qPCR + Next Generation Sequencing (NGS)

DNA diagnostics for challenging infection cases

MicroGenDX

qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

New hope for patients suffering from challenging infections.

Dear Healthcare Provider,

Thank you for choosing MicroGenDX for your microbial diagnostic testing needs.

This binder answers questions you may have about our testing and describes the process MicroGenDX undertakes to help you diagnose and treat your patients' infections. Please see the next page for a table of contents.

Who we are as a company

MicroGen Diagnostics (MicroGenDX) is a CAP-accredited and CLIA-licensed clinical diagnostic laboratory focused primarily on microbes and infections, and uses qPCR+NGS molecular technology in its analysis. MicroGenDX was founded by esteemed wound care doctor Randall Wolcott in 2008, and is currently owned and operated by former Pfizer executive Rick Martin, who witnessed the positive clinical impact of qPCR+NGS firsthand. MicroGenDX brings state-of-the-art microbial DNA sequencing diagnostics to more patients every day – processing more than 100,000 samples each year. Our mission at MicroGenDX is to improve clinical outcomes by offering clinicians and their patients the most informative and impactful microbial diagnostic tests that science can provide.

MicroGenDX has run more than 500,000 next-gen DNA sequencing tests at our state-of-the-art molecular diagnostic facility. Our advanced instrumentation, including Illumina Miseq sequencers, provides accurate and reliable microbial diagnostics for ENT/AFB, microbiology laboratories, orthopedics, urology, wound care, podiatry, pulmonology, explants, periodontics, podiatry/nail, OB-GYN, infectious disease, and many other medical specialties. Our laboratory is supported by a team of molecular biologists, biochemists, bioinformaticians, computer scientists, and physicians. MicroGenDX employs over 200 passionate employees under a leadership model that swiftly adapts to global health concerns and new technologies. We want to help as many people as possible with microbial identification of challenging infections.

We look forward to assisting you with better treatments so your patients can achieve better outcomes.

Thank you,

Rick Martin

Please watch our patient stories video for more information.

microgendx.qrd.by/psvideo

ALL CONTENTS SUBJECT TO CHANGE.

Get more answers.

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

www.MicroGenDX.com
info@microgendx.com
855.208.0019

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

Table of contents

List of important contacts/information

Customer Service
Hours: M-F 8AM–8PM EST
(855) 208-0019
info@microgenx.com

Billing
Hours: M-F 8am–8pm EST, Saturday 9am–6pm EST
(855) 208-0019, extension 2002
Spanish extension 2011

EOB/Insurance Appeals/Other
Hours: 9AM–6PM EST
(855) 208-0019, extension 2003
Spanish extension 2012

Account Executive card here

My Organization ID: _____ [write in]

Prescribing providers for MicroGenDX at this practice: [write in]

Name	NPI

Places to visit on our website

Learn more about how MicroGenDX can help you be effective within your specialty:

microgendx.qrd.by/specialties

Read one of over 70 studies that use our testing:

microgendx.qrd.by/studies

Request a peer consult:

microgendx.qrd.by/peerconsult

Read our blog:

microgendx.qrd.by/blog

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Covered insurances

The most up-to-date list of insurances and other billing information can always be found at: **microgendx.qrd.by/insurances**

Medicare Part B (PLA)
Railroad Medicare (PLA)
Allwell from MHS
Amerigroup
BCBS of Arizona
- Indemnity Plan
- PPO
- HMO Choice Select
- Senior Preferred
- Neighborhood

BCBS Carefirst of DC/Maryland
- All Plans (EXCLUDING HMO PLANS)

BCBS Federal
BCBS of Idaho
- BING (Bingham Memorial Direct)
- BlueChoice Options HRA Plan
- BlueChoice Options PPO Plan
- Jewel 881 BlueChoice Options
- PPO
- TRAD Traditional Provider Network

BCBS of Illinois
- PPO
- Community Plan

BCBS of Iowa (Wellmark)
- All Plans

BCBS of South Dakota (Wellmark)
- All Plans

BCBS of Texas
- HMO
- PPO

BCBS of Wyoming (PLA)
- FEP
- Blue Select
- WY Total Choice
- WY Select
- WY Choice

CareFirst BCBS Medicare Advantage PPO
- Contract starts 6/1/22

Driscoll Health Plan
- CHIP
- STAR
- STAR Kids

FirstCare
- CHIP
- FirstCare Access PPO
- FirstCare Select HMO
- FirstCare Select Plus HMO
- Hendrick Health Employee Plan
- Pyco Industries Employee Plan
- BSW Plus PPO
- BSW Plus HMO
- FirstCare Advantage Dual SNP (HMO SNP)
- STAR Medicaid

Iowa Total Care
MDWise
- Hoosier Healthwise
- Healthy Indiana Plan
- Medicare

Meridian Illinois
- Medicaid
- Oklahoma Complete Health Contract starts 6/3/22
- Medicaid
- Medicare
- Commercial-Exchange

Prime Health Services
Providence Washington (Non-Seattle)
- Medicare
- Medicaid

State of WA Dept of Labor
Superior
United Mine Workers
Humana Military
Tricare
Tricare for Life
Triwest

Carolina Complete

- Absolute Total Care, Inc – SC
- Ambetter of Magnolia, Inc – MS
- Ambetter of NC, Inc
- Ambetter of Peach State, Inc
- Arkansas Health & Wellness Health Plan, Inc
- Arkansas Total Care
- Bridgeway Health Plan – AZ Community Solutions, Inc
- Buckeye Community Health Plan, Inc – OH
- California Health and Wellness Plan
- Carolina Complete Health, Inc
- Celtic Insurance Company
- CeltiCare Health Plan of Massachusetts, Inc
- Coordinated Care Corporation, dba Managed Health Services – IN
- Coordinated Care of Washington, Inc
- Michigan Complete Health, Inc
- Granite State Health Plan, Inc – NH
- Health Net Community Solutions, Inc – CA
- Health Net Health Plan of Oregon, Inc
- Health Net Life Insurance Company – CA
- Health Net of Arizona, Inc dba Arizona Complete Health
- Health Net of California, Inc
- Home State Health Plan, Inc – MO
- IlliniCare Health Plan, Inc
- Iowa Total Care, Inc
- Louisiana Healthcare Connections, Inc
- Magnolia Health Plans, Inc – MS
- Managed Health Services Insurance Corporation
- Nebraska Total Care, Inc
- New York Quality Healthcare Corporation, dba Fidelis Care – NY
- NovaSys Health, Inc – AR
- Peach State Health Plan, Inc
- Pennsylvania Health & Wellness, Inc
- SilverSummit Healthplan, Inc – NV
- Sunflower State Health Plan, Inc – KS
- Sunshine Health Plan Community Solutions, Inc
- Sunshine State Health Plan, Inc – FL
- Superior HealthPlan Community Solutions, Inc
- Superior Healthplan, Inc – TX
- Trillium Community Health Plan, Inc – OR
- Western Sky Community Care, Inc – NM
- AcariaHealth, Inc – FL
- Cenpatico Behavioral Health, LLC
- Centurion, LLC
- Envolve Benefits Options, Inc
- Envolve PeopleCare, Inc
- Envolve Pharmacy Solutions, Inc
- Envolve, Inv
- LifeShare Management Group LLC
- US Medical Management Group LLC
- VPA of Texas, PLLC dba Visiting Physicians Association
- VPA, PC dba Visiting Physicians Association

State Medicaid

- Alabama
- Alaska
- Arizona
- Arkansas
- Colorado
- DC
- Georgia
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky (PLA)
- Louisiana
- Maine
- Michigan
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Mexico
- North Carolina
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- South Carolina
- Tennessee
- Texas
- Vermont
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming

How-to section

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

Ordering a test

Providers can order either completed test kits or bulk supplies (including lab requisitions) shipped to their office. With these materials providers can collect samples from patients (please see Collection Instructions Section for more information). As part of sample collection process, providers must fill out a lab requisition with their information and the patient's information.

A provider can also have patients order the test themselves and either bring the kit into the office for sample collection or self-collect the sample at home. In order for a test sample to be processed, the lab requisition must either have the prescribing physician's signature or the prescribing physician's signature must be on file at MicroGenDX.

Complete test kits:
microgendx.qrd.by/providerorder

Have the patient order the kit for you (send them to this link):
microgendx.qrd.by/patientorder
You will need to sign the requisition for them to send this in (or have a signature on file with us).

Pre-Filled Lab Requisitions:
microgendx.qrd.by/prelabreq

Have a Provider Service Agreement on file with us:
microgendx.qrd.by/psa

Testing Collection Supplies:
microgendx.qrd.by/supplies

Filling out a Lab Requisition

Step 1: Patient information

Please fill out your patient's information or provide patient face sheet (see page 12 for an example of a patient face sheet). For accuracy it is suggested that the patient fill this out.

- Including your patient's email address will give the patient access to our Patient Portal to obtain results (see page 39).
- Including the last four of their social security number will make it easier for patients to call customer service to receive information about their test.

PATIENT INFORMATION		
Name (First and Last): **(Include Face Sheet)**		
John Smith		
Date of Birth:	Gender:	Last 4 of SSN:
01 / 01 / 1980	M	1111
Patient CELL Phone:	**Patient Email:**	
(999) 888-7777	john.smith@example.com	
Address:		
1234 Example ST		
City:	State:	Zip:
Example City	FL	32822

Step 2: Clinic and physician information

This must be filled out.

CLINIC INFORMATION		PHYSICIAN INFORMATION
Clinic Name:		☑ Physician Name: Gregg Smith
Wound Care Co		NPI#: 1122334455
Organization ID:		☐ Physician Name:
112233		NPI#:
Clinic Address:		☐ Physician Name:
4321 Place DR, Example City, FL 32832		NPI#:
Clinic Phone:	Clinic Fax:	☐ Physician Name:
(111) 222-3333	(111) 222-3334	NPI#:
Clinic Email:		☐ Physician Name:
wound.care@example.com		NPI#:

Although multiple physicians may be entered into the "Physician Information" section, ONLY ONE box should be checked. This physician should also be the person signing the "Physician Signature" section of the lab req. Any healthcare provider who has an NPI number and the ability to prescribe medication may sign for this test.

- The NPI number given MUST be the NPI number of the individual, not the organization or office.
- The organization ID is obtained from MicroGenDX.

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Step 3: Specimen Info

Specimen Source: This should indicate the location where the sample was taken from and any clinically relevant context. Examples: "Right nostril" or "Urine from catheter." This will appear on your lab result.

Sample Type: All specimens accepted by MicroGenDX will fall into one or more of these categories. Please select those that most closely apply to your specimen. If sending in hardware, please indicate "Swab."

SPECIMEN INFO	
Date Collected:	Number of Samples:
4 / 5 / 22	1
Specimen Source:	
L BAK Wound	
Sample Type:	
☐ Blood ☐ Saliva ☑ Swab	
☐ Fluid ☐ Sputum ☐ Tissue	
☐ Nails ☐ Stool ☐ Urine	

Step 4: Diagnostic Information

This is information about why you are ordering this test. This section must be filled out if the sample is going to be billed to insurance. Example: Primary Diagnosis: Non-healing surgical wound, Secondary Diagnosis: Diabetes.

DIAGNOSTIC INFORMATION
Primary Diagnosis/Clinical Diagnosis:
Non-healing Surgical Wound
Secondary Diagnosis/Clinical Diagnosis:
Diabetes
ICD-10 Codes (common codes on reverse):
E11.622, L97 512
Notes:
Previous empiric antibiotic therapy failed

ICD-10 codes are required for medical necessity. Please see the back of the lab requisition for a non-comprehensive list of codes.

Notes:

- Z-codes cannot be used by themselves, but only as a secondary code.
- If possible, please use at least two ICD-10 codes (when appropriate).
- ICD-10 codes are decided on and provided by the prescribing physician (examples of commonly used ICD-10 codes are located on the back of the lab requisition).
- Filling in "Notes"section also helps with insurance coverage.

Step 5: Insurance Information

Please fill out your patient's insurance information when the patient wants to charge to insurance. Please include a copy of their up-to-date insurance card and demographics sheet.

Note: MicroGenDX is required by law to bill any insurance information put in this section. If your patient wishes to pay directly for this test DO NOT fill out this section. Instead fill out the "Payment Information" section at the bottom of the lab requisition instead.

INSURANCE INFORMATION		
Primary Insurance: **(Send Front & Back of INSURANCE CARD)**		
Medicare Part B		
Claims Billing Address:		
343 Example Way		
Claims City:	State:	Zip:
Example City	FL	32922
Subscriber ID:	Medicare Claim Number:	
	12345678	

Step 6: Test and Panel Type

If you are ordering a qPCR+NGS test (blue section) you must first select a panel by checking one of the boxes in Part 1 and then checking the box in Part 2. BOTH BOXES MUST BE CHECKED.

If you are ordering a PCR-only product (purple section), check the box in that section.

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST

PART 1
Choose Panel Type

- ☐ AFB
- ☐ Blood
- ☐ ENT/Pulmonary
- ☐ Nail
- ☐ Orthopedic
- ☐ Rectal Swab
- ☐ UTI/Prostate* *(Urine or Semen)*
- ☐ Vaginal*
- ☑ Wound

**Full STI Panel can be added*

PART 2
Confirm Test Order by checking box below

☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.

and /or

PCR ONLY TEST

- ☐ Full STI
- ☐ Basic STI
- ☐ HSV
- ☐ HPV
- ☐ MRSA Screening
- ☐ Oral HPV
- ☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)

Note: "Full STI" may be added to the UTI/Prostate and Vaginal tests (in Part 1) at a discounted rate. The "Full STI" Box must also be checked along with boxes in Part 1 and Part 2.

Step 7: Physician Signature

Please have the prescribing healthcare provider sign this requisition to confirm order.

PHYSICIAN SIGNATURE

The test ordered is medically necessary for the diagnosis indicated. By signing the requisition, I certify that I have informed consent from the patient as required by any applicable state or federal laws with respect to each test ordered. The physician has obtained informed written consent and conveyed to the patient that his/her insurance may or may not pay for some, or all of, the labs/tests ordered and has verbally acknowledged and accepted responsibility for payment.

Physician Signature: _____

Step 8: Patient Signature

Please make the patient aware that you are ordering this testing and explain, as needed, the necessity and potential cost of the testing (for information to share with your patient, please see page 37).

The patient MUST sign here to consent to receive this testing.

STOP BEFORE SENDING PLEASE HAVE PATIENT READ & SIGN BELOW

I consent allowing MicroGenDX, its agents, and assignees to contact me by email, phone, and SMS message* communication using any contact information that I have given to MicroGenDX, the physician or facility, for purposes related to my care including treatment, payment, collections, or operations. I authorize MicroGenDX to furnish my designated insurance carrier with the information herein. I authorize benefits to be payable to "MicroGenDX". If my insurer pays me directly, I agree to endorse the check, and forward the payment and corresponding EOB to MicroGenDX within 5 days of receipt. I understand that I am responsible for any amount due after insurance including the full amount if my insurance does not pay or is not contracted with MicroGenDX. Self-pay amounts can be found at www.microgendx.com *See microgendx.com for further policy and procedures.

PATIENT SIGNATURE HERE: _____

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Step 9: Payment Information

If the patient would like to pay directly for this testing (please see patient self-pay rates on website for each product), they may do so by filling out this section.

This section may also be filled out by those patients requesting that insurance also be billed, because it will allow them to be billed automatically for the difference (up to the self-pay rate) if insurance does not fully cover the full cost of the test (unless MicroGenDX is contracted with that insurance company).

PAYMENT INFORMATION:

☐ Pay By Check (please attach check to this form)

☐ Credit Card ☐ Visa ☐ MasterCard ☐ Other_____ Card #: _____ Expiration (MM/YY): _____ CVV: _____

Patient Face Sheet example

This may be sent instead of filling out Patient Information section of the lab requisition.

John Smith
42 y.o. male (DOB: 1/1/1980)

4/5/2022

Pt Class	**Outpatient**	Admitting	
Service		Attending	
Location	**Wound Care Co.**	Referring	**No ref. provider found**
		Dx	

Patient Demographics
1234 Example St.
Example City, FL 32822

PCP **Gregg Smith, MD**
Languag **English**
Phone **111-222-3333**

Emergency Contacts
Jane Doe (Aunt) 444-555-7777

Guarantor

SMITH,JOHN

Relation **Self**
Address **1234 EXAMPLE ST.**
Example City, FL 32822

Home **999-888-7777**
Work
Mobile
Employed at

Coverages

MEDICARE/MEDICARE PART A AND B

Subscriber **SMITH, JOHN**
Relation **Self**
Sub ID # **########**
Group #

MEDICADE IN STATE/MEDICADE IN STATE

Subscriber **SMITH, JOHN**
Relation **Self**
Sub ID # **########**
Group #

Medical Record #
Hospital Account #
Contact Serial #

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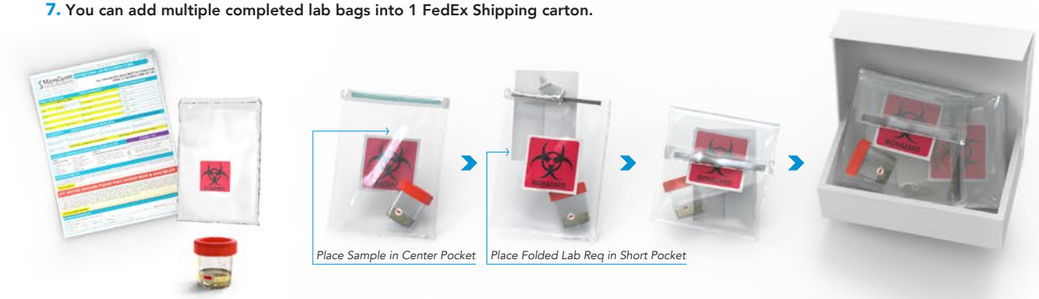
Shipping an order

PACKING SAMPLES FOR SHIPMENT

1. Place the 90mL Urine Collection Cup into the center/sealable pocket of Biohazard Lab Bag.
2. Place folded Lab Requisition Form into the short pocket of the Lab Bag.
3. IMPORTANT: Place only one Sample and one Lab Requisition in each Lab Bag.
4. Peel strip off Lab Bag to expose adhesive backing and follow instructions printed on Bag to create a continuous, airtight seal.
5. Place the sealed Lab Bag into the Prepaid FedEx Shipping Box.
6. Close the shipping box and seal with the included clear sealing sticker or tape.
7. **You can add multiple completed lab bags into 1 FedEx Shipping carton.**



3 CONVENIENT FEDEX SHIPPING METHODS

1. Drop into FedEx Dropbox including Kinkos FedEx locations
2. For Physician Offices Only: Call for pick up 1-800-GoFedEx (1-800-463-3339). Say "agent" twice to speak to agent. Let them know it's prepaid pick up.
3. For Physician Offices Only: Use our online "schedule a pick up" page at MicroGenDX.com. *Make sure to retain your tracking number.*

Scan QR code to locate nearest FedEX Drop Box:
microgendx.qrd.by/dropbox

Receiving a report/registering for the Lab Portal

Create a MicroGenDX online Lab Portal account so your staff can:

- Easily order tests and retrieve reports
- Review sample pickup instructions

1. Sign up for a MicroGenDX website account: **microgendx.qrd.by/get-started**

2. A customer service representative will reach out with steps on how to complete registration for the Provider Portal (lab portal) account: **microgendx.qrd.by/registerproviderportal**

   This is a separate account than your MicroGenDX website account but you may use the same information

3. Once your new Provider Portal Account has been approved you may sign in here to receive results: **microgendx.qrd.by/providerportal**

Missing sample procedure

Customer inquiries regarding missing samples

In the event that a sample does not arrive on time or appears to be lost, please review the following information.

Note: Delays can sometimes occur because the lab requisition was not filled out with the correct information. Please ensure that lab requisitions are included with every sample and filled out completely. The physician signature step can be omitted after signing a Provider Service Agreement with MicroGenDX.

Customer information needed for inquiries

- Patient Name and DOB
- Full Organization Name (please do not use acronyms)
- Full Provide Name
- NGS or COVID sample
- FedEx Tracking Number

Please contact customer service directly to help us locate your missing sample. For self service, please follow these steps:

1. **Double-check for the sample in Lab Portal.**
   a. Search using each of the following criteria: patient name, patient date of birth, provider name, organization

2. **Check the tacking number with FedEx.com. Does the tracking number show that the sample was delivered?**
   a. *If no delivery:* Contact FedEx Customer Service with the tracking number at 1-800-463-3339.
   b. *If delivery is confirmed:* Reach out to your account executive and ask them to investigate.

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Reading a report (also see larger example of report instructions on following pages)

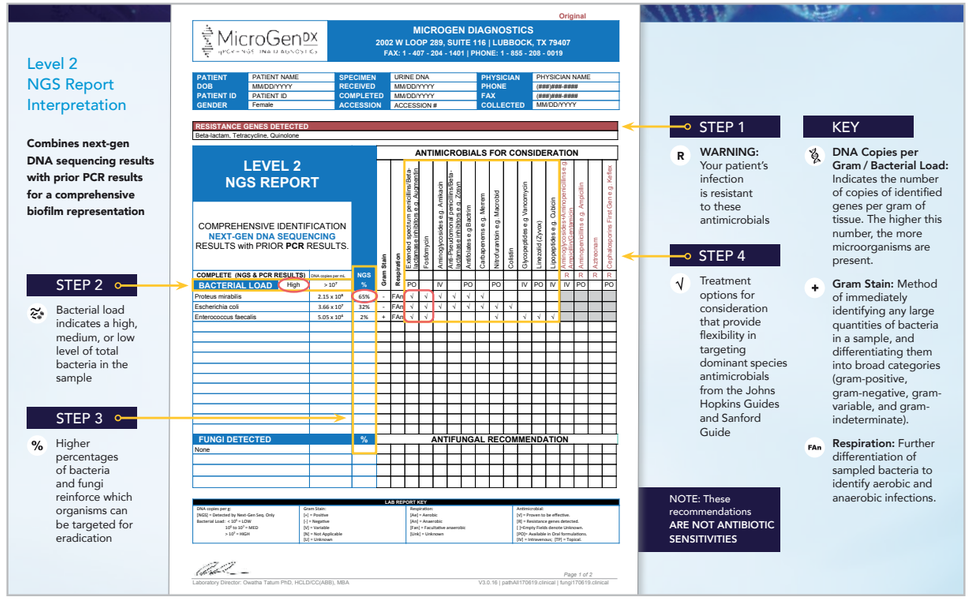
In combination with other diagnostic tools such as WBC, L/E, CRP, and patient symptoms, the **Level 2 NGS Report** refines the antibiotic and antifungal options most appropriate to treat detected microbes, including biofilm communities. The listed antibiotic and antifungal options are representative of effective, widely available antimicrobials, with any detected resistance genes called out in **Step 1** of the report interpretation below.

Step 2 indicates the bacterial load in the sample, which provides an immediate snapshot of infections with potential etiological significance.

The NGS percentages in **Step 3** indicate the total distribution of microbes detected in the sample, and are listed from highest to lowest concentration. One treatment approach is to target all the species detected, not just the dominant species. This strategy has to take into consideration the use of multiple antimicrobials and the potential impact to the host.

For example, topical delivery of antimicrobials in wound and ENT treatment allows targeting of microbes with a much lower risk to patient microbiomes throughout the rest of the body. In contrast, IV and oral delivery of systemic antibiotics need to focus on the dominant species to reduce negative impacts on patient microbiomes.

As indicated in **Step 4** of the report interpretation below, it might also be the case that one antimicrobial is effective against both the dominant species and most or even all of the other microbes detected in the sample, further refining the efficacy of available options.



Level 2 NGS Report Interpretation

Combines next-gen DNA sequencing results with prior PCR results for a comprehensive biofilm representation

STEP 2

Bacterial load indicates a high, medium, or low level of total bacteria in the sample

STEP 3

Higher percentages of bacteria and fungi reinforce which organisms can be targeted for eradication

Original

MicroGenDX qPCR + NGS DNA DIAGNOSTICS

MICROGEN DIAGNOSTICS
2002 W LOOP 289, SUITE 116 | LUBBOCK, TX 79407
FAX: 1 - 407 - 204 - 1401 | PHONE: 1 - 855 - 208 - 0019

PATIENT	PATIENT NAME	SPECIMEN	URINE DNA	PHYSICIAN	PHYSICIAN NAME
DOB	MM/DD/YYYY	RECEIVED	MM/DD/YYYY	PHONE	(###)###-####
PATIENT ID	PATIENT ID	COMPLETED	MM/DD/YYYY	FAX	(###)###-####
GENDER	Female	ACCESSION	ACCESSION #	COLLECTED	MM/DD/YYYY

RESISTANCE GENES DETECTED
Beta-lactam, Tetracycline, Quinolone

LEVEL 2 NGS REPORT

COMPREHENSIVE IDENTIFICATION
NEXT-GEN DNA SEQUENCING
RESULTS with PRIOR **PCR** RESULTS.

ANTIMICROBIALS FOR CONSIDERATION

COMPLETE (NGS & PCR RESULTS)		DNA copies per mL	NGS %	Gram Stain	Respiration	Extended spectrum penicillins/Beta-lactamase inhibitors e.g. Augmentin	Fosfomycin	Aminoglycosides e.g. Amikacin	Anti-Pseudomonal penicillins/Beta-lactamase inhibitors e.g. Zosyn	Antifolates e.g Bactrim	Carbapenems e.g. Merrem	Nitrofurantoin e.g. Macrobid	Colistin	Glycopeptides e.g Vancomycin	Linezolid (Zyvox)	Lipopeptides e.g. Cubicin	Aminoglycosides+Aminopenicillins e.g Ampicillin/Gentamicin	Aminopenicillins e.g. Ampicillin	Aztreonam	Cephalosporins First Gen e.g. Keflex
BACTERIAL LOAD	High	> 10^7	%			PO		IV		PO		PO		IV	PO	IV	IV	PO		PO
						R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
Proteus mirabilis		2.15×10^8	65%	-	FAn	√	√	√	√	√	√									
Escherichia coli		3.66×10^7	32%	-	FAn	√	√	√	√	√	√	√	√							
Enterococcus faecalis		5.05×10^4	2%	+	FAn	√	√					√		√	√	√				

FUNGI DETECTED	%	ANTIFUNGAL RECOMMENDATION
None		

LAB REPORT KEY

DNA copies per g:	Gram Stain:	Respiration:	Antimicrobial:
[NGS] = Detected by Next-Gen Seq. Only Bacterial Load: < 10^5 = LOW 10^5 to 10^7 = MED > 10^7 = HIGH	[+] = Positive [-] = Negative [V] = Variable [N] = Not Applicable [U] = Unknown	[Ae] = Aerobic [An] = Anaerobic [Fan] = Facultative anaerobic [Unk] = Unknown	[V] = Proven to be effective. [R] = Resistance genes detected. [ ]=Empty Fields denote Unknown. [PO]= Available in Oral formulations. [IV] = Intravenous; [TP] = Topical.

Page 1 of 2

Laboratory Director: Owatha Tatum PhD, HCLD/CC(ABB), MBA

V3.0.16 | pathAll170619.clinical | fungi170619.clinical

KEY

DNA Copies per Gram / Bacterial Load: Indicates the number of copies of identified genes per gram of tissue. The higher this number, the more microorganisms are present.

Gram Stain: Method of immediately identifying any large quantities of bacteria in a sample, and differentiating them into broad categories (gram-positive, gram-negative, gram-variable, and gram-indeterminate).

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Original

MicroGenDX qPCR + NGS DNA DIAGNOSTICS

MICROGEN DIAGNOSTICS
2002 W LOOP 289, SUITE 116 | LUBBOCK, TX 79407
FAX: 1 - 407 - 204 - 1401 | PHONE: 1 - 855 - 208 - 0019

PATIENT	PATIENT NAME	SPECIMEN	URINE DNA	PHYSICIAN	PHYSICIAN NAME
DOB	MM/DD/YYYY	RECEIVED	MM/DD/YYYY	PHONE	(###)###-####
PATIENT ID	PATIENT ID	COMPLETED	MM/DD/YYYY	FAX	(###)###-####
GENDER	Female	ACCESSION	ACCESSION #	COLLECTED	MM/DD/YYYY

RESISTANCE GENES DETECTED
Beta-lactam, Tetracycline, Quinolone

LEVEL 2 NGS REPORT

COMPREHENSIVE IDENTIFICATION
NEXT-GEN DNA SEQUENCING
RESULTS with PRIOR **PCR** RESULTS.

ANTIMICROBIALS FOR CONSIDERATION

COMPLETE (NGS & PCR RESULTS)		DNA copies per mL	NGS %	Gram Stain	Respiration	Extended spectrum penicillins/Beta-lactamase inhibitors e.g. Augmentin	Fosfomycin	Aminoglycosides e.g. Amikacin	Anti-Pseudomonal penicillins/Beta-lactamase inhibitors e.g. Zosyn	Antifolates e.g Bactrim	Carbapenems e.g. Merrem	Nitrofurantoin e.g. Macrobid	Colistin	Glycopeptides e.g Vancomycin	Linezolid (Zyvox)	Lipopeptides e.g. Cubicin	Aminoglycosides+Aminopenicillins e.g Ampicillin/Gentamicin	Aminopenicillins e.g. Ampicillin	Aztreonam	Cephalosporins First Gen e.g. Keflex
BACTERIAL LOAD	High	> 10^7	%			PO		IV		PO		PO		IV	PO	IV	IV	PO		PO
						R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
Proteus mirabilis		2.15×10^8	65%	-	FAn	√	√	√	√	√	√									
Escherichia coli		3.66×10^7	32%	-	FAn	√	√	√	√	√	√	√	√							
Enterococcus faecalis		5.05×10^4	2%	+	FAn	√	√					√		√	√	√				

FUNGI DETECTED	%	ANTIFUNGAL RECOMMENDATION
None		

LAB REPORT KEY

DNA copies per g:	Gram Stain:	Respiration:	Antimicrobial:
[NGS] = Detected by Next-Gen Seq. Only Bacterial Load: < 10^5 = LOW 10^5 to 10^7 = MED > 10^7 = HIGH	[+] = Positive [-] = Negative [V] = Variable [N] = Not Applicable [U] = Unknown	[Ae] = Aerobic [An] = Anaerobic [Fan] = Facultative anaerobic [Unk] = Unknown	[V] = Proven to be effective. [R] = Resistance genes detected. [ ]=Empty Fields denote Unknown. [PO]= Available in Oral formulations. [IV] = Intravenous; [TP] = Topical.

Page 1 of 2

Laboratory Director: Owatha Tatum PhD, HCLD/CC(ABB), MBA

V3.0.16 | pathAll170619.clinical | fungi170619.clinical

STEP 1

R **WARNING:** Your patient's infection is resistant to these antimicrobials

STEP 4

√ Treatment options for consideration that provide flexibility in targeting dominant species antimicrobials from the Johns Hopkins Guides and Sanford Guide

NOTE: These recommendations **ARE NOT ANTIBIOTIC SENSITIVITIES**

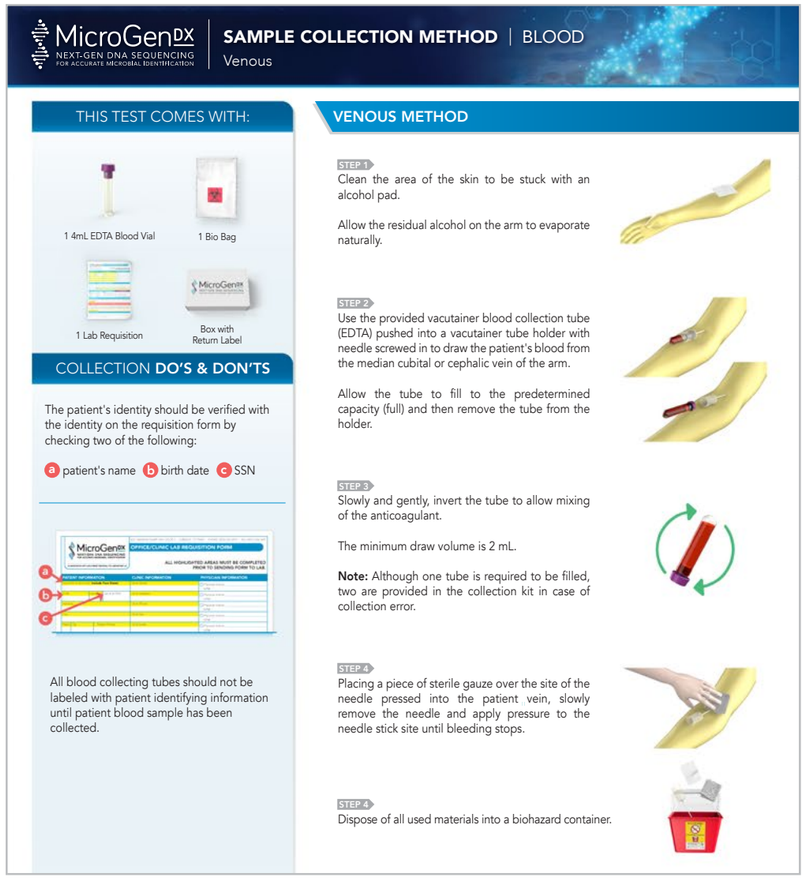
FAn **Respiration:** Further differentiation of sampled bacteria to identify aerobic and anaerobic infections.

Collection instructions

All collection instructions can be obtained on the website:
microgendx.qrd.by/collection

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

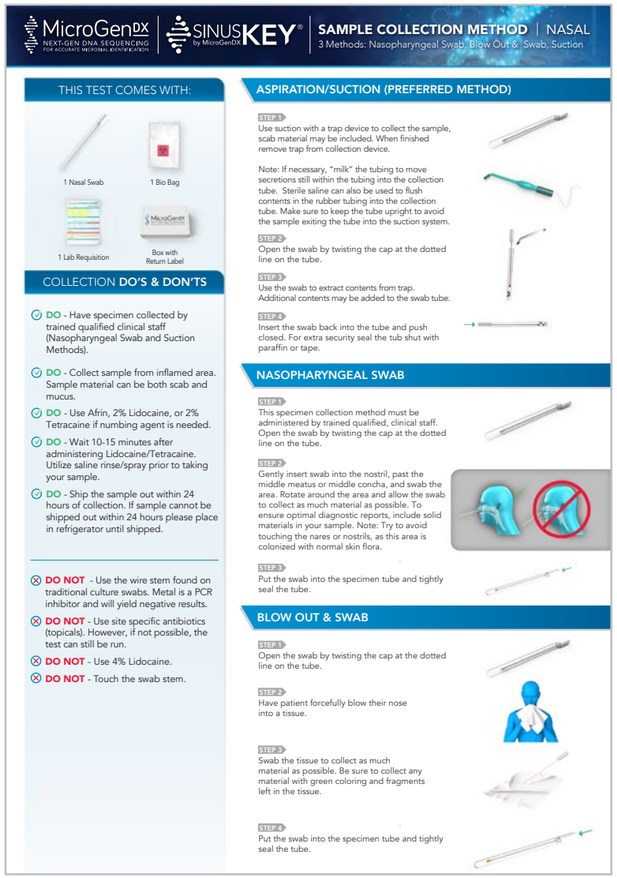
Blood Sample Collection Method



Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST			
PART 1 **Choose Panel Type** ☐ AFB ☑ Blood ☐ ENT/Pulmonary ☐ Nail ☐ Orthopedic	☐ Rectal Swab ☐ UTI/Prostate* *(Urine or Semen)* ☐ Vaginal* ☐ Wound **FULL STI Panel can be added*	**PART 2** **Confirm Test Order by checking box below** ☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	☐ Full STI	☐ Basic STI	☐ HSV	☐ HPV
			☐ MRSA Screening		☐ Oral HPV	
			and /or	☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)		

Nasal Sample Collection Method



Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST			
PART 1 Choose Panel Type		**PART 2** Confirm Test Order by checking box below	☐ Full STI	☐ Basic STI	☐ HSV	☐ HPV
☐ AFB	☐ Rectal Swab	☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	☐ MRSA Screening		☐ Oral HPV	
☐ Blood	☐ UTI/Prostate* *(Urine or Semen)*	**and /or**	☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)			
☑ ENT/Pulmonary	☐ Vaginal*					
☐ Nail	☐ Wound					
☐ Orthopedic	**FULL STI Panel can be added*					

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

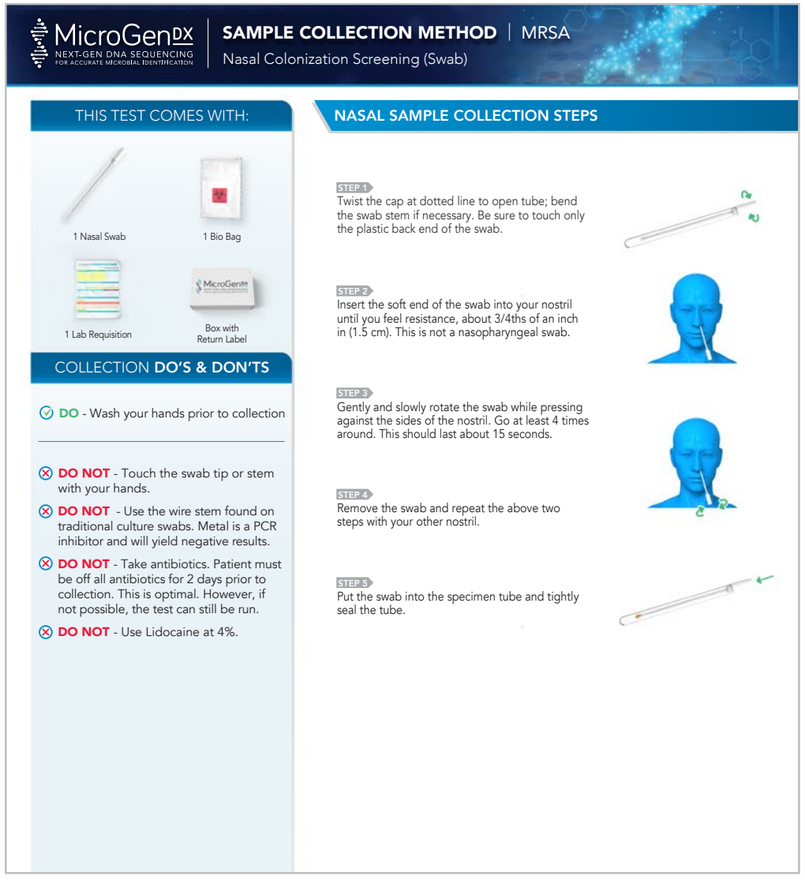
Stool Sample Collection Method

microgendx.qrd.by/stoolvideo

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST			
PART 1 Choose Panel Type		**PART 2** Confirm Test Order by checking box below	☐ Full STI	☐ Basic STI	☐ HSV	☐ HPV
☐ AFB	☐ Rectal Swab	☐ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	☐ MRSA Screening		☐ Oral HPV	
☐ Blood	☐ UTI/Prostate* *(Urine or Semen)*	**and /or**	☑ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)			
☐ ENT/Pulmonary	☐ Vaginal*					
☐ Nail	☐ Wound					
☐ Orthopedic	**FULL STI Panel can be added*					

MRSA Sample Collection Method

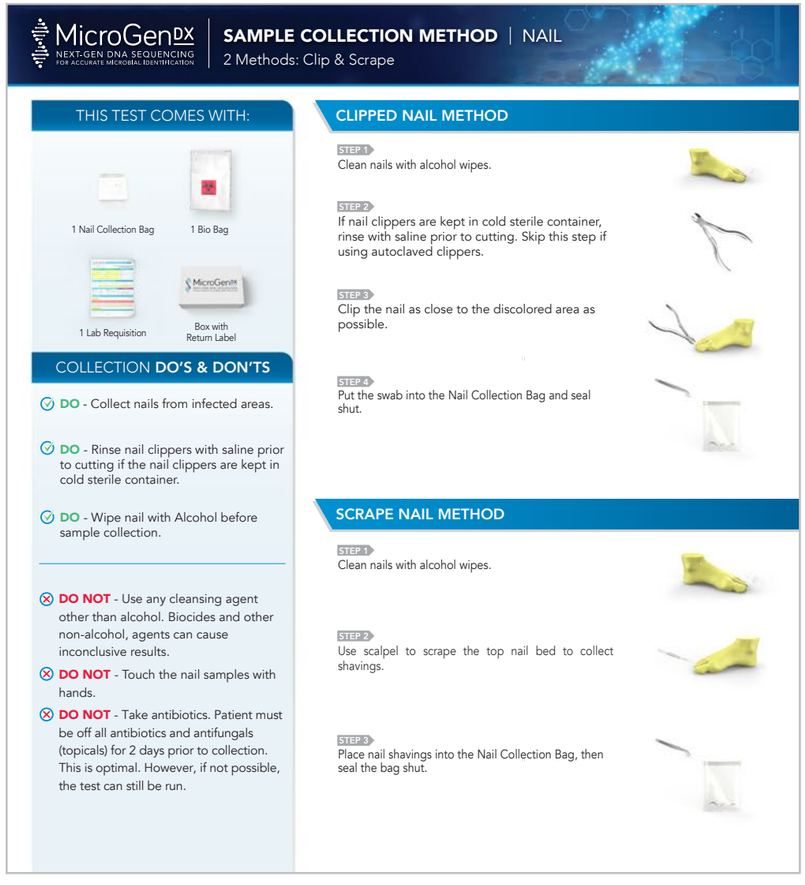


Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST
PART 1 **Choose Panel Type** ☐ AFB ☐ Rectal Swab ☐ Blood ☐ UTI/Prostate* *(Urine or Semen)* ☐ ENT/Pulmonary ☐ Vaginal* ☐ Nail ☐ Wound ☐ Orthopedic **FULL STI Panel can be added*	**PART 2** **Confirm Test Order by checking box below** ☐ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	**and /or**	☐ Full STI ☐ Basic STI ☐ HSV ☐ HPV ☑ MRSA Screening ☐ Oral HPV ☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

Nail Sample Collection Method



microgendx.qrd.by/nail

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST
PART 1 **Choose Panel Type** ☐ AFB ☐ Rectal Swab ☐ Blood ☐ UTI/Prostate* *(Urine or Semen)* ☐ ENT/Pulmonary ☐ Vaginal* ☑ Nail ☐ Wound ☐ Orthopedic **FULL STI Panel can be added*	**PART 2** **Confirm Test Order by checking box below** ☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	**and /or**	☐ Full STI ☐ Basic STI ☐ HSV ☐ HPV ☐ MRSA Screening ☐ Oral HPV ☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)

Ortho Sample Collection Method

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST

PART 1 - **Choose Panel Type**

☑ **OrthoKey PJI Clinic**

Total 16S Bacterial Load and Resistance Genes
Quinolone resistance, Methicillin resistance, Vancomycin resistance, Beta-lactam resistance, Carbapenem resistance, Macrolide resistance, Aminoglycoside resistance, Tetracycline resistance, Bactrim resistance, Extended Spectrum Beta Lactamase CTX-M resistance

Bacteria: Enterococcus faecalis, Streptococcus agalactiae (group B), Streptococcus pyogenes (group A), Pseudomonas aeruginosa, Staphylococcus aureus, Klebsiella pneumoniae, Propionibacterium (Cutibacterium) acnes
Fungi: Candida albicans

PART 2
Confirm Test Order by checking box below

☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.

and /or

☑ **Biomarkers**
Elevated Synovial WBC
Elevated Synovial PMN (%)
Elevated Synovial CRP

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PJI Sample Collection Method

microgendx.qrd.by/ortho-sample

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING

Choose Panel Type

☑ **OrthoKEY PJI OR** *(PJI Surgeries)* ***Includes Biomarkers****, qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi. ***(*Requires Synovial Fluid)***

☐ **SurgeryKEY** *(All Other Surgeries)* qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi. ***(No Biomarkers)***

Semen Sample Collection Method

MicroGenDX NEXT-GEN DNA SEQUENCING FOR ACCURATE MICROBIAL IDENTIFICATION

SEMEN
SAMPLE COLLECTION METHOD | **FOR MEN**

THIS TEST COMES WITH:

COLLECTION **DO'S & DON'TS**

- **DO** - Clean the genital area with soap and water before collecting the sample.
- **DO NOT** - Use a condom to collect the semen.
- **DO NOT** - Let the specimen come into contact with anything other than the collection cup. Including hands or any other body part.
- **DO NOT** - Take antibiotics. Patient must be off all antibiotics for 2 days prior to collection. This is optimal. However, if not possible, the test can still be run.

COLLECTING SEMEN SAMPLE

STEP 1
Clean the genital area with included Alcohol Prep Pad.

STEP 2
a. Collect semen excretion into sterile container.

b. If enough excretion is collected (more than a pea size amount), cap and seal the container and prepare for shipping. *If you have only collected a minimal amount, proceed to step 3.*

STEP 3
If only a minimal amount of semen excretion is collected (pea size amount) use the swab to collect the fluid by rolling swab through the fluid in the collection cup collecting as much fluid as possible on the swab tip.

STEP 4
Place the swab into the tube and cap the tube firmly.

microgendx.qrd.by/semenvideo

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST

PART 1
Choose Panel Type

- ☐ AFB
- ☐ Blood
- ☐ ENT/Pulmonary
- ☐ Nail
- ☐ Orthopedic
- ☐ Rectal Swab
- ☑ UTI/Prostate* *(Urine or Semen)*
- ☐ Vaginal*
- ☐ Wound

**FULL STI Panel can be added*

PART 2
Confirm Test Order by checking box below

☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.

and /or

PCR ONLY TEST

- ☐ Full STI ☐ Basic STI ☐ HSV ☐ HPV
- ☐ MRSA Screening ☐ Oral HPV
- ☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

Respiratory Sample Collection Method

MicroGenDX NEXT-GEN DNA SEQUENCING FOR ACCURATE MICROBIAL IDENTIFICATION

SAMPLE COLLECTION METHOD | RESPIRATORY/RTI
Sputum

THIS TEST COMES WITH:

COLLECTION **DO'S & DON'TS**

- **DO** - Have patient drink plenty of fluids on the evening before the test, provided they are not on a fluid restriction.
- **DO** - For best results, obtain the sample first thing in the morning. If you can't obtain the sample before the patient has breakfast, wait at least an hour after they have eaten before trying. Before you begin, describe the procedure.
- **DO** - Collect at least 5-10 ml of the thick sputum secretions
- **DO NOT** - Allow patients to brush their teeth or use mouthwash. Doing so could kill bacteria in the sputum, rendering it useless.
- **DO NOT** - Collect too much saliva
- **DO NOT** - Touch the inside of the sterile collection cup

COLLECTING SPUTUM

STEP 1
Explain that deep breathing helps loosen secretions and bring them to the back of the throat and will be necessary in collecting a good sample. Emphasize the importance of bringing up sputum, the thick secretions from the lungs, rather than expectorating saliva, the thin secretions from the mouth.

STEP 2
Position your patient in a chair or on the side of the bed. If they are unable to sit up on their own, place them in a high-Fowler's position. Remove patient's dentures if they have them.


HIGH-FOWLER'S POSITION

STEP 3
Have the patient rinse their mouth with plain water. This will help in reducing cross contaminates of microbiota found in the mouth.

Put on gloves and goggles. Uncap the container, carefully avoid touching the inside to ensure that it remains sterile.

STEP 4
Have the patient perform 3 deep breaths and cough as instructed, expectorating the sputum into container.

If you don't get an adequate sample on the first try, have patient continue to cough until you're able to collect a minimum of 5ml.

If the patient has trouble bringing up secretions, have them breathe into a nebulizer and try again.

Once you've collected the specimen, securely cap the container. Remove and discard your gloves and wash hands thoroughly. Allow the patient to rinse out their mouth and provide a tissue.

Note: Our test is not time or temp sensitive. You may send patient home with kit to collect if no sample can be provided at the time of office visit.

microgendx.qrd.by/sputumvideo

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST

PART 1
Choose Panel Type

- ☐ AFB
- ☐ Blood
- ☑ ENT/Pulmonary
- ☐ Nail
- ☐ Orthopedic
- ☐ Rectal Swab
- ☐ UTI/Prostate* *(Urine or Semen)*
- ☐ Vaginal*
- ☐ Wound

**FULL STI Panel can be added*

PART 2
Confirm Test Order by checking box below

☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.

and /or

PCR ONLY TEST

- ☐ Full STI ☐ Basic STI ☐ HSV ☐ HPV
- ☐ MRSA Screening ☐ Oral HPV
- ☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)

Rectal Sample Collection Method

MicroGendx NEXT-GEN DNA SEQUENCING FOR ACCURATE MICROBIAL IDENTIFICATION

RECTAL SWAB
SAMPLE COLLECTION METHOD

THIS TEST COMES WITH:

COLLECTION **DO'S & DON'TS**

- **DO** - Take from the ampule of rectum / distal part of bowel.
- **DO NOT** - Use gel or other greasy ointment before insertion of the rectal stick.
- **DO NOT** - Touch skin around anus in order to prevent any contamination from skin.
- **DO NOT** - Take antibiotics. Patient must be off all antibiotics for 2 days prior to collection. This is optimal. However, if not possible, the test can still be run.
- **DO NOT** - Touch the swab stem.

RECTAL SWAB METHOD

Particular care should be taken in patients with existing external hemorrhoid nodules that are inflamed to avoid any laceration with subsequent bleeding.

STEP 1
Insertion of the stick has to be gentle with some swirling movement until stick is inside of rectal ampule to at least a depth of 5-6 cm.

STEP 2
The removal of the stick should be performed carefully to avoid any contact with skin around anus.

Transfer the stick with swab head directly inside of tube that is going to be shipped.

STEP 3
The change of stick tip color towards brownish, or the presence of small pieces of feces on tip of stick suggests a quality sample.

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST		PCR ONLY TEST			
PART 1 Choose Panel Type	**PART 2** Confirm Test Order by checking box below	☐ Full STI	☐ Basic STI	☐ HSV	☐ HPV
☐ AFB	☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	☐ MRSA Screening		☐ Oral HPV	
☐ Blood	**and /or**	☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)			
☐ ENT/Pulmonary					
☐ Nail					
☐ Orthopedic					
☐ Rectal Swab					
☑ UTI/Prostate* *(Urine or Semen)*					
☐ Vaginal*					
☐ Wound					
**FULL STI Panel can be added*					

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

Urine Sample Collection Method

MicroGendx NEXT-GEN DNA SEQUENCING FOR ACCURATE MICROBIAL IDENTIFICATION

URINE
SAMPLE COLLECTION METHOD

THIS TEST COMES WITH:

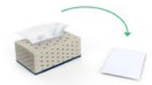
COLLECTION **DO'S & DON'TS**

- **DO** - Clean the genital area with soap and water before collecting the sample.
- **DO** - Perform a preparatory urination two hours in advance of first sample.
- **DO** - Ship the sample within 5 days of collection. If this is not possible place in refrigerator until shipped. *If shipping internationally please ship out within 24 hours of sample collection or refrigerate.*
- **DO NOT** - Use Lidocaine gel. If collecting urine via catheter, Lidocaine gel can render sample invalid or give false negative test results.
- **DO NOT** - Take in any fluids two hours in advance of first sample.
- **DO NOT** - Take antibiotics. Patient must be off all antibiotics for 2 days prior to collection. This is optimal. However, if not possible, the test can still be run.

COLLECTING URINE SAMPLE

STEP 1
Wash hands thoroughly. Cleanse all areas around the urinary exit with soap and water. With a clean tissue, blot off the urethra without touching any part of genital area with hands.

STEP 2
Spread a clean tissue on a surface close to the toilet bowl. Remove the lid from the urine cup and place it top-side down on the tissue. Place the open urine cup next to the tissue, being careful not to touch the rim of the cup or lid with fingers or body surface at any time.



STEP 3
For Women: Before urination, separate the labia, avoid touching the urethra opening.

For Men: Before urination, retract the foreskin (if uncircumcised), avoid touching the urethra opening.

STEP 4
Hold the empty cup in one hand. Begin urination into toilet, not cup, stop urination partway through then continue urination into cup. Keep urinating into cup until the amount in the cup is level with the red arrow sticker. Do not fill the cup more than 1/2 full. Finish urinating into toilet.

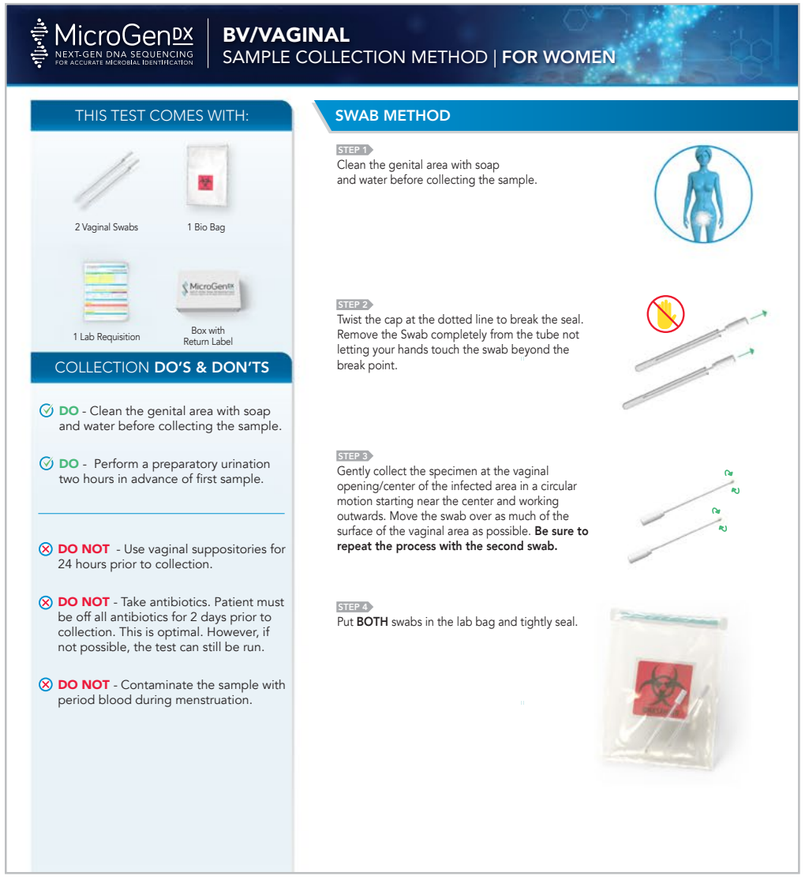
STEP 5
Secure the lid tightly by placing the lid directly on the cup and turning until you hear two clicks. This indicates the cup is locked.

microgendx.qrd.by/v0g9r6

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST		PCR ONLY TEST			
PART 1 Choose Panel Type	**PART 2** Confirm Test Order by checking box below	☐ Full STI	☐ Basic STI	☐ HSV	☐ HPV
☐ AFB	☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	☐ MRSA Screening		☐ Oral HPV	
☐ Blood	**and /or**	☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)			
☐ ENT/Pulmonary					
☐ Nail					
☐ Orthopedic					
☐ Rectal Swab					
☑ UTI/Prostate* *(Urine or Semen)*					
☐ Vaginal*					
☐ Wound					
**FULL STI Panel can be added*					

BV/Vaginal Sample Collection Method



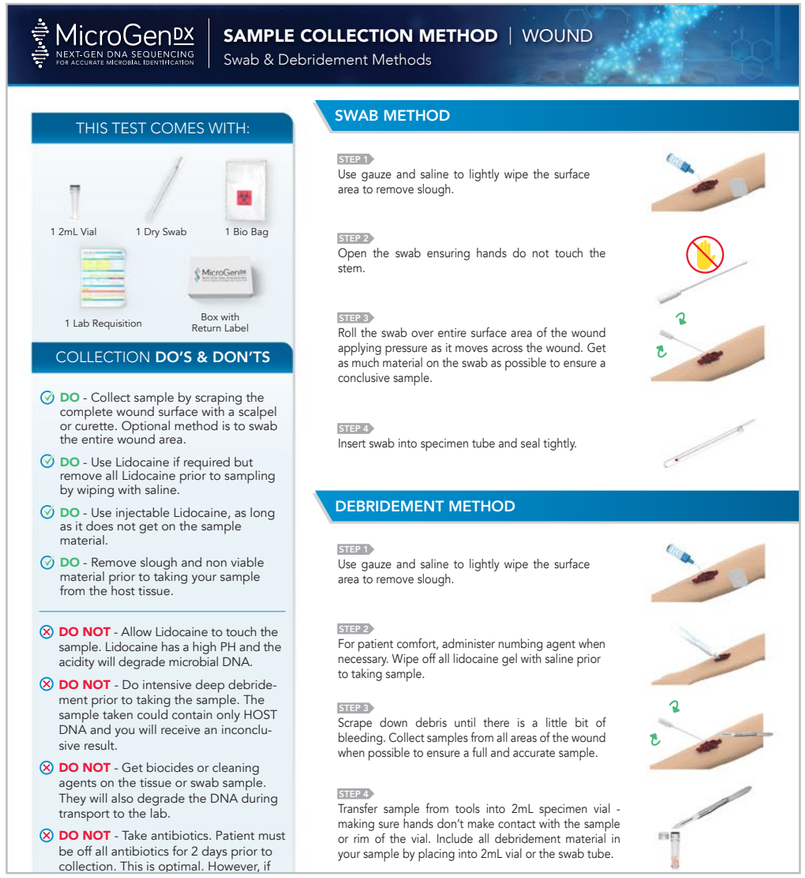
microgendx.qrd.by/28ypdl

Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST			
PART 1 Choose Panel Type		**PART 2** Confirm Test Order by checking box below	☐ Full STI	☐ Basic STI	☐ HSV	☐ HPV
☐ AFB	☐ Rectal Swab	☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	☐ MRSA Screening		☐ Oral HPV	
☐ Blood	☐ UTI/Prostate* *(Urine or Semen)*	and /or	☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)			
☐ ENT/Pulmonary	☑ Vaginal*					
☐ Nail	☐ Wound					
☐ Orthopedic	**FULL STI Panel can be added*					

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

Wound Sample Collection Method



Ordering looks like this on the lab req:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST			
PART 1 Choose Panel Type		**PART 2** Confirm Test Order by checking box below	☐ Full STI	☐ Basic STI	☐ HSV	☐ HPV
☐ AFB	☐ Rectal Swab	☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	☐ MRSA Screening		☐ Oral HPV	
☐ Blood	☐ UTI/Prostate* *(Urine or Semen)*	and /or	☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)			
☐ ENT/Pulmonary	☐ Vaginal*					
☐ Nail	☑ Wound					
☐ Orthopedic	**FULL STI Panel can be added*					

How to order +STI

To add +STI to a urine, vaginal, or semen test, complete the form as shown in the following graphic:

qPCR RAPID SCREENING AND NEXT-GEN DNA SEQUENCING TEST			PCR ONLY TEST			
PART 1 **Choose Panel Type** ☐ AFB ☐ Blood ☐ ENT/Pulmonary ☐ Nail ☐ Orthopedic ☐ Rectal Swab ☑ UTI/Prostate* *(Urine or Semen)* ☐ Vaginal* ☐ Wound **FULL STI Panel can be added*	**PART 2** **Confirm Test Order by checking box below** ☑ qPCR Rapid Screening and Next-Gen Comprehensive DNA Sequencing for Unknown Microbes including Bacteria and Fungi.	and /or	☑ Full STI	☐ Basic STI	☐ HSV	☐ HPV
			☐ MRSA Screening		☐ Oral HPV	
			☐ Gastrointestinal Panel tests for the presence of 22 species of bacteria, viruses, and parasites (Stool in Cary Blair Media Only)			

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

Info for patients

Why is your health provider ordering this DNA diagnostic test?

Maybe you have an infection that keeps coming back. Or you have a new infection that you want quickly and accurately diagnosed. A DNA diagnostic test from MicroGenDX can identify the potential causes, whatever your infection is and wherever it's located in your body.

Greater reliability

MicroGDX's qPCR+NGS DNA diagnostic testing is much more accurate and reliable than standard lab cultures, which often don't identify all of the pathogens involved in an infection. In fact, MicroGenDX can identify more than 50,000 bacteria and fungi that may be in a sample, including all of the ones that culture can't.

Faster results to your physician

qPCR will identify major pathogens and antimicrobial resistance genes in just 24-48 hours. After this, in 3.5 days, Next-Gen DNA Sequencing (NGS) will identify all infective bacteria and fungi in a sample — and also show which pathogens are most abundant and should be considered in treatment.

Making it easy for you

Once your doctor has approved your diagnostic test, most of our tests are available for convenient sampling in your home. Then you can simply mail the sample directly to the MicroGenDX lab in the postage-paid package provided.

No more guesswork

MicroGenDX qPCR+NGS tests take the guesswork out of diagnosing infections, so that health providers have the information they need to help you heal.

Growing cultures vs DNA analysis

Culture Lab	MicroGen DX DNA Lab
Identifies less than 1% of the microbes in a sample	Identifies 100% of the microbes in a sample
15%-30% accuracy	99.9% accuracy
50% chance of "no growth" results	Matches DNA to 50,000+ microbes
Up to 20+ days for results on fungi	Returns results in 3-4 days

Most tests cost $199; contracted insurances may change this rate.

For a handout with this information to give to your patients, please contact your account executive.

Patient payment information

IMPORTANT PATIENT INFORMATION

What You Need to Know:

Medicare/Insurance:
MicroGenDX will file claims to Medicare, Medicare Advantage, Medicaid, Medicaid Advantage, Federal Plans and all commercial plans EXCEPT Aetna Commercial Insurance.

Patient Obligation:
For any patient responsibility after insurance has processed, we will send you a statement. If Insurance reimburses the patient for service rendered by MicroGenDX, we will expect you to send us the check or make a payment in the amount that was reimbursed to you. If a non-contracted insurance does not pay, we will bill the patient $199 directly.*

**Certain products have different prices. Please see the "I am a patient" section of the ordering part of the website.*

Cash Payment:
Tests can be paid for directly by the patient using the below methods. Tests can also be purchased in advance of use by the patient.

Payment can be made via:

- Check or Money Order
- Credit Card
- Calling the Billing Department
- Online

21-0037-04

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

Get more answers.
www.MicroGenDX.com
info@microgendx.com
855.208.0019

Patient website: microgendx.qrd.by/patientwebsite

Where to see patient self-pay pricing: microgendx.qrd.by/patientorder

Patient billing information: microgendx.qrd.by/patientbilling

qPCR + Next-Generation Sequencing | *DNA diagnostics for challenging infection cases*

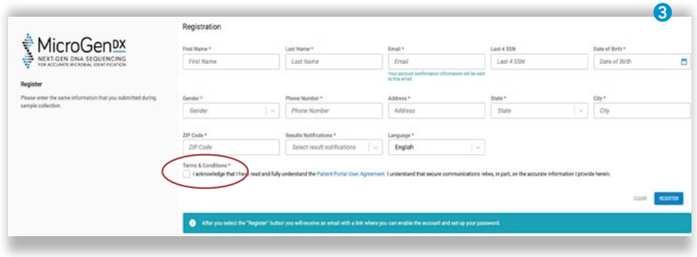
Patient Portal instructions

Patient Portal Instructions for MicroGenDX Test Results

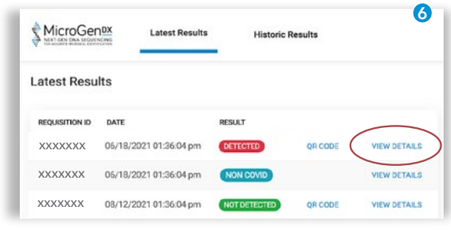
1. To view your MicroGenDX test results, navigate to **https://microgendx.qrd.by/myresults** or scan the QR code on the right with your phone.
2. If you do not have an account, select **Register here.**
3. Complete the required information and agree to the **Terms & Conditions** before clicking **Register.**
   IMPORTANT: Use your same email address that was used on your requisition form.
4. Check your email inbox for a verification message from results@microgendx.com and click the **Set your password** button in the email.
5. Set your password and log in.
6. Click **View details** for your test results.

1

2



3



6

Please contact Customer Service at 855.208.0019 or info@microgendx.com for assistance accessing the patient portal.

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

Get more answers.
www.MicroGenDX.com
info@microgendx.com
855.208.0019

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS
CLIA Certified

Patient Consent Form

Please inform any patients that you intend to test through MicroGenDX that it may not be fully covered by their insurance, and therefore it will be an additional cost. It is recommended that you get the patient to sign a patient consent form in addition to the lab req, and send that along with the lab requisition.

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qPCR + NGS DNA DIAGNOSTICS
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IN ASSOCIATION WITH SOUTHWEST REGIONAL PCR LABORATORY, LLC

Patient Acknowledgment, Consent and Authorization Form for MicroGenDX Testing

Patient Initials

_____ I, _____, hereby give my consent to authorize my treating physician to order the MicroGenDX test if deemed medically necessary.

_____ I understand that the MicroGenDX testing laboratory is designated to conduct DNA analysis tests for infectious disease and provide diagnostics to determine the absence or the presence of microbial species in suspected infection sites through the use of my sample(s) as specified by the test to assist in my physician's determination of treatment decisions.

_____ I understand that MicroGenDX will bill most insurance plans and that MicroGenDX participates with Medicare and other governmental payers.

_____ I understand that my insurance company will review the claim and determine my responsibility for cost (patient responsibility).

_____ I understand that if paid out of pocket, I am responsible for the cost of testing based on MicroGenDX current price list as indicated on https://microgendx.com/microgendx-patient-test-service-dm-intl/

_____ I understand that I am responsible for any amounts not paid by insurance for reasons including but not limited to, non-covered, and non-authorized services.

_____ I permit a copy of this authorization to be used in place of the original.

Patient Signature: _____ Patient Name Printed: _____

Date: _____ / _____ / _____

About MicroGenDX:
Founded in 2008, MicroGenDX is a CAP and CLIA certified lab utilizing Next Generation DNA sequencing to identify the microbes in a sample with 99.2% accuracy. Through the utilization of our curated database of 50,000+ microbial species, MicroGenDX provides clinicians and their patients with the most informative microbial diagnostic testing that science can offer; resulting in better outcomes.

Unlike the traditional culturing of samples, Next Generation DNA Sequencing is able to extract the microbial DNA from the sample provided and report the bacteria and fungi that may be causing the infection without having to grow anything. This technology allows for faster and more accurate diagnostics resulting in improved treatment and healing times in clinical outcomes.

More information on MicroGenDX can be found at: www.microgendx.com or customer service can be reached at 855-208-0019.

1-855- 208-0019 microgendx.com info@microgendx.com Get more answers.

FAQs

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

Company FAQs

How is MicroGenDX different from other reference laboratories?

MicroGenDX is an innovative, CAP accredited, CLIA licensed, molecular diagnostic laboratory. MicroGenDX uses a 2-Part DNA testing service, combining both quantitative Polymerase Chain Reaction (qPCR) and Next Generation Sequencing (NGS) technology. This process uses MicroGenDX's proprietary bioinformatics system and curated database that provides precise detection of infectious diseases at high levels of sensitivity and specificity.

What certifications does MicroGenDX have?

MicroGenDX is CAP and CLIA certified. The College of American Pathologists (CAP) is a laboratory accreditation program that is widely recognized as the gold standard and has served as a model for various federal, state, and private laboratory accreditation programs throughout the world. The Clinical Laboratory Improvement Amendments (CLIA) establish quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. MicroGenDX is also approved for use in the state of New York.

How long has MicroGenDX been in business?

MicroGenDX was founded in 2008 under the DBA Pathogenius by Randy Wolcott, MD of Southwest Regional PCR. In 2017 the company was acquired and rebranded as MicroGenDX Laboratory. Collectively this laboratory has been used by more than 10,000 healthcare providers and delivered over 500,000 NGS lab results.

What are the key benefits of using MicroGenDX's service?

- 24-hour turn-around for qPCR lab results (determined by sample receipt)
- Detection of resistance genes
- NGS results in just 3-5 business days
- Cost reduction and avoidance
- Reduced need to prescribe antibiotics and better antibiotic stewardship
- Increased heal rates (in combination with targeted antimicrobial therapy)
- Increased patient satisfaction
- Greater clinical value by reducing the subjectivity of identification associated with conventional culture technology

Technology FAQs

What is qPCR?

Quantitative Polymerase Chain Reaction (qPCR) is a molecular biology technique that amplifies a DNA base pair sequence up to several orders of magnitude (billions and trillions of copies). qPCR is a proprietary technology that accomplishes the task of DNA amplification in a multiplex format, such as amplifying the DNA of multiple organisms in a single reaction.

What is Next Generation Sequencing (NGS)?

Next Generation Sequencing (NGS) refers to non-Sanger-based high-throughput DNA sequencing technologies. Millions or billions of DNA strands can be sequenced in parallel, yielding substantially more throughput and minimizing the need for the fragment-cloning methods that are often used in Sanger sequencing of genomes.

What distinct advantages does MicroGenDX NGS technology offer?

Advantages include:

- Superior specificity of 99.9% microbes within an infection site
- Fast results in 3-5 business days (determined by sample receipt)
- Simultaneous identification of bacteria fungus and antibiotic resistance genes
- Viable to use while patient is already on antibiotics
- Increased sensitivity and specificity
- Simplicity of sample collection
- Samples are not sensitive to time or temperature

Which panel should I order?

For bacterial and fungal infection, choose the qPCR panel type that best applies to the infection in Part 1 and check the box for Part 2.

Why does MicroGenDX send out two separate lab reports instead of both Level 1 (qPCR) and Level 2 (NGS) at the same time?

Level 1 qPCR detects microbes on the chosen panel within 24 hours along with bacterial load. It also detects 17 resistance genes for immediate antibiotic therapy. Note: Resistance genes reported may be present in bacteria reported in the Level 2 (NGS) test.

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Level 2 (NGS) is delivered within 3-5 business days of sample receipt. The superior data delivered in the Level 2 report provides a list of all the bacteria and fungi detected within the sample and their relative abundances. With this next level of data, physicians can target therapy. This report will also list all organisms and resistance genes detected in Level 1 (qPCR).

Does MicroGenDX test for antibiotic susceptibilities?

No. However, we do test for the following resistance genes:

- Quinolone
- Methicillin
- Vancomycin
- Beta-lactam
- Carbapenem
- Macrolide
- Aminoglycoside
- Tetracycline
- Bactrim
- Extended Spectrum Beta Lactamase CTX-M

We also provide the antimicrobials for consideration for each species detected. These antimicrobials are based on the Johns Hopkins and Sanford guides. Please note the antimicrobials offered for consideration do not take into account patient antimicrobial allergies and prescription is at healthcare provider discretion. Please consult local antibiogram and infectious disease professionals for additional guidance, if necessary.

Does MicroGenDX perform gram stains?

No. MicroGenDX does molecular testing, not microbiological testing. However, we do specify the class of antibiotics per species found from the National Library of Microbiology.

FedEx® Shipping FAQs

How many lab bags can I put in one FedEx® box?

You may fill the box with as many lab bags as possible that will still allow the box to close well. Please seal the box with tape or use the included seal sticker for extra security.

How do I schedule a FedEx® pick-up?

Call FedEx® at 1-800-GOFEDEX (1-800-463-3339) and give them the tracking number (12-digit number under the barcode). When calling say "agent" twice to speak to an agent. Let them know it's a biohazard prepaid pick-up.

Can I take the FedEx® package to a FedEx® location?

Our packages are accepted at FedEx® main facility locations and FedEx® drop boxes. FedEx® office locations will not accept this type of package. Visit FedEx.com to find a location near you.

I am out of FedEx® labels. What can I do?

Call 1-855-208-0019 and request that more labels be shipped to you. If you require a label for a same-day shipment, one can be emailed to you. FedEx® labels cannot be faxed due to the poor reproduction quality of fax machines.

How can I verify that my package arrived at MicroGenDX?

Please record the tracking number for any package sent. Go to FedEx.com and enter the tracking number of your package to check the delivery status.

What is the latest time I can call for a FedEx® pickup?

FedEx® routes may vary from location to location. Call 1-800-GO-FEDEX (1-800-463-3339) to obtain a pickup schedule for your area. Only request a FedEx Express® pickup schedule, because other FedEx® methods do not apply.

Can I give the package to any FedEx® driver?

Only FedEx Express® drivers will accept UN3373 Clinical Paks. FedEx Ground® drivers will not accept packages classified as such.

Supplies FAQs

What options are available for sending in supply orders?

In addition to online (see previous How-To section), supplies can be ordered via phone (1-855-208-0019) or email (supplies@microgendx.com).

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What if I did not receive enough supplies – or the wrong supplies?

Please contact customer service at 1-855-208-0019

How long does it take for supplies to be shipped?

All supply orders are shipped via FedEx® flat rate two business day delivery.

What volume of supplies will I receive?

You order the amount of supplies you need based on your need.

What should I do if I have not received my supply order in the estimated time?

Please call the customer service line at 1-855-208-0019 if you have not received your supplies in two days.

What should I do if I have not received my test results?

If you have not received your results within 48 hours, please call customer service at 1-855-208-0019.

Who do I call if I am having FedEx® issues?

Please call MicroGenDX customer service at 1-855-208-0019 with any issues or go to https://microgendx.com/contact-microgen-dx/ to contact us. We will help resolve the issue or connect you with a FedEx® representative.

What if I am out of shipping boxes?

You may use any sturdy box to ship samples. Be sure to contact MicroGenDX for a shipping label. You can order more boxes from microgendx.com

Clinical Diagnosis FAQs

Is it appropriate to make treatment decisions based solely on the results of a qPCR or the NGS test?

Diagnostic tests such as qPCR and NGS are tools used in conjunction with patient symptoms, history, and other appropriate companion diagnostic tests (complete blood count, inflammatory markers, etc.) that the provider deems appropriate to properly diagnose and treat your infection.

Does the information obtained with conventional culture correlate with MicroGenDX lab results?

Multiplex and comprehensive molecular technology is more sensitive than culture and can reliably detect multiple organisms in the specimen in the presence of antimicrobial therapy. NGS removes the human bias and variation of culture from microbiology laboratories and does not require organism viability. Results might not always correlate since NGS can detect organisms that are not readily grown in culture.

What is the sensitivity and specificity for NGS?

Both sensitivity (or the limit of detection [LoD]) and specificity of NGS testing are determined as a part of our validation protocol. The steps outlined by the Clinical Laboratory Standards Institute are summarized in a document prepared by MicroGenDX and available for circulation to our clients and their staff. Additional information about the sensitivity and specificity of a particular target on any one of the panels is also available upon request.

What are important considerations in diagnosing urinary tract infections (UTI)?

Recurrent or chronic UTIs are sometimes the result of more than just a single infectious organism. Urine culture is biased towards a single infectious organism based on colony-forming unit (CFU) count, possibly leading to inappropriate therapy. Some problematic organisms are not readily grown in culture, which may lead to incorrect treatment or non-treatment. An advantage of NGS is the ability to test and detect multiple organisms simultaneously, including those that might not grow readily in culture. And if the patient is currently on antibiotic therapy or has a recent history of antibiotic therapy, detection of pathogens by NGS is not impacted by the presence of antibiotics.

Testing FAQs

If a patient is on anti-herpes medication, will it interfere with the test results?

Anti-herpes medications disrupt the process by which the virus makes copies of itself and spreads to new cells. The antiviral works by inhibiting an enzyme that the virus has but human cells do not, and therefore interrupts the virus' ability to synthesize its DNA. By reducing the replication of the herpes virus, the number of virus particles shed by the host is reduced and tests (even molecular assays) might not always be able to detect viral shedding.

Does MicroGenDX test for parasites?

Yes. The Gastrointestinal Panel includes tests for *Giardia lamblia* and *Cryptosporidium parvum*.

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When I order the UTI Panel, will I receive a list of antibiotic resistances?

Yes.

Does MicroGenDX test for Sexually Transmitted Infections (STIs aka STDs)?

Yes. We currently offer multiple qPCR options for STI testing and our NGS will pick up some bacterial STIs as well.

Lab Report FAQs

How do I retrieve my lab reports?

There are three ways to retrieve your lab reports:

1. MDX labs Secure Portal
2. MDX secure email
3. Secure FAX

How can I better understand my qPCR Level 1 and NGS Level 2 lab reports?

MicroGenDX provides peer discussion services to help you go over difficult reports. For general questions ask your MicroGenDX representative.

What do the "antimicrobials for consideration" sections indicate?

We provide antimicrobial options for consideration for each species detected. These antimicrobial options are based on the Sanford Guide and Johns Hopkins Guides. When a more typical bacteria like E. coli is detected that is easily grown in the micro lab, your local antibiogram that tracks local resistance patterns should be referenced, although this will only apply to 20-25 microbial species that are easily grown in culture.

Why do some species show up in Level 2 but not Level 1?/Why is there disagreement between the Level 1 (qPCR) and Level 2 (NGS) results?

When a species is detected by qPCR but not by NGS:

- qPCR can be more sensitive, detecting organisms below the NGS detection threshold, which is 2% relative abundance. Species under the 2% threshold are not included on NGS results.

When a species is detected by NGS but not qPCR:

- The key difference between the two technologies is discovery power. qPCR is limited to the organisms that are included on the panel. While NGS is also limited by the database size, sequence databases are much larger than qPCR panels and the MicroGenDX database currently houses sequences from over 50,000 unique bacterial and fungal species.
- When an organism is included on the qPCR panel but is only detected by NGS, it is likely that mutations in the primer or probe binding sites have prevented binding and may represent strain level differences. This scenario is precisely why MicroGenDX uses qPCR and NGS concurrently as the two technologies complement each other.

Specimen Collection FAQs

Which specimens are acceptable?

We accept urine, blood, fluid, bone, tissue, hardware, mucus, fecal matter, semen, sputum, nail clipping, scrapings, and swabs. Each sample will have its own guidelines. Please refer to the "How to Collect a Sample" information available for every test (and reviewed in the previous Collection Instructions section).

Does MicroGenDX accept tissue as a specimen source?

Tissue can be accepted as a specimen source, but it is recommended that the tissue be no larger than the size of a pea.

A client has a bronchial aspirate specimen that is clotted. Can the specimen be submitted for respiratory panel testing?

Yes.

When swabbing a wound, should I swab some of the area or all of it?

Be thorough swabbing the entire area of suspected infection site. Detailed instructions are in the collection instructions section of the website.

Do I collect the sluff in my collection process?

Yes. Sluff will carry the DNA of microbes.

Is urine an acceptable specimen for the Bacterial Vaginosis and Candidiasis panels?

Yes.

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What is the proper amount of urine for a specimen?

Add approximately 8 mLs of urine.

Can a a urine or vaginal sample be collected during menstruation?

Yes. For highest quality sample, please avoid getting menstrual fluid in the sample as much as possible.

Are there any holistic/natural remedies that can interfere with the test?

Please avoid contact of sample with holistic/natural treatments to ensure a quality sample. For example: Oil of oregano is an antimicrobial and may interfere with sample quality.

Q: Does urine have to be on ice?

No.

If I missed the last pick up from FedEx®, can I ship the following day or will I need to recollect the sample?

The next day or week is just fine. DNA is not easily affected by time and temperature. If you are not able to ship out the same day or even missed last time on a Friday, ship the sample the next business day. Please do not hold the sample.

Negative or Inconclusive Lab Report

Q: Why did I receive a negative report?

Five reasons why your sample might have been compromised:

1. Sample was collected from a site where there was no microbial species.
2. Biocides or Lidocaine at 4% or higher was on the sample.
3. Sample contained an overabundance of host DNA.
4. Sample contained only nonviable material – i.e., pus, mucus.
5. In the case of urine, an antibiotic active metabolite was in the sample vial and degraded the DNA. This can occur if the patient was on antibiotics while taking the urine sample.

Antibiotic Sensitivities & Viable vs Nonviable Bacteria

Can NGS technology replace traditional culture if it doesn't provide antibiotic sensitivities?

Reasons NGS can replace culture include:

- MicroGenDX provides antibiotic resistance by detecting the resistant gene for the antibiotic classes.
- Culture sensitivities can only be performed if the microbe "grows."
- Being able to culture (i.e. "grow") a microbe is not the determining factor to verify if the species is a problem for the host.
- Only 1% of all known microorganisms can be grown in culture.
- The MicroGenDX database contains more than 50,000 species of microbes.
- A micro lab cannot provide the same lab sensitivities of the more than 10,000 species MicroGenDX has detected in human samples.
- ECSMID guidelines make the point that antibiotic sensitivities have no clinical value when treating a biofilm infection.
- Breakpoints to determine S-I-R have been established for planktonic bacteria. However, breakpoints haven't been established for the biofilm or community of microorganisms.

How do you determine if the bacteria species are viable?

Dead or nonviable bacteria DNA degrades within 24 hours within the host environment.

After viable or live bacteria are removed from the host environment, it will take about five days for the DNA to die or degrade and become nonviable.

1. If you refrigerate the sample it will be good for weeks. If you freeze the sample, the DNA will not degrade, and it will be good forever.
2. Due to the rapid degradation of DNA in dead bacterial cells, it becomes extremely challenging for sequencing technology to reach the threshold of DNA reads. If we don't achieve enough DNA reads, we cannot detect the species.
3. If the bacterial species is listed in our report it has met our criteria for DNA reads.

What do I treat?

Treatment decisions are based on multiple diagnostic criteria. The MicroGenDX report is not to be used in isolation. A common approach is to treat the dominant species when there is a concern for using multiple antimicrobials.

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Is there a cut off-off for how many species to treat?

No. Multiple species identified could be interpreted as a biofilm. In the case of biofilm infections, the microorganisms are a "collaborative community" and are highly synergistic. When the sample is taken from a site other than the mouth, sinus cavity, gut, or areas in the body where we have an established microbiome, there are no commensal bacteria (good bacteria). Commensals need specific host-related mechanisms, and those host-dependent processes are not possible in wounds, RTI, UTI, or joint infections.

What is found in noninfected patients?

MicroGenDX provides a report on the microorganisms that were detected based on the sample sent to us from the patient. Depending on where the sample was taken, a natural microbiome might be present. However, all species detected might not be pathogenic. Healthcare providers should consider other indications of infection in addition to the MicroGenDX report when making treatment decisions.

Why doesn't the combined percentage of species add up to 100%?

MicroGenDX only reports species that make up more than 2% of the DNA detected.