwestern HWY Suite-120, Southfield, MI 48034 T: (248) 301-6917 www.nwlabs.com
Lab Director: Eugene Olsowka MD CLIA ID# 23D2126347

All tests are performed at Northwest Labs, 29580 Northwestern Hwy Suite 120, Southfield, MI 48034 except some are performed at LabCorp

NORTH WEST LABS

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nwlabs.com

LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

FINAL

OLSOWKA, EUGENE MD		**TEST, TEST**		**Accession:**	**XXXX**
29580 NORTHWESTERN HWY	**Patient: #:**	XXXXXX	**MRN:**	**Collected Date:**	11/12/2025 3:05 PM LG
Southfield, MI48034	**DOB:**	1/1/1990	**Sex:** Female	**Received Date:**	11/12/2025 3:05 PM
Organization: NORTH WEST LABS					

Test Name	Result	Units	Flag	Reference Range/Cutoff
Molecular				
Vaginal Panel-MSWAB [VP]				*Run by LG on 11/12/2025 3:05:40 PM at Location*
Bacterial Vaginosis [BV]	NEGATIVE			NEGATIVE
Notes:	[Gardnerella vaginalis, Lactobacillus spp. (L. crispatus and L. jensenii), Atopobium vaginae, BVAB-2, Megasphaera-1]			
Candida Group [CGRP]	POSITIVE		**POSITIVE**	NEGATIVE
Notes:	[C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis]			
Candida Krusei [CKRU]	NEGATIVE			NEGATIVE
Candida Glabrata [CGLA]	NEGATIVE			NEGATIVE
Trichomonas vaginalis [TV]	POSITIVE		**POSITIVE**	NEGATIVE

Location 1000B: NORTH WEST LABS 29580 Northwestern HWY Suite-120, Southfield, MI 48034 T: (248) 301-6917 www.nwlabs.com
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CLIA ID# 23D2126347

FINAL

Dr. Test
123 Main Street
Southfield, MI 48034
Organization: NORTH WEST LABS

TEST, TESTING
Patient: #: XXXX **MRN:**
DOB: 01/01/2001 **Sex:** Female

Accession: XXXXX.
Collected Date: 11/14/2025 3:01 PM XX
Received Date: 11/14/2025 9:00 PM

Test Name	Result	Units	Flag	Reference Range/Cutoff
Molecular				
Mycoplasma genitalium/hominis [MYCOP]				*Run by MS on 11/21/2025 3:53:28 PM at Locatio*
Mycoplasma hominis [MHOM]	NEGATIVE			NEGATIVE
Mycoplasma genitalium [MGEN]	NEGATIVE			NEGATIVE
Ureaplasma urealyticum/parvum [UREAP]				*Run by MS on 11/21/2025 3:53:28 PM at Locatio*
Ureaplasma parvum [UPARV]	POSITIVE		**POSITIVE**	NEGATIVE
Ureaplasma urealyticum [UUREA]	POSITIVE		**POSITIVE**	NEGATIVE
Vaginal Panel Comprehensive-MSWAB [VPCMP]				*Run by MS on 11/17/2025 3:36:11 PM at Locatio*
Bacterial Vaginosis [BV]	NEGATIVE			NEGATIVE
Notes:	[Gardnerella vaginalis, Lactobacillus spp. (L. crispatus and L. jensenii), Atopobium vaginae, BVAB-2, Megasphaera-1]			
Candida Group [CGRP]	NEGATIVE			NEGATIVE
Notes:	[C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis]			
Candida Krusei [CKRU]	NEGATIVE			NEGATIVE
Candida Glabrata [CGLA]	POSITIVE		**POSITIVE**	NEGATIVE
Chlamydia Trachomatis [CT]	NEGATIVE			NEGATIVE
Neisseria Gonorrhoeae [NG]	NEGATIVE			NEGATIVE
Trichomonas vaginalis [TV]	NEGATIVE			NEGATIVE

Location 1000B: NORTH WEST LABS 29580 Northwestern HWY Suite-120, Southfield, MI 48034 T: (248) 301-6917 www.nwlabs.com
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NORTH WEST LABS

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nwlabs.com

LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

FINAL

OLSOWKA, EUGENE MD		**TEST, TEST**		**Accession:**	**xxxxxx**
29580 NORTHWESTERN HWY	**Patient: #:**	xxxxx	**MRN:**	**Collected Date:**	4/16/2025 2:12 PM
Southfield, MI48034	**DOB:**	01/01/1980	**Sex:** Female	**Received Date:**	4/16/2025 2:12 PM
Organization: NORTH WEST LABS					

Test Name	Result	Units	Flag	Reference Range/Cutoff
Molecular				
Vaginal Panel Comprehensive-MSWAB [VPCMP]				*Run by LG on 11/12/2025 3:03:07 PM at Locatio*
Bacterial Vaginosis [BV]	POSITIVE		**POSITIVE**	NEGATIVE
Notes:	[Gardnerella vaginalis, Lactobacillus spp. (L. crispatus and L. jensenii), Atopobium vaginae, BVAB-2, Megasphaera-1]			
Candida Group [CGRP]	NEGATIVE			NEGATIVE
Notes:	[C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis]			
Candida Krusei [CKRU]	POSITIVE		**POSITIVE**	NEGATIVE
Candida Glabrata [CGLA]	NEGATIVE			NEGATIVE
Chlamydia Trachomatis [CT]	NEGATIVE			NEGATIVE
Neisseria Gonorrhoeae [NG]	POSITIVE		**POSITIVE**	NEGATIVE
Trichomonas vaginalis [TV]	NEGATIVE			NEGATIVE

Location 1000B: NORTH WEST LABS 29580 Northwestern HWY Suite-120, Southfield, MI 48034 T: (248) 301-6917 www.nwlabs.com
Lab Director: Eugene Olsowka MD CLIA ID# 23D2126347

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LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

FINAL

Dr. Test Test	**TEST, TEST**			**Accession:**	XXXXXX
123 Main St.	**Patient: #:** 0000	**MRN:**		**Collected Date:**	01/01/2021 2:05 PM OFC
Southfield, MI 48034	**DOB:** 01/01/2001	**Sex:**	Female	**Received Date:**	01/01/2021 9:00 PM

Organization: NORTH WEST LABS

Test Name	Result	Units	Flag	Reference Range/Cutoff
Molecular				
HPV PANEL [HPV]				*Run by ME on XX/XX/XXXX 11:50:21 PM*
HPV Genotype 16	NEGATIVE			
HPV Genotype 18	NEGATIVE			
HPV Genotype 31	NEGATIVE			
HPV Genotype 45	POSITIVE		**ABNORMAL**	
HPV Genotype 51	NEGATIVE			
HPV Genotype 52	NEGATIVE			
HPV Genotype P1 (33/58)	NEGATIVE			
HPV Genotype P2 (56/59/66)	NEGATIVE			
HPV Genotype P3 (35/39/68)	NEGATIVE			

GYNECOLOGIC PAP TEST, LIQUID BASED (IMAGE-GUIDED) *Run by ME on XX/XX/XXXX 11:50:21 PM*

Specimen Received: ThinPrep Vial
Specimen Source: CERVICAL.

Report Status	NORMAL	F
INTERPRETATION:		F
NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY.		
Additional Comments:	INFLAMMATION PRESENT.	F
Specimen Adequacy		F
Satisfactory for evaluation. An endocervical component is identified.		
COMMENTS:		F

(a) The Pap smear is a screening test designed to aid in the detection of premalignant and malignant conditions of the uterine cervix. It is not a diagnostic procedure and should not be used as the sole means of detecting cervical cancer. Both false-positive and false-negative reports do occur. (b) This liquid based Thin Prep (R) pap test was screened with the use of an image guided system.

Performed by:	TES TEST , CT (ASCP).	F
Electronically signed by:	TES TEST , CT (ASCP).	F
Performing Site:		F

Technical and professional Components Performed at: KC Pathology Laboratory, LLC,: 44400 Van Dyke Ave, Suite 102, Sterling Heights MI 48314-2370. CLIA# 23D2276072.Medical Director: Fayez Daaboul, MD This test was developed and its performance and characteristics determined by KC Pathology Laboratory LLC. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

Location 1000B:	NORTH WEST LABS 29580 Northwestern HWY Suite-120, Southfield, MI 48034 T: (248) 301-6917 www.nwlabs.com Lab Director: Eugene Olsowka MD CLIA ID# 23D2126347
StratusDX [KC] performing site:	KC PATHOLOGY LABORATORY LLC 44400 VAN DYKE AVE STE 102A STERLING HEIGHTS, MI 48314-2370

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29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

NORTH WEST LABS

| Newborn™ | Carrier Screening Analysis Requisition Form

29580 Northwestern Hwy Suite 120 ♦ Southfield, MI ♦ ☎ 2483016917 ♦ FAX 2483016805 ♦ ✉ www.nwlabs.com

1. PATIENT INFORMATION *

Last Name: MI: First Name: Suffix:

Date of Birth: Gender: ◯ Female ◯ Male

Email: Phone:

Street Address:

City: State: Zip:

Race/Ethnicity:

- ◯ African American/Black
- ◯ Ashkenazi Jewish
- ◯ White (Non-Hispanic)
- ◯ Caucasian
- ◯ French Canadian
- ◯ Hispanic/Latin American
- ◯ East Asian
- ◯ South Asian
- ◯ Southeast Asian
- ◯ Mediterranean
- ◯ Middle Eastern
- ◯ Native American
- ◯ Native Hawaiian or other Pacific Islander
- ◯ Adopted
- ◯ Other_____

2. ORDERING PHYSICIAN *

Name: NPI #:

Facility Name:

Street Address:

City: State: Zip:

Phone: Fax:

3. TEST REQUESTED *

◯ **Newborn™** ***(Hereditary Carrier Screening Analysis) (GTR000567624.2)*** *HBA1, HBA2, SLC2A10, ARSA, HBB, BLM, ASPA, GALT, COL4A1, CFTR, CA12, SCNN1A, SCNN1B, SCNN1G, DLD, COL3A1, IKBKAP, ABCC8, ACTA2, MYH11, MYLK, FANCA, FANCC, FANCF, FANCG, FMR1, GBA, G6PC1, SLC37A4, GAA, GBE1, KCNE1, KCNQ1,BCKDHA, BCKDHB, DBT, ACADM, MCOLN1, SMPD1, NPC1, NPC2, GJB2, GJB6, GJB3, KCNQ4, COL11A2, OTC, SLC26A4, PAH, HBB, DHCR7, SMN1, SMN2, DYNC1H1, UBA1, VAPB, HEXA, MYO7A, USH1C, CDH23, PCDH15, USH2A, ATP7B*

◯ **Custom** *(specific genes from Newborn™ Panel)* _____

◯ **Fragile X** *(Female Patients Only)*

◯ **Partner has been tested by GeneID**

4. CLINICAL INFORMATION *

Patient Pregnant: ◯ Yes ◯ No

◯ 1st Trimester ◯ 2nd Trimester ◯ 3rd Trimester

Partner Pregnant: ◯ Yes ◯ No

Partner's Ancestry:

5. PERSONAL/FAMILY HISTORY

◯ Family History of Genetic Disease ◯ Family Member is a Known Carrier

(C) - Family Member is a Known Carrier of the Disease

Relationship	Disease	Variant (If Known)

6. PARTNER HISTORY

◯ Family History of Genetic Disease ◯ Family Member is a Known Carrier

(C) - Family Member is a Known Carrier of the Disease

Relationship (To Partner)	Disease	Variant (If Known)

7. ICD-10 CODES *

For Reference:

Z13.228: Encounter for screening for other metabolic disorders
Z13.79: Encounter for other screening for genetic and chromosomal anomalies
Z31.430: Encounter of female for testing for genetic disease carrier status for procreative management
Z31.440: Encounter of male for testing for genetic disease carrier status for procreative management
Z81.0: Family history of intellectual disabilities
Z84.81: Family history of carrier of genetic disease

Selected ICD10 Codes:

- ◯ **Z81.0:** Family history of intellectual disabilities
- ◯ **Z81.8:** Family history of Anxiety
- ◯ **Z83.49:** Family history of Cystic Fibrosis
- ◯ **Z31.430:** Encounter of female for testing for genetic disease carrier status for procreative management
- ◯ **Z13.0:** Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
- ◯ **Z13.228:** Encounter for screening for other metabolic disorders
- ◯ **Z13.79:** Encounter for other screening for genetic and chromosomal anomalies
- ◯ **Z15.89:** Genetic Susceptibility to Other Disease
- ◯ Other ICD10 Codes: _____

8. STATEMENT OF MEDICAL NECESSITY *

TEST REQUESTS WITHOUT A SIGNATURE WILL NOT BE PROCESSED
I affirm that I am authorized under applicable federal and state laws to order genetic testing and have determined that the requested test(s) are medically necessary based on the patient's clinical presentation, personal and/or family history, or differential diagnosis. I certify that all diagnosis codes have been provided to the best of my clinical knowledge and that I have obtained and documented written informed consent from the patient or their legally authorized representative. This consent includes a clear explanation of the purpose, scope, risks, benefits, limitations, and potential outcomes of the testing, as well as the implications for the patient and their family. The patient has also consented to the release of results to a third-party genetic counselor for interpretation, counseling, and insurance-related purposes. I accept responsibility for interpreting and communicating the results to the patient, ensuring appropriate follow-up care, and retaining all related documentation, including the signed informed consent, in the patient's medical record. I confirm that the information submitted on this requisition form is accurate and complete to the best of my knowledge.

9. SAMPLE REQUIREMENTS *

◯ **Mouthwash Sample** OR ◯ **Buccal Swab**

Ordering Physician Signature | Test Ordered Date | Specimen Collected Date

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

NORTH WEST LABS

29580 Northwestern Hwy, Ste 121
Southfield, MI 48034
Phone: (248) 301-6917
Fax: (248) 301-6785
www.nwlabs.com
support@nwlabs.com

Newborn
Genetic Carrier Testing

Dr. Daniel Cohen, M.D. **Laboratory Director**

PATIENT AND SPECIMEN INFORMATION			
PATIENT NAME:		SPECIMEN TYPE:	Saliva
AMD ACCESS #:	NBP-22-XXXXX	COLLECTION DATE:	
DATE OF BIRTH:		COMPLETION OF TESTING:	

ORDERED BY			
ORDERING PHYSICIAN'S NAME:		PHYSICIAN'S ADDRESS:	
PHONE:		FAX:	

REPORT SUMMARY

POSITIVE RESULT	
DISEASE:	Deafness, Autosomal Recessive 1A
GENE:	GJB2
RESULTS:	Heterozygous Missense Variant
VARIANT:	NM_004004.5(GJB2): c.101T>C (p.Met34Thr); Chr13: 20763620 (on Assembly GRCh37); p.M34T; rs35887622.

Dr. Daniel Cohen, MD, Laboratory Director

This report was electronically signed.

Disclaimer: The accompanying Technical Specifications summary describes the analysis, method, performance characteristics, nomenclature, and interpretive criteria of this test. This test result does not exclude the possibility of other predisposing mutations that have been reported in individuals with increased risk. This test may be considered investigational by some states. This test and its performance characteristics were determined by North West Labs. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

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EXPLANATION OF POSITIVE RESULTS

The results of this analysis are consistent with a heterozygous GJB2 (Gap Junction Protein Beta 2) single nucleotide mutation detected within exon 2 of the GJB2 gene, noted as c.101T>C (rs35887622; Chr13: 20763620), which results in an amino acid substitution at position 34, where a methionine (M) is replaced by a threonine (T), noted as (p.Met34Thr) or p.M34T.

The p.M34T pathogenic variant in the GJB2 gene has been reported previously in association with autosomal recessive non-syndromic sensorineural hearing loss and it is associated with a milder severity and later onset of hearing loss compared to other reported pathogenic variants in the GJB2 gene (Wilcox et al., 2000; Houseman et al., 2001; Snoeckx et al., 2005).

Across a selection of literature, the c.101T>C (p.M34T) variant has been identified in a homozygous state in 35 patients, in a compound heterozygous state in 66 patients (at least 59 of whom had a pathogenic deletion), and in a heterozygous state in 18 patients (Houseman et al, 2001; Feldman et al. 2004; Snoeckx et al. 2005; Pollak et al. 2007; Tang et al. 2006; Lopponen et al. 2012; Doria et al. 2015; Mikstiene et al. 2016). This variant is generally associated with mild to moderate nonsyndromic hearing loss, and segregation was observed in a three-generation family (Lopponen et al. 2012).

The p.M34T variant was detected in 66 of 5380 control chromosomes mainly in a heterozygous state, and also in family members with normal audiograms, including two with the variant in a homozygous state, five in a compound heterozygous state, and 23 in a heterozygous state (Feldman et al. 2004; Lopponen et al. 2012). This conflicting evidence may be due to reduced penetrance, estimated at 10% in one study (Pollak et al. 2007), presence of other modifying factors (Houseman et al, 2001; Bicego et al. 2006), or due to an age-dependent effect (Pollak et al. 2007).

The ClinVar Database (NCBI, National Library of Medicine, NIH, Bethesda, MD) shows conflicting interpretations of this finding, but most submitters consider this finding as a pathogenic mutation. In general terms, an individual who inherits one copy of a GJB2 gene mutation is a “carrier” and is not expected to have related health problems. An individual who inherits two mutations in this gene, one from each parent, is expected to be affected.

If both members of a couple are carriers, the risk for an affected child is 25% in each pregnancy; therefore, it is especially important that the reproductive partner of a carrier be offered testing.

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Newborn
Genetic Carrier Testing

List of Targeted Genes and Diseases:

DISEASE	GENE
Alpha Thalassemia	HBA1
	HBA2
Arterial Tortuosity Syndrome	SLC2A10
Arylsulfatase A Deficiency	ARSA
Beta Thalassemia	HBB
Bloom Syndrome	BLM
Canavan Disease	ASPA
Classical Galactosemia	GALT
Congenital Aneurysms	COL4A1
Cystic Fibrosis	CFTR
Cystic Fibrosis-related – CA12	CA12
Cystic Fibrosis-related – SCNN1A	SCNN1A
Cystic Fibrosis-related – SCNN1B	SCNN1B
Cystic Fibrosis-related – SCNN1G	SCNN1G
Dihydrolipoamide Dehydrogenase Deficiency	DLD
Ehlers Danlos Syndrome Type 4	COL3A1
Familial Dysautonomia	IKBKAP
Familial Hyperinsulinism	ABCC8
Familial TAAD – ACTA2-related	ACTA2
Familial TAAD – MYH11-related	MYH11
Familial TAAD – MYLK-related	MYLK
Fanconi Anemia Type A	FANCA
Fanconi Anemia Type C	FANCC
Fanconi Anemia Type F	FANCF
Fanconi Anemia Type G	FANCG
Fragile-X Syndrome (available upon request)	FMR1
Gaucher Disease	GBA
Glycogen Storage Disease Type I	G6PC1
Glycogen Storage Disease Type I	SLC37A4
Glycogen Storage Disease II – Pompe Disease	GAA
Glycogen Storage Disease IV	GBE1
Jervell and Lange-Nielsen – LQT5	KCNE1
Jervell and Lange-Nielsen – LQT11	KCNQ1
Loeys-Dietz Syndrome Type 1	TGFBR1
Loeys-Dietz Syndrome Type 2	TGFBR2

DISEASE	GENE
Loeys-Dietz Syndrome Type 3	SMAD3
Long QT Syndrome 3	SCN5A
Long QT Syndrome 6	KCNE2
Long QT Syndrome 11	AKAP9
Maple Syrup Urine Disease Type 1A	BCKDHA
Maple Syrup Urine Disease Type 1B	BCKDHB
Maple Syrup Urine Disease Type 2	DBT
Marfan Syndrome	FBN1
Medium-Chain Acyl-CoA Dehydrogenase Deficiency	ACADM
Mucolipidosis IV	MCOLN1
Niemann-Pick Disease Type A/B	SMPD1
Niemann-Pick Disease Type C1	NPC1
Niemann-Pick Disease Type C2	NPC2
Nonsyndromic Hearing Loss (Connexin 26)	GJB2
Nonsyndromic Hearing Loss (Connexin 30)	GJB6
Nonsyndromic Hearing Loss (Connexin 31)	GJB3
Nonsyndromic Hearing Loss (DFNA2)	KCNQ4
Nonsyndromic Hearing Loss (DFNA13)	COL11A2
Ornithine Transcarbamylase Deficiency	OTC
Pendred Syndrome	SLC26A4
Phenylketonuria	PAH
Sickle Cell Disease	HBB
Smith-Lemli-Opitz Syndrome	DHCR7
Spinal Muscular Atrophy (Werdnig-Hoffman)	SMN1
Spinal Muscular Atrophy – Modifier	SMN2
Spinal Muscular Atrophy – DYNC1H1-related	DYNC1H1
Spinal Muscular Atrophy – UBA1-related	UBA1
Spinal Muscular Atrophy – VAPB-related	VAPB
Tay Sachs Disease	HEXA
Usher Syndrome Type 1B	MYO7A
Usher Syndrome Type 1C	USH1C
Usher Syndrome Type 1D	CDH23
Usher Syndrome Type 1F	PCDH15
Usher Syndrome Type 2A	USH2A
Wilson Disease	ATP7B

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TEST METHODOLOGY

Genomic DNA from **XXXXXXXXXX's** submitted specimen was enriched for the complete coding regions and splice site junctions of the genes described in the panel using a hybrid-capture based protocol. The products were sequenced using Illumina Next Generation Sequencing platform. The sequences were aligned to reference sequences based on Human Genome build GRCh37/UCSChg19. SMN-1 (survival motor neuron-1 gene) - SPINAL MUSCULAR ATROPHY - exon 7 deletion/duplication testing was performed by Multiplexed PCR assay (AmplideX-PCR/CE SMN1). PCR products are represented by two dye-labeled amplicons, one for EC gene and one for the SMN1 gene that are resolved by CE. Comparative analysis (SMN-1 copy number) from FSA electropherogram files are calculated by the AmplideX PCR-CE Reporter (Asuragen, Inc, Austin, TX). SMN-1 risk estimates include testing for presence or absence of the intron 7 polymorphism g.27134T>G, which improves the accuracy of residual risk in different populations (1).

Sequencing bio-informatics pipelines were analyzed by Illumina VariantStudio v.3.0 and Torrent Suite Software v.4.0.2., respectively. Discrepancies between platforms, if any, were resolved by selective incorporation of chain-terminating dideoxynucleotides (Sanger Sequencing) targeting with specific FWD/REV primers, 5' M13 tailed and HPLC purified. All sequence alterations are described according to the Human Genome Variation Society (HGVS) nomenclature guidelines. Genetic data is stored under Variant Call Format (VCF)(2)(3).

(1) Luo, M. et al. Genetics in Medicine 16, 149–156, 2014. (2) Bio-IT World, Davies, K. Powering Preventative Medicine. Bio-IT World, 2011. (3) GenomeWeb DNA Electronics Licenses IP to Ion Torrent. August 2010.

RECOMMENDATIONS

It is recommended that this test result be communicated to the patient in a setting that includes appropriate genetic counseling by a licensed/certified genetic counselor. This test result should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members.

DISCLAIMERS & TEST LIMITATIONS

The accompanying Technical Specifications summary describes the analysis, method, performance characteristics, nomenclature, and interpretive criteria of this test. This test result does not exclude the possibility of other predisposing mutations that have been reported in individuals with increased risk. This test may be considered investigational by some states. This test and its performance characteristics were determined by North West Labs. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Clinically significant long homopolymer tracts, triplet repeat expansions, large genomic rearrangements, deep intronic variants and mutations located in regulatory regions may not be identified with the technologies used by this assay. Genes with closely related pseudogenes are not well analyzed by this method. Rare variants in primer or probe hybridization sites may compromise analytical sensitivity. Depending on the availability of parental DNA, the chromosomal phase of identified pathogenic variants may not be determined (i.e., whether variants are in cis or trans).

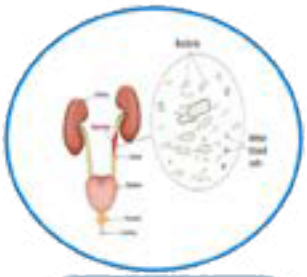
AMD follows internal policies and ACMG recommendations for variant classification (4). Pathogenic and Likely pathogenic variants are evaluated by reviewing reports of allele frequencies in cases and controls, population data, functional studies, variant annotation and effect prediction, previous classification in reputable databases and segregation studies.

All variants that are recognized cause of disease will be reported. In addition, variants that have not previously been established as a recognized cause of pathology may be identified. In these cases, only variants classified as "pathogenic" or "likely pathogenic" are described. Benign variants, variants of uncertain significance, and variants not directly associated with the intended disease phenotype are not reported but are available upon request.

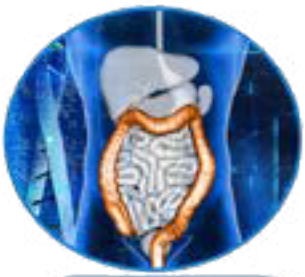
(4) Richards, S. et al. Genetics in Medicine. May; 17(5):405-24, 2015.

Nail

Wound



UTI



GI

Respiratory

PCR PANELS

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

NORTH WEST LABS
29580 Northwestern Hwy
Suite 120, Southfield, MI 48034
(248) 301-6917
nwlabs.com
LAB DIRECTOR Eugene Olsowka, MD
CLIA ID# 23D2126347

Wound Sepsis PCR

BACTERIA

- Escherichia coli
- Streptococcus agalactiae
- Klebsiella oxytoca
- Staphylococcus saprophyticus
- Pseudomonas aeruginosa
- Staphylococcus haemolyticus
- Enterococcus faecium
- Enterococcus faecalis
- Acinetobacter calcoaceticus
- baumannii complex
- Klebsiella aerogenes
- Klebsiella pneumoniae
- Staphylococcus aureus
- Streptococcus pyogenes
- Streptococcus pneumoniae
- Streptococcus dysgalactiae
- Staphylococcus lugdunensis
- Staphylococcus epidermidis

FUNGI

- Candida krusei
- Candida tropicalis
- Candida glabrat
- Candida parapsilosis
- Candida albicans
- Fusarium solani
- Microsporum spp
- Trichophyton spp

VIRUSES

- Herpes Simplex Virus 1
- Herpes Simplex Virus 2

ANTIMICROBIAL RESISTANCE

- Methicillin Resistance (MecA + C)

Nail Fungal PCR

FUNGI

- Microsporum gypseum
- Microsporum canis / audouinii
- Trichophyton spp
- Malassezia furfur
- Malassezia sympodialis
- Candida krusei
- Candida albicans
- Candida glabrata
- Candida parapsilosis
- Candida auris
- Aspergillus niger
- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus terreus
- Epidermophyton floccosum
- Fusarium oxysporum
- Trichosporon asahii
- Trichosporon mucoides

Antibiotic Resistance PCR

ANTIMICROBIAL RESISTANCE

- KPC – Carbapenem resistance
- NDM - Carbapenem resistance
- VIM - Carbapenem resistance
- IMP - Carbapenem resistance
- qnr - Quinolone resistance
- vanB - Vancomycin resistance
- OXA-48 - Carbapenem resistance
- mecA / mecC - Methicillin resistance
- CTX-M ESBL
- sul - Sulfonamide resistance
- vanA - Vancomycin resistance
- dfrA - Trimethoprim resistance

Urinary Tract Infection PCR

BACTERIA

- Escherichia coli
- Streptococcus agalactiae
- Klebsiella oxytoca
- Staphylococcus saprophyticus
- Serratia marcescens
- Proteus mirabilis
- Aerococcus urinae
- Treponema pallidum
- Enterobacter cloacae
- Pseudomonas aeruginosa
- Klebsiella aerogenes
- Citrobacter freundii
- Klebsiella pneumoniae
- Morganella morganii
- Corynebacterium urealyticum
- Enterococcus faecium
- Enterococcus faecalis
- Acinetobacter baumannii
- Proteus vulgaris
- Staphylococcus aureus
- Ureaplasma
- Providencia stuartii

FUNGI

- Candida parapsilosis
- Candida glabrata
- Candida auris
- Candida tropicalis
- Candida krusei
- Candida albicans

H PYLORI/ CLARITHROMYCIN RESISTANCE

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SOUTHFIELD, MI 48075

NORTH WEST LABS

Final Report

North West Labs
29580 Northwestern Hwy
Southfield, MI 48034
CLIA# 23D2126347

PATIENT		SPECIMEN		SITE INFO	
Name:	TEST	**Sample ID:**	0000	**Facility:**	North West Labs
DOB:	01-01-2001 (22y)	**Collected:**	01-01-2001 13:21:00	**Phone:**	1111111111
Gender:	Female	**Received:**	01-01-2001 13:23:33	**Address:**	29580 Northwestern Hwy, Southfield, MI 48034
Race:	Unknown	**Resulted:**	01-01-2001 13:27:28	**Provider:**	NORTH LABS, INC.
Ethnicity:	Unknown	**Sample Type:**	Urine		
Address:	123 place Cedar Park, Texas, 78613	**Sample Location:**	N/A		

Prescribed Meds	None Provided	Allergies	None Provided

PCR SAMPLE REPORT

Detected Organism(s)

Organisms	Result	Estimated Load
Ureaplasma	High	(1.72x10^8 - 1.72x10^9)
Citrobacter freundii	High	(> 10^6)

Detected Resistance Gene Marker(s)

Resistance Gene Marker
vanA - Vancomycin resistance
NDM - Carbapenem resistance

- QUANTITATIVE Assay demonstrates microbes found. Quantitative test (CT values) are not designed to provide indication of infection. Provider must use theclinical assessment of patient's symptoms and signs to make nal judgement of infection present and antibiotic intervention needed.

Medication Recommendations

Drug Of Choice

Medication Name	Route	Dosage
Levofloxacin	PO	Acute simple cystitis: 250mg po daily x 3 days (female) x 5 days (male). Complicated infection: 750 mg po daily x 5-7 days. Enterobacter infection: 750mg IV once daily. Stenotrophomonas infection: 750mg PO once daily.
Recommended for Target: C freundii, Ureaplasma		
Consideration: N/A		

Alternative Drugs/Combination

Medication Name	Route	Dosage
Ciprofloxacin	PO	Acute simple cystitis: 250 mg PO BID x 3 days (female); 500 mg PO BID x 5-7 days (male). Empiric complicated cystitis, catheter-related: 500 mg po BID q12h x 7-14 days. Empiric low-risk bacteria pyelonephritis: 500 mg PO BID q12h x 5-7 days if uncomplicated. Enterobacter sp: 400mg IV Q12hr. Aerococcus urinae: 500 mg PO BID
Recommended for Target: C freundii		
Consideration: No hepatic adjustment necessary but consider d/c cipro if suspected cipro-induced liver injury (that requires hospitalization)		
Moxifloxacin	PO	400 mg PO daily
Recommended for Target: C freundii		
Consideration: B Frag: Resistance to Moxifloxacin is increasing.		
Trimethoprim/Sulfamethoxazole	PO	Acute simple cystitis: 1 double strength tab (160/800mg) PO BID x 3 days (female) x 7 days (male). Complicated infection: 1 DS tab PO BID x 14 days. Stenotrophomonas infection: 8-12mg/kg/day PO divided q8-12hr
Recommended for Target: C freundii		
Consideration: No hepatic adjustment necessary but if drug induced liver injury is suspected then consider d/c		

North West Labs
29580 Northwestern Hwy
Southfield, MI 48034
CLIA# 23D2126347

Final Report

Drugs Not Tested For ABR But Commonly Used

Medication Name	Route	Dosage
Cefepime	IV	2g IV q12hr x 5-14 days dependent on clinical response. Switch to appropriate oral regimen once symptoms improve if cultures and sensitivities allows
Recommended for Target: C freundii		
Consideration: High risk-MDR pyelonephritis only		
Doxycycline	PO	100-200 mg/day PO in 1-2 divided doses
Recommended for Target: Ureaplasma		
Consideration: Not currently indicated for UTI but has activity against various bugs which may be cause of UTI - not first line. Doxycycline is not recommended in pregnancy.		
Azithromycin	PO	500 mg PO for 10-14 days
Recommended for Target: Ureaplasma		
Consideration: Not currently labeled for ureaplasma treatment but studies have found azithromycin to be an effective alternative treatment		

Note:

1. In patients reporting an allergy to a medication, a detailed history should be obtained to evaluate the nature of the allergic reaction. In many cases, patient reports of "allergy" represent intolerance, rather than an immunologic reaction. In general, when a previous severe reaction (eg, hepatotoxicity, Stevens-Johnson syndrome) has occurred, repeated exposure to the medication and other medications in the same pharmacological class, should be avoided. An individualized risk:benefit assessment must be performed in situations in which mild reactions were noted or when no suitable alternative therapy exists.

Not detected organisms and resistance genes

Resistance Gene Marker			
CTX-M ESBL	KPC - Carbapenem resistance	Vancomycin Resistance (VanB)	mecA/mecC - Methicillin resistance
sul - Sulfonamide resistance	OXA-48 - Carbapenem resistance	qnr - Quinolone resistance	dfrA - Trimethoprim resistance
IMP - Carbapenem resistance	VIM - Carbapenem resistance		
Bacteria			
Staphylococcus saprophyticus	Staphylococcus aureus	Serratia marcescens	Klebsiella pneumoniae
Streptococcus agalactiae	Pseudomonas aeruginosa	Proteus vulgaris	Proteus mirabilis
Morganella morganii	Aerococcus urinae	Corynebacterium urealyticum	Klebsiella oxytoca
Providencia stuartii	Escherichia coli	Enterococcus faecium	Enterococcus faecalis
Enterobacter cloacae	Treponema pallidum	Acinetobacter baumannii	Klebsiella aerogenes
FUNGI			
Candida albicans	Candida tropicalis	Candida krusei	Candida auris
Candida glabrata	Candida parapsilosis		

Respiratory Pathogen Testing (QPCR)

Respiratory Pathogen Panel (RPP) detects specific nucleic acid pathogens from patients exhibiting signs and symptoms of respiratory illness. RPP testing provides proper diagnosis and detection of both viral and bacterial infections with 24-hour turnaround time. Covid-19 is included on our panel. Respiratory panel testing is non-invasive which helps to minimize patient's discomfort.

The following is a list of **Pathogens** that can be ordered:

VIRAL
Coronavirus SARS-CoV-2
Influenza A virus A/H3
Influenza B virus
Respiratory syncytial virus

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SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

North West Labs
29580 Northwestern Hwy
Southfield, MI 48034
CLIA# 23D2126347

GI Panel

	BD Max Enteric Bacterial Panel		BD MAX Enteric Parasite Panel	BD MAX Enteric Viral Panel	BD MAX Cdiff Assay
Targets	• Salmonella spp • Campylobacter spp. (jejuni and coli) • Shigella spp./Enteroinvasive E. coli (EIEC) • Shiga toxin 1 & 2* (E. coli [STEC], Shigella dysenteriae	• Plesmiomonas Shigelloides • Vibrio (V. vulnificus, V. Parahaemolyticus, and V. cholerae) • Entertoxigenic E. coli (ETEC) • Yersinia entercolitica	• Giardia Lamblia • Cryptosporidium (C. hominis and C. parvum) • Entamoeba histolytica	• Norovirus GI/GII • Rotavirus A • Adenovirus F40/41 • Sapovirus (geno-groups I, II, IV, V) • Human Astrovirus (hAstro)	• Clostridium difficile toxin B gene (tcdB)
Specimen Types	• Unpreserved soft to diarrheal stool • Cary-Blair preserved stool		• Unpreserved soft to diarrheal stool • 10% Formalin fixed stool	• Unpreserved soft to diarrheal stool • Cary-Blair preserved stool	• Unpreserved soft to diarrheal stool

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SOUTHFIELD, MI 48034

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SOUTHFIELD, MI 48075

NORTH WEST

GASTROINTESTINAL (GI) TEST REQUISITION FORM

29580 Northwestern Hwy
Suite 120, Southfield, MI 48034
(248) 301-6917 | www.nwlabs.com

ORDERING PHYSICIAN

Physician to receive additional result report:

Clinical Impression:

Clinical History:

PATIENT INFORMATION

Patient Demo Attached ☐

Last Name: _____

First Name: _____

Middle Name: _____ Sex: ☐ Male ☐ Female

Address: _____

City: _____ State: _____ Zip: _____

DOB: _____ Mobile: _____

Email: _____

Race: ☐ Alaska Native or American Indian ☐ Asian ☐ Multiracial ☐ White
☐ Black or African American ☐ Native Hawaiian or other Pacific Islander
☐ Does not wish to disclose ☐ Not provided ☐ Other race

BILLING INFORMATION (Please include a copy of the front & back of card.)

Billing type: ☐ Patient ☐ Insurance ☐ Client **Relation:** ☐ Self ☐ Spouse ☐ Dependant

Insured's SS#: _____ Insured's DOB: _____

Primary Insurance Carrier: _____ Medicare, Medicaid or Policy ID#: _____

Claims Address: _____

Employer/Group Name: _____ Group#: _____

BIOPSY INFORMATION

ICD 10 codes (required):

Date Collected	Time Collected	Collected Signature	No of vials collected

Type:

☐Adenoma ☐Crohn's ☐H. pylori ☐Microscopic Colitis ☐Barrett's Esophagus
☐Dysplasia ☐Hepatitis ☐Proctitis ☐Cancer ☐Eosinophilic Esophagitis ☐IBD
☐Sprue ☐Candida ☐Fungi ☐Lymphoma ☐Steatohepatitis ☐Other:

Endoscopic Finding Code:

1. Normal	6. Friable	11. Hemorrahgic	16. Abn. Vascular Pattern
2. Edema	7. Erosion	12. Mass	17. Punctate Hemorrhage
3. Barrett's Mucosa	8. Hyperemia	13. Ulcer	18. Submucosal Nodule
4. Granular	9. Telangiectactic	14. Stricture	19. Pseudomembrane
5. Nodular	10. Polyp	15. Polyposis	20. Other:

Anatomic Site of Biopsy: Container	Organ & Site	Distance (cm)	Endoscopic Finding (see codes above)
1.			
2.			
3.			
4.			
5.			

Special stains for: ☐H. pylori ☐Fungus ☐TB ☐Virus ☐Other

GI Panel

■ ***BD Max Enteric Bacteria Panel*** ☐
- Salmonella spp • Campylobacter spp. (jejuni and coli)
- Shigella spp./Enteroinvasive E. coli (EIEC) • Yersinia enterocolitica
- Shiga toxin 1 & 2 (E. coli [STEC], Shigella dysenteriae)
- Vibrio (V. vulvunificus, V. parahaemolyticus & V. cholerae)
- Enterotoxigenic E. coli (ETEC) • Plesiomonas Shigelloides
- Specimen Types: Unpreserved soft to diarrheal stool, Cary-Blair preserved stool

■ ***BD Max Enteric Parasite Panel*** ☐
- Giardia Lamblia • Cryptosporidium (C. hominis and C. parvum)
- Entamoeba histolytica
- Specimen Types: Unpreserved soft to diarrheal stool, 10% Formalin fixed stool

■ ***BD Max Enteric Viral Panel*** ☐
- Norovirus GI/GII • Rotavirus A • Adenovirus F40/41
- Sapovirus (geno-groups I, II, IV, V) • Human Astrovirus (hAstro)
- Specimen Types: Unpreserved soft to diarrheal stool, Cary-Blair preserved stool

■ ***BD Max Cdiff Assay*** ☐
- Clostridium difficile toxin B gene (tcdB)
- Specimen Types: Unpreserved soft to diarrheal stool

OTHER TEST/PANELS:

ICD 10 codes (required):

Physician Authorization

I, the undersigned healthcare provider, acknowledge that when ordering a Urinary Tract Infection (UTI), Nail, or Wound PCR panel through North West Labs, located at 29580 Northwestern Hwy., Suite 120, Southfield, MI 48034 (NPI: 1568994879, Tax ID: 813538903) I understand and agree to the following terms:

1. In some or all instances, UTI, Wound, and Nail panels and their associated antibiotic resistance markers tests will be forwarded to PCR Labs of America (1464 E Whitestone Blvd, Ste 2401, Cedar Park, TX 78613; Phone: (512) 456-0071; Fax: (512) 456-0072) for processing and analysis.
2. Any pathology, cytology, and thin prep specimens will be forwarded to KC Pathology Laboratory (44400 Van Dyke Ave, Ste 102, Sterling Heights, MI 48314; Phone: (586) 262-4243; Podiatric Pathology Form Fax: (586) 262-4241) for evaluation and reporting.
3. I understand that while the initial order is placed with North West Labs, the actual testing may be performed by their partner laboratories as specified above.
4. I acknowledge that this referral process may affect billing procedures and timeline for results, and I accept this as part of the standard operating procedure for these specific test types.
5. I confirm that I have informed my patients about this testing arrangement as appropriate and in accordance with applicable regulations.

Physician Signature _____ **Date:** _____

Patient Consent and Authorization

I authorize the release of my medical information including test results for submission of personalized reports to my healthcare providers and insurance carrier(s). I request that payment of benefits be made to North West Labs, Inc. on my behalf. If my policy does not allow for direct payment, I agree to relinquish allocated funds to North West Labs, Inc as compensation for services rendered. I also acknowledge that I will be liable for payments of deductibles, co payments and/or co insurance as detailed by my healthcare insurer. I understand that I am liable for charges not covered by my healthcare insurer. I also authorize North West Labs, Inc to appeal insurance claims on my behalf. I acknowledge the benefits, risk and limitations of this testing as describe to me by a qualified healthcare provider. My insurance may not cover or pay full amount for testing; I may be responsible for full or part of amount charged due to out of network benefits, deductible and co pays. North West Labs, Inc has my permission to bill my insurance carrier(s), this notice gives me the option to proceed with the procedure or decline. By signing this I have read all of the above and understand it. Medicare Advance Beneficiary Notice: Medicare will only pay for services that it determines to be reasonably and necessary under section 1882 (a) (1) of the Medicare Law. If Medicare determines that a particular service, although it would otherwise be covered, is not reasonable and necessary under the Medicare Program standards, Medicare will deny payment for that service. Medicare usually does not pay for these tests for the reported diagnosis. By signing the Patient/Responsible Party Signature on this requisition, you are confirming your agreement to assume financial responsibility for the payment of these tests.

Patient Signature _____ **Date:** _____

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

Pathology Testing

Our specialties:

- Epidermal never fiber density testing
- Prostate and Urologic Pathology
- Hepatopathy
- Perinatal and gynecological/ obstetrical
- Neuropathology
- Pancreas and hepatobiliary
- Pulmonary oncologic
- Breast pathology
- Bone and soft tissue
- Podiatric pathology
- Cytopathology
- Dermatopathology
- Gastrointestinal pathology
- Oral pathology
- Placenta pathology

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

NORTH WEST LABS

29580 Northwestern Hwy, STE 120
Southfield, MI 48034
Phone: 248 301 6917
Fax: 248 301 6805
support@nwlabs.com

Small Fiber Neuropathy Testing

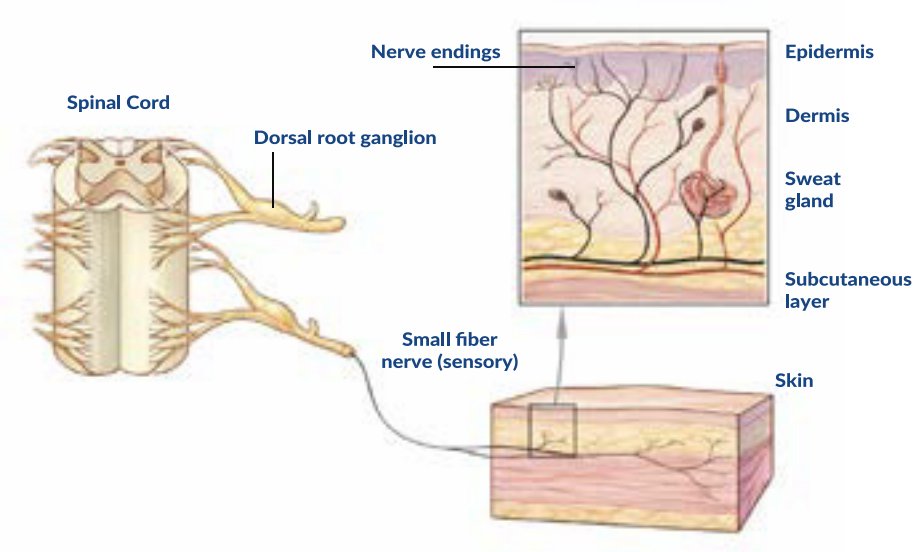
Neuropathy affects 15–20 million people nationally.
Small-Fiber Neuropathy (SFN) is a peripheral neuropathy that affects the sensory and autonomic nervous system.

Associated Causes and Diagnoses

- Alcohol Abuse
- Amyloidosis
- Autoimmune Diseases
- Celiac Disease
- Complex RPS
- Connective Tissue Disorders
- Diabetes
- Fabry's Disease
- Fibromyalgia
- Lupus
- Guillain-Barre Syndrome
- Multiple Sclerosis
- Parkinson's
- Pharmacological and Neurotoxic Drug Exposure
- Restless Leg Syndrome
- Sarcoidosis
- Sjogren's Syndrome
- Vibratory Trauma
- Vitamin B12 Deficiency

Skin Biopsy to Diagnose Small Fiber Neuropathy

Performing a skin biopsy to analyze and quantify nerve fibers in the epidermis is a relatively simple and convenient way to identify and monitor small fiber neuropathy. Studies support the high sensitivity and the specificity of skin biopsy in detecting small nerve fiber loss. It has been used not only in diagnosis but also to evaluate disease progression and treatment success. ENFD studies have been shown to have 88.4% sensitivity in detection compared with 54.6% for clinical exams alone. Moreover, the test can detect early nerve fiber damage, even in asymptomatic patients.



SFN Symptoms

- Bowel and Bladder Disturbances
- Burning Sensation
- Loss of Balance
- Issues Walking
- Digestive Issues
- Dizziness
- Itching
- Loss of Touch Sensation
- Muscle Cramping
- Numbness and Tingling
- Pain Sensitivity
- Restless Leg Syndrome
- Weakness
- Temperature Sensitivity

NORTH WEST LABS

29580 Northwestern Hwy, STE 120
Southfield, MI 48034
Phone: 248 301 6917
Fax: 248 301 6805
support@nwlabs.com

No More Rinsing or Refrigeration

Simplify Small Fiber Neuropathy (SFN) Testing

When EMG and NCV results are normal but your patient still reports neuropathic pain, our NW Labs Small Fiber Neuropathy Test provides objective evidence needed for a confident diagnosis.

WHY PROVIDERS CHOOSE NORTH WEST LABS

- No More Refrigeration – Simplified collection and shipping process
- All-Inclusive Kits – Pre-labeled vials, collection forms, surgical tools, and patient materials
- Fast 5-Day Turnaround – Reports interpreted by a board certified pathologist
- Objective Results – Positive/negative diagnosis with length dependent detail
- Training & Support – Step-by-step collection guidance and expert support

IDEAL FOR PATIENTS WITH

- Burning, tingling, or freezing pain in feet or hands
- Unexplained numbness or balance loss
- Normal EMG/NCV but persistent neuropathic symptoms
- Diagnoses such as Fibromyalgia or Autoimmune Neuropathy

IN OFFICE PROCEDURE AND REIMBURSABLE

Common CPT Codes:
99213, 11104, 11105

Typical Office Reimbursement:
$327 per patient

TEST WORKFLOW

1. Perform a 3–4 site skin punch biopsy (thigh, calf, or ankle)
2. Place tissue in provided Zamboni vials (no refrigeration required)
3. Complete the SFN Requisition Form (SPN-002)
4. Ship at ambient temperature using the pre-labeled mailer
5. Receive results in 5 business days

REQUEST YOUR COMPLIMENTARY SFN TEST KIT TODAY!

NWlabs.com **248-301-6917**

NORTH WEST LABS

This reference guide is intended for providers performing punch biopsies for epidermal nerve fiber density (ENFD) testing. The laboratory studies below may assist in identifying the underlying etiology of Small Fiber Neuropathy (SFN) and guide treatment decisions based on whether the presentation is length-dependent (LD) or non-length-dependent (NLD).

Recommended Follow-Up Testing

Test Category	Specific Tests	Suggestive Pattern	Clinical Rationale	ICD-10 Codes	Common CPT
Glycemic / Metabolic	HbA1c, Fasting Gluc. 2-hr OGTT	LD-SFN	Most common cause of distal SFN	E11.x, R73.09	83036, 82947, 82951
Vitamin Deficiency	Vitamin B12 ± MMA, Folate	LD-SFN	Common in elderly neuropathy	E53.8, D51.x	82607, 83921, 82746
Thyroid Function	TSH, Free T4	LD-SFN	Assoc. w/ periph. neuropathy	E03.9	84443, 84439
Monoclonal Gammopathy	SPEP, IFE, Free Lt Chains	LD or NLD	Paraproteinemias can cause SFN	D47.2, C90.0	84165, 86334, 83883
Autoimmune Inflammatory	ANA, ESR, CRP	NLD-SFN	Immune-mediated SFN often NLD	M35.9, R76.8	86038, 85652, 86140
Sjögren's Syndrome	SSA (Ro), SSB (La)	NLD-SFN	Strong association with NLD-SFN	M35.01	86235
Celiac Disease	tTG IgA, Total IgA	NLD-SFN	Gluten sensitivity may cause SFN	K90.0	83516, 82784
Infectious Causes	HIV, Hepatitis C	LD or NLD	Chronic infection-associated neuropathy	B20, B18.2	86703, 86803
Amyloidosis (If Suspected)	Serum/Urine IFE, Fat Pad Biopsy	NLD-SFN	Systemic amyloid neuropathy	E85.x	86334, 38505

Clinical Use Notes: Length-dependent SFN is most commonly associated with metabolic, nutritional, and toxic causes. Non-length-dependent SFN is more frequently linked to autoimmune, inflammatory, or systemic disease. Follow-up testing should be individualized based on ENFD pattern, symptoms, and patient comorbidities.

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

TESTS PERFORMED (CPT):
H&E level 3 tissue exam (88305);
Congo Red HC stain (88314); and
ENFD IHC by PGP 9.5 antibody (88342),
analysis and interpretation (88356)

SMALL FIBER NEUROPATHY TEST

ALL FORM FIELDS REQUIRED

CLIA Certified
CLIA# 23D2126347

NORTH WEST LABS, INC.
29580 NORTHWESTERN HWY | STE 120
SOUTHFIELD, MI 48034-1087
Phone: 248-301-6917 | Fax: 248-301-6805
Lab Director: Dr. Eugene S. Olsowka, MD

NORTH WEST LABS

Patient Information

Last Name: _____ First Name: _____

Gender: _____ DOB: _____ Phone: _____

Address: _____ City, State, Zip: _____

Patient Insurance - *attach copy of insurance card and/or face sheet.*

Primary Insurance: _____ ID #: _____ Group #: _____

Phone: _____ Insured Name: _____ Employer's Name: _____

Submitting Facility

Facility Name: _____

Ordering Physicians/NPI: _____

Address: _____ City, State, Zip: _____ Phone: _____

Diagnosis ICD-10 Codes – *minimum 2 codes required.*

☐ **G60.8** Other Hereditary/Idiopathic Neuropathy
☐ **G90.50** Complex Regional Pain Syndrome, Unspecified
☐ **G60.3** Idiopathic Progressive Neuropathy
☐ **G90.09** Other Idiopathic Peripheral Autonomic Neuropathies
☐ **M79.7** Fibromyalgia
☐ **G90.59** Complex Regional Pain Syndrome of Other Specified Site
☐ Other _____
☐ Other _____
☐ Other _____

Clinical Information

Needle electromyography (EMG) and nerve conduction velocity studies are normal and show no evidence of large fiber neuropathy.	☐ Y	☐ N
Physical examination shows no evidence of findings consistent with large-fiber neuropathy, such as reduced or absent muscle-stretch reflexes or reduced proprioception and vibration sensation.	☐ Y	☐ N
Individual presents with painful sensory neuropathy.	☐ Y	☐ N

Tentative Clinical Diagnosis

Specimen Collection

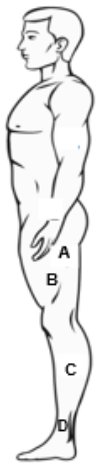
Date _____ Time _____ ☐ AM ☐ PM

Sample Locations

Biopsy Site (note side of body from where sample was collected)

Right Side	Left Side
☐	☐

Sample A:	Proximal Thigh
Sample B:	Distal Thigh
Sample C:	Mid-Calf
Sample D:	Ankle



Proximal Thigh (A)
10 cm below greater trochanter (hip joint).

Distal Thigh (B)
10 cm above the lateral joint line of the knee.

Mid-Calf (C)
10 cm below lateral knee.

Ankle (D)
10 cm above lateral ankle.

Please include the following required information with this form:

- *Neurology Clinical Notes*
- *NCS/EMG Results If Performed*
- *Copy of Patient Medical History*

Physician Name Printed	**Physician Signature**	**Date**

TESTS PERFORMED (CPT):
H&E level 3 tissue exam (88305);
Congo Red HC stain (88314); and
ENFD IHC by PGP 9.5 antibody (88342),
analysis and interpretation (88356)

SMALL FIBER NEUROPATHY TEST

ALL FORM FIELDS REQUIRED

CLIA Certified
CLIA# 23D2126347

NORTH WEST LABS, INC.
29580 NORTHWESTERN HWY | STE 120
SOUTHFIELD, MI 48034-1087
Phone: 248-301-6917 | Fax: 248-301-6805
Lab Director: Dr. Eugene S. Olsowka, MD

NORTH WEST LABS

Patient Information

Last Name: _____ First Name: _____

Gender: _____ DOB: _____/_____/_____ Phone: _____

Address: _____ City, State, Zip: _____

Patient Insurance - *attach copy of insurance card and/or face sheet.*

Primary Insurance: _____ ID #: _____ Group #: _____

Phone: _____ Insured Name: _____ Employer's Name: _____

Submitting Facility

Facility Name: _____ Ordering Physician: _____ NPI#: _____

Address _____ City State: _____ Zip: _____ Phone: _____

Diagnosis ICD-10 Codes – *minimum 2 codes required.*

- ☐ **G60.8** Other Hereditary/Idiopathic Neuropathy
- ☐ **G90.50** Complex Regional Pain Syndrome, Unspecified
- ☐ **G60.3** Idiopathic Progressive Neuropathy
- ☐ **G90.09** Other Idiopathic Peripheral Autonomic Neuropathies
- ☐ **G90.3** Multi-System Degeneration of Autonomic Nervous System
- ☐ **G90.59** Complex Regional Pain Syndrome of Other Specified Site
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____

Clinical Information

Needle electromyography (EMG) and nerve conduction velocity studies are normal and show no evidence of large fiber neuropathy.	☐ Y	☐ N
Physical examination shows no evidence of findings consistent with large-fiber neuropathy, such as reduced or absent muscle-stretch reflexes or reduced proprioception and vibration sensation.	☐ Y	☐ N
Individual presents with painful sensory neuropathy.	☐ Y	☐ N

Tentative Clinical Diagnosis

Specimen Collection

Date _____ Time _____ ☐ AM ☐ PM

Sample Locations

Biopsy Site (note side of body from where Sample C Calf sample was collected)

		Right Side	Left Side
Sample A:	Right Ankle	X	
Sample B:	Left Ankle		X
Sample C:	Calf		

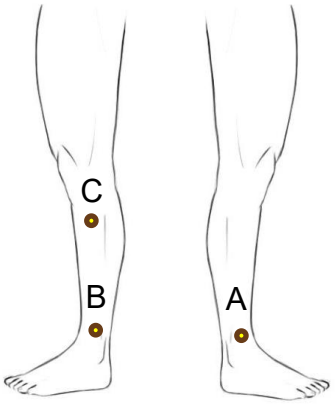
Please include the following required information with this form:

- *Neurology Clinical Notes*
- *NCS/EMG Results If Performed*
- *Copy of Patient Medical History*

A: **Right Ankle (RA)**
10 cm above lateral ankle.

B: **Left Ankle (LA)**
10 cm above lateral ankle

C: **Calf (C)**
15 cm below the lateral joint line of the knee



Physician Name Printed	**Physician Signature**	**Date**

NORTH WEST LABS
29580 Northwestern HWY Suite 120,
Southfield, MI 48034
T: (248) 301-6917 www.nwlabs.com
Lab Director: Eugene Olsowka MD
CLIA ID# 23D2126347

FINAL

Dr Test Test
123 Main St
Southfield, MI 48034

Test, Test
Patient: #: 0000
DOB: 01/01/2001

MRN:
Sex: Female

Accession: xxxxx
Collected Date: 01/01/2001 1:00 PM LAB
Received Date: 01/01/2001 7:10 PM

Organization: NORTH WEST LABS

Test Name	Result	Units	Flag	Reference Range/Cutoff

EXAMPLE TEST

ENFD - Epidermal Nerve Fiber Density Analysis (4 Punch) *Run on 3/2/2026 10:59:50 AM at StratusDX perf*

****Performing site: KC*

Clinical Data: G60.3
Specimen Received: A: Proximal Thigh.
Specimen Received [B]: B: Distal Thigh.
Specimen Received [C]: C: Mid-Calf
Specimen Received [D]: D: Ankle

Report Status	Normal	F

FINAL DIAGNOSIS F

A. Left Proximal Thigh:
- No small vessel vasculitis and other significant abnormalities seen.
- PGP 9.5 immunostain shows normal fiber density (more than 11.2 fibres/mm).
- Congo red special stain is negative for amyloid deposits.

FINAL DIAGNOSIS [B] F

B. Left Distal Thigh:
- No small vessel vasculitis and other significant abnormalities seen.
- PGP 9.5 immunostain shows normal fiber density (more than 11.2 fibres/mm).
- Congo red special stain is negative for amyloid deposits.

FINAL DIAGNOSIS [C] F

C. Left Mid Calf:
- No small vessel vasculitis and other significant abnormalities seen.
- PGP 9.5 immunostain shows normal fiber density (more than 11.2 fibres/mm).
- Congo red special stain is negative for amyloid deposits.

FINAL DIAGNOSIS [D] F

D. Left Ankle:
- No small vessel vasculitis and other significant abnormalities seen.
- PGP 9.5 immunostain shows normal fiber density (more than 11.2 fibres/mm).
- Congo red special stain is negative for amyloid deposits.

GROSS DESCRIPTION F

A: Proximal Thigh: Received is 5x3x3 mm punch biopsy skin specimen fixed in Zamboni fixative in a vial. Specimen is submitted in one cassette, 1 piece. A :1 piece.

GROSS DESCRIPTION [B] F

B: Distal Thigh: Received is 5x3x3 mm punch biopsy skin specimen fixed in Zamboni fixative in a vial. Specimen is submitted in one cassette, 1 piece. B :1 piece.

GROSS DESCRIPTION [C] F

C: Mid-Calf: Received is 5x3x3 mm punch biopsy skin specimen fixed in Zamboni fixative in a vial. Specimen is submitted in one cassette, 1 piece. C:1 piece.

GROSS DESCRIPTION [D] F

D: Ankle: Received is 3x3x2 mm punch biopsy skin specimen fixed in Zamboni fixative in a vial. Specimen is submitted in one cassette, 1 piece. D :1 piece.

NORTH WEST LABS
29580 Northwestern HWY Suite 120,
Southfield, MI 48034
T: (248) 301-6917 www.nwlabs.com
Lab Director: Eugene Olsowka MD
CLIA ID# 23D2126347

FINAL

Dr Test Test
123 Main St
Southfield, MI 48034

Test, Test
Patient: #: 0000
DOB: 01/01/2001
MRN:
Sex: Female

Accession: xxxxx
Collected Date: 01/01/2001 1:00 PM LAB
Received Date: 01/01/2001 7:10 PM

Organization: NORTH WEST LABS

Test Name	Result	Units	Flag	Reference Range/Cutoff

EXAMPLE TEST

COMMENTS: F

Parts A, B, C, and D:
Each Biopsy specimen also underwent routine hematoxylin & eosin (H&E) evaluation for microscopic evidence of vasculitis, Congo Red staining for detection of any amyloid deposition and nerve fiber density using PGP9.5 immunohistochemical stain. Specimen processing for epidermal nerve fiber density assessment was performed as per recent consensus guidelines (Lauria et al., Journal of the Peripheral Nervous System 2010; 15:79-92). Normal values for biopsies from distal leg (calf) are adjusted for age and gender as per Lauria et al. (JPNS 2010; 15:202-207). Age and gender adjusted normative values have not been determined for other sites. Small fiber neuropathies that are not length dependent may be more commonly associated with abnormal glucose metabolism or autoimmune disorders (Garson et al., J Neural Neurosurg Psychiatry 2008; 79:163-169).
ENFD Normative Values by Age and Sex:
Age Group (Years)

Females (Fibers/mm)	Males (Fibers/mm)
20–2 13.5 (Median)	10.9 (Median)
30–39 12.4	10.3
40–49 11.2	9.6
50–59 9.8	8.9
60–69 8.7	8.3
70–79 7.6	7.7
=80 6.7	7.2

Influence of Age and Sex:
Age: ENFD decreases with advancing age. This decline is observed in both sexes and is a normal aspect of aging.
Sex: Females generally exhibit higher ENFD values than males across all age groups. This difference is statistically significant and should be considered during clinical assessments.
INTERPRETIVE COMMENTARY - SMALL FIBER NEUROPATHY
Interpretation: Epidermal nerve fiber density is reduced at the sampled site(s), consistent with Small Fiber Neuropathy (SFN). This provides objective, pathology-based confirmation of small fiber involvement, which may not be detected by standard EMG/NCS testing.
Pattern-Based Interpretation: The distribution of epidermal nerve fiber loss may assist in distinguishing:
Length-Dependent SFN (LD-SFN): Most commonly associated with metabolic, toxic, or nutritional etiologies, including diabetes or pre-diabetes, alcohol exposure, medication-related neurotoxicity, and vitamin deficiencies.
Non-Length Dependent SFN (NLD-SFN): May raise consideration for immune-mediated, inflammatory, infectious, or genetic etiologies and can be associated with more widespread or patchy symptom patterns.
Suggested Clinical Correlation & Follow-Up (Non-Prescriptive):
Clinical correlation is recommended. Depending on the clinical context, consideration may be given to further evaluation for underlying etiologies commonly associated with SFN, including:
Metabolic / Nutritional, Glucose dysregulation ,Vitamin B12, B6, Folate, Thyroid dysfunction, Immune / Inflammatory, Autoimmune serologies, Connective tissue disease marker, Paraneoplastic evaluation when clinically indicate Other, Medication or toxin exposure, Hereditary neuropathy assessment in select cases
Clinical Utility: This objective, pathology-based diagnosis may assist in refining the differential diagnosis, guiding additional evaluation, and informing longitudinal neurologic or pain management strategies.

Electronically signed by: Dr. Fayez Daaboul, MD F

Performing Site: F

Technical and professional Components Performed at: KC Pathology Laboratory, LLC, 44400 Van Dyke Ave, Suite 102, Sterling Heights MI 48314-2370. CLIA#23D2276072. Medical Director: FAYEZ DAABOUL, MD. This test was developed and its performance and characteristics determined by the KC Pathology Laboratory LLC. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. "All controls show appropriate reactivity "This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

StratusDX [KC] performing site:	KC PATHOLOGY LABORATORY LLC 44400 VAN DYKE AVE STE 102A STERLING HEIGHTS, MI 48314-2370

* Any Toxicology Drug Confimation Testing value that falls below the cutoff will be reported as a negative outcome.
This is a laboratory-developed test, which is not FDA approved.

Final Report

NORTH WEST LABS
29580 Northwestern Hwy.
STE 120.

Southfield, MI 48034
Phone: (248) 301-6917
Fax: (248) 301-3805

Patient		
	Last Name	**DOE 1**
	First Name	**JANE**
	Gender	**Female**
	Age	**xx**
	Date of Birth	**01/01/2001**
	Patient ID#	**0000**

Specimen		
	Status	**Final**
	Accession #	**xxxxx**
	Collection Date	**01/01/2001**
	Received Date	**01/01/2001**
	Report Date	**01/01/2001**
	Specimen Type	

Provider Information		
	Ordering Physician	**TEST**
	Referring Physician	
	Organization	**NORTH WEST LABS**
	Location	**LAB**

General Pathology

Specimen Received
A: Endocervical (ECC).

Specimen Received [B]
B: Cervix-12 o'clock.

FINAL DIAGNOSIS
A. Endocervical, ECC: Fragments of endocervical epithelium, negative dysplasia or malignancy.

FINAL DIAGNOSIS [B]
B. Cervix, 12 o'clock, biopsy: Focal koilocytic changes compatible with low grade squamous intraepithelial lesion/Cervical intraepithelial neoplasm 1 (LSIL/ CIN I). Endocervical mucosa identified.

GROSS DESCRIPTION
A: Labeled as "Endocervical (ECC), Multiple pieces "Received is a 20x9x1 mm, Color-Tan-Brown Biopsy specimen fixed in formalin. The specimen is submitted in one cassette A. A: Multiple pieces.

GROSS DESCRIPTION [B]
B: Labeled as "Cervix-12 o'clock, 1 piece "Received is a 5x4x1 mm, Color-White-Brown Biopsy specimen fixed in formalin. Specimen is submitted in one cassette B. B: 1 piece.

CPT CODE
88305

CPT CODE [B]
88305

ICD 10 CODES:
R87.618

Electronically signed by:
Dr. Fayez Daaboul, MD

Report Status
Abnormal

Final

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

NORTH WEST LABS

North West Labs
29580 Northwestern Hwy
Southfield, MI 48034

Phone: (248) 301 6917
Fax: (248) 301 6805

support@nwlabs.com

Patient Details ☐ Demographics Attached

Last Name: | M.I.

First Name | Date of Birth:

Address: | Zip Code

City, State

Phone #: | Gender: ☐ Male ☐ Female

Provider Information:

Patient Insurance Details

Primary Insurance Carrier: | Insured name: | Date of Birth:

Policy #: | Group #:

Authorization Code: | ☐ SELF PAY / NO INSURANCE | Relation to insured: (Select one) ☐ Self ☐ Spouse ☐ Guardian

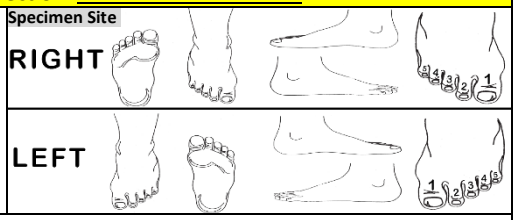
Relevant Clinical Information & ICD10

REQUIRED - **Date of Collection:** _____ **Time of Collection:** _____

ICD10 (*REQUIRED*)

- ☐ Z16.29 Resistance to other single spec. anti
- ☐ L85.8 Other specified epidermal thickening
- ☐ B96.89 Other specified bacterial agent
- ☐ B95.2 Enterococcus
- ☐ 95.7 Other Staphylococcus
- ☐ Other _____
- ☐ Z16.29 Resistance to other single spec. anti
- ☐ L85.8 Other specified epidermal thickening
- ☐ B96.89 Other specified bacterial agent
- ☐ B96.5 Pseudomonas
- ☐ L89._____ Pressure Ulcer (6-digit code Req'd)
- ☐ L97._____Non-Pressure Ulcer (6-digit code Req'd)
- ☐ L60.0 Ingrown toenails
- ☐ 7835.1 Onychomycosis
- ☐ B35.3 Tinea Pedis
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____

Specimen Site



ADDITIONAL CODES AVAILABLE ON REAR

- ☐ B49 Unspecified Mycosis
- ☐ L03.011 Cellulitis of the right finger
- ☐ L03.012 Cellulitis of the left Finger
- ☐ L03.021 Cellulitis of the right toe
- ☐ L03.022 Cellulitis of the left toe
- ☐ I87.311 Chronic venous hypertension w ulcer of rght low extremity
- ☐ E11.621 Type 2 diabetes mellitus with foot ulcer
- ☐ E11.622Type 2 diabetes mellitus with other skin ulcer
- ☐ L03.019 Cellulitis of unspecified finger
- ☐ L03.03 Cellulitis of toe
- ☐ L03.115 Cellulitis of right lower limb
- ☐ I87.312 Chronic venous hypertension w ulcer of left low extremity
- ☐ L03.81 Cellulitis of other sites
- ☐ L08.89 Other Specified Local Infections of the Skin & Subcutaneous Tissue
- ☐ L02.91 Cutaneous Abscess, Unspecified
- ☐ L60.8 Other nail disorders
- ☐ L03.116 Cellulitis of left lower limb
- ☐ I87.313 Chronic venous hypertension w ulcer of bilateral low extremity
- ☐ L60.1 Onycholysis
- ☐ L60.4 Beau's Lines
- ☐ L60.3 Nail Dystrophy
- ☐ L60.5 Yellow nail syndrome
- ☐ R21 Rash and other nonspecific skin eruption

Test Menu

SPECIMEN A
Collect in Eswab

Location of Infection:_____

☐ **Wound / Sepsis PCR Panel** Panel includes

BACTERIA

Escherichia coli	Klebsiella aerogenes
Streptococcus agalactiae	Klebsiella pneumoniae
Klebsiella oxytoca	Staphylococcus aureus
Staphylococcus saprophyticus	Streptococcus pyogenes
Pseudomonas aeruginosa	Streptococcus pneumoniae
Staphylococcus haemolyticus	Streptococcus dysgalactiae
Enterococcus faecium	Staphylococcus lugdunensis
Enterococcus faecalis	Staphylococcus epidermidis
Acinetobacter calcoaceticus- baumannii complex	

FUNGI

Candida krusei	Candida albicans	Candida parapsilosis
Candida tropicalis	Fusarium solani	Trichophyton spp
Candida glabrata	Microsporum spp	

Panel includes

ANTIMICROBIAL RESISTANCE
Methicillin Resistance (MecA+C)

☐ **Fungal & Nail PCR** Panel includes

Aspergillus flavus	Malassezia sympodialis
Aspergillus fumigatus	Mentagrophytes/interdigitale
Aspergillus niger	Microsporum audouinii
Aspergillus terreus	Microsporum canis
Candida albicans	Microsporum gypseum
Candida auris	Trichophyton
Candida glabrata	Trichophyton rubrum
Candida krusei	Trichophyton soudanense
Candida parapsilosis	Trichophyton terrestre
Epidermophyton floccosum	Trichophyton tonsurans
Fusarium oxysporum	Trichophyton verrucosum
Malassezia furfur	Trichophyton violaceum
Malassezia globosa	Trichosporon asahii
Malassezia restricta	Trichosporon mucoides

SPECIMEN B
Collect in Eswab

Location of Infection:_____

☐ **Wound / Sepsis PCR Panel** Panel includes

BACTERIA

Escherichia coli	Klebsiella aerogenes
Streptococcus agalactiae	Klebsiella pneumoniae
Klebsiella oxytoca	Staphylococcus aureus
Staphylococcus saprophyticus	Streptococcus pyogenes
Pseudomonas aeruginosa	Streptococcus pneumoniae
Staphylococcus haemolyticus	Streptococcus dysgalactiae
Enterococcus faecium	Staphylococcus lugdunensis
Enterococcus faecalis	Staphylococcus epidermidis
Acinetobacter calcoaceticus- baumannii complex	

FUNGI

Candida krusei	Candida albicans	Candida parapsilosis
Candida tropicalis	Fusarium solani	Trichophyton spp
Candida glabrata	Microsporum spp	

ANTIMICROBIAL RESISTANCE
Methicillin Resistance (MecA+C)

☐ **Fungal & Nail PCR** Panel includes

Aspergillus flavus	Malassezia sympodialis
Aspergillus fumigatus	Mentagrophytes/interdigitale
Aspergillus niger	Microsporum audouinii
Aspergillus terreus	Microsporum canis
Candida albicans	Microsporum gypseum
Candida auris	Trichophyton
Candida glabrata	Trichophyton rubrum
Candida krusei	Trichophyton soudanense
Candida parapsilosis	Trichophyton terrestre
Epidermophyton floccosum	Trichophyton tonsurans
Fusarium oxysporum	Trichophyton verrucosum
Malassezia furfur	Trichophyton violaceum
Malassezia globosa	Trichosporon asahii
Malassezia restricta	Trichosporon mucoides

SPECIMEN C
Collect in Eswab

Location of Infection:_____

☐ **Wound / Sepsis PCR Panel** Panel includes

BACTERIA

Escherichia coli	Klebsiella aerogenes
Streptococcus agalactiae	Klebsiella pneumoniae
Klebsiella oxytoca	Staphylococcus aureus
Staphylococcus saprophyticus	Streptococcus pyogenes
Pseudomonas aeruginosa	Streptococcus pneumoniae
Staphylococcus haemolyticus	Streptococcus dysgalactiae
Enterococcus faecium	Staphylococcus lugdunensis
Enterococcus faecalis	Staphylococcus epidermidis
Acinetobacter calcoaceticus- baumannii complex	

FUNGI

Candida krusei	Candida albicans	Candida parapsilosis
Candida tropicalis	Fusarium solani	Trichophyton spp
Candida glabrata	Microsporum spp	

ANTIMICROBIAL RESISTANCE
Methicillin Resistance (MecA+C)

☐ **Fungal & Nail PCR** Panel includes

Aspergillus flavus	Malassezia sympodialis
Aspergillus fumigatus	Mentagrophytes/interdigitale
Aspergillus niger	Microsporum audouinii
Aspergillus terreus	Microsporum canis
Candida albicans	Microsporum gypseum
Candida auris	Trichophyton
Candida glabrata	Trichophyton rubrum
Candida krusei	Trichophyton soudanense
Candida parapsilosis	Trichophyton terrestre
Epidermophyton floccosum	Trichophyton tonsurans
Fusarium oxysporum	Trichophyton verrucosum
Malassezia furfur	Trichophyton violaceum
Malassezia globosa	Trichosporon asahii
Malassezia restricta	Trichosporon mucoides

Pathology

Collection Procedure:
☐ Biopsy_____ ☐ Excision ☐ Nail ☐ Other_____

Skin (Formalin)**
- ☐ Tinea
- ☐ Pigmented Lesion (E.G., Melanoma)
- ☐ Non-Pigmented Lesion (E.G., Verruca)
- ☐ Dermatitis/Rash
- ☐ Ulceration (E.G. Vasculitis)

Soft Tissue (Formalin)**
- ☐ Tumor (Cyst, Lipoma, Sarcoma)
- ☐ Inflammatory (Abscess)
- ☐ Inflammatory (Tophus)

Nail (Dry nail bag)**
- ☐ Trauma
- ☐ Pigmented Streak
- ☐ Non-Pigmented Lesion
- ☐ Nail Granulation
- ☐ R/O Melanoma
- ☐ Other_____

Onychomycosis (Dry nail bag)**
- ☐ Routine (PAS)
- ☐ High Sensitivity (PAS, GMS)
- ☐ Highest Sensitivity (PAS, GMS, FM)

Bone (formalin)
- ☐ Suspect Osteomyelitis / Infection
- ☐ Lesion (cyst, Neoplasm, etc.)
- ☐ Deformity
- ☐ Arthritis

Collection Site: _____

Collection Procedure:
☐ Biopsy_____ ☐ Excision ☐ Nail ☐ Other_____

Skin (Formalin)**
- ☐ Tinea
- ☐ Pigmented Lesion (E.G., Melanoma)
- ☐ Non-Pigmented Lesion (E.G., Verruca)
- ☐ Dermatitis/Rash
- ☐ Ulceration (E.G. Vasculitis)

Soft Tissue (Formalin)**
- ☐ Tumor (Cyst, Lipoma, Sarcoma)
- ☐ Inflammatory (Abscess)
- ☐ Inflammatory (Tophus)

Nail (Dry nail bag)**
- ☐ Trauma
- ☐ Pigmented Streak
- ☐ Non-Pigmented Lesion
- ☐ Nail Granulation
- ☐ R/O Melanoma
- ☐ Other_____

Onychomycosis (Dry nail bag)**
- ☐ Routine (PAS)
- ☐ High Sensitivity (PAS, GMS)
- ☐ Highest Sensitivity (PAS, GMS, FM)

Bone (formalin)
- ☐ Suspect Osteomyelitis / Infection
- ☐ Lesion (cyst, Neoplasm, etc.)
- ☐ Deformity
- ☐ Arthritis

Collection Site: _____

Physician Authorization

I, the undersigned healthcare provider, acknowledge that when ordering a Urinary Tract Infection (UTI), Nail, or Wound PCR panel through North West Labs, located at 29580 Northwestern Hwy., Suite 120, Southfield, MI 48034 (NPI: 1568994879, Tax ID: 813538903) I understand and agree to the following terms:

1. In some or all instances, UTI, Wound, and Nail panels and their associated antibiotic resistance markers tests will be forwarded to PCR Labs of America 1464 E Whitestone Blvd, Ste 2401, Cedar Park, TX 78613; Phone: (512) 456-0071; Fax: (512) 456-0072) for processing and analysis.
2. Any pathology, cytology, and thin prep specimens will be forwarded to KC Pathology Laboratory 44400 Van Dyke Ave, Ste 102, Sterling Heights, MI 48314; Phone: (586) 262-4243; Podiatric Pathology Form Fax: (586) 262-4241) for evaluation and reporting.
3. I understand that while the initial order is placed with North West Labs, the actual testing may be performed by their partner laboratories as specified above.
4. I acknowledge that this referral process may affect billing procedures and timeline for results, and I accept this as part of the standard operating procedure for these specific test types.
5. I confirm that I have informed my patients about this testing arrangement as appropriate and in accordance with applicable regulations.

Physician Signature _____ **Date:**_____

Patient Consent and Authorization

I authorize the release of my medical information including test results for submission of personalized reports to my healthcare providers and insurance carrier(s). I request that payment of benefits be made to North West Labs, Inc. on my behalf. If my policy does not allow for direct payment, I agree to relinquish allocated funds to North West Labs, Inc as compensation for services rendered. I also acknowledge that I will be liable for payments of deductibles, co payments and/or co insurance as detailed by my healthcare insurer. I understand that I am liable for charges not covered by my healthcare insurer. I also authorize North West Labs, Inc to appeal insurance claims on my behalf. I acknowledge the benefits, risk and limitations of this testing as describe to me by a qualified healthcare provider. My insurance may not cover or pay full amount for testing; I may be responsible for full or part of amount charged due to out of network benefits, deductible and co pays. North West Labs, Inc has my permission to bill my insurance carrier(s), this notice gives me the option to proceed with the procedure or decline. By signing this I have read all of the above and understand it. Medicare Advance Beneficiary Notice: Medicare will only pay for services that it determines to be reasonably and necessary under section 1882 (a) (1) of the Medicare Law. If Medicare determines that a particular service, although it would otherwise be covered, is not reasonable and necessary under the Medicare Program standards, Medicare will deny payment for that service. Medicare usually does not pay for these tests for the reported diagnosis. By signing the Patient/Responsible Party Signature on this requisition, you are confirming your agreement to assume financial responsibility for the payment of these tests.

Patient Signature _____ **Date:**_____

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

Final Report

North West Labs
29580 Northwestern Hwy
Ste 120
Southfield, MI 48034
Phone: (248) 301-6917
Fax: (248) 301-6805

Patient		
	Last Name	**DOE 5**
	First Name	**JOHN**
	Gender	**Male**
	Age	**XX**
	Date of Birth	**01/01/2001**
	Patient ID#	**test 5**

Specimen		
	Status	**Final**
	Accession #	**XXXXX**
	Collection Date	
	Received Date	
	Report Date	**10/01/2025**
	Specimen Type	

Provider Information		
	Ordering Physician	
	Referring Physician	
	Organization	**Test Example**
	Location	**LAB**

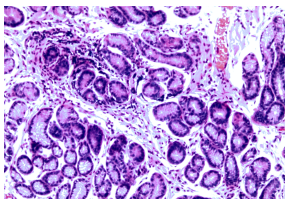
SPECIMEN RECEIVED

Upper GI Biopsy.

CLINICAL DATA

INDICATIONS: Gastroesophageal reflux disease, Follow-up of Barrett's esophagus.
IMPRESSIONS:
- LA Grade A reflux esophagitis with no bleeding.
- Non-erosive gastropathy.
ICD9 CODES : K21.00, K29.70, K22.70.

FINAL DIAGNOSIS



A. STOMACH, ANTRUM, BODY, BIOPSY:
- GASTRIC MUCOSA WITH NO SPECIFIC PATHOLOGICAL CHANGES.
- MODIFIED TOLUIDINE BLUE (MTB) STAIN FOR H. PYLORI LIKE ORGANISMS IS NEGATIVE.

B. ESOPHAGUS, LOWER, BIOPSY:
- ESOPHAGEAL SQUAMOUS MUCOSA WITH INCREASED INTRAEPITHELIAL INFLAMMATORY CELLS, INCLUDING EOSINOPHILS (FOCALLY ONLY 7-8 EOSINOPHILS PER HIGH POWER FIELD) AND REFLUX CHANGES.
- NO INTESTINAL GOBLET CELL METAPLASIA IS SEEN.

GROSS DESCRIPTION

Received is a 2-part case: 2 H+E slides and HPMTB labeled SKC24-1795 Internally labeled as 3172/S24-1839. The specimen received with the patient's name and medical record number in 2 parts.
The 1- part is labeled "Stomach, Body, Antrum". It consists of 3 fragments that measure 0.4cm-0.1cm, submitted in cassette A.
The 2- part is labeled "Esophagus, Lower Third". It consists of 3 fragments that measure 0.3cm-0.3cm, submitted in cassette B.
H&E CONTROL SLIDE WAS EVALUATED BY A PATHOLOGIST.
THE MTB H. PYLORI CONTROL SLIDE WAS EVALUATED BY A PATHOLOGIST.
This document was electronically signed by XXXX XXXXXX on 10/01/2025 02:31 PM

CPT CODE

88305(X2), 88312.

Technical Component Performed at: KC Pathology Laboratory, LLC, 44400 Van Dyke Ave, Suite 102B, Sterling Heights MI 48314-2370. CLIA# 23D2276072.

Professional Component Performed at: KC Pathology Associates, LLC, 44400 Van Dyke Ave, Suite 102B, Sterling Heights MI 48314-2370. CLIA# 23D2274504.
Medical Director: Ali Gabali, MD

This test was developed and its performance and characteristics determined by KC Pathology Laboratory LLC. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

Final Report

North West Labs
29580 Northwestern Hwy
Ste 120
Southfield, MI 48034
Phone: (248) 301-6917
Fax: (248) 301-6805

Patient		
	Last Name	**DOE 2**
	First Name	**JOHN**
	Gender	**Male**
	Age	**59**
	Date of Birth	**01/01/2001**
	Patient ID#	**TEST 2**

Specimen		
	Status	**Final**
	Accession #	**XXXX**
	Collection Date	
	Received Date	
	Report Date	**10/01/2025**
	Specimen Type	

Provider Information		
	Ordering Physician	**XXXX XXXX**
	Referring Physician	
	Organization	**North West Labs**
	Location	**LAB**

General Pathology

CPT CODE
88305,88312,88313

Final
Release

Specimen Received
TA

FINAL DIAGNOSIS
TA, excision: Fragments of nail with few fungal organisms, consistent with onychomycosis.
Special stain results:
PAS, GMS, and Fontana-Mansion special stains: Highlights few fungal organisms
Controls stain appropriately.

Report Status
ABNORMAL

GROSS DESCRIPTION
Labeled as "TA Dry Nail, 5 pieces, Color- Tan "Received is 10x4x1 mm Nail specimen. Specimen is submitted in one cassette A. A: 5 pieces. PAS Fungal stain,GMS Stain,Fontana-Masson Stain.

Electronically signed by:
DR.NAME

Performing Site:
Technical and professional Components Performed at: KC Pathology Laboratory, LLC : 44400 Van Dyke Ave, Suite 102, Sterling Heights MI 48314-2370. CLIA# 23D2276072.Medical Director: Fayez Daaboul, MD This test was developed and its performance and characteristics determined by the KC Pathology Laboratory LLC. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

ICD 10 CODES:
B35.1

Technical Component Performed at: KC Pathology Laboratory, LLC: 44400 Van Dyke Ave, Suite 102B, Sterling Heights MI 48314-2370. CLIA# 23D2276072.

Professional Component Performed at: KC Pathology Associates, LLC: 44400 Van Dyke Ave, Suite 102B, Sterling Heights MI 48314-2370. CLIA# 23D2274504.
Medical Director: Ali Gabali, MD

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CLIA: xxxxxx

Accession: xxxxxx

NORTH WEST

DERMATOLOGY TEST REQUISITION FORM

29580 Northwestern Hwy
Suite 120, Southfield, MI 48034
(248) 301-6917 | www.nwlabs.com

ORDERING PHYSICIAN:

Physician to receive additional result report:

Clinical Impression:

Clinical History:

PATIENT INFORMATION

Patient Demo Attached ☐

Last Name: _____

First Name: _____

Middle Name: _____ Sex: ☐ Male ☐ Female

Address: _____

City: _____ State: _____ Zip: _____

DOB: _____ Mobile: _____

Email: _____

Race: ☐ Alaska Native or American Indian ☐ Asian ☐ Multiracial ☐ White
☐ Black or African American ☐ Native Hawaiian or other Pacific Islander
☐ Does not wish to disclose ☐ Not provided ☐ Other race

BILLING INFORMATION (Please include a copy of the front & back of card.)

Billing type: ☐ Patient ☐ Insurance ☐ Client **Relation:** ☐ Self ☐ Spouse ☐ Dependant

Insured's SS#: _____ Insured's DOB: _____

Primary Insurance Carrier: _____ Medicare, Medicaid or Policy ID#: _____

Claims Address: _____

Employer/Group Name: _____ Group#: _____

BIOPSY INFORMATION

Date Collected	Time Collected	Collected Signature	No of vials collected

Type: ☐Punch Biopsy D ☐Shave Removal (Ink) ☐Shave Biopsy ☐Excision (Ink)
☐Alopecia Sections Punch Excision (Ink) ☐DIF ☐Currettage

1 Sites _____
Clinical Findings
☐Nevus Atypical ☐SCC ☐FEP
☐Melanoma DBCC ☐AK ☐DF
☐SK ☐VV

3 Sites _____
Clinical Findings
☐Nevus Atypical ☐SCC ☐FEP
☐Melanoma DBCC ☐AK ☐DF
☐SK ☐VV

2 Sites _____
Clinical Findings
☐Nevus Atypical ☐SCC ☐FEP
☐Melanoma DBCC ☐AK ☐DF
☐SK ☐VV

4 Sites _____
Clinical Findings
☐Nevus Atypical ☐SCC ☐FEP
☐Melanoma DBCC ☐AK ☐DF
☐SK ☐VV

LIST ALL APPLICABLE ICD10 CODES :

_____
_____
_____

OTHER TEST/PANELS:

LOCATION OF INFECTIONS: _____

☐ Wound/Sepsis PCR Panel

Panel includes

BACTERIA

- Escherichia coli
- Streptococcus agalactiae
- Klebsiella oxytoca
- Staphylococcus saprophyticus
- Pseudomonas aeruginosa
- Staphylococcus haemolyticus
- Enterococcus faecium
- Enterococcus faecalis
- Acinetobacter calcoaceticus-baumannii complex
- Klebsiella aerogenes
- Klebsiella pneumoniae
- Staphylococcus aureus
- Streptococcuspyogenes
- Streptococcus pneumoniae
- Streptococcus dysgalactiae
- Staphylococcus lugdunensis
- Staphylococcus epidermidis

FUNGI

- Candida krusei
- Candida tropicalis
- Candida glabrata
- Candida albicans
- Fusarium solani
- Microsporum spp
- Candida parapsilosis
- Trychophyton spp

ANTIMICROBIAL RESISTANCE PANEL

- KPC-Carbapenem resistance
- NDM-Carbapenem resistance
- VIM-Carbapenem resistance
- IMP-Carbapenem resistance
- qnr-Quinolone resistance
- vanB-Vancomycin resistance
- OXA-48-Carbapenem resistance
- mecA/mecC-Methicilin resistance
- CTX-M ESBL
- sul-Sulfonamide resistance
- vanA-Vancomycin resistance
- dfrA-Trimethoprim resistance

Physician Authorization

I, the undersigned healthcare provider, acknowledge that when ordering a Urinary Tract Infection (UTI), Nail, or Wound PCR panel through North West Labs, located at 29580 Northwestern Hwy., Suite 120, Southfield, MI 48034 (NPI: 1568994879, Tax ID: 813538903) I understand and agree to the following terms:

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2. Any pathology, cytology, and thin prep specimens will be forwarded to KC Pathology Laboratory (44400 Van Dyke Ave, Ste 102, Sterling Heights, MI 48314; Phone: (586) 262-4243; Podiatric Pathology Form Fax: (586) 262-4241) for evaluation and reporting.
3. I understand that while the initial order is placed with North West Labs, the actual testing may be performed by their partner laboratories as specified above.
4. I acknowledge that this referral process may affect billing procedures and timeline for results, and I accept this as part of the standard operating procedure for these specific test types.
5. I confirm that I have informed my patients about this testing arrangement as appropriate and in accordance with applicable regulations.

Physician Signature _____ **Date:** _____

Patient Consent and Authorization

I authorize the release of my medical information including test results for submission of personalized reports to my healthcare providers and insurance carrier(s). I request that payment of benefits be made to North West Labs, Inc. on my behalf. If my policy does not allow for direct payment, I agree to relinquish allocated funds to North West Labs, Inc as compensation for services rendered. I also acknowledge that I will be liable for payments of deductibles, co payments and/or co insurance as detailed by my healthcare insurer. I understand that I am liable for charges not covered by my healthcare insurer. I also authorize North West Labs, Inc to appeal insurance claims on my behalf. I acknowledge the benefits, risk and limitations of this testing as describe to me by a qualified healthcare provider. My insurance may not cover or pay full amount for testing; I may be responsible for full or part of amount charged due to out of network benefits, deductible and co pays. North West Labs, Inc has my permission to bill my insurance carrier(s), this notice gives me the option to proceed with the procedure or decline. By signing this I have read all of the above and understand it. Medicare Advance Beneficiary Notice: Medicare will only pay for services that it determines to be reasonably and necessary under section 1882 (a) (1) of the Medicare Law. If Medicare determines that a particular service, although it would otherwise be covered, is not reasonable and necessary under the Medicare Program standards, Medicare will deny payment for that service. Medicare usually does not pay for these tests for the reported diagnosis. By signing the Patient/Responsible Party Signature on this requisition, you are confirming your agreement to assume financial responsibility for the payment of these tests.

Patient Signature _____ **Date:** _____

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

Final Report

NORTH WEST LABS
29580 Northwestern Hwy.
STE 120.

Southfield, MI 48034
Phone: (248) 301-6917
Fax: (248) 301-3805

Patient		
	Last Name	**DOE 1**
	First Name	**JANE**
	Gender	**Female**
	Age	**84**
	Date of Birth	**01/01/2001**
	Patient ID#	**0000**

Specimen		
	Status	**Final**
	Accession #	**XXXXX**
	Collection Date	**01/01/2001**
	Received Date	**01/01/2001**
	Report Date	**01/01/2001**
	Specimen Type	

Provider Information		
	Ordering Physician	**TEST**
	Referring Physician	
	Organization	**NORTH WEST LABS**
	Location	**LAB**

General Pathology

Report Status

Malignant

Specimen Received

Left Lower shin skin.

FINAL DIAGNOSIS

Skin, left lower shin, biopsy: - Squamous cell carcinoma, well differentiated. See comment.

Comment:

The tumor extends to the base of the specimen. Stasis changes are seen.

GROSS DESCRIPTION

Labeled as "Left lower shin ,2 pieces "Received is 18x10x2 mm, Color-White Friable tissue shave skin specimen fixed in the formalin Specimen is sectioned to 8 pieces and submitted in one cassette A. A: 8 pieces.

CPT CODE

88305+0753T

ICD 10 CODES:

C44.729

Electronically signed by:

DR. ABIDA KADI. MD. (Site# 7)

Final

Release

Performing Site:

Technical and professional Components Performed at: KC Pathology Laboratory, LLC, 44400 Van Dyke Ave, Suite 102, Sterling Heights MI 48314-2370. CLIA#23D2276072. Medical Director: FAYEZ DAABOUL, MD. This test was developed and its performance and characteristics determined by KC Pathology Laboratory LLC. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. "All controls show appropriate reactivity "This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

29580 NORTHWESTERN HWY, SUITE 120
SOUTHFIELD, MI 48034

2000 TOWN CENTER, SUITE 850
SOUTHFIELD, MI 48075

Wound Test Requisition Form

29580 Northwestern Hwy
Southfield, MI 48034
Phone: (248) 301 6917
Fax: (248) 301 6805
support@nwlabs.com

Patient Details ☐ Demographics Attached

Last Name: | M.I.

First Name | Date of Birth:

Address: | Zip Code

City, State

Phone #: | Gender: ☐ Male ☐ Female

Provider Information:

Patient Insurance Details

Primary Insurance Carrier: | Insured name: | Date of Birth:

Policy #: | Group #:

Authorization Code: | ☐ SELF PAY / NO INSURANCE | Relation to insured: (Select one) ☐ Self ☐ Spouse ☐ Guardian

Relevant Clinical Information & ICD10

REQUIRED - **Date of Collection:** _____ **Time of Collection:** _____

ICD10 (*REQUIRED*)

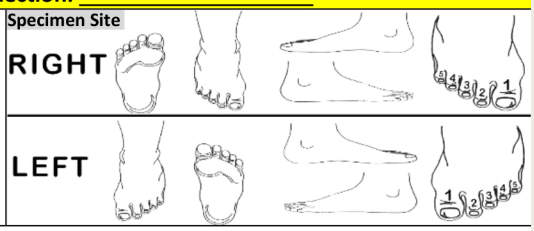
- ☐ Z16.29 Resistance to other single spec. anti
- ☐ L85.8 Other specified epidermal thickening
- ☐ B96.89 Other specified bacterial agent
- ☐ B95.2 Enterococcus
- ☐ 95.7 Other Staphylococcus
- ☐ Other _____

- ☐ Z16.29 Resistance to other single spec. anti
- ☐ L85.8 Other specified epidermal thickening
- ☐ B96.89 Other specified bacterial agent
- ☐ B96.5 Pseudomonas
- ☐ L89._____ Pressure Ulcer (6-digit code Req'd)
- ☐ L97._____Non-Pressure Ulcer (6-digit code Req'd)

ADDITIONAL CODES AVAILABLE ON REAR

- ☐ L60.0 Ingrown toenails
- ☐ 7835.1 Onychomycosis
- ☐ B35.3 Tinea Pedis
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____

Specimen Site



- ☐ B49 Unspecified Mycosis
- ☐ L03.011 Cellulitis of the right finger
- ☐ L03.012 Cellulitis of the left Finger
- ☐ L03.021 Cellulitis of the right toe
- ☐ L03.022 Cellulitis of the left toe
- ☐ I87.311 Chronic venous hypertension w ulcer of rght low extremity
- ☐ E11.621 Type 2 diabetes mellitus with foot ulcer
- ☐ E11.622Type 2 diabetes mellitus with other skin ulcer
- ☐ L03.019 Cellulitis of unspecified finger
- ☐ L03.03 Cellulitis of toe
- ☐ L03.115 Cellulitis of right lower limb
- ☐ I87.312 Chronic venous hypertension w ulcer of left low extremity
- ☐ L03.81 Cellulitis of other sites
- ☐ L08.89 Other Specified Local Infections of the Skin & Subcutaneous Tissue
- ☐ L02.91 Cutaneous Abscess, Unspecified
- ☐ L60.8 Other nail disorders
- ☐ L03.116 Cellulitis of left lower limb
- ☐ I87.313 Chronic venous hypertension w ulcer of bilateral low extremity
- ☐ L60.1 Onycholysis
- ☐ L60.4 Beau's Lines
- ☐ L60.3 Nail Dystrophy
- ☐ L60.5 Yellow nail syndrome
- ☐ R21 Rash and other nonspecific skin eruption

Test Menu

SPECIMEN A
Collect in Eswab

Location of Infection:_____

☐ **Wound / Sepsis PCR Panel** Panel includes

BACTERIA

Escherichia coli	Klebsiella aerogenes
Streptococcus agalactiae	Klebsiella pneumoniae
Klebsiella oxytoca	Staphylococcus aureus
Staphylococcus saprophyticus	Streptococcus pyogenes
Pseudomonas aeruginosa	Streptococcus pneumoniae
Staphylococcus haemolyticus	Streptococcus dysgalactiae
Enterococcus faecium	Staphylococcus lugdunensis
Enterococcus faecalis	Staphylococcus epidermidis
Acinetobacter calcoaceticus- baumannii complex	

FUNGI

Candida krusei	Candida albicans	Candida parapsilosis
Candida tropicalis	Fusarium solani	Trichophyton spp
Candida glabrata	Microsporum spp	

Antimicrobial Resistance Markers

KPC - Carbapenem resistance
NDM - Carbapenem resistance
VIM - Carbapenem resistance
IMP - Carbapenom resistance
qnr - Quinolone resistance
vanB - Vancomycin resistance
OXA-48 - Carbapenem resistance
mecA mecC - Methicillin resistance
CTX-M - ESB
sul - Sulfonamide resistance
vanA - Vancomycin resistance
dfrA - Trimethoprim resistance

SPECIMEN B
Collect in Eswab

Location of Infection:_____

☐ **Wound / Sepsis PCR Panel** Panel includes

BACTERIA

Escherichia coli	Klebsiella aerogenes
Streptococcus agalactiae	Klebsiella pneumoniae
Klebsiella oxytoca	Staphylococcus aureus
Staphylococcus saprophyticus	Streptococcus pyogenes
Pseudomonas aeruginosa	Streptococcus pneumoniae
Staphylococcus haemolyticus	Streptococcus dysgalactiae
Enterococcus faecium	Staphylococcus lugdunensis
Enterococcus faecalis	Staphylococcus epidermidis
Acinetobacter calcoaceticus- baumannii complex	

FUNGI

Candida krusei	Candida albicans	Candida parapsilosis
Candida tropicalis	Fusarium solani	Trichophyton spp
Candida glabrata	Microsporum spp	

Antimicrobial Resistance Markers

KPC - Carbapenem resistance
NDM - Carbapenem resistance
VIM - Carbapenem resistance
IMP - Carbapenom resistance
qnr - Quinolone resistance
vanB - Vancomycin resistance
OXA-48 - Carbapenem resistance
mecA mecC - Methicillin resistance
CTX-M - ESBL
sul - Sulfonamide resistance
vanA - Vancomycin resistance
dfrA - Trimethoprim resistance

Pathology

Collection Procedure:
☐ Biopsy_____ ☐ Excision ☐ Other_____

Skin (Formalin)** | **Soft Tissue** (Formalin)**
- ☐ Tinea
- ☐ Pigmented Lesion (E.G., Melanoma)
- ☐ Non-Pigmented Lesion (E.G., Verruca)
- ☐ Dermatitis/Rash
- ☐ Ulceration (E.G. Vasculitis)
- ☐ Tumor (Cyst, Lipoma, Sarcoma)
- ☐ Inflammatory (Abscess)
- ☐ Inflammatory (Tophus)

Wound
- ☐ Aspirate
- ☐ Incisional
- ☐ Excisional

Bone (Formalin)
- ☐ Suspect Osteomyelitis / Infection
- ☐ Lesion (cyst, Neoplasm, etc.)
- ☐ Deformity
- ☐ Arthritis

Collection Site:_____

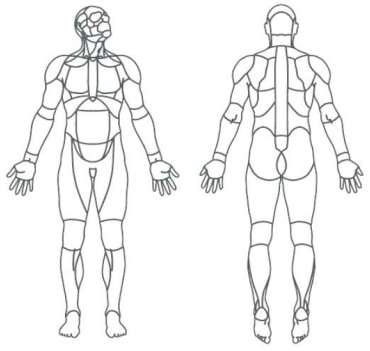
Collection Procedure:
☐ Biopsy_____ ☐ Excision ☐ Nail ☐ Other_____

Skin (Formalin)** | **Soft Tissue** (Formalin)**
- ☐ Tinea
- ☐ Pigmented Lesion (E.G., Melanoma)
- ☐ Non-Pigmented Lesion (E.G., Verruca)
- ☐ Dermatitis/Rash
- ☐ Ulceration (E.G. Vasculitis)
- ☐ Tumor (Cyst, Lipoma, Sarcoma)
- ☐ Inflammatory (Abscess)
- ☐ Inflammatory (Tophus)

Nail (Dry nail bag)** | **Onychomycosis** (Dry nail bag)**
- ☐ Trauma
- ☐ Pigmented Streak
- ☐ Non-Pigmented Lesion
- ☐ Nail Granulation
- ☐ R/O Melanoma
- ☐ Other_____
- ☐ Routine (PAS)
- ☐ High Sensitivity (PAS, GMS)
- ☐ Highest Sensitivity (PAS, GMS, FM)

Bone (Formalin)
- ☐ Suspect Osteomyelitis / Infection
- ☐ Lesion (cyst, Neoplasm, etc.)
- ☐ Deformity
- ☐ Arthritis

Collection Site:_____



Clinical Impression:

Clinical History:

Physician Authorization

I, the undersigned healthcare provider, acknowledge that when ordering a Urinary Tract Infection (UTI), Nail, or Wound PCR panel through North West Labs, located at 29580 Northwestern Hwy., Suite 120, Southfield, MI 48034 (NPI: 1568994879, Tax ID: 813538903) I understand and agree to the following terms:

1. In some or all instances, UTI, Wound, and Nail panels and their associated antibiotic resistance markers tests will be forwarded to PCR Labs of America (1464 E Whitestone Blvd, Ste 2401, Cedar Park, TX 78613; Phone: (512) 456-0071; Fax: (512) 456-0072) for processing and analysis.
2. Any pathology, cytology, and thin prep specimens will be forwarded to KC Pathology Laboratory (44400 Van Dyke Ave, Ste 102, Sterling Heights, MI 48314; Phone: (586) 262-4243; Podiatric Pathology Form Fax: (586) 262-4241) for evaluation and reporting.
3. I understand that while the initial order is placed with North West Labs, the actual testing may be performed by their partner laboratories as specified above.
4. I acknowledge that this referral process may affect billing procedures and timeline for results, and I accept this as part of the standard operating procedure for these specific test types.
5. I confirm that I have informed my patients about this testing arrangement as appropriate and in accordance with applicable regulations.

Physician Signature _____ **Date:**_____

Patient Consent and Authorization

I authorize the release of my medical information including test results for submission of personalized reports to my healthcare providers and insurance carrier(s). I request that payment of benefits be made to North West Labs, Inc. on my behalf. If my policy does not allow for direct payment, I agree to relinquish allocated funds to North West Labs, Inc as compensation for services rendered. I also acknowledge that I will be liable for payments of deductibles, co payments and/or co insurance as detailed by my healthcare insurer. I understand that I am liable for charges not covered by my healthcare insurer. I also authorize North West Labs, Inc to appeal insurance claims on my behalf. I acknowledge the benefits, risk and limitations of this testing as describe to me by a qualified healthcare provider. My insurance may not cover or pay full amount for testing; I may be responsible for full or part of amount charged due to out of network benefits, deductible and co pays. North West Labs, Inc has my permission to bill my insurance carrier(s), this notice gives me the option to proceed with the procedure or decline. By signing this I have read all of the above and understand it. Medicare Advance Beneficiary Notice: Medicare will only pay for services that it determines to be reasonably and necessary under section 1882 (a) (1) of the Medicare Law. If Medicare determines that a particular service, although it would otherwise be covered, is not reasonable and necessary under the Medicare Program standards, Medicare will deny payment for that service. Medicare usually does not pay for these tests for the reported diagnosis. By signing the Patient/Responsible Party Signature on this requisition, you are confirming your agreement to assume financial responsibility for the payment of these tests.

Patient Signature _____ **Date:**_____

Final Report

NORTH WEST LABS
29580 Northwestern Hwy.
STE 120.

Southfield, MI 48034
Phone: (248) 301-6917
Fax: (248) 301-3805

Patient		Specimen		Provider Information	
Last Name	**DOE 1**	Status	**Final**		
First Name	**JANE**	Accession #	**xxxxx**	Ordering Physician	**TEST**
Gender	**Female**	Collection Date	**01/01/2001**	Referring Physician	
Age	**xx**	Received Date	**01/01/2001**	Organization	**NORTH WEST LABS**
Date of Birth	**01/01/2001**	Report Date	**01/01/2001**	Location	**LAB**
Patient ID#	**0000**	Specimen Type			

General Pathology

Specimen Received
A: Right Medial foot skin Biopsy (punch).

Specimen Received [B]
B: Right Lateral foot skin Biopsy (punch).

FINAL DIAGNOSIS
Skin, right medial foot, punch biopsy: Hypertrophic and acanthotic skin with cutaneous horn. PAS/d special stain for fungus is negative.

FINAL DIAGNOSIS [B]
Skin, right lateral foot, punch biopsy: Hypertrophic and acanthotic skin with cutaneous horn. PAS/d special stain for fungus is negative.

GROSS DESCRIPTION
A: Labeled as " Right Medial foot skin ,1 piece "Received is 12x3x3 mm, Color-White Biopsy skin specimen fixed in the formalin Specimen is submitted in one cassette A. A: 1 piece.

GROSS DESCRIPTION [B]
B: Labeled as " Right Lateral foot skin ,1 piece "Received is 4x3x3 mm, Color-White Biopsy skin specimen fixed in the formalin Specimen is submitted in one cassette B. B: 1 piece.

CPT CODE
88305,88313

CPT CODE [B]
88305,88313

ICD 10 CODES:
L98.9

Electronically signed by:
Daniel Neill, M.D.

Report Status
n/a

CONTACT

248 301 6917

support@nwlabs.com

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Ste 120
Southfield, MI 48034

NORTH WEST
LABS

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SOUTHFIELD, MI 48034

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