CLIENT SERVICE MANUAL
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## About / Instructions

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## Test Catalog

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## Supplies / References

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Diatherix Laboratories, Inc.
601 Genome Way, Suite 2100
Huntsville, Alabama 35806
CLIA ID Number: 01-D1085737

**Chairman and CEO:** Dennis Grimaud

**President and COO:** Randy Ward, M.T. (ASCP)

**VP of Operations & Laboratory Director:** Donald R. Stalons, Ph.D., D(ABMM), MPH

**Medical Director:** Frank Honkanen, M.D.

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**Client Services**

**Toll free:** 866.979.4242

**Fax:** 256.327.0984

**Hours:**
- 8:00 - 5:30 CST  Monday - Friday
- 8:30 - 5:00 CST  Saturday

**Compliance Hotline (anonymous):** 256.327.5222

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**Billing Department**

**Toll free:** 866.829.1854

**Fax:** 256.327.5259

**Hours:** 8:00 – 4:30 CST  Monday - Friday

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**Supplies & Shipping**

**Toll free:** 877.820.8047  *(voice mail monitoring until 8:00pm CST)*

**Fax:** 256.327.9858

**Email:** supplies@diatherix.com

**FedEx:** 1.800.463.3339  *(Press 0 for the first three prompts to reach an operator)*
Diatherix is an innovative, CLIA-certified, molecular diagnostic laboratory utilizing proprietary TEM-PCR™ (Target Enriched Multiplex Polymerase Chain Reaction) technology for precise detection of infectious diseases – linking diagnostics to therapeutics.

**Diatherix Distinctions:**

- Simultaneous identification of bacteria, viruses, parasites, Candida and selected antibiotic resistance genes
- Detection of bacteria in the presence of antibiotics
- Increased sensitivity and specificity
- Simplicity of single sample collection
- One day results*

* Determined by sample receipt.

**TEM-PCR Benefits:**

TEM-PCR technology is a unique, multiplex amplification platform designed to overcome the challenges that exist with conventional laboratory methods and real-time PCR applications.

Improved speed and accuracy of laboratory results lead to:

- Improved patient outcomes
- Cost reduction and avoidance
- Reduced antibiotic utilization
- Increased patient satisfaction
- Greater clinical value

**Billing:**

Billing for laboratory services has become complicated and unpredictable due to the increased number of plans with different co-pays and deductibles. Much like your business, it is difficult to know in advance what a specific insurance plan will cover for a patient, and therefore what may be the patient’s responsibility.

Diatherix is dedicated to assisting patients with billing questions. If a patient requires assistance, please ask them to call our Billing Department at 866.829.1854.
SPECIMEN PREPARATION INSTRUCTIONS

– Please read all instructions for collecting and shipping of specimens before beginning the collection process.

1. Choose the appropriate Diatherix test panel. Pages 8-18

2. Follow the appropriate specimen collection procedure. Pages 19-24
   – Specimen collection protocols in this manual are those that are recommended for each of the panels that Diatherix offers. Substitution of collection kit components or specimen types must be preapproved by Diatherix before the specimen is submitted for testing.

3. Prevent specimen rejection:
   – Make sure the top is seated properly and screwed down tightly on the tube.
   – Label the specimen transfer tube with two identifiers. Preferred identifiers are the patient’s first and last name and barcode label from the requisition. This name and barcode must match the name and barcode on the requisition.*

4. Fill out all required fields on the requisition. Writing must be legible.

5. Package and ship the specimen and requisition according to instructions. Page 5

* Other examples of acceptable identifiers include: date of birth, hospital number, social security number, unique random number. Each of the two identifiers must match on the tube and the requisition.

Requirements for Acceptance of Specimen

Specimens must be:
• appropriate for the test requested.
• accompanied by a properly completed, legible Diatherix Laboratory Request.
• transported to the lab according to packaging and shipping instructions.
• in a properly sealed biohazard specimen bag.
• labeled with two identifiers, preferably with the patient’s name and barcode label which matches the requisition.
• intact, in the proper container and not leaking.
• in the appropriate specimen transport media.
• within the specimen transport stability range of 5 days, at ambient temperature, measured from time of collection to the time of receipt for laboratory testing. (For ThinPrep® pap solution, the specimen transport stability range is 30 days.)

Clients will be contacted as soon as possible if any issues need to be resolved.

Results are typically reported the same day our laboratory receives the specimen.
PACKAGING / SHIPPING INSTRUCTIONS

- **Specimens for all test panels should be shipped at ambient temperature.**
- **Each biohazard bag must contain only one patient sample.**

1. Place the labeled transport tube in the zippered pouch in the front of the biohazard bag with the absorbent pad. Seal the bag.

2. Fold and place the completed Diatherix Test Requisition in the flap pocket (no zipper) in the back of the biohazard transport bag.
   
   **Verify that the sample tube and the requisition are in the correct pouch:**
   - Requisition is located in the pouch on the back side of the bag
   - Specimen sample is located in the front side in the zippered pouch

3. Place the biohazard specimen bag(s), each containing only one sample, in the Diatherix specimen shipping box.
   
   **More than one specimen bag may be shipped in the same box.**

4. Place the Diatherix specimen shipping box(s) into the FedEx® UN 3373 Clinical Pak and seal it.
   
   **More than one box may be placed in the Clinical Pak.**

5. Apply the barcoded shipping label to the FedEx® UN 3373 Clinical Pak. Detach and retain the top portion of the shipping label for your records.

6. Call **1-800-463-3339** (1-800-GOFEDEX) to schedule a pickup. Listen to the automated system until after it states “in a few words please describe what you are calling about.” Then, press 0 for the next three prompts to be connected to an operator. State that you have an Express Prepaid Label and provide your address. No other information will be needed.

   **If your package cannot be picked up, it may be placed in a FedEx® Drop Box. A FedEx® Drop Box can be located by calling FedEx® or going to FedEx.com. Do not take this package to a FedEx® Office location as they will not accept this type of shipment.**

   **TIP:** For your records, write the pickup confirmation number in the space provided on the confirmation label.
### Viral Respiratory

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus

### Bacterial Pneumonia

Acinetobacter baumannii  
Bordetella pertussis  
Chlamydophila pneumoniae  
Haemophilus influenzae  
Haemophilus influenzae (Type B)  
Klebsiella pneumoniae  
Legionella pneumophila  
MRSA  
PVL 2 gene  
Moraxella catarrhalis  
Mycoplasma pneumoniae  
Neisseria meningitidis  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Streptococcus pneumoniae  
Streptococcus pyogenes (Group A)  
+ Antibiotic resistance genes*

### Atypical Pneumonia

Bordetella pertussis  
Chlamydophila pneumoniae  
Legionella pneumophila  
Mycoplasma pneumoniae

### Influenza

Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4

### Respiratory Infection

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus  
Acinetobacter baumannii  
Chlamydophila pneumoniae  
Haemophilus influenzae  
Haemophilus influenzae (Type B)  
Klebsiella pneumoniae  
Legionella pneumophila  
MRSA  
PVL 2 gene  
Moraxella catarrhalis  
Mycoplasma pneumoniae  
Neisseria meningitidis  
Pseudomonas aeruginosa  
Staphylococcus aureus  
Streptococcus pneumoniae  
Streptococcus pyogenes (Group A)  
+ Antibiotic resistance genes*

### Ear Nose & Throat

Acinetobacter baumannii  
Chlamydophila pneumoniae  
Enterobacter aerogenes  
Enterobacter cloacae  
Haemophilus influenzae  
Haemophilus influenzae (Type B)  
Klebsiella pneumoniae  
MRSA  
PVL 2 gene  
Moraxella catarrhalis  
Mycoplasma pneumoniae  
Neisseria meningitidis  
Proteus mirabilis  
Pseudomonas aeruginosa  
Serratia marcescens  
Staphylococcus aureus  
Stenotrophomonas maltophilia  
Streptococcus pneumoniae  
Streptococcus pyogenes (Group A)  
+ Antibiotic resistance genes*

### Upper Respiratory Infection

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Rhinovirus  
Haemophilus influenzae  
Haemophilus influenzae (Type B)  
Moraxella catarrhalis  
Streptococcus pneumoniae  
Streptococcus pyogenes (Group A)

### Pediatric Respiratory

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus  
Bordetella pertussis  
Chlamydophila pneumoniae  
Haemophilus influenzae  
Haemophilus influenzae (Type B)  
Moraxella catarrhalis  
Mycoplasma pneumoniae  
Neisseria meningitidis  
Streptococcus pneumoniae  
Streptococcus pyogenes (Group A)

### Pharyngitis

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus  
Chlamydophila pneumoniae  
Mycoplasma pneumoniae  
Streptococcus pneumoniae  
Streptococcus pyogenes (Group A)

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1 Methicillin-resistant Staphylococcus aureus  
2 Panton-Valentine leukocidin
Sexually Transmitted Disease
- Atopobium vaginae
- Chlamydia trachomatis
- Gardnerella vaginalis
- Mycoplasma genitalium
- Mycoplasma hominis
- Neisseria gonorrhoeae
- Trichomonas vaginalis
- Ureaplasma urealyticum

CT + NG + T. vaginalis
- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas vaginalis

Bacterial Vaginosis
- Atopobium vaginae
- Gardnerella vaginalis
- Mycoplasma genitalium
- Mycoplasma hominis
- Ureaplasma urealyticum

Infectious Disease
- Acinetobacter baumannii
- Enterobacter aerogenes
- Enterobacter cloacae
- Enterococcus faecalis
- Enterococcus faecium
- Escherichia coli
- Klebsiella pneumoniae
- Proteus mirabilis
- Pseudomonas aeruginosa
- Serratia marcescens
- Streptococcus pyogenes (Group A)
- MRSA
- Staphylococcus aureus
- PVL gene
- MRCoNS
- Coagulase-Negative Staphylococci
- Staphylococcus epidermidis
- Antibiotic resistance genes
- Vancomycin resistance

C. difficile
- Clostridium difficile (Toxin B gene)

Gastrointestinal
- Campylobacter jejuni
- Clostridium difficile (Toxin B gene)
- Enterohemorrhagic E. coli (EHEC)
  - Shiga-like toxin gene (stx1)
  - Shiga-like toxin gene (stx2)
- Enteroinvasive E. coli/Shigella (EIEC)
- Enteropathogenic E. coli (EPEC)
- Enterotoxigenic E. coli (ETEC)
- Salmonella enterica
- Vibrio parahaemolyticus
- Adenovirus 40, 41
- Norovirus
- Rotavirus
- Cryptosporidium parvum
- Giardia lamblia

Herpes Simplex Virus
- Herpes Simplex Virus type 1
- Herpes Simplex Virus type 2

Candidiasis
- Candida albicans
- Candida glabrata
- Candida krusei
- Candida parapsilosis
- Candida tropicalis

HPV High Risk Typing
- HPV High Risk types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 67, 68

Group B Streptococcus
- Group B Streptococcus
  - (Streptococcus agalactiae)

Staph. Differentiation
- MRSA
- Staphylococcus aureus
- PVL gene
- MRCoNS
- Coagulase-Negative Staphylococci
- Staphylococcus epidermidis
- Antibiotic resistance genes

Urinary Tract Infection
- Enterobacter cloacae
- Enterococcus faecalis
- Escherichia coli
- Klebsiella pneumoniae
- Proteus mirabilis
- Pseudomonas aeruginosa

*Antibiotic Resistance Genes
- Aminoglycosides
- Cephalosporin (Staphylococcal)
- Erythromycin/Clindamycin
- Methicillin (Staphylococcal)
- Tetracycline

1 Methicillin-resistant Staphylococcus aureus
2 Panton-Valentine leukocidin
3 Methicillin-resistant Coagulase-Negative Staphylococci
ATYPICAL PNEUMONIA PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Bordetella pertussis*
- *Chlamydophila pneumoniae*
- *Legionella pneumophila*
- *Mycoplasma pneumoniae*

**Collection Procedures:**
- Bronchial Aspirate.........................21
- Sputum Specimen Swab .................21
- Nasopharyngeal Aspirate/Wash...20
- Nasopharyngeal Swab .................20

BACTERIAL PNEUMONIA PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Acinetobacter baumannii*
- *Bordetella pertussis*
- *Chlamydophila pneumoniae*
- *Haemophilus influenzae*
- *Haemophilus influenzae* (Type B)
- *Klebsiella pneumoniae*
- *Legionella pneumophila*
- *Moraxella catarrhalis*
- *MRSA*¹
- *MRSA*² gene
- *Mycoplasma pneumoniae*
- *Neisseria meningitidis*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes* (Group A)

**Antibiotic Resistance Genes:**
- Aminoglycosides
- Cephalosporin (Staphylococcal)
- Erythromycin/Clindamycin
- Methicillin (Staphylococcal)
- Tetracycline

**Collection Procedures:**
- Bronchial Aspirate.........................21
- Sputum Specimen Swab .................21
- Nasopharyngeal Aspirate/Wash...20
- Nasopharyngeal Swab .................20

¹ Methicillin-resistant *Staphylococcus aureus*
² Panton-Valentine leukocidin
BACTERIAL VAGINOSIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Atopobium vaginae*
- *Gardnerella vaginalis*
- *Mycoplasma genitalium*
- *Mycoplasma hominis*
- *Ureaplasma urealyticum*

Collection Procedure:
Vaginal Swab ..................24

BRONCHITIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Adenovirus types 3, 4, 7, 21*
- *Human coronavirus (4 types)*
- *Human metapneumovirus*
- *Influenza A - Human influenza*
- *Influenza A - H1N1-09*
- *Influenza B*
- *Parainfluenza virus types 1, 2, 3, 4*
- *Respiratory Syncytial Virus*
- *Rhinovirus*
- *Bordetella pertussis*
- *Chlamydia pneumoniae*
- *Haemophilus influenzae*
- *Haemophilus influenzae (Type B)*
- *Klebsiella pneumoniae*
- *Moraxella catarrhalis*
- *Mycoplasma pneumoniae*
- *Pseudomonas aeruginosa*
- *Streptococcus pneumoniae*

Collection Procedures:
Bronchial Aspirate..................21
Sputum Specimen Swab ..........21
Nasopharyngeal Aspirate/Wash....20
Nasopharyngeal Swab ..........20

CANDIDIASIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Candida albicans*
- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*

Collection Procedures:
Vaginal Swab ..................24
ThinPrep® Pap Solution .........21
Endocervical Swab ..........23
DIATHERIX TEST PANELS

CT + NG + T. VAGINALIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Trichomonas vaginalis*

Collection Procedures:

- Endocervical Swab ............... 23
- Vaginal Swab ..................... 24
- ThinPrep® Pap Solution ............. 21
- Male Urethral Swab ............... 24
- Urine Specimen for STD Testing ... 23

**DISCLAIMER:** The Diatherix Laboratories Sexually Transmitted Disease Panels are not recommended for evaluation of suspected sexual abuse or for other medico-legal indications.

**NOTE:** Because certain organisms are intracellular, there must be enough human cells present to detect the organism. Diatherix tests the specimen for human DNA to ensure that an adequate number of cells are present for a valid result.

CLOSTRIDIUM DIFFICILE TOXIN B GENE

This assay utilizes TEM-PCR to detect a molecular target that identifies:

- *Clostridium difficile* Toxin B gene

Collection Procedures:

- Stool Specimen Swab ............... 21
- Rectal Swab ......................... 21
**EAR NOSE & THroat PANEL**

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Acinetobacter baumannii*
- *Chlamydophila pneumoniae*
- *Enterobacter aerogenes*
- *Enterobacter cloacae*
- *Haemophilus influenzae*
- *Haemophilus influenzae* (Type B)
- *Klebsiella pneumoniae*
- *Moraxella catarrhalis*
- MRSA\(^1\)
- PVL\(^2\) gene

**Antibiotic Resistance Genes:**

- Aminoglycosides
- Cephalosporin (Staphylococcal)
- Erythromycin/Clindamycin
- Methicillin (Staphylococcal)
- Tetracycline

**Collection Procedures:**

- Throat Swab ......................19
- Ear Swab .........................19
- Nasopharyngeal Aspirate/Wash 20
- Nasopharyngeal Swab ............20

**GASTROINTESTINAL PANEL**

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Campylobacter jejuni*
- *Clostridium difficile* (Toxin B gene)
- Enterohemorrhagic *E. coli* (EHEC)
- - Shiga-like toxin gene (*stx1*)
- - Shiga-like toxin gene (*stx2*)
- Enteroinvasive *E. coli/Shigella* (EIEC)
- Enteropathogenic *E. coli* (EPEC)
- Enterotoxigenic *E. coli* (ETEC)
- *Salmonella enterica*
- *Vibrio parahaemolyticus*
- *Adenovirus types 40, 41*
- *Norovirus*
- *Rotavirus*
- *Cryptosporidium parvum*
- *Giardia lamblia*

**Collection Procedures:**

- Stool Specimen Swab .............21
- Rectal Swab .......................21

---

\(^{1}\) Methicillin-resistant *Staphylococcus aureus*

\(^{2}\) Panton-Valentine leukocidin
GROUP B STREPTOCOCCUS

This assay utilizes TEM-PCR to detect molecular targets that identify:

Group B Streptococcus (*Streptococcus agalactiae*)

Collection Procedure:

Vaginal/Rectal Swab ............22

**NOTE:** It is strongly recommended by CDC that a vaginal/rectal swab be collected for pregnant women. Cervical specimens are not recommended and a speculum should not be used for swab collection. The ESwab™ transport tube (white top) must be used. **Do not use the STD-Genital Health Collection Kit (orange top tube).**

Antibiotic susceptibility testing is available on GBS by request. Susceptibility testing can only be performed when the white top ESwab™ tube is used for transport. **Specimen stability for susceptibility is two days at ambient Temperature.**

The GBS sample will be inoculated into a broth supplement overnight if negative on the first day it is tested. It will then be tested again the second day after incubation. This is a CDC recommendation.

HERPES SIMPLEX VIRUS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Herpes Simplex Virus 1
Herpes Simplex Virus 2

Collection Procedures:

General swab (eye, lesion, etc) ....19
ThinPrep® Pap Solution ............21

**NOTE:** Because certain organisms are intracellular, there must be enough human cells present to detect the organism. Diatherix tests the specimen for human DNA to ensure that an adequate number of cells are present for a valid result.

ThinPrep® pap solution is stable for 30 days.

HSV Panel can also be tested with the swab specimen or urine specimen collected with the Diatherix Genital Health Collection Kit to test along with the STD Panel.
**HPV HIGH RISK Typing Panel**

This panel utilizes TEM-PCR to detect molecular targets that identify:

**HPV High Risk types:** 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 67, 68

**Collection Procedures:**

Endocervical Swab ..................23  
ThinPrep® Pap Solution ............21  
Throat Swab ..........................19

**NOTE:** Urine specimens are not acceptable. ThinPrep® pap solution is stable for 30 days.

**Infectious Disease Panel**

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Acinetobacter baumannii*
- *Enterobacter aerogenes*
- *Enterobacter cloacae*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Serratia marcescens*
- *Streptococcus pyogenes* (Group A)
- *Staphylococcus aureus*
- *PVL* gene
- *MRSA*¹
- *Staphylococcus epidermidis*
- *Coagulase-Negative Staphylococci*

**Antibiotic Resistance Genes:**

- Aminoglycosides
- Cephalosporin (Staphylococcal)
- Erythromycin/Clindamycin
- Methicillin (Staphylococcal)
- Tetracycline
- Vancomycin

**Collection Procedures:**

General Swab (wound, etc) ..........19  
Clean Catch Urine Specimen .......22  
Synovial Fluid ......................21

¹ Methicillin-resistant *Staphylococcus aureus*  
² Panton-Valentine leukocidin  
³ Methicillin-resistant Coagulase-Negative *Staphylococci*
**INFLUENZA PANEL**

This panel utilizes TEM-PCR to detect molecular targets that identify:

- Influenza A - Human influenza
- Influenza A - H1N1-09
- Influenza B
- Parainfluenza virus types 1, 2, 3, 4

**Collection Procedures:**

- Nasopharyngeal Aspirate/Wash...20
- Nasopharyngeal Swab.............20
- Throat Swab.....................19
- Bronchial Aspirate..............21
- Sputum Specimen Swab.........21

**PEDIATRIC RESPIRATORY PANEL**

This panel utilizes TEM-PCR to detect molecular targets that identify:

- Adenovirus types 3, 4, 7, 21
- Enterovirus group
- Human bocavirus
- Human coronavirus (4 types)
- Human metapneumovirus
- Influenza A - Human influenza
- Influenza A - H1N1-09
- Influenza B
- Parainfluenza virus types 1, 2, 3, 4
- Respiratory Syncytial Virus
- Rhinovirus
- Bordetella pertussis
- Chlamydia phila pneumoniae
- Haemophilus influenzae
- Haemophilus influenzae (Type B)
- Moraxella catarrhalis
- Mycoplasma pneumoniae
- Neisseria meningitidis
- Streptococcus pneumoniae
- Streptococcus pyogenes (Group A)

**Collection Procedures:**

- Nasopharyngeal Aspirate/Wash...20
- Nasopharyngeal Swab.............20
- Bronchial Aspirate..............21
- Sputum Specimen Swab.........21
DIATHERIX TEST PANELS

PHARYNGITIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- Adenovirus types 3, 4, 7, 21
- Enterovirus group
- Human coronavirus (4 types)
- Influenza A - Human influenza
- Influenza A - Human influenza
- Influenza B
- Parainfluenza virus types 1, 2, 3, 4
- Respiratory Syncytial Virus
- Rhinovirus
- Chlamydia pneumoniae
- Mycoplasma pneumoniae
- Streptococcus pyogenes (Group A)

Collection Procedures:

Throat Swab .......................19
Nasopharyngeal Aspirate/Wash ....20
Nasopharyngeal Swab .............20

RESPIRATORY INFECTION PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- Adenovirus types 3, 4, 7, 21
- Enterovirus group
- Human bocavirus
- Human coronavirus (4 types)
- Human metapneumovirus
- Influenza A - Human influenza
- Influenza A - H1N1-09
- Influenza B
- Parainfluenza virus types 1, 2, 3, 4
- Respiratory Syncytial Virus
- Rhinovirus
- Acinetobacter baumannii
- Bordetella pertussis
- Chlamydia pneumoniae
- Haemophilus influenzae
- Haemophilus influenzae (Type B)
- Klebsiella pneumoniae
- Legionella pneumophila
- Moraxella catarrhalis
- MRSA¹
- PVL² gene
- Mycoplasma pneumoniae
- Neisseria meningitidis
- Pseudomonas aeruginosa
- Staphylococcus aureus
- Streptococcus pneumoniae
- Streptococcus pyogenes (Group A)

Antibiotic Resistance Genes:

- Aminoglycosides
- Cephalosporin (Staphylococcal)
- Erythromycin/Clindamycin
- Methicillin (Staphylococcal)
- Tetracycline

Collection Procedures:

Nasopharyngeal Aspirate/Wash .......20
Nasopharyngeal Swab .................20
Bronchial Aspirate ....................21
Sputum Specimen Swab ..............21

¹ Methicillin-resistant Staphylococcus aureus
² Panton-Valentine leukocidin
### RHINOSINUSITIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<table>
<thead>
<tr>
<th>Virus/Pathogen</th>
<th>Collection Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus types 3, 4, 7, 21</td>
<td>Nasopharyngeal Aspirate/Wash . . . 20</td>
</tr>
<tr>
<td>Human coronavirus (4 types)</td>
<td>Nasopharyngeal Swab . . . . . . . . . . . . 20</td>
</tr>
<tr>
<td>Human metapneumovirus</td>
<td>ThinPrep® Pap Solution . . . . 21</td>
</tr>
<tr>
<td>Influenza A - Human influenza</td>
<td>Ureaplasma urealyticum</td>
</tr>
<tr>
<td>Influenza A - H1N1-09</td>
<td>Neisseria gonorrhoeae</td>
</tr>
<tr>
<td>Influenza B</td>
<td>Trichomonas vaginalis</td>
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</table>

<table>
<thead>
<tr>
<th>Virus/Pathogen</th>
<th>Collection Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parainfluenza virus types 1, 2, 3, 4</td>
<td>Endocervical Swab . . . . . . . . . . . . 23</td>
</tr>
<tr>
<td>Respiratory Syncytial Virus</td>
<td>Vaginal Swab . . . . . . . . . . . . . . . . 24</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>ThinPrep® Pap Solution . . . . 21</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>Male Urethral Swab . . . . . . . . . . . . 24</td>
</tr>
<tr>
<td>Haemophilus influenzae (Type B)</td>
<td>Urine Specimen for STD Testing . . 23</td>
</tr>
<tr>
<td>Moraxella catarrhalis</td>
<td></td>
</tr>
</tbody>
</table>

### SEXUALLY TRANSMITTED DISEASE PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<table>
<thead>
<tr>
<th>Organism</th>
<th>Collection Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atopobium vaginae</td>
<td>Endocervical Swab . . . . . . . . . . . . 23</td>
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<tr>
<td>Chlamydia trachomatis</td>
<td>Vaginal Swab . . . . . . . . . . . . . . . . 24</td>
</tr>
<tr>
<td>Gardnerella vaginalis</td>
<td>ThinPrep® Pap Solution . . . . 21</td>
</tr>
<tr>
<td>Mycoplasma genitalium</td>
<td>Male Urethral Swab . . . . . . . . . . . . 24</td>
</tr>
<tr>
<td>Mycoplasma hominis</td>
<td>Urine Specimen for STD Testing . . 23</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae</td>
<td></td>
</tr>
<tr>
<td>Ureaplasma urealyticum</td>
<td></td>
</tr>
</tbody>
</table>

**DISCLAIMER:** The Diatherix Laboratories Sexually Transmitted Disease Panels are not recommended for evaluation of suspected sexual abuse or for other medico-legal indications.

**NOTE:** When collecting a urethral swab or a 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 the large amount of cells usually present.

ThinPrep® pap solution is stable for 30 days.

Because certain organisms are intracellular, there must be enough human cells present to detect the organism. Diatherix tests the specimen for human DNA to ensure that an adequate number of cells are present for a valid result.

---

1 Methicillin-resistant *Staphylococcus aureus*
STAPHYLOCOCCUS DIFFERENTIATION PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- MRSA\(^1\)
- *Staphylococcus aureus*
- PVL\(^2\) gene
- MRCoNS\(^3\)
- Coagulase-Negative *Staphylococci*
- *Staphylococcus epidermidis*

**Antibiotic Resistance:**

- Aminoglycosides
- Cephalosporin
- Erythromycin/Clindamycin
- Methicillin
- Tetracycline

**Collection Procedures:**

- General Swab (wound, etc\(^4\)) ...........19
- Nasal Swab ................................20
- Synovial Fluid .........................21
- Clean Catch Urine Specimen ........22

UPPER RESPIRATORY INFECTION PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

- Adenovirus types 3, 4, 7, 21
- Enterovirus group
- Human coronavirus (4 types)
- Human metapneumovirus
- Influenza A - Human influenza

- Influenza A - H1N1-09
- Influenza B
- Parainfluenza virus types 1, 2, 3, 4
- Rhinovirus
- *Haemophilus influenzae* (Type B)
- *Moraxella catarrhalis*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes* (Group A)

**Collection Procedures:**

- Nasopharyngeal Aspirate/Wash ...20
- Nasopharyngeal Swab ...............20
- Throat Swab ............................19
- Bronchial Aspirate ......................21
- Sputum Specimen Swab ............21

\(^1\) Methicillin-resistant *Staphylococcus aureus*

\(^2\) Panton-Valentine leukocidin

\(^3\) Methicillin-resistant Coagulase-Negative *Staphylococci*

\(^4\) Axillary and perineal areas are also useful in detecting MRSA colonization
**DIATHERIX TEST PANELS**

**URINARY TRACT INFECTION PANEL**

This panel utilizes TEM-PCR to detect molecular targets that identify:

- *Enterobacter cloacae*
- *Enterococcus faecalis*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*

**Collection Procedure:**

Clean Catch Urine Specimen .... 22

**NOTE:** When collecting a urine specimen from a male or female patient, the patient should not have urinated for at least an hour before the specimen is collected.

**VIRAL RESPIRATORY PANEL**

This panel utilizes TEM-PCR to detect molecular targets that identify:

- Adenovirus types 3, 4, 7, 21
- Enterovirus group
- Human bocavirus
- Human coronavirus (4 types)
- Human metapneumovirus
- Influenza A - Human influenza
- Influenza A - H1N1-09
- Influenza B
- Parainfluenza virus types 1, 2, 3, 4
- Respiratory Syncytial Virus
- Rhinovirus

**Collection Procedures:**

Nasopharyngeal Aspirate/Wash .... 20
Nasopharyngeal Swab .............. 20
Throat Swab ...................... 19
Bronchial Aspirate ............... 21
Sputum Specimen Swab ......... 21
SPECIMEN COLLECTION PROCEDURES

GENERAL SWAB

Wound/Abscess

Syringe aspiration of purulent material from a loculated, palpable lesion is preferred.

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 an ESwab™ (white top) transfer tube and screw the top on tightly.

Open, Draining Wounds, and Decubitus Ulcers

1. Use the ESwab™ Collection Kit (white top tube).
2. Cleanse and debride the wound with sterile gauze and saline.
3. Exudate and brushings of the wound base (including advancing margins) should be collected using the swab from an ESwab™ collection kit.
4. Without contaminating the swab, place the swab into the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.

Throat, Ear, Eye, and Dermal (other than Wound, Ulcer, and Abscess)

1. Use the ESwab™ Collection Kit (white top tube).
2. Open the ESwab™ Collection Kit and remove the swab and transfer tube, being careful to prevent contamination.
3. Rub the swab on the area to be tested. Any infectious site can be swabbed with the ESwab™ for the appropriate panel.
4. Without contaminating the swab, place the swab into the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.

For general video instructions on using the ESwab™ Collection Kit click the Copan ESwab™ Training Video link at http://www.diatherix.com/videos.html
SPECIMEN COLLECTION PROCEDURES

NASOPHARYNGEAL (NP)

NP Aspirate/Wash Collection

_The diagnosis of otitis media, sinusitis, and infections of the upper respiratory tract in general is best achieved using a properly collected NP wash/aspirate._

1. Place the aspirate directly into an ESwab™ transport tube
2. Screw the top tightly on the transport tube.

NP Swab Collection

1. Use the ESwab™ Collection Kit (white top tube) along with a nasopharyngeal flocked swab (packaged separately).
2. Open the nasopharyngeal swab. Ask the patient to attempt to cough twice, if possible. Then insert the nasopharyngeal swab through one nostril straight back along the floor of the nasal passage until reaching the posterior wall of the pharynx. Rotate the swab for 5 to 10 seconds, leave it in place for a few seconds, and then slowly withdraw.
3. Open the ESwab™ kit and remove the transport tube only. Without contaminating the swab, place the NP swab into the white top transport tube all the way to the bottom and rotate the swab 5 times in the solution. Remove and discard the swab.
4. Screw the top tightly on the transport tube.

For a video demonstrating the NP Swab procedure click the Nasopharyngeal Swab Collection Video link at [http://www.diatherix.com/videos.html](http://www.diatherix.com/videos.html)

NASAL SWAB

1. Use the ESwab™ Collection Kit (white top tube).
2. If the patient has nasal discharge, ask the patient to attempt to clear the discharge by blowing his/her nose into non-scented tissue paper.
   - _Do not clear the discharge with swabs, as this might be excessively traumatic. Assist children whenever necessary._
3. Remove the swab and transfer tube from the collection kit. Do not contaminate.
4. Carefully insert the swab into the patient’s nostril up to 1 inch from the edge of the nare.
5. Rub the swab 5 times against the surface of the nare. Insert the same swab into the second nostril and roll the swab 5 times against the surface of the nare.
   - _Sampling the inside portion of the alar rima is also useful in determining nasal carriage of S. aureus._
6. Without contaminating the swab, place the swab in the white top transport tube all the way to the bottom of the tube. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
7. Screw the top tightly on the transport tube.
SPECIMEN COLLECTION PROCEDURES

FLUID SPECIMEN

**Urine (not STD), Synovial Fluid, Bronchial Aspirate, or ThinPrep® Pap Solution***

1. Use the ESwa™ Collection Kit (white top tube).
2. Open the collection kit and discard the swab.
   - Add approximately 2 ml of the specimen fluid to the 1 ml of fluid already in the tube. Do not fill the tube to the top.
3. Screw the top tightly on the transport tube.

*ThinPrep® Pap Solution ONLY*

Pour out all of the media solution in the ESwa™ tube. Then add approximately 2 to 3 ml of the ThinPrep® pap solution to the empty tube. Do not fill the tube to the top.

SPUTUM OR STOOL

1. Use the ESwa™ Collection Kit (white top tube).
2. Remove the swab and transfer tube from the collection kit. Do not contaminate.
3. Both sputum and stool samples should be carefully examined to identify portions of the specimen; e.g. blood and mucous flecks, that often contain infectious pathogens. These areas of the specimen should be carefully collected by placing the ESwa™ tip directly into the representative area identified.
4. Without contaminating the swab, place the swab in the ESwa™ transport tube all the way to the bottom of the tube. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.

RECTAL SWAB (GASTROINTESTINAL ILLNESS)

1. Use the ESwa™ Collection Kit (white top tube).
2. Remove the swab and transfer tube from the collection kit. Do not contaminate.
3. Insert the tip of the sterile flocked swab approximately 1 inch beyond the anal sphincter.
4. Carefully rotate the swab to sample the anal crypts then withdraw the swab.
5. Without contaminating the swab, place the swab in the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
6. Screw the top tightly on the transport tube.
CLEAN CATCH URINE SPECIMEN (NOT FOR STD TESTING)

1. Instruct the patient with the instructions provided below.
2. Follow the Fluid Specimen Collection Procedure (page 21) after obtaining the specimen.

Patient Instructions:
1. Wash hands with soap and warm water.
2. Follow gender specific instructions:
   - Females: Spread the labia (folds of skin) apart with one hand and wipe with a towelette. Wipe from front to back. Repeat this process the second time with a fresh towelette.
   - Males: If uncircumcised, retract the foreskin.
3. Follow gender specific instructions:
   - Females: Continue holding the labia apart. As you start to urinate, allow a small amount of urine to fall into the toilet bowl. (This clears the urethra of contaminants). Do not touch the inside of the collection cup.
   - Males: Wipe the end of the penis with a towelette. As you start to urinate, allow a small amount of urine to fall into the toilet bowl. (This clears the urethra of contaminants). Do not touch the inside of the collection cup.
4. After the urine stream is well established, pass the collection cup into the urine stream and, after the cup is ½ full, remove the cup from the urine stream and finish urinating into the toilet bowl.
5. Screw the lid on the cup tightly (do not touch inside of cup or lid). Give the sealed cup to the nurse or attendant.

For a video demonstrating the clean catch urine procedure click the Clean Catch Urine Collection Video link at http://www.diatherix.com/videos.html

VAGINAL/RECTAL SWAB (PREGNANCY RELATED GBS COLONIZATION)

Vaginal/Rectal swab is the specimen of choice for pregnancy related GBS colonization.

1. Use the ESwab™ Collection Kit (white top tube). Do not use the orange top Genital Health tube.
2. Remove the swab and transfer tube from the collection kit. Do not contaminate.
3. Swab the lower vagina (vaginal introitus), followed by the rectum (insert the swab through the anal sphincter) using the same swab. Move the swab from side to side, or rotate the swab at the collection site; allowing a few seconds for the organisms to be absorbed by the swab.
   - Cervical specimens and speculum assisted collections are not recommended.
4. Without contaminating the swab, place the swab in the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.
SPECIMEN COLLECTION PROCEDURES

URINE SPECIMEN FOR STD TESTING (MALE OR FEMALE)

1. Use the Genital Health Collection Kit (orange top tube).
2. Patient should not have urinated for at least one hour prior to sample collection. First morning specimen is preferred.
3. Specimens collected on female patients should be obtained without cleansing the external genitalia.
4. Collect approximately 5-10 mL of the first-catch urine into a preservative free specimen collection cup. Please note that larger volumes will dilute the specimen and yield false negative results. After collecting the desired amount of urine, the specimen container can be removed from the stream so that the void can be completed.
5. Open the Genital Health Collection Kit and discard the collection swabs.
6. Transfer the urine (2-3 mL) into an orange top transport tube using the plastic transfer pipette.
7. Recap the transport tube carefully, ensuring that the cap seals tightly.
8. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.

ENDOCERVICAL SWAB

1. Use the Genital Health Collection Kit (orange top tube).
2. Open the collection kit and discard the plastic disposable pipette. Remove the sterile endocervical swab from the wrapper being careful not to contaminate the swab.
3. Insert the white tip of the specimen swab into the endocervix canal with minimal contact with the vaginal wall.
4. Gently rotate the swab for 15 seconds to ensure adequate sampling.
5. Withdraw the swab carefully avoiding unnecessary contact with the vaginal wall.
6. Place the swab into the orange top transport tube, rotate the swab 5 times in the solution, and discard the swab.
7. Recap the transport tube carefully, ensuring that the cap seals tightly.
8. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.
VAGINAL SWAB

1. Use the Genital Health Collection Kit (orange top tube).
2. Open the Genital Health Collection Kit and discard the plastic disposable pipette. Remove the sterile vaginal swab from the wrapper being careful not to contaminate the swab by touching it to any surface.
3. Insert the white tip of the specimen swab about two inches (5 cm) into the opening of the vagina¹.
4. Gently rotate the swab for 15 to 30 seconds against the sides of the vagina to ensure adequate sampling.
5. Withdraw the swab carefully.
6. Handle the cap and tube carefully to avoid contamination.
7. Without contaminating the swab, place the swab into the orange top transport tube all the way to the bottom. Carefully break the swab at the line on the shaft; use care to avoid splashing of contents.
8. Recap the transport tube carefully. Ensure the cap seals tightly.
9. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.

MALE URETHRAL SWAB

1. The patient should not have urinated for at least one hour prior to sample collection.
2. Open the Genital Health Collection Kit and discard the plastic disposable pipette. Remove the sterile urethral swab from the wrapper being careful not to contaminate the swab by touching it to any surface.
3. Insert the white tip of the specimen swab ¾ to 1 ½ inches (2 to 4 cm) into the urethra.
4. Gently rotate the swab for 2 to 3 seconds to ensure adequate sampling.
5. Withdraw the swab carefully.
6. Handle the cap and tube carefully to avoid contamination.
7. Without contaminating the swab, place the swab in the orange top transport tube all the way to the bottom. Rotate the swab 5 times in the solution and discard the swab.
8. Recap the transport tube carefully. Ensure the cap seals tightly.
9. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.

¹ A sampling of vaginal vault fluid may improve the detection of bacterial vaginosis pathogens.
COLLECTION RECOMMENDATIONS

RESPIRATORY SPECIMEN COLLECTIONS

**Upper Respiratory Tract (Otitis Media, Rhinitis, and Acute Sinusitis)**

To avoid invasive techniques such as tympanocentesis and imaging guided percutaneous aspiration of sinus cavities, properly collected nasopharyngeal swabs or aspirates are useful methods of collecting upper respiratory tract infections. Proper positioning of the patient (prone with head tilted to the posterior) will allow the insertion of the collection device (catheter for collection of NP washes or a flocked swab) into the nasopharyngeal pool that accumulates the drainage of the eustation tube, the sinus cavities, and, to a lesser extent, the posterior pharynx. Swabs should be left in contact with the NP pooled secretions to absorb as much diagnostic material as possible.

**Lower Respiratory Tract (Bronchitis and Pneumonitis)**

The accurate diagnosis of lower respiratory tract infection is totally dependent upon the quality of the specimen collected. Several methods have been employed to screen sputum specimens and to improve the reliability of lower airway collections using bronchial washing or specimens obtained via bronchoscopy. It suffices to say that lower respiratory secretions obtained via sputum collection, bronchial alveolar lavage, bronchoscopy, or transtracheal aspiration that are optimized to reduce the likelihood of oropharyngeal contamination are preferred. The diagnostic yield of sputum specimen collections can be improved by thoroughly rinsing the oropharyngeal cavity with water before instructing the patient a produce a “deep cough” specimen. Many patients are unable to provide a proper sputum specimen and induction techniques with the assistance of respiratory therapists may be required. Suctioning of lower airway secretions can also be considered.

**Pharyngitis**

The sensitivity of any test used to rule out the presence of Group A Streptococcal Pharyngitis is dependent upon a properly collected swab obtained from the posterior pharynx and tonsils. Although the majority of pharyngitis cases are viral in origin, ruling out the presence of Group A Strep is essential. Proper visualization of the posterior oropharynx is required to identify areas of inflammation and exudate that may be present. Depression of the tongue and careful introduction of the swab to the site of inflammation is an important part of the collection technique that avoids contamination of the specimen with oral secretions.
<table>
<thead>
<tr>
<th>Panel</th>
<th>Specimen Containers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Copan ESwab™ 1</td>
</tr>
<tr>
<td>Atypical Pneumonia</td>
<td>●</td>
</tr>
<tr>
<td>Bacterial Pneumonia</td>
<td>●</td>
</tr>
<tr>
<td>Bacterial Vaginosis</td>
<td>● ●</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>●</td>
</tr>
<tr>
<td>C. difficile Toxin B gene</td>
<td>●</td>
</tr>
<tr>
<td>Candidiasis</td>
<td>● ●</td>
</tr>
<tr>
<td>CT + NG + T. vaginalis *</td>
<td>●</td>
</tr>
<tr>
<td>Ear Nose &amp; Throat</td>
<td>●</td>
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<tr>
<td>Gastrointestinal</td>
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<tr>
<td>Group B Streptococcus</td>
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<tr>
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<td>HPV High Risk Typing</td>
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<td>Staphylococcus Differentiation</td>
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</tr>
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<td>Urinary Tract Infection</td>
<td>●</td>
</tr>
<tr>
<td>Viral Respiratory</td>
<td>●</td>
</tr>
</tbody>
</table>

* Must be submitted in the Genital Health tube (orange top), even when ordered in combination with another panel.
CLIENT SUPPLIES

1. **ESwab™ Collection Kit Supplies**
   - a. ESwab™ White Top Tube with Standard Flocked Swab
   - b. Biohazard Bag

   *Nasopharyngeal Flocked swab is available by request.*

2. **Genital Health Collection Kit Supplies**
   - a. Diatherix Orange Top Tube
     - Standard Nylon Flocked Swab
     - Male Urethral or Endocervical Nylon Flocked Swab
     - Urine Pipette
   - b. Biohazard Bag

3. **Patient Take Home Stool Collection Kit**
   - English/Spanish Patient Instructions
   - Latex Free Glove
   - Biohazard Bag
   - Absorbent Pad
   - ESwab™ White Top Tube With Standard Flocked Swab

4. **Stool Collection Device**

5. **FedEx® UN3373 Clinical Pak**

6. **Prepaid FedEx® Label**

7. **Laboratory Request Form**

8. **Specimen Shipping Box**
NOTES

Supplies can be ordered via phone, fax or email. The order form can be filled out electronically using Adobe Reader, it can then be saved, printed, faxed or emailed by clicking the submit button at the bottom.

A current PDF of this form can always be found at diatherix.com.

---

**CLIENT SUPPLY ORDER FORM**

- All supply orders are shipped via FedEx® Ground.
- Orders received after 3:00 PM CST may be shipped the following business day.

Client Number: ___________________ Client Name: ___________________

Address: __________________________

City: ___________________ State: _______ Zip: _______

Contact Name: ___________________

Phone: _______________ Email: _______________

Comments: ___________________

---

### Specimen Collection Supplies

<table>
<thead>
<tr>
<th>QTY</th>
<th>ITEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ESwab™ Collection Tube (White Top Tube)</td>
</tr>
<tr>
<td></td>
<td>ESwab™ Collection Bag</td>
</tr>
<tr>
<td></td>
<td>Genital Health Collection Tube (Orange Top Tube)</td>
</tr>
<tr>
<td></td>
<td>Genital Health Collection Bag</td>
</tr>
<tr>
<td></td>
<td>Patient Stool Collection Kit</td>
</tr>
<tr>
<td></td>
<td>Patient Stool Collection Device</td>
</tr>
</tbody>
</table>


### Shipping Supplies

<table>
<thead>
<tr>
<th>QTY</th>
<th>ITEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Specimen Shipping Boxes</td>
</tr>
<tr>
<td></td>
<td>FedEx® Clinical Pak</td>
</tr>
<tr>
<td></td>
<td>FedEx® Shipping Label</td>
</tr>
</tbody>
</table>

### Other Supplies

<table>
<thead>
<tr>
<th>QTY</th>
<th>ITEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preprinted Requisition Form</td>
</tr>
<tr>
<td></td>
<td>Nasopharyngeal Swab</td>
</tr>
</tbody>
</table>

---

Click to email this order to supplies@diatherix.com: SUBMIT
**DIRECTIONS**

Complete each section following any instructions given to the right of the section header.

**Note:** At least one checkbox must be selected in the Test/Panel Selection section. *Certain panels may be combined on the same specimen provided the specimen is acceptable for each panel requested.*

In the Billing Information section, either attach a face sheet or complete the form with the applicable information.

---

**SAMPLE TEST REQUISITION**

**LABORATORY REQUEST**

***SPECIMEN INFORMATION:*** Print patient’s name on the label and apply along the length of specimen tube. Print legibly to complete the fields below including ICD-9 / chief complaint(s).

**Patient:**

- **First Name:**
- **Last Name:**
- **Gender:**
- **DOB:**
- **mm**
- **dd**
- **yyyy**
- **Time**

**Specimen:**

- **Source:**
- **Type:**
- **Collected:**
- **mm**
- **dd**
- **yyyy**
- **Time**

**ICD-9 Code(s) or Chief Complaint:**

- **Optional:**

**PROVIDER INFORMATION:**

- **Ordering Physician:**
  - **First Name:**
  - **Last Name:**
  - **NPI Number:**

**Supervising Physician:**

- **First Name:**
- **Last Name:**
- **NPI Number:**

**TEST/PANEL SELECTION:**

- **Multiple panels may be selected for a specimen provided there is sufficient quantity and the specimen is appropriate for each panel.**

**Comment:**

**BILLING INFORMATION:**

- **After selecting bill class, you may attach a face sheet and insurance card copy containing the patient and insurance information requested below.**

**Bill Class:**

- **Insurance:**
- **Medicare:**
- **Medicaid:**
- **Patient Self Pay:**
- **Client Bill:**
- **Other:**

**Patient Information:**

- **Social Security Number:**
- **Phone Number:**

**Address:**

- **Street:**
- **City:**
- **State:**
- **Zip:**

**Primary Insurance:**

- **Policy/ID:**
- **Group #:**

**Subscriber:**

- **Name (if other than patient):**
- **Relationship to patient:**

**Insurance company:**

- **Name:**
- **Phone:**

**Address (where claims are submitted):**

- **Street:**
- **City:**
- **State:**
- **Zip:**

**Is this a Worker’s Comp claim?**

- **Yes**
- **No**
- **Date of Injury:**
- **Adjuster’s name/phone:**

**SECONDARY INSURANCE:**

- **Policy/ID:**
- **Group #:**

**Subscriber:**

- **Name (if other than patient):**
- **Relationship to patient:**

**Insurance company:**

- **Name:**
- **Phone:**

**Address (where claims are submitted):**

- **Street:**
- **City:**
- **State:**
- **Zip:**

---

**Diatherix Laboratories, Inc.**

**866.979.4242 / www.diatherix.com**

**LABORATORY REQUEST**

**Document:** FO-110601     Rev. 3-100314

---
A Laboratory Report is generated for each individual panel ordered. Reports can be received via fax, email, Web Client online portal, and direct computer interface. To review examples of other panel specific reports, visit www.diatherix.com/test-catalog.html and select the desired panel.

### SAMPLE LABORATORY REPORT

<table>
<thead>
<tr>
<th>PATIENT:</th>
<th>ORDERING PHYSICIAN:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender:</td>
<td>ID:</td>
</tr>
<tr>
<td>Age:</td>
<td>Dob:</td>
</tr>
<tr>
<td>DOB:</td>
<td>Ethnicity:</td>
</tr>
<tr>
<td>Name:</td>
<td>Phone:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SPECIMEN:</th>
<th>CLIENT:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source:</td>
<td>Name:</td>
</tr>
<tr>
<td>Type:</td>
<td>Code:</td>
</tr>
<tr>
<td>Specimen ID:</td>
<td>Address:</td>
</tr>
<tr>
<td>Accession ID:</td>
<td></td>
</tr>
</tbody>
</table>

**Respiratory Infection Panel:**

- Viral Infections
  - Adenovirus
  - Enterovirus group
  - Human Bocavirus
  - Human Coronavirus
  - Human Metapneumovirus
  - Influenza A - Human Influenza
  - Influenza A - H1N1-09
  - Influenza B
  - Parainfluenza
  - Respiratory Syncytial Virus
  - Rhinovirus

- Bacterial Infections
  - Acinetobacter baumannii
  - Bordetella pertussis
  - Chlamydia pneumoniae
  - Haemophilus influenzae
  - Haemophilus influenzae Type B
  - Klebsiella pneumoniae
  - Legionella pneumonia
  - Moraxella catarrhalis
  - MRSA
  - Mycoplasma pneumoniae
  - Neisseria meningitidis
  - Pantion-Valentine leukocidin (PVL) gene
  - Pseudomonas aeruginosa
  - Staphylococcus aureus
  - Streptococcus pneumoniae
  - Streptococcus pyogenes (Group A Strep)

- Antibiotic Resistance
  - Aminoglycosides resistance
  - Cephalosporin resistance (Staphylococcal)
  - Erythromycin/Lincosamycin resistance
  - Methicillin resistance (Staphylococcal)
  - Tetracycline resistance

**Linking Diagnostics to Therapeutics**

*Testing performed by TBiOMS™ (Target Enriched Multiplex Polymerase Chain Reaction)*

*Patient ID 7891.548 42*
<table>
<thead>
<tr>
<th>Order Code</th>
<th>Diatherix Test Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>APP</td>
<td>Atypical Pneumonia Panel</td>
</tr>
<tr>
<td>BPP</td>
<td>Bacterial Pneumonia Panel</td>
</tr>
<tr>
<td>BVP</td>
<td>Bacterial Vaginosis Panel</td>
</tr>
<tr>
<td>BRN</td>
<td>Bronchitis Panel</td>
</tr>
<tr>
<td>CAND</td>
<td>Candidiasis Panel</td>
</tr>
<tr>
<td>GNT</td>
<td><em>Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis</em></td>
</tr>
<tr>
<td>CDIF</td>
<td><em>Clostridium difficile</em> Toxin B Gene</td>
</tr>
<tr>
<td>ENT</td>
<td>Ear Nose &amp; Throat Panel</td>
</tr>
<tr>
<td>GP</td>
<td>Gastrointestinal Panel</td>
</tr>
<tr>
<td>GBS</td>
<td>Group B <em>Streptococcus</em></td>
</tr>
<tr>
<td>HSV</td>
<td>Herpes Simplex Virus Panel</td>
</tr>
<tr>
<td>HPV</td>
<td>HPV (Human Papillomavirus) High Risk Typing Panel</td>
</tr>
<tr>
<td>IDP</td>
<td>Infectious Disease Panel</td>
</tr>
<tr>
<td>FLU</td>
<td>Influenza Panel</td>
</tr>
<tr>
<td>PRP</td>
<td>Pediatric Respiratory Panel</td>
</tr>
<tr>
<td>PHP</td>
<td>Pharyngitis Panel</td>
</tr>
<tr>
<td>RES</td>
<td>Respiratory Infection Panel</td>
</tr>
<tr>
<td>RHP</td>
<td>Rhinosinusitis Panel</td>
</tr>
<tr>
<td>STD</td>
<td>Sexually Transmitted Disease Panel</td>
</tr>
<tr>
<td>GNTH</td>
<td>STD 5</td>
</tr>
<tr>
<td>SDP</td>
<td><em>Staphylococcus</em> Differentiation Panel</td>
</tr>
<tr>
<td>URI</td>
<td>Upper Respiratory Infection</td>
</tr>
<tr>
<td>UTI</td>
<td>Urinary Tract Infection Panel</td>
</tr>
<tr>
<td>VRP</td>
<td>Viral Respiratory Panel</td>
</tr>
<tr>
<td>BVPCAND</td>
<td>Bacterial Vaginosis + Candidiasis Panel</td>
</tr>
<tr>
<td>STDCAND</td>
<td>Sexually Transmitted Disease + Candidiasis Panel</td>
</tr>
<tr>
<td>STDH</td>
<td>Sexually Transmitted Disease + Herpes Simplex Virus Panel</td>
</tr>
<tr>
<td>STDHCAND</td>
<td>Sexually Transmitted Disease + Herpes Simplex Virus + Candidiasis</td>
</tr>
<tr>
<td>STDMGN</td>
<td>CT + NG + <em>T. vaginalis + M. genitalium</em></td>
</tr>
</tbody>
</table>
WEBCLIENT ACCESS INFORMATION:

Username: _____________________________

Password: _____________________________

Click Client Log-In to enter WebClient from any page on diatherix.com

During the first login, please change the password to ensure privacy.

ADDITIONAL NOTES: