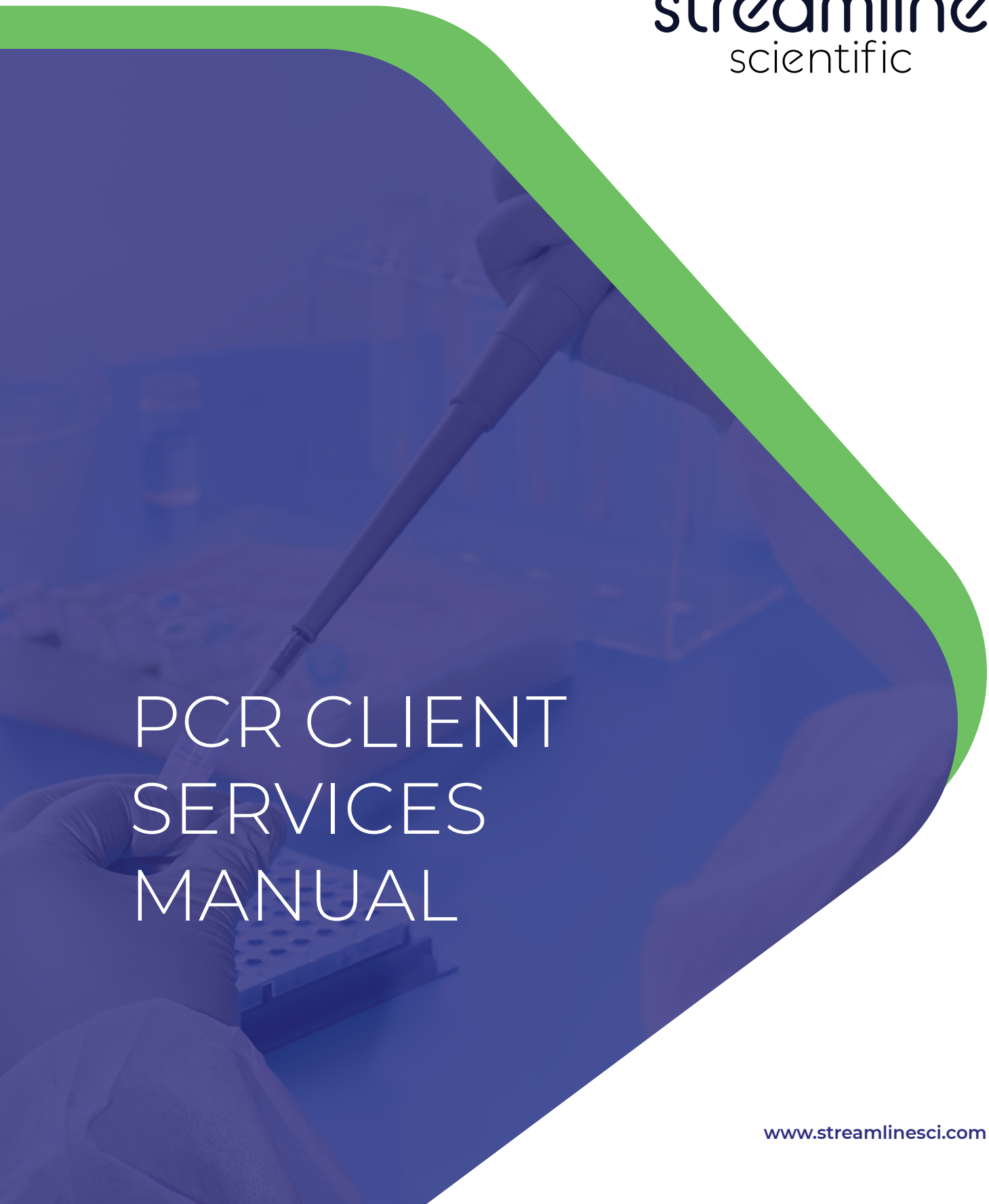
streamline scientific



PCR CLIENT SERVICES MANUAL

www.streamlinesci.com

WELCOME LETTER

Dear Customer,

Thank you for trusting Streamline Scientific for your molecular, microbiology, and toxicology testing. As a physician-founded company, we are passionate about the services we provide and know that the appropriate diagnostic information informs your decision making, and improves patient care.

Since our start in 2011, we have focused on simplifying the delivery of molecular technologies for both medical practices and patients. We do this by arming clinicians with the insights needed to prescribe the most appropriate treatment - within 24 hours.

Our sister organization, Molecular Designs, is a leading developer and manufacturer of PCR assays. In March of 2020, upon the news of the novel coronavirus, Molecular Designs was one of the first of 5 labs in the nation to submit an EUA and be granted FDA authorization.

This spirit of innovation continues today, developing novel tests to meet market needs and exploring new ways to better serve our many Alabama-based customers. Several of the elements that define the "Streamline Difference" include:

- Industry-leading technology and customer portal
- EMR integrations
- Unmatched customer support and dedicated team
- Door-to-door courier service
- An improved patient experience with multiple tests from a single swab

You are in exceptional hands with our Business Development and Client Relations teams, and the enclosed documentation will serve as a useful resource.

Should you have any questions or input on how we can better serve you, please don't hesitate to contact me directly.

Sincerely yours,

SHAWN HOOD
President
shood@StreamlineSci.com

DIRECTORY

BIRMINGHAM

2868 Acton Road
Suite 207
Birmingham, AL 35243

CLIA – 01D2074949
COLA – 25348

AUSTIN

13413 Galleria Circle
Suite Q-140
Bee Cave, TX 78738

CLIA – 45D2268534
COLA – 32244

CLIENT SERVICES CONTACT INFORMATION

Monday – Sunday:	8AM – 5PM
Email:	clientservices@streamlinesci.com
Local:	205.558.0095
Toll Free:	855.319.4459
Fax:	877.796.6185

BILLING SERVICES CONTACT INFORMATION

Email:	patientbilling@streamlinesci.com
Local:	844.364.9969

LAB OPERATIONS

7 days a week

(Any holiday closures will be announced in advance and posted on streamlinesci.com)

SAMPLE COLLECTION GUIDELINES

COLLECTION CONTAINERS

- Synthetic Flocked Swab with Liquid Amies Transport buffer
- Biotech Saline Swab (Nasopharyngeal/ Oropharyngeal) – COVID and Respiratory Panels ONLY
- Urine Vacutainers
- Sterile Toxicology Cup with temperature strip (**labeled as**: Clicktainer Vial, Temperature Strip Label, Assembled) – Toxicology Samples Only
- Sterile Dry Tubes (**labeled as**: Transport Tube, 5ml, Capped, Self-Standing, Sterile, case 50) – Fungal Infection Panel ONLY

SPECIMEN TYPE CONSIDERATIONS

PCR Testing:

- Swabs – Ideal samples are taken from the source of the potential infection. Ex. Nasopharyngeal, oropharyngeal, throat, superficial/subdermal wounds, vaginal tract, etc.
- Urine – If sending in urine specimens, clean-catch urine is required for UTI. Clean-catch urine is not recommended for STI or Candida testing.

Antimicrobial Susceptibility Testing:

- Swabs – Can be used from most sources. For pure nasal swabs, only culturing performed (Antimicrobial Susceptibility Testing is not recommended for nasal swabs due to the lack of clinical **significance**).
- Urine (bacteriostatic preservative) – No special requirements.

REJECTION CRITERIA

General criteria (applicable to all tests and sample types):

- Specimen is unlabeled or improperly labeled. Properly labeled includes two patient identifiers matching submitted requsition form.
- Requisition form is missing or incomplete.
- Specimen is improperly sealed, resulting in leakage and possible contamination during transport.
- Incorrect specimen type for selected panel.
- Insufficient sample volume for testing.

Swab Specimens:

- Swab specimens received with no original swab present in tube.
- Dry swab with no buffer present in tube.

Urine Specimens for UTI Testing:

- Urine specimens submitted in Aptima buffer or other container with no **bacteriostatic** preservative.

PCR Testing (any panel):

- Specimens received after 5 days post-collection.

Culturing and Antimicrobial Susceptibility Testing:

- Swab specimens received after 2 days post-collection.
- Swab specimens received in a non-liquid Amies buffer (such as viral transport medium).
- Nasal swab specimens (exceptions – see specimen type considerations).
- Urine specimens received after 3 days post-collection.
- STI or Vaginitis specimens – Antimicrobial Susceptibility Testing is not available.

GENERAL DISCLAIMERS

Applies to all patient specimens submitted to Streamline Scientific: Proper patient identification and accurate specimen labeling is required per CLIA (Clinical Laboratory Improvement Amendment). Streamline Scientific has determined the analytical performance characteristics of the molecular tests. They have not been cleared or approved by the U.S. Food and Drug Administration. It is preferable that all specimen types are received within 2 days of collection. They will need to be received within the specimen stability range stated by the manufacturer of the collection device measured from the time of collection to time of receipt for laboratory testing, to prevent a disclaimer on the test report.

streamline scientific

Alabama - CLIA: 01D2074949
2868 Acton Road, Suite 207, Birmingham, AL 35243
p: 855.319.4459 | f: 877.796.6185 | StreamlineSci.com

Texas - CLIA: 45D2268534
13413 Galleria Circle, Suite Q-140, Bee Cave, TX 78738
p: 855.319.4459 | f: 877.796.6185 | StreamlineSci.com

VERSION: 1.1.23

1 Patient Information

STEP 1

Last Name / First Name /

Address /

City / Stat

Phone

DOB

SSN

Insurance

Subscriber ID

Group #

Bill to: ☐ Insurance ☐ Facility ☐ Uninsured

☐ Male ☐ Female

Race:
☐ Asian ☐ Black ☐ Caucasian ☐ Hispanic ☐ Native American ☐ Other ☐ N/A

Ethnicity:
☐ Hispanic ☐ Non-Hispanic ☐ N/A

2 Provider Information

STEP 2

Client Name / Account

Address / APT#

City / State / Zip

Phone

Ordering Provider

Collection Date

Specimen Collected

State Collected

Collection Time

3 Medical Necessity

STEP 3

As part of my antibiotic stewardship policy, I find it medically necessary to rapidly determine a n order to treat with or without a nd timely data available to me direc Empiric treatment and manageme c use (50% according to the CDC) onsequences.

Provider Signature

☐ Verbal Order ☐ Standing Order

4 Provider Information

STEP 4

The information I have provided on this form is accurate. I authorize Streamline Scientific to releas or facility. I hereby a ine Scientific for services I rece n out of network provider with my i for all co-pays and yers.

Patient Signature

Date

5 Panel List

STEP 5

☐ COVID-19 Only

☐ COVID/Flu/RSV
- ☐ COVID-19 (Coronavirus)
- ☐ Influenza A & B
- ☐ RSV (types A & B)

☐ COVID Respiratory Lite
(includes all the pathogens in the panel)
- ☐ Haemophilus influenzae
- ☐ Moraxella catarrhalis
- ☐ Mycoplasma pneumoniae
- ☐ Strep. pyogenes (Group A)

☐ COVID Respiratory
(includes all the pathogens in the panel)
- ☐ Adenovirus
- ☐ Bocavirus
- ☐ Bordetella pertussis
- ☐ Chlamydophila pneumoniae
- ☐ Coronavirus (229E, HKU1, NL63, OC43)
- ☐ EBV (mononucleosis)
- ☐ Enterovirus
- ☐ HMPV A & B
- ☐ Parainfluenza virus (type 1-4)
- ☐ Rhinovirus (types A & B)
- ☐ Staphylococcus aureus
- ☐ Streptococcus pneumoniae

☐ COVID Respiratory Plus
(includes all the pathogens in the panel)
- ☐ Acinetobacter baumannii
- ☐ Enterobacter cloacae
- ☐ Klebsiella aerogenes
- ☐ Klebsiella pneumoniae
- ☐ Legionella pneumophila
- ☐ Proteus mirabilis
- ☐ Pseudomonas aeruginosa
- ☐ Staphylococcus epidermidis
- ☐ ABX Resistance Marker Methicillin/Oxacillin (mecA)

ICD 10 CODES
- ☐ R09.81 Congestion ☐ R50.9 Fever
- ☐ J02.9 Pharyngitis ☐ Z20.89 Exposure
- ☐ R05.9 Cough, unspecified
- ☐ _____

COVID VACCINATION STATUS:
- ☐ Z28.311 Partially vaccinated for COVID-19
- ☐ Z28.310 Unvaccinated for COVID-19
- ☐ Z28.39 Other underimmunization status

SPECIMEN SOURCE
- ☐ Nasal Swab ☐ Ear Swab
- ☐ Nasopharyngeal Swab
- ☐ Oropharyngeal Swab
- ☐ Sputum
- ☐ Other: _____

☐ UTI w/ ABX Resistance
- ☐ Acinetobacter baumannii
- ☐ Bacteroides fragilis
- ☐ Citrobacter braakii/ freundii
- ☐ Citrobacter koseri
- ☐ Enterobacter cloacae
- ☐ Enterococcus spp.
- ☐ Escherichia coli
- ☐ Klebsiella aerogenes
- ☐ K. oxytoca/michiganensis
- ☐ Klebsiella pneumoniae
- ☐ Morganella morganii
- ☐ Proteus mirabilis
- ☐ Pseudomonas aeruginosa
- ☐ Serratia marcescens
- ☐ Staphylococcus aureus
- ☐ Staphylococcus epidermidis
- ☐ Staphylococcus saprophyticus
- ☐ Strep. pyogenes (Group A)

ABX Resistance Markers
- ☐ β-lactamase (blaKPC)
- ☐ β-lactamase (CTX-M-Group 1)
- ☐ metallo-β-lactamase (blaNDM)
- ☐ Fluoroquinolones
- ☐ Methicillin/Oxacillin (mecA)
- ☐ Sulfonamides
- ☐ Trimethoprim

☐ UTI Plus
(includes all the pathogens in the panel)
- ☐ Candida albicans
- ☐ Candida dubliniensis
- ☐ Candida glabrata
- ☐ Candida krusei
- ☐ Candida parapsilosis
- ☐ Candida tropicalis
- ☐ Mycoplasma genitalium
- ☐ Mycoplasma hominis
- ☐ Prevotella bivia
- ☐ Strep. agalactiae (Group B)
- ☐ Ureaplasma urealyticum

ICD 10 CODES
- ☐ R35.0 Frequency of Micturition
- ☐ Z22.39 Carrier of other specified bacterial disease
- ☐ R30.0 Dysuria
- ☐ N30.00- Acute cystitis without hematuria
- ☐ N30.20 Other chronic cystitis w/o hematuria
- ☐ N41.0- Acute prostatis

SPECIMEN SOURCE
- ☐ Clean catch urine
- ☐ Urethral swab

☐ Wound/Derm w/ ABX Resistance
- ☐ Acinetobacter baumannii
- ☐ Bacteroides fragilis
- ☐ Citrobacter braakii/ freundii
- ☐ Citrobacter koseri
- ☐ Enterobacter cloacae
- ☐ Pseudomonas aeruginosa
- ☐ Staphylococcus aureus
- ☐ Staphylococcus epidermidis
- ☐ Staphylococcus saprophyticus
- ☐ Strep. pyogenes (Group A)
- ☐ Varicella Zoster (Shingles)

ABX Resistance Markers
- ☐ β-lactamase (blaKPC)
- ☐ β-lactamase (CTX-M-Group 1)
- ☐ metallo-β-lactamase (blaNDM)
- ☐ Fluoroquinolones
- ☐ Methicillin/Oxacillin (mecA)
- ☐ Sulfonamides
- ☐ Trimethoprim

ICD 10 CODES
- ☐ L08.9 Local infection of the skin and subcutaneous tissue, unspecified
- ☐ Z22.39 Carrier of other specified bacterial diseases
- ☐ Z22.322 Carrier or suspected carrier of MRSA
- ☐ _____
- ☐ _____
- ☐ _____

SPECIMEN SOURCE
- ☐ Aspiration
- ☐ Other: _____

☐ Culture ID w/ Reflexive Antimicrobial Susceptibility Testing *(AST is not available for STI or Vaginitis)*

ICD 10 CODES
- ☐ _____ ☐ _____
- ☐ _____ ☐ _____

☐ Vaginitis
- ☐ Atopobium vaginae
- ☐ Bacteroides fragilis
- ☐ BVAB-2
- ☐ Candida albicans
- ☐ Candida dubliniensis
- ☐ Candida glabrata
- ☐ Candida krusei
- ☐ Haemophilus ducreyi
- ☐ HHV-1 & 2 (Herpes Simplex)
- ☐ Lactobacillus crispatus
- ☐ Lactobacillus gasseri
- ☐ Lactobacillus iners
- ☐ Lactobacillus jensenii
- ☐ Megasphaera Type 1 & 2
- ☐ Mobiluncus curtisii
- ☐ Mobiluncus mulieris
- ☐ Mycoplasma genitalium
- ☐ Mycoplasma hominis
- ☐ Neisseria gonorrhoeae
- ☐ Prevotella bivia
- ☐ Staphylococcus aureus
- ☐ Strep. agalactiae (Group B)
- ☐ Treponema pallidum
- ☐ Trichomonas vaginalis
- ☐ Ureaplasma urealyticum

ICD 10 CODES
- ☐ N76.0 Acute vaginitis
- ☐ N77.1 Vaginitis, vulvitis, & vulvovaginitis
- ☐ B37.3 Candidiasis of vulva & vagina
- ☐ Z30.9 Encounter for contraceptive management
- ☐ _____
- ☐ _____

SPECIMEN SOURCE
- ☐ Vaginal Swab

☐ STI
- ☐ Atopobium vaginae
- ☐ Chlamydia trachomatis
- ☐ Gardnerella vaginalis
- ☐ Haemophilus ducreyi
- ☐ HHV-1 & 2 (Herpes Simplex)
- ☐ Niesseria gonorrhoeae
- ☐ Treponema pallidum
- ☐ Trichomonas vaginalis

ICD 10 CODES
- ☐ N76.0 Acute vaginitis
- ☐ N89.8 Other specified noninflammatory disorders of vagina
- ☐ R36.9 Urethral discharge unspecified
- ☐ Z30.9 Encounter for contraceptive management
- ☐ _____
- ☐ _____
- ☐ _____

SPECIMEN SOURCE
- ☐ Urine ☐ Other: _____

☐ Gastrointestinal
- ☐ Adenovirus
- ☐ Astrovirus
- ☐ Campylobacter coli/jejuni/lari
- ☐ Clostridium difficile
- ☐ E. coli (VTEC, 0157)
- ☐ Norovirus (GI/GII)
- ☐ Rotavirus
- ☐ Salmonella spp.
- ☐ Sapovirus
- ☐ Shigella spp.
- ☐ Yersinia enterocolitica

ICD 10 CODES
- ☐ R19.7 Diarrhea, unspecified
- ☐ A06.0 Acute Dysentery
- ☐ R50.9 Fever
- ☐ E86.0 Dehydration
- ☐ _____
- ☐ _____

SPECIMEN SOURCE
- ☐ Rectal Swab ☐ Other: _____
- ☐ Stool Specimen

☐ Fungal Infection
- ☐ Alternaria spp.
- ☐ Aspergillus spp.
- ☐ Fusarium spp.
- ☐ Scytalidium dimidiatum
- ☐ Sarocladium strictum
- ☐ Candida albicans
- ☐ Candida glabrata
- ☐ Candida krusei
- ☐ Candida parapsilosis
- ☐ Candida tropicalis
- ☐ Cryptococcus spp.
- ☐ Malassezia spp.
- ☐ Meyerozyma guilliermondii
- ☐ Trichophyton anthropophilic spp.
- ☐ Trichophyton zoophilic spp.
- ☐ Microsporum canis

☐ Bacterial Add On
- ☐ Pseudomonas aeruginosa

ABX Resistance Marker
- ☐ Methicillin/Oxacillin (mecA)

ICD 10 CODES
- ☐ B35.1 Onychomycosis
- ☐ _____
- ☐ _____ ☐ _____

SPECIMEN SOURCE
- ☐ Nail Clipping ☐ Other: _____
- ☐ Skin Scraping

☐ Candida
- ☐ Candida albicans
- ☐ Candida dubliniensis
- ☐ Candida glabrata
- ☐ Candida krusei
- ☐ Candida lusitaniae
- ☐ Candida parapsilosis
- ☐ Candida tropicalis

ICD 10 CODES
- ☐ N76.0 Acute ☐ N89.8 Other specified noninflammatory disorders of vagina

SPECIMEN SOURCE
- ☐ Urine ☐ Other: _____

☐ Antibiotic Resistance
- ☐ β-lactamase (blaKPC)
- ☐ β-lactamase (CTX-M-Group 1)
- ☐ metallo-β-lactamase (blaNDM)
- ☐ Fluoroquinolones
- ☐ Methicillin/Oxacillin (mecA)
- ☐ Sulfonamides
- ☐ Trimethoprim
- ☐ Vancomycin (vanA, vanB)

ICD 10 CODES
- ☐ Z22.322 Carrier or suspected carrier of MRSA
- ☐ Z16.19 Resistance to other specified Beta Lactam antibiotics
- ☐ _____
- ☐ _____

STEP 6

6 Please indicate if your patient has taken antibiotics in the past 72 hours. ☐ Yes ☐ No

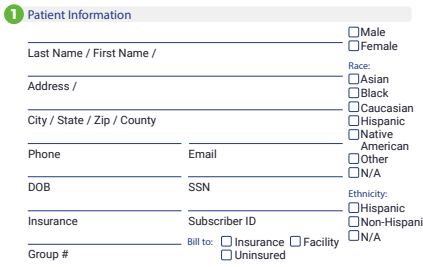
FOR MOST UP TO DATE REQUISITION FORM, PLEASE VISIT WWW.STREAMLINESCI.COM/FORMS-SUMMARY-LINKS

REQUISITION FORM INSTRUCTIONS

STEP 1

PATIENT INFORMATION

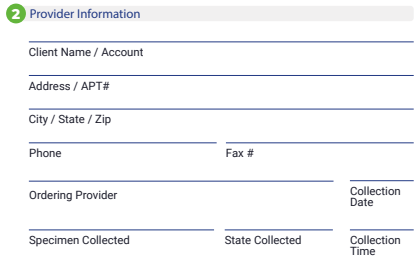
Fill in the patient's information including their name, gender, address, race, phone number, email, date of birth, social security number, insurance, ethnicity and billing information.



STEP 2

PROVIDER INFORMATION

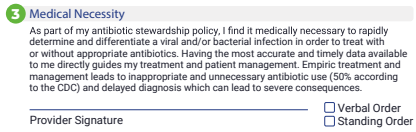
Fill in the provider's information, including client name or account number, address, phone number, ordering physician, collection date, specimen collector, collection time, and state where sample was collected.



STEP 3

MEDICAL NECESSITY

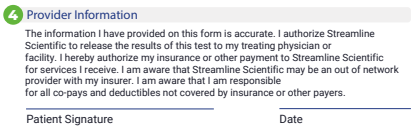
Have the physician read, sign, and choose either a verbal or standing order for the medical necessity.



STEP 4

CONSENT FOR TESTING

Have the patient read and sign the medical necessity.

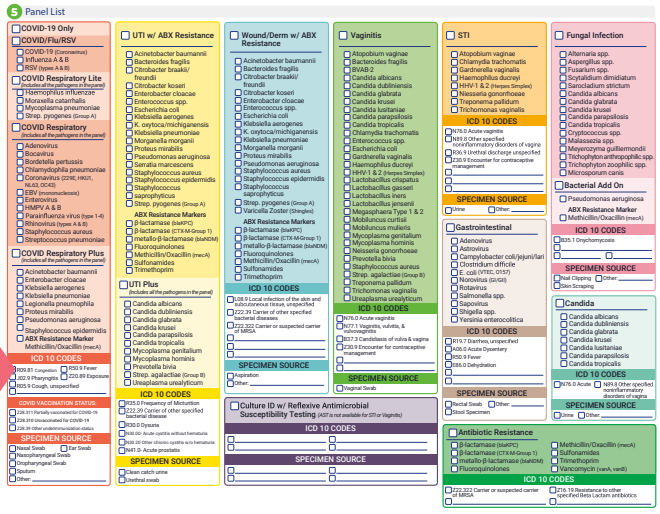


STEP 5

PANEL LIST

Check appropriate panels that address your patients' needs. Tests can be ordered individually. Select the box(es) that describes the specimen source.

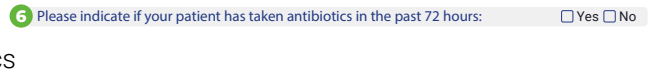
Make sure to check any ICD-10 codes found at the end of each panel.



STEP 6

HAS PATIENT TAKEN ANTIBIOTICS?

Check "yes" if your patient has taken antibiotics within the past 72 hours or "no" if they have not.



streamline scientific

SPECIMEN PACKAGING, TRANSPORT, AND RESULT DELIVERY

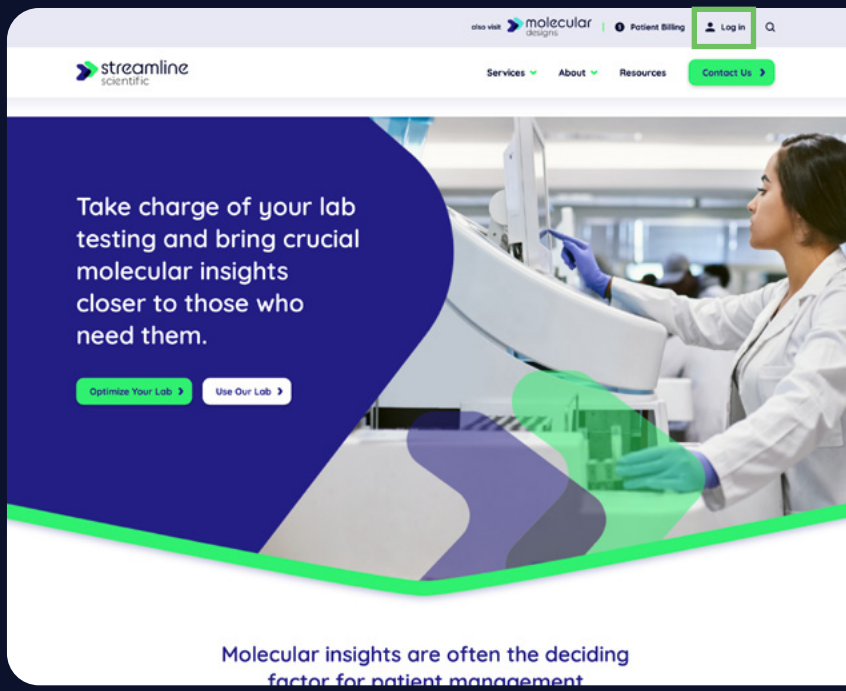
SPECIMEN PACKAGING AND TRANSPORT

1. Ensure sample lids are secure to avoid leakage or contamination
2. Place specimen into a provided biohazard bag
3. Insert requisition form, including all patient insurance information and demographics, into the specimen biohazard bag's side pocket
4. Place the biohazard bag containing the patient specimen into the provided lock box.
5. Enter a pickup request ticket through the online portal or contact Streamline Scientific customer service team to schedule a pickup (unless a nightly pickup schedule has been established).

RESULT DELIVERY

Results will be available via our online portal system. This portal can be accessed by visiting our website

Result delivery via Secure Fax or Secure email is available. If you would prefer either of these methods, please contact customer service for setup.



RESPIRATORY PANEL TARGET CATALOG

VIRAL PATHOGENS

- Adenovirus
- Bocavirus
- COVID-19 (SARS-CoV-2)
- Coronavirus 229E
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus OC43
- EBV (mononucleosis)
- Enterovirus
- Human Metapneumovirus A
- Human Metapneumovirus B
- Influenza A
- Influenza B
- Parainfluenza Virus type 1
- Parainfluenza Virus type 2
- Parainfluenza Virus type 3
- Parainfluenza Virus type 4
- Respiratory Syncytial Virus
- Rhinovirus

BACTERIAL PATHOGENS

- Acinetobacter baumannii*
- Bordetella pertussis
- Chlamydophila pneumoniae
- Enterobacter cloacae*
- Haemophilus influenzae*
- Klebsiella aerogenes*
- Klebsiella pneumoniae*
- Legionella pneumonophila
- Moraxella catarrhalis*
- Mycoplasma pneumoniae
- Proteus mirabilis*
- Pseudomonas aeruginosa*
- Staphylococcus aureus*
- Staphylococcus epidermidis
- Streptococcus pneumoniae*
- Streptococcus pyogenes (Group A)**

ABX RESISTANCE MARKER

- Methicillin/Oxacillin (mecA)

*Limitation: Test does not differentiate between a patient with acute infection or an asymptomatic carrier.

**S. pyogenes detected from a throat swab is diagnostic of pharyngitis; S. pyogenes detected from a nasopharyngeal swab could indicate an asymptomatic carrier.

For panel offerings, please visit streamlinesci.com

RESPIRATORY INFECTION SAMPLE COLLECTION

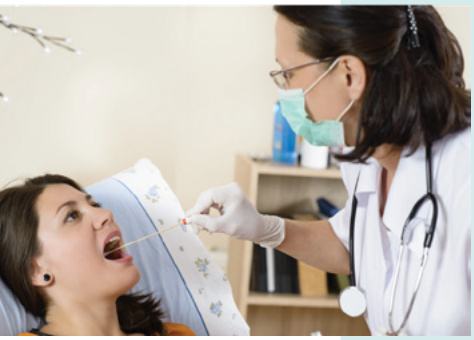
Follow the instructions below depending on the specimen source:

NASOPHARYNGEAL SWAB:

1. Tilt the patient's head back 70 degrees.
2. Insert the swab into the nostril (the swab should reach depth equal to the distance from nostril to outer opening of the ear). Leave the swab in place for several seconds to absorb secretions.
3. Slowly remove the swab while rotating it.

MID-TURBINATE (PEDIATRIC) SWAB:

1. Gently insert the swab into the nostril.
2. Using a gentle rotation, push the swab until a slight resistance is met at the level of turbinates.
3. Rotate the swab several times against the nasal wall.



OROPHARYNGEAL SWAB:

1. Insert the swab into the posterior pharynx and tonsillar areas.
2. Rub the swab over both tonsillar pillars and posterior oropharyngeal and avoid touching the tongue, teeth, and gums.

SPUTUM:

1. Educate the patient about the difference between sputum and oral secretions
2. Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile screw-cap collection cup or sterile dry container.
3. Transfer this sputum to a Copan E-swab tube with a liquid buffer for transport

Molecular PCR Summary Lab Report

2868 Acton Road, Suite 207
Birmingham, AL, 35243
Phone: (855) 319-4459
CLIA ID: 01-D2074949

CLINIC INFORMATION

Name: Streamline Pathology Laboratory
Address: 2868 Acton Road Suite 207 BIRMINGHAM, AL 35243
Provider: Test, Doctor MD

PATIENT INFORMATION

Name: PATIENT, TEST
DOB: 6/30/1980 Sex: M
Phone: (205)332-3160
Address: 2868 ACTON ROAD VESTAVIA, AL35243

SPECIMEN INFORMATION

Lab Accession Number: S-08232210321
Date Collected: 08/22/22 12:00:00 AM
Date Accessioned: 08/23/2022
Date Reported: 08/23/2022
Faxed to: 18777966185

Controls

Patient Extraction Control [1]	PASS
Endogenous Positive Control [1]	PASS
Pathogen Positive Control [2]	PASS
Pathogen Negative Control [3]	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Test Results	Comments
COVID-19		**Collection Type: Nasopharyngeal Swab**
COVID-19	Not Detected	[08/23/22] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization #200522.
nCoV_N1 (CT Value)	0	[08/23/22] CT value indicates the number of amplification cycles of real-time PCR needed to detect COVID-19, a specific SARS-CoV-2 gene sequence. CT values are inversely proportional to the amount of target nucleic acid in the sample (i.e. the lower the CT level, the greater the amount of target nucleic acid in the sample). The reference range for Assurance Scientific Laboratories RT-PCR assays is <40 cycles of amplification.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY COVID Respiratory Plus			**Collection Type: Nasopharyngeal Swab**
Acinetobacter baumannii	DETECTED - HIGH	1.00E+06	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.
mecA (Methicillin/Oxacillin resistance)	DETECTED	DETECTED	
Rhinovirus (types A & B)	DETECTED - MEDIUM	1.00E+03	[08/23/22] Assay is developed to detect all strains of this pathogen [08/23/22] May cross-react with Enterovirus
Streptococcus pneumoniae	DETECTED - LOW	1.00E+01	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.

Test results must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved unless otherwise indicated.
Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.
Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

2868 Acton Road, Suite 207
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Phone: (855) 319-4459
CLIA ID: 01-D2074949

Molecular PCR Summary Lab Report

CLINIC INFORMATION

Name: Streamline Pathology Laboratory
Address: 2868 Acton Road
Suite 207
BIRMINGHAM, AL 35243
Provider: Test, Doctor MD

PATIENT INFORMATION

Name: PATIENT, TEST
DOB: 6/30/1980 Sex: M
Phone: (205)332-3160
Address: 2868 ACTON ROAD
VESTAVIA, AL35243

SPECIMEN INFORMATION

Lab Accession Number: S-08232210321
Date Collected: 08/22/22 12:00:00 AM
Date Accessioned: 08/23/2022
Date Reported: 08/23/2022
Faxed to: 18777966185

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
COVID Respiratory Plus			**Collection Type: Nasopharyngeal Swab**
Acinetobacter baumannii	DETECTED - HIGH	1.00E+06	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.
Adenovirus	Not Detected	Not Detected	[08/23/22] Assay is developed to detect all strains of this pathogen
Bocavirus	Not Detected	Not Detected	[08/23/22] Assay is developed to detect all strains of this pathogen
Bordetella pertussis	Not Detected	Not Detected	[08/23/22] Shares homology with B.holmesii.
Chlamydophila pneumoniae	Not Detected	Not Detected	
Coronavirus 229E	Not Detected	Not Detected	
Coronavirus HKU1	Not Detected	Not Detected	
Coronavirus NL63	Not Detected	Not Detected	
Coronavirus OC43	Not Detected	Not Detected	
EBV (Mononucleosis)	Not Detected	Not Detected	
Enterobacter cloacae	Not Detected	Not Detected	
Enterovirus	Not Detected	Not Detected	[08/23/22] Enterovirus includes Coxsackievirus types A9, A10, A16, B5, and Echovirus serotypes [08/23/22] May cross-react with Rhinovirus (types A and B)
Haemophilus influenzae	Not Detected	Not Detected	
HMPV A (Human Metapneumovirus)	Not Detected	Not Detected	
HMPV B (Human Metapneumovirus)	Not Detected	Not Detected	
Influenza A	Not Detected	Not Detected	
Influenza B	Not Detected	Not Detected	
Klebsiella aerogenes	Not Detected	Not Detected	
Klebsiella pneumoniae	Not Detected	Not Detected	
Legionella pneumophila	Not Detected	Not Detected	
mecA (Methicillin/Oxacillin resistance)	DETECTED	DETECTED	
Moraxella catarrhalis	Not Detected	Not Detected	
Mycoplasma pneumoniae	Not Detected	Not Detected	
Parainfluenza 1	Not Detected	Not Detected	
Parainfluenza 2	Not Detected	Not Detected	
Parainfluenza 3	Not Detected	Not Detected	
Parainfluenza 4	Not Detected	Not Detected	
Proteus mirabilis	Not Detected	Not Detected	
Pseudomonas aeruginosa	Not Detected	Not Detected	

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Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.
Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
Rhinovirus (types A & B)	DETECTED - MEDIUM	1.00E+03	[08/23/22] Assay is developed to detect all strains of this pathogen [08/23/22] May cross-react with Enterovirus
RSV A/B (Respiratory Syncytial Virus)	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Staphylococcus epidermidis	Not Detected	Not Detected	
Streptococcus pneumoniae	DETECTED - LOW	1.00E+01	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	

UTI PANEL TARGETS

PATHOGENS

- Acinetobacter baumannii
- Bacteroides fragilis
- Candida albicans
- Candida dubliniensis
- Candida glabrata
- Candida krusei
- Candida parapsilosis
- Candida tropicalis
- Citrobacter braakii/freundii
- Citrobacter koseri
- Enterobacter cloacae
- Enterococcus spp.
- Escherichia coli
- Klebsiella aerogenes
- K. oxotyca/michiganensis
- Klebsiella pneumoniae
- Morganella morganii
- Mycoplasma genitalium
- Mycoplasma hominis
- Prevotella bivia
- Proteus mirabilis
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Staphylococcus epidermidis
- Staphylococcus saprophyticus
- Streptococcus agalactiae (Group B)
- Streptococcus pyogenes (Group A)
- Ureaplasma urealyticum

ABX RESISTANCE MARKER

- β-lactamase (blaKPC)
- β-lactamase (CTX-M-Group 1)
- metallo-β-lactamase (blaNDM)
- Fluoroquinolones
- Methicillin/Oxacillin (mecA)
- Sulfonamides
- Trimethoprim

For panel offerings, please visit streamlinesci.com

UTI SAMPLE COLLECTION

Collect the patient sample using one of the procedures below:

URINE SAMPLE:

If submitting a urine sample: Collect a urine sample from the patient in a urine collection cup with lid-integrated transfer device using the following gender-specific instructions:

Female Urine Sample

1. Patient should use a packaged, moist towel to clean the vulva and perianal area starting from front to back. Repeat with a second moist towel.
2. Patient should then spread their labia with one hand and start urinating into the toilet. With the other hand, they should put the urine container under the genital area to catch the stream of urine without touching any skin.

Male Urine Sample

1. Patient should retract the foreskin from the penis if necessary and use the packaged towel to clean the penis from the tip to the base. Repeat with a second moist towel.
2. Patient should retract the foreskin if necessary with one hand and start urinating into the toilet. Then, position the urine conainer with the other hand to catch the stream without touching any skin.

Replace and tighten the collection cup lid, and transfer the urine sample into a vacutainer tube with preservative:

1. Remove the sticker from the lid to access the integrated transfer device.
2. Insert the vacutainer tube vertically into the transfer device, puncturing the rubber septum and allowing the tube to fill with urine.
3. Remove the vacutainer tube and discard the collection cup. Mix urine and preservative by gently inverting the tube 8-10 times.

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Controls

Patient Extraction Control [1]	PASS
Endogenous Positive Control [1]	PASS
Pathogen Positive Control [2]	PASS
Pathogen Negative Control [3]	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY UTI Pathogens Plus			**Collection Type: Urine clean catch**
Acinetobacter baumannii	DETECTED - HIGH	1.00E+05	
Morganella morganii	DETECTED - MEDIUM	1.00E+03	
Streptococcus agalactiae (GBS)	DETECTED - LOW	1.00E+02	

Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances (Antibiotics to Avoid)
SUMMARY UTI Antibiotic Resistance Markers			**Collection Type: Urine clean catch**
Class A Beta-lactamase (CTX-M-Group 1)	DETECTED	blaCTX-M-1,3,10,12,15,22,23,28; blaFEC-1	[08/23/22]Cephalosporins, Penicillins, Aztreonam

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Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.
Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
UTI Pathogens Plus			**Collection Type: Urine clean catch**
Acinetobacter baumannii	DETECTED - HIGH	1.00E+05	
Bacteroides fragilis	Not Detected	Not Detected	
Candida albicans	Not Detected	Not Detected	
Candida dubliniensis	Not Detected	Not Detected	
Candida glabrata	Not Detected	Not Detected	
Candida krusei	Not Detected	Not Detected	
Candida parapsilosis	Not Detected	Not Detected	
Candida tropicalis	Not Detected	Not Detected	
Citrobacter freundii/braakii	Not Detected	Not Detected	
Citrobacter koseri	Not Detected	Not Detected	
Enterobacter cloacae	Not Detected	Not Detected	
Enterococcus spp.	Not Detected	Not Detected	
Escherichia coli	Not Detected	Not Detected	[08/23/22] Shares homology with Shigella spp.
Klebsiella aerogenes	Not Detected	Not Detected	
Klebsiella oxytoca/michiganesis	Not Detected	Not Detected	
Klebsiella pneumoniae	Not Detected	Not Detected	
Morganella morganii	DETECTED - MEDIUM	1.00E+03	
Mycoplasma genitalium	Not Detected	Not Detected	
Mycoplasma hominis	Not Detected	Not Detected	
Prevotella bivia	Not Detected	Not Detected	
Proteus mirabilis	Not Detected	Not Detected	
Pseudomonas aeruginosa	Not Detected	Not Detected	
Serratia marcescens	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Staphylococcus epidermidis	Not Detected	Not Detected	
Staphylococcus saprophyticus	Not Detected	Not Detected	
Streptococcus agalactiae (GBS)	DETECTED - LOW	1.00E+02	
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	
Ureaplasma urealyticum	Not Detected	Not Detected	

Test results must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved unless otherwise indicated.
Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.
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In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

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Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances (Antibiotics to Avoid)
UTI Antibiotic Resistance Markers			**Collection Type: Urine clean catch**
Class A Beta-lactamase (blaKPC)	Not Detected	KPC-2-8,10,11,13-22,24-33	[08/23/22] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors, Aztreonam
Class A Beta-lactamase (CTX-M-Group 1)	DETECTED	blaCTX-M-1,3,10,12,15,22,23,28; blaFEC-1	[08/23/22] Cephalosporins, Penicillins, Aztreonam
Class B metallo Beta-lactamase (blaNDM)	Not Detected	NDM (1-21)	[08/23/22] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors
Fluoroquinolones	Not Detected	qnrS 1-5,7-9; qnrB Group 1; qnrB Group 5	[08/23/22] Ciprofloxacin, Gemifloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofloxacin
mecA (Methicillin/Oxacillin resistance)	Not Detected	mecA	[08/23/22] Oxacillin
Sulfonamides	Not Detected	sul1; sul2; sul3	[08/23/22] Sulfadiazine, Sulfamethizole, Sulfamethoxazole, Sulfasalazine, Sulfisoxazole
Trimethoprim	Not Detected	dfrA1; dfrA5; dfrA11; dfrA17	[08/23/22] Primsol
vanA (Vancomycin)	Not Detected	vanA	[08/23/22] Vancomycin
vanB (Vancomycin)	Not Detected	vanB	[08/23/22] Vancomycin

WOUND PANEL

PATHOGENS

- Acinetobacter baumannii
- Bacteroides fragilis
- Citrobacter braakii/freundii
- Citrobacter koseri
- Enterobacter cloacae
- Enterococcus spp.
- Escherichia coli
- Klebsiella aerogenes
- K. oxytoca/michiganensis
- Klabsiella pneumoniae
- Morganella morganii
- Proteus mirabilis
- Pseudomonas aeruginosa
- Staphylococcus aureus
- Staphylococcus epidermidis
- Staphylococcus saprophyticus
- Streptococcus pyogenes (Group A)
- Varicella Zoster (Shingles)

ABX RESISTANCE MARKER

- β-lactamase (blaKPC)
- β-lactamase (CTX-M-Group 1)
- metallo-β-lactamase (blaNDM)
- Fluoroquinolones
- Methicillin/Oxacillin (mecA)
- Sulfonamides
- Trimethoprim

For panel offerings, please visit streamlinesci.com

WOUND/INFECTION SAMPLE COLLECTION

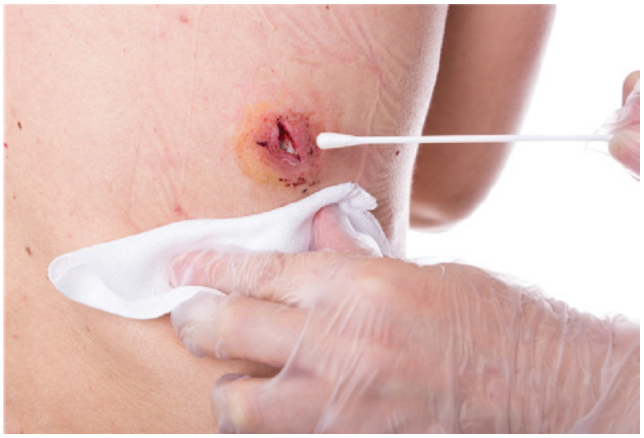
Collect the patient sample using one of the procedures below:

ASPIRATION

1. The surface of the wound/abscess should be carefully cleansed and debrided using sterile gauze and saline before attempting to aspirate the specimen.
2. Aspirate the specimen and place 0.5 to 1.0 mL of the aspirate directly into a Copan eSwab® transport tube.
3. Without contaminating the included swab, place the swab into the Copan eSwab® transport tube all the way to the bottom. Break the swab at the scored breakpoint indication line and leave the bottom portion inside the transport tube, partially submerged in buffer solution. Screw the top onto the tube tightly to secure the specimen.

SWAB

1. Cleanse and debride the wound with sterile gauze and saline.
2. Exudate and brushings of the wound base (including advancing margins) should be collected using the swab.
3. Without contaminating the swab, place the swab into the transport tube all the way to the bottom.
4. Break the swab at the scored breakpoint indication line and leave the bottom portion inside the Copan eSwab® transport tube, partially submerged in buffer solution. Screw the top onto the tube tightly to secure the specimen.



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PATIENT INFORMATION

Name: PATIENT, TEST
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SPECIMEN INFORMATION

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Date Collected: 08/22/22 12:00:00 AM
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Controls

Patient Extraction Control [1]	PASS
Endogenous Positive Control [1]	PASS
Pathogen Positive Control [2]	PASS
Pathogen Negative Control [3]	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY Wound/Dermatology Panel			**Collection Type: Not Specified**
Enterococcus spp.	DETECTED - LOW	1.00E+02	
Escherichia coli	DETECTED - HIGH	1.00E+04	[08/23/22] Shares homology with Shigella spp.
Staphylococcus epidermidis	DETECTED - MEDIUM	1.00E+03	

Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances (Antibiotics to Avoid)
SUMMARY Wound Antibiotic Resistance Markers			**Collection Type: Not Specified**
mecA (Methicillin/Oxacillin resistance)	DETECTED	mecA	[08/23/22]Oxacillin

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
Wound/Dermatology Panel			**Collection Type: Not Specified**
Acinetobacter baumannii	Not Detected	Not Detected	
Bacteroides fragilis	Not Detected	Not Detected	
Citrobacter freundii/braakii	Not Detected	Not Detected	
Citrobacter koseri	Not Detected	Not Detected	
Enterobacter cloacae	Not Detected	Not Detected	
Enterococcus spp.	DETECTED - LOW	1.00E+02	
Escherichia coli	DETECTED - HIGH	1.00E+04	[08/23/22] Shares homology with Shigella spp.
Klebsiella aerogenes	Not Detected	Not Detected	
Klebsiella oxytoca/michiganesis	Not Detected	Not Detected	
Klebsiella pneumoniae	Not Detected	Not Detected	
Morganella morganii	Not Detected	Not Detected	
Proteus mirabilis	Not Detected	Not Detected	
Pseudomonas aeruginosa	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Staphylococcus epidermidis	DETECTED - MEDIUM	1.00E+03	
Staphylococcus saprophyticus	Not Detected	Not Detected	
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	
Varicella Zoster virus	Not Detected	Not Detected	

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Class (Gene Name)	Lab Result (Qualitative)	Resistance Gene Targets Identified	Associated Resistances (Antibiotics to Avoid)
Wound Antibiotic Resistance Markers			**Collection Type: Not Specified**
Class A Beta-lactamase (blaKPC)	Not Detected	KPC-2-8,10,11,13-22,24-33	[08/23/22] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors, Aztreonam
Class A Beta-lactamase (CTX-M-Group 1)	Not Detected	blaCTX-M-1,3,10,12,15,22,23,28; blaFEC-1	[08/23/22] Cephalosporins, Penicillins, Aztreonam
Class B metallo Beta-lactamase (blaNDM)	Not Detected	NDM (1-21)	[08/23/22] Carbapenems, Cephalosporins, Penicillins, Beta-lactamase inhibitors
Fluoroquinolones	Not Detected	qnrS 1-5,7-9; qnrB Group 1; qnrB Group 5	[08/23/22] Ciprofloxacin, Gemifloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofloxacin
mecA (Methicillin/Oxacillin resistance)	DETECTED	mecA	[08/23/22] Oxacillin
Sulfonamides	Not Detected	sul1; sul2; sul3	[08/23/22] Sulfadiazine, Sulfamethizole, Sulfamethoxazole, Sulfasalazine, Sulfisoxazole
Trimethoprim	Not Detected	dfrA1; dfrA5; dfrA11; dfrA17	[08/23/22] Primsol
vanA (Vancomycin)	Not Detected	vanA	[08/23/22] Vancomycin
vanB (Vancomycin)	Not Detected	vanB	[08/23/22] Vancomycin

STI PANEL

PATHOGENS

- Atopobium vaginae
- Chlamydia trachomatis
- Gardnerella vaginalis
- Haemophilus ducreyi
- HHV-1 (Herpes Simplex)
- HHV-2 (Herpes Simplex)
- Neisseria gonorrhoeae
- Treponema pallidum
- Trichonomas vaginalis

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STI SAMPLE COLLECTION

If submitting a urine sample: Collect a urine sample from the patient in urine collection cup with lid-integrated transfer device:

Replace and tighten the collection cup lid, and transfer the urine sample into a vacutainer tube with preservative:

1. Remove the sticker from the lid to access the integrated transfer device.
2. Insert the vacutainer tube vertically into the transfer device, puncturing the rubber septum and allowing the tube to fill with urine.
3. Remove the vacutainer tube and discard the collection cup. Mix urine and preservative by gently inverting the tube 8-10 times.

If submitting a swab sample: Collect a swab sample from the patient with a synthetic flocked swab by following the instructions below depending on the specimen source:

Vaginal swab:

1. Remove the swab applicator and collect a specimen by rotating the swab against the wall of the vaginal canal several times for 20-30 seconds.
2. Withdraw the swab without touching the vaginal surface.

Urethral swab:

1. Gently insert the swab into the urethra (1-2 cm for women, 2-4 cm for men).
2. Rotate the swab in one direction for a minimum of 10 seconds.
3. Withdraw the swab.

*If an ulcer is the intended specimen source, please refer to wound specimen collection instructions

Valid specimen type for Chlamydia trachomatis/Neisseria gonorrhoeae/ Trichomonas vaginalis testing only:

Throat swab (Oropharyngeal swab):

1. Insert the swab into the posterior pharynx and tonsillar areas.
2. Rub the swab over both tonsillar pillars and posterior oropharyngeal avoid touching the tongue, teeth, and gums.

Rectal swab:

1. Insert a sterile swab approximately 2.5 cm into the anal canal.
2. Move the swab from side to side in the anal canal. Allow the swab to remain 10-30 seconds for the absorption of organisms onto the swab.
3. Remove the swab and insert it into a vial containing 1-3ml of transport media.

Disclaimer/Collection - Note:

PCR tests can be used to confirm a suspicion of the presence of sexually transmitted infections in the routine clinical setting. However, in cases of rape or sexual abuse in children under the age of 15, confirmatory testing (along with the appropriate chain of custody as outlined by the CDC) should be performed as recommended by the CDC.

Neisseria gonorrhoeae assay may also detect Neisseria meningitidis due to sequence homology; therefore, a positive result may be interpreted as either Neisseria gonorrhoeae or Neisseria meningitidis for oral STI screening. The patient should be treated based on the clinical presentation of symptoms.

HHV1 assay may also detect HHV2 due to sequence homology; therefore, a positive result may be interpreted as HHV1 or HHV2 infection. The patient should be treated based on the clinical presentation of symptoms.

When collecting a urethral swab or urine specimen from a male or female patient, the patient should not have urinated for **at least an hour** before the specimen is collected. The first-morning urine specimen is preferred due to a large number of cells usually present.

NOTE: Certain organisms are intracellular; therefore, there must be enough human cells present to detect the organism.

Molecular PCR Summary Lab Report

2868 Acton Road, Suite 207
Birmingham, AL, 35243
Phone: (855) 319-4459
CLIA ID: 01-D2074949

CLINIC INFORMATION

Name: Streamline Pathology Laboratory
Address: 2868 Acton Road
Suite 207
BIRMINGHAM, AL 35243
Provider: Test, Doctor MD

PATIENT INFORMATION

Name: PATIENT, TEST
DOB: 6/30/1980 Sex: M
Phone: (205)332-3160
Address: 2868 ACTON ROAD
VESTAVIA, AL35243

SPECIMEN INFORMATION

Lab Accession Number: S-08242210101
Date Collected: 08/22/22 12:00:00 AM
Date Accessioned: 08/24/2022
Date Reported: 08/24/2022
Faxed to: 18777966185

Controls

Patient Extraction Control [1]	PASS
Endogenous Positive Control [1]	PASS
Pathogen Positive Control [2]	PASS
Pathogen Negative Control [3]	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY Sexually Transmitted Infection Pathogens			**Collection Type: Swab**
Atopobium vaginae	DETECTED - HIGH	1.00E+06	
HHV-1 (Herpes Simplex Virus)	DETECTED - MEDIUM	1.00E+03	[08/24/22] HHV-1 assay may also detect HHV-2 due to sequence homology; therefore, a positive result may be interpreted as HHV-1 or HHV-2 infection. The patient should be treated based on the clinical presentation of symptoms.

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
Sexually Transmitted Infection Pathogens			**Collection Type: Swab**
Atopobium vaginae	DETECTED - HIGH	1.00E+06	
Chlamydia trachomatis	Not Detected	Not Detected	
Gardnerella vaginalis	Not Detected	Not Detected	
Haemophilus ducreyi	Not Detected	Not Detected	
HHV-1 (Herpes Simplex Virus)	DETECTED - MEDIUM	1.00E+03	[08/24/22] HHV-1 assay may also detect HHV-2 due to sequence homology; therefore, a positive result may be interpreted as HHV-1 or HHV-2 infection. The patient should be treated based on the clinical presentation of symptoms.
HHV-2 (Herpes Simplex Virus)	Not Detected	Not Detected	
Neisseria gonorrhoeae	Not Detected	Not Detected	
Treponema pallidum	Not Detected	Not Detected	
Trichomonas vaginalis	Not Detected	Not Detected	

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Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.
Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

VAGINITIS PANEL

PATHOGENS

- Atopobium vaginae
- Bacteroides fragilis
- BVAB-2
- Candida albicans
- Candida dubliniensis
- Candida glabrata
- Candida krusei
- Candida lusitaniae
- Candida parapsilosis
- Candida tropicalis
- Chlamydia trachomatis
- Enterococcus spp.
- Escherichia coli
- Gardnerella vaginalis
- Haemophilus ducreyi
- HHV-1 (Herpes Simplex)
- HHV-2 (Herpes Simplex)
- Lactobacillus crispatus
- Lactobacillus gasseri
- Lactobacillus iners
- Lactobacillus jensenii
- Megasphaera Type 1
- Megasphaera Type 2
- Mobiluncus curtisii
- Mobiluncus mulieris
- Mycoplasma genitalium
- Mycoplasma hominis
- Neisseria gonorrhoeae
- Prevotella bivia
- Staphylococcus aureus
- Streptococcus agalactiae (Group B)
- Treponema pallidum
- Trichonomas vaginalis
- Ureaplasma urealyticum

VAGINITIS SAMPLE COLLECTION

Collect a vaginal sample from the patient using a synthetic flocked swab by inserting the swab into the vagina and turn the swab 3 times.

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HHV1 assay may also detect HHV2 due to sequence homology; therefore, a positive result may be interpreted as HHV1 or HHV2 infection. The patient should be treated based on the clinical presentation of symptoms.

NOTE: Certain organisms are intracellular; therefore, there must be enough human cells present to detect the organism.

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VESTAVIA, AL35243

SPECIMEN INFORMATION

Lab Accession Number: S-08232210335
Date Collected: 08/22/22 12:00:00 AM
Date Accessioned: 08/23/2022
Date Reported: 08/23/2022
Faxed to: 18777966185

Controls

Patient Extraction Control [1]	PASS
Endogenous Positive Control [1]	PASS
Pathogen Positive Control [2]	PASS
Pathogen Negative Control [3]	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY Vaginitis Pathogens			**Collection Type: Not Specified**
Candida dubliniensis	DETECTED - HIGH	1.00E+05	
Candida tropicalis	DETECTED - LOW	1.00E+02	
Lactobacillus crispatus	DETECTED - MEDIUM	8.90E+02	
Lactobacillus gasseri	DETECTED - HIGH	8.37E+03	
Lactobacillus iners	DETECTED - LOW	1.83E+02	

FOR MORE VAGINITIS PANEL SAMPLE LAB REPORTS, CLICK HERE

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Molecular PCR Summary Lab Report

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
Vaginitis Pathogens			**Collection Type: Not Specified**
Atopobium vaginae	Not Detected	Not Detected	
Bacteroides fragilis	Not Detected	Not Detected	
BVAB-2	Not Detected	Not Detected	
Candida albicans	Not Detected	Not Detected	
Candida dubliniensis	DETECTED - HIGH	1.00E+05	
Candida glabrata	Not Detected	Not Detected	
Candida krusei	Not Detected	Not Detected	
Candida lusitaniae	Not Detected	Not Detected	
Candida parapsilosis	Not Detected	Not Detected	
Candida tropicalis	DETECTED - LOW	1.00E+02	
Chlamydia trachomatis	Not Detected	Not Detected	
Enterococcus spp.	Not Detected	Not Detected	
Escherichia coli	Not Detected	Not Detected	
Gardnerella vaginalis	Not Detected	Not Detected	
Haemophilus ducreyi	Not Detected	Not Detected	
HHV-1 (Herpes Simplex Virus)	Not Detected	Not Detected	
HHV-2 (Herpes Simplex Virus)	Not Detected	Not Detected	
Lactobacillus crispatus	DETECTED - MEDIUM	8.90E+02	
Lactobacillus gasseri	DETECTED - HIGH	8.37E+03	
Lactobacillus iners	DETECTED - LOW	1.83E+02	
Lactobacillus jensenii	Not Detected	Not Detected	
Megasphaera Type 1	Not Detected	Not Detected	
Megasphaera Type 2	Not Detected	Not Detected	
Mobiluncus curtisii	Not Detected	Not Detected	
Mobiluncus mulieris	Not Detected	Not Detected	
Mycoplasma genitalium	Not Detected	Not Detected	
Mycoplasma hominis	Not Detected	Not Detected	
Neisseria gonorrhoeae	Not Detected	Not Detected	
Prevotella bivia	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Streptococcus agalactiae (GBS)	Not Detected	Not Detected	
Treponema pallidum	Not Detected	Not Detected	
Trichomonas vaginalis	Not Detected	Not Detected	

Lab Director: Ty Thomas, MD

Test results must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved unless otherwise indicated.
Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.
Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
Ureaplasma urealyticum	Not Detected	Not Detected	

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Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

GASTROINTESTINAL PANEL

PATHOGENS

- Adenovirus
- Astrovirus
- Campylobacter (coli, jejuni, lari)
- Clostidium difficile
  - c. difficile toxin A
  - c. difficile toxin B
- Escherichia coli (VTEC)
  - Shiga-toxin 1
  - Shiga-toxin 2
  - E.Coli)157
- Norovirus GI
- Norovirus GII
- Rotavirus
- Salmonella spp.
- Sapovirus
- Shigella spp.
- Yersinia enterocolitica

For panel offerings, please visit streamlinesci.com

GASTROINTESTINAL SAMPLE COLLECTION

Collect a gastrointestinal stool specimen sample or a rectal swab from the patient using a swab with Cary Blair buffer (ex: Copan Eswab). Use the Cary Blair buffer specimen collection swab for the transport of either specimen swab or rectal swab by using the following instructions:

1. Remove the swab and transport tube from the packaging. Do not contaminate.
2. For stool specimen swabs, carefully collect a portion of the specimen by placing the swab tip directly into the specimen.
3. For rectal swabs, insert the tip of the swab approximately 1 inch beyond the anal sphincter.
4. Carefully rotate the swab to sample the anal crypts, then withdraw the swab.

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SPECIMEN INFORMATION

Lab Accession Number: S-08232210337
Date Collected: 08/22/22 12:00:00 AM
Date Accessioned: 08/23/2022
Date Reported: 08/24/2022
Faxed to: 18777966185

Controls

Patient Extraction Control [1]	PASS
Endogenous Positive Control [1]	PASS
Pathogen Positive Control [2]	PASS
Pathogen Negative Control [3]	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY Gastrointestinal Panel - Bacterial Pathogens			**Collection Type: Not Specified, Stool - Fecal**
Escherichia coli (VTEC)	DETECTED - LOW	DETECTED - LOW	
Salmonella spp.	DETECTED - HIGH	1.00E+04	[08/23/22] Salmonella was detected by PCR and is a Notifiable Pathogen per ADPH. Result to be confirmed by lab via bacterial culture before reporting to ADPH. The required time for the ordering provider to notify ADPH is within 5 days from receipt of report.
SUMMARY Gastrointestinal Panel - Viral Pathogens			**Collection Type: Not Specified, Stool - Fecal**
No Positive Results Detected			

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
Gastrointestinal Panel - Bacterial Pathogens			**Collection Type: Not Specified, Stool - Fecal**
Campylobacter coli/jejuni/lari	Not Detected	Not Detected	
Clostridium difficile	Not Detected	Not Detected	
--- Toxin A (tcdA)	Not Detected	Not Detected	
--- Toxin B (tcdB)	Not Detected	Not Detected	
Escherichia coli (VTEC)	DETECTED - LOW	DETECTED - LOW	
--- O157	Not Detected	Not Detected	
--- STX1	Not Detected	Not Detected	
--- STX2	Not Detected	Not Detected	
Salmonella spp.	DETECTED - HIGH	1.00E+04	[08/23/22] Salmonella was detected by PCR and is a Notifiable Pathogen per ADPH. Result to be confirmed by lab via bacterial culture before reporting to ADPH. The required time for the ordering provider to notify ADPH is within 5 days from receipt of report.
Shigella spp.	Not Detected	Not Detected	
Yersinia enterocolitica	Not Detected	Not Detected	
Gastrointestinal Panel - Viral Pathogens			**Collection Type: Not Specified, Stool - Fecal**
Adenovirus	Not Detected	Not Detected	
Astrovirus	Not Detected	Not Detected	
Norovirus GI	Not Detected	Not Detected	
Norovirus GII	Not Detected	Not Detected	
Rotavirus	Not Detected	Not Detected	
Sapovirus	Not Detected	Not Detected	

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Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

FUNGAL INFECTION PANEL

PATHOGENS

- Alternaria spp.
- Aspergillus spp.
- Fusarium spp.
- Scytalidium dimidiatum
- Sarocladium strictum
- Candida albicans
- Candida glabrata
- Candida krusei
- Candida parapsilosis
- Candida tropicalis
- Cryptococcus spp.
- Malassezia spp.
- Meyerozyma guillermondii
- Trichophyton anthropophilic spp.
- Trichophyton zoophilic spp.
- Mircosporum canis

BACTERIA ADD ON

- Pseudomonas aeruginosa

ABX RESISTANCE MARKER

- Methicillin/Oxacillin (mecA)

FUNGAL SPECIMEN COLLECTION

ACCEPTABLE SPECIMENS:

Nail clippings and skin scrapings in a dry collection tube. If a wound is infected, the area should be collected by a swab in liquid amies media.

DIRECTIONS FOR COLLECTING A NAIL CLIPPING

1. Wipe the nail collection site with 70% isopropyl alcohol.
2. Debride and discard nail clippings.
3. Obtain specimen from the most proximal area of nail and hyponychium. Minimum specimen amount size of nail and subungual debris is 3mm to 6mm (small pieces to obtain this size are preferred).
4. Use a curette to obtain any additional subungual debris.
5. Place the dry nail sample and debris into a dry sterile tube.

DIRECTIONS FOR A SKIN SCRAPING

1. Remove any traces of skin products, medications, or surface contaminants by wiping the area with a 70% isopropyl alcohol wipe.
2. Choose the best area to scrape by determining where fungal growth is most active.
3. Scrape the skin using a scalpel held at a blunt angle into dry collection tube. The greater amount of specimen, the better the result.

DIRECTIONS FOR A WOUND COLLECTION

1. Cleanse and debride the infected area with 70% isopropyl alcohol using sterile gauze. Saline can be used if there is an open wound.
2. Exudate and brushing of the base of the infected area (including advancing margins) should be collected using the swab. Without contaminating the swab, place the swab in the media.

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Controls

Patient Extraction Control [1]	PASS
Endogenous Positive Control [1]	PASS
Pathogen Positive Control [2]	PASS
Pathogen Negative Control [3]	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY Fungal Infection Panel			**Collection Type: Swab**
Meyerozyma guilliermondii	DETECTED - MEDIUM	1.00E+03	
Trichosporon spp.	DETECTED - HIGH	1.00E+06	

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
Fungal Infection Panel			**Collection Type: Swab**
Alternaria spp.	Not Detected	Not Detected	
Aspergillus spp.	Not Detected	Not Detected	
Candida albicans	Not Detected	Not Detected	
Candida glabrata	Not Detected	Not Detected	
Candida krusei	Not Detected	Not Detected	
Candida parapsilosis	Not Detected	Not Detected	
Candida tropicalis	Not Detected	Not Detected	
Cryptococcus spp.	Not Detected	Not Detected	
Curvularia spp.	Not Detected	Not Detected	
Epidermophyton floccosum	Not Detected	Not Detected	
Fusarium spp.	Not Detected	Not Detected	
Malassezia spp.	Not Detected	Not Detected	
Meyerozyma guilliermondii	DETECTED - MEDIUM	1.00E+03	
Microsporum canis	Not Detected	Not Detected	
Sarocladium strictum	Not Detected	Not Detected	
Scytalidium dimidiatum	Not Detected	Not Detected	
Trichophyton anthropophilic spp.	Not Detected	Not Detected	[08/23/22] Targets: T. rubrum, T. violaceum, T. soudanense, T. concentricum and other species
Trichophyton zoophilic spp.	Not Detected	Not Detected	[08/23/22] Targets: T. mentagrophytes, T. interdigitale (anthropophilic but related to T. mentagrophytes), T. tonsurans (anthropophilic but related to T. equinum), T. verrucosum, T. simii, T. benhamiae, T. equinum, and other species
Trichosporon spp.	DETECTED - HIGH	1.00E+06	

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