

COMPASS LABORATORY SERVICES

MOLECULAR DIAGNOSTIC TEST COLLECTION PROCEDURES



HAVE CONFIDENCE IN YOUR DIRECTION

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COMPANY INFORMATION

Compass Laboratory Services

1910 Nonconnah Blvd

Suite 108

Memphis, TN 38132

1-877-836-1140

Hours of Operation: Monday-Saturday 8:00 - 5:00 CST

CLIENT SERVICES

Toll Free: (877)-836-1140

Local: (901)-348-5774

Fax: (901)-348-5738

Email: customerservice@compasslabservices.com

BILLING CONTACT

Toll Free: (877)-836-1140

Local: (901)-348-5774

Fax: (901)-348-5738

Email: billing@compasslabservices.com

SAMPLE SUBMISSION

TEST REQUISITION

All samples submitted for testing must be accompanied by a proper test requisition form. Form must be completed and contain the following information

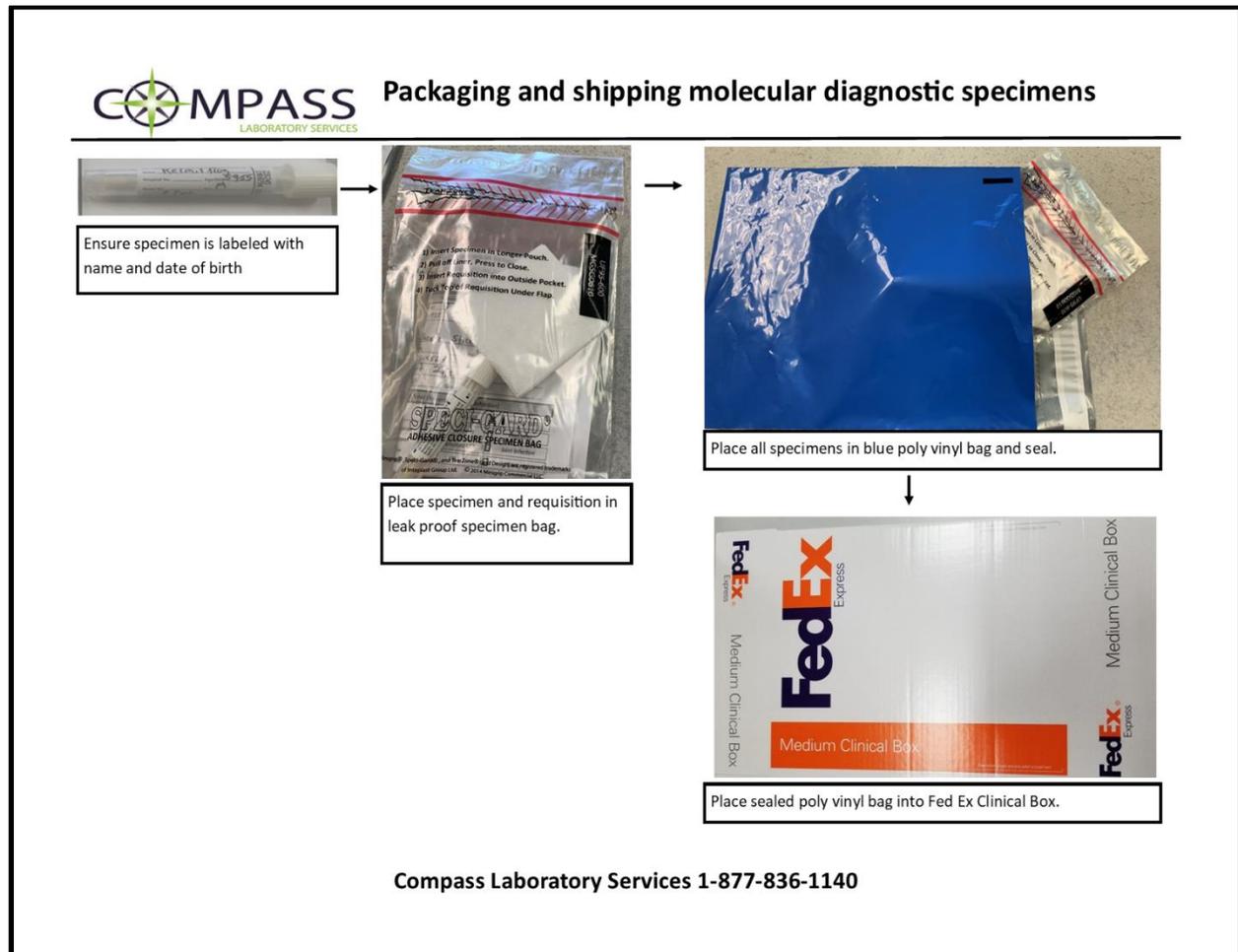
- Full patient name
- Date of birth
- Gender
- Date and time of collection
- Tests requested
- Specimen source
- Ordering provider
- Insurance information (If possible, please include a copy of the insurance card)
- List of active diagnosis codes in ICD10 format
- Provider signature
- Patient signature

SAMPLE REQUIREMENTS

- Collect the appropriate sample type for test requested (See panels for more information)
- Each sample must be accompanied by a properly completed test requisition
- Primary container must be labeled with two positive identifiers that are included on the requisition
 - Full name, date of birth, social security number, or unique patient identifier
- Properly packaged in a sealed specimen bag
 - Ensure that caps are fully seated properly to prevent sample leakage
- Sample must be received within the published stability

SHIPPING MOLECULAR SAMPLES

- All molecular samples must be shipped at ambient temperature to the laboratory in an individual specimen bag with an absorbent sheet. **NOTE: See UN3373 shipping instructions for SARS-CoV-2 and other Respiratory Pathogens located on pages 20 & 21.**
- Ensure the completed requisition sheet is not in the same compartment as the sample.
- Place all packaged specimens into the blue poly bag for shipment to laboratory. Seal the bag once all specimens are inside.
- Place sealed poly-vinyl bag into a Fed Ex Clinical box and affix supplied shipping label.



COMPASS LABORATORY SERVICES TEST PANELS

URINARY TRACT INFECTIONS

COLLECTION PROCEDURES

Specimen Type: All urine specimens submitted for suspected urinary tract infection must be collected using mid-stream, clean catch. Sample stability is 48 hours if sample is collected using a sterile container and 72 hours if transferred to a boric acid stabilized container. Volume required is 3.0ml. **Ship at ambient temperature.** Expected turnaround time is 48 hours from receipt in the laboratory.

Clean catch urine:

1. Wash hands with soap and water.
2. Do not touch the inside of the urine container.
3. Use gender specific instructions
 - a. Female
 - i. Spread labia apart with one hand and wipe with supplied Castille soap towelette from front to back. Repeat this process with a second fresh towelette.
 - ii. While holding the labia apart, begin to urinate into toilet for a few seconds. Hold the urine flow while moving the urine container into the urine stream. Reinitiate urine flow into the container, allow the container to collect approximately 20 ml of urine.
 - iii. Finish urinating into the toilet if required.
 - iv. Screw the lid onto the container and return to the nurse.
 - b. Male
 - i. Wash the head of the penis with Castille soap towelette. If uncircumcised, retract the foreskin and hold while cleansing the head of the penis.
 - ii. Initiate urination into toilet for a few seconds. Hold the urine flow while moving the urine container into the urine stream. Reinitiate urine flow into the container, allow the container to collect approximately 20 ml of urine.
 - iii. Finish urinating into the toilet if required.
 - iv. Screw the lid onto the container and return to the nurse.
4. Immediately label the urine container with full patient name and date of birth.
5. Complete test requisition form. Ensure all required information is supplied to prevent in delays of testing.
6. Place the labeled specimen in the provided specimen bag with absorbent sheet.
7. Place the completed test requisition in the pocket of the specimen bag.
8. Samples should be placed into supplied Fed Ex clinical box.

UTI PANELS

COMMUNITY ACQUIRED UTI

Organisms

- *Enterococcus faecalis*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Staphylococcus saprophyticus*
- *Streptococcus agalactiae*
- Antibiotic resistance panel will be reported on all positive samples

RECURRENT UTI

Organisms

- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Staphylococcus saprophyticus*
- *Streptococcus agalactiae*
- Antibiotic resistance panel will be reported on all positive samples

COMPLICATED UTI

Organisms

- *Enterobacter aerogenes*
- *Enterobacter cloacae*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Proteus vulgaris*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Staphylococcus saprophyticus*
- *Streptococcus agalactiae*
- Antibiotic resistance panel will be reported on all positive samples

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom UTI panel based upon their needs. Providers are responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

PROSTATITIS PANEL

This panel is intended for use in men that present with suspected bacterial prostatitis.

COLLECTION PROCEDURE

Sample Type: A swab or a clean catch urine sample (3ml required) collected following a digital prostate exam. Sample stability is 48 hours if shipped in sterile container and 72 hours if shipped in a boric acid stabilized tube.
Ship at ambient temperature. Expected turnaround time is 48 hours from receipt in the laboratory.

EXPRESSED PROSTATIC SECRETIONS

Collection instructions:

1. Cleanse head of penis using Castille soap towelette. Retract foreskin if required prior to cleansing.
2. Have patient urinate to expel approximately 10-20 ml of urine.
3. Perform digital prostate exam (contraindicated if acute bacterial prostatitis is suspected)
4. Have patient urinate into collection container.
5. Screw the lid onto the sample container.
6. Immediately label the urine container with full patient name and date of birth.
7. Complete test requisition form. Ensure all required information is supplied to prevent in delays of testing.
8. Place the labeled specimen in the provided specimen bag with absorbent sheet.
9. Place the completed test requisition in the pocket of the specimen bag.
10. Samples should be placed into supplied Fed Ex clinical box.

TEST PANELS

PROSTATITIS PANEL

Organisms:

- *Chlamydia trachomatis*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Mycoplasma hominis*
- *Neisseria gonorrhoeae*
- *Pseudomonas aeruginosa*
- *Serratia marcescens*
- *Ureaplasma urealyticum*
- Antibiotic resistance panel will be reported on all positive samples

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

WOUND/ SKIN/ SOFT TISSUE INFECTION PANEL**COLLECTION PROCEDURE**

Sample Type: Swab or tissue from suspected infection site shipped in UTM or tissue in a sterile container. Stability is 7 days in UTM or 48 hours in a sterile container. **Ship at ambient temperature.** Expected turnaround time is 48 hours from receipt in the laboratory.

WOUND SWAB**Collection Instructions:**

1. Ensure all required supplies are assembled and within easy reach including sample collection swab, gloves, sterile saline/water, and gauze sponges
2. Using sterile saline/water, cleanse the wound edges to remove contaminating flora
3. Remove contaminating material such as tissue slough, necrotic tissue, dried exudate, and adhered dressing residue
4. Use care to ensure that the swab only comes in contact with wound surface
5. Do not touch the swab below the score line. Only handle the swab from the top.
6. Use the appropriate process
 - a. Superficial wound
 - i. Place the swab onto the wound bed being cautious to avoid the wound edges
 - ii. While pressing pressure against the tissue, rotate the swab 2- 3 times collecting exudate if present
 - iii. Using a Z-track method, run the swab over the wound bed to collect samples from the entire wound bed while continuing to rotate the swab
 - b. Wound with tract
 - i. Cautiously place the swab into the wound tract to the deepest point if possible.
 - ii. Once at the deepest location within the wound, rotate the swab 2-3 times while firmly pressing against the side of the wound tract.
 - iii. Remove the swab while continuing to rotate
7. Insert the swab into the supplied Amies medium tube and snap off the excess swab at the scored break point. Be careful not to contaminate the lower portion of the swab. If contamination is suspected, please recollect.
8. Secure the cap onto the tube but do not over tighten. Over tightening of the swab cap may lead to sample leakage and rejection.
9. Label the specimen tube with at least two positive identifiers that match the requisition and place into the supplied specimen bag with absorbent sheet.
10. Place the completed test requisition in the pocket of the specimen bag.
11. Samples should be placed into the blue clinical overwrap and placed into a Fed Ex clinical box.

TEST PANELS

WOUND/ SKIN/ SOFT TISSUE PANEL

Organisms:

- *Acinetobacter baumannii*
- *Bacteroides fragilis*
- *Candida albicans*
- *Corynebacterium striatum*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Morganella morganii*
- *Pseudomonas aeruginosa*
- *Serratia marcescens*
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Streptococcus agalactiae*
- *Streptococcus dysgalactiae*
- *Streptococcus pyogenes*
- Antibiotic resistance panel will be reported on all positive samples

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

SEXUALLY TRANSMITTED INFECTIONS**COLLECTION PROCEDURES**

Sample Types: Swab (vaginal or urethral) in UTM, or urine (non-clean catch). Sample stability is 7 days for a swab in UTM or 48 hours in sterile container. For non-clean catch urine, stability is 48 hours in a sterile container or 72 hours in boric acid stabilized container. **Ship at ambient temperature.** Expected turnaround time is 48 hours from receipt in the laboratory.

Collection Instructions:**VAGINAL SWAB**

1. Ensure all required supplies are assembled and within easy reach including sample collection swab
2. Insert the tip of the flocked swab into the vaginal introitus approximately 2 inches
3. Rotate the swab against the vaginal wall for 5 to 10 seconds to collect vaginal secretions. Continue rotating the swab while slowly withdrawing
4. Insert the swab into the supplied Amies medium tube and snap off the excess swab at the scored break point. Be careful not to contaminate the lower portion of the swab. If contamination is suspected, please recollect.
5. Secure the cap onto the tube but do not over tighten. Over tightening of the swab cap may lead to sample leakage and rejection.
6. Label the specimen tube with at least two positive identifiers that match the requisition and place into the supplied specimen bag with absorbent sheet.
7. Place the completed test requisition in the pocket of the specimen bag.
8. Samples should be placed into the blue clinical overwrap and placed into a Fed Ex clinical box.

URETHRAL SWAB

1. Ensure all required supplies are assembled and within easy reach including sample collection swab
2. Gently insert the swab approximately $\frac{3}{4}$ " into urethra. Rotate the swab to capture any exudate and urethral cells.
3. Slowly rotate the swab while withdrawing from the urethra.
4. Insert the swab into the supplied Amies medium tube and snap off the excess swab at the scored break point. Be careful not to contaminate the lower portion of the swab. If contamination is suspected, please recollect.
5. Secure the cap onto the tube but do not over tighten. Over tightening of the swab cap may lead to sample leakage and rejection.
6. Label the specimen tube with at least two positive identifiers that match the requisition and place into the supplied specimen bag with absorbent sheet.
7. Place the completed test requisition in the pocket of the specimen bag.
8. Samples should be placed into the blue clinical overwrap and placed into a Fed Ex clinical box.

NON-CLEAN CATCH URINE (DIRTY CATCH)

1. Best to collect specimens using first morning void if possible
2. Wash hands with soap and water.

3. Do not touch the inside of the urine container.
4. Instruct the patient to void directly into the urine container collecting 10-15 ml of urine.
5. Label the specimen tube with at least two positive identifiers that match the requisition and place into the supplied specimen bag with absorbent sheet.
6. Place the completed test requisition in the pocket of the specimen bag.
7. Samples should be placed into the blue clinical overwrap and placed into a Fed Ex clinical box.

TEST PANELS

SEXUALLY TRANSMITTED INFECTIONS

- *Chlamydia trachomatis*
- *Mycoplasma genitalium*
- *Mycoplasma hominis*
- *Neisseria gonorrhoeae*
- *Treponema pallidum*
- *Trichomonas vaginalis*
- *Ureaplasma urealyticum*
- Antibiotic resistance reported on all positive samples

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

ONYCHOMYCOSIS**Toenail Clipping Collection Instructions**

1. Clean nails with alcohol wipes
2. Clip infected nails with sterilized clippers. Do not touch nail bed with hands.
3. Add nails to provided collection bag and seal tightly.
4. Label the bag with patient information.
 - a. Full name and date of birth must be provided.
5. Complete the test requisition form.
6. Physician must sign the requisition form.
7. If possible, provide a face sheet with demographics including patient insurance information along with test requisition.
8. Place sample into laboratory sample bag and paperwork in outer pocket.
9. Samples should be placed into the blue clinical overwrap and placed into a Fed Ex clinical box.
10. Sample stability is 7 days from collection. **Ship at ambient temperature.**
11. Expected turnaround time is 48 hours from receipt in the laboratory.

TEST PANELS

TOENAIL FUNGUS INFECTIONS

- *Aspergillus fumigatus*
- *Aspergillus niger*
- *Aspergillus terreus*
- *Candida albicans*
- *Epidermophyton floccosum*
- *Fusarium solani*
- *Trichophyton interdigitale*
- *Trichophyton rubrum*
- *Trichophyton violaceum*

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

SEPTIC ARTHRITIS/ JOINT FLUID PATHOGEN PANEL**Joint Fluid Pathogen Collection Instructions**

1. Cleanse site with povidone-iodine solution unless contraindicated.
2. Using a 1 inch 21 gauge needle attached to a 10 ml sterile syringe, the syringe is inserted into the joint following standard orthopedic procedures.
3. Sample is aspirated into the syringe and fluid is placed into a sterile, nuclease free collection tube. Collection tube must be labeled with patient name and date of birth.
4. Label the bag with patient information.
 - a. Full name and date of birth must be provided.
5. Complete the test requisition form.
6. Physician must sign the requisition form.
7. If possible, provide a face sheet with demographics including patient insurance information along with test requisition.
8. Place sample into laboratory sample bag and paperwork in outer pocket.
9. Samples should be placed into the blue clinical overwrap and placed into a Fed Ex clinical box.
10. Sample stability is 48 hours from collection. **Ship at ambient temperature.**
11. Expected turnaround time is 48 hours from receipt in the laboratory.

TEST PANELS

JOINT INFECTIONS

- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Streptococcus agalactiae*
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus saprophyticus*
- Antibiotic resistance reported on all positive samples

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

NASOPHARYNGEAL COLLECTION INSTRUCTIONS FOR SARS-COV-2 & OTHER RESPIRATORY PATHOGENS**Nasopharyngeal Collection Instructions**

Gather collection kit from supply area

1. Wash hands prior to collecting the sample.
2. Wear personal protective equipment as required
 - a. Gloves
 - b. Disposable lab coat
 - c. Eye protection
 - d. Droplet protection (Surgical mask or N95 mask if Co-VID19 suspected)
3. Ensure the sample collection container is labeled with name and date of birth.
4. Collect the NP swab
 - a. Open the Swab kit while ensuring sterility of swab.
 - b. Insert the swab into the nostril as far as you can. If you meet resistance, do not push through as you may cause damage to nasal mucosa.
 - c. Once inserted fully, hold in place for three seconds then slowly rotate for five seconds.
 - d. Withdraw the swab and place into the tube with media. Break at the break point.
 - e. Ensure that you do not contaminate the swab while placing into the transport medium.
 - f. Close the lid but do not overtighten. Overtightening of the transport medium may increase chance of specimen leak out. Specimens that leak out will not be processed



Figure 1: Location of swab placement into nasopharynx

5. Ensure transport tube is labeled with name and date of birth of patient (CLIA requires two positive identifiers) and place into specimen shipping bag with absorbent sheet.
6. Complete the test requisition and provide billing information as required. Place this sheet into the requisition pocket. Do not place in same section of bag as the specimen.
7. Place plastic bag with tubes into Federal Express Clinical Box labeled with UN3373 label.
8. Affix shipping label to Fed Ex box and call for pick up.
9. Call 901-348-5774 with any questions.
10. Stability is 7 days in UTM for SARS-CoV-2 and Variants. Stability is 72 hours for all other respiratory testing. **Ship at ambient temperature.**
11. Expected turnaround time is 48 hours from receipt in the laboratory.

Anterior Nares Collection Instructions – *alternate collection for SARS-CoV-2 only*

1. Gather collection kit from supply area
2. Wash hands prior to collecting the sample.
3. Wear personal protective equipment as required
 - a. Gloves
 - b. Disposable lab coat
 - c. Eye protection
 - d. Droplet protection (Surgical mask or N95 mask if Co-VID19 suspected)
4. Ensure the sample collection container is labeled with name and date of birth.
5. Collect the anterior nares swab
 - a. Open the Swab kit while ensuring sterility of swab.
 - b. Insert the swab into the nostril approximately $\frac{3}{4}$ inch. If you meet resistance, do not push through as you may cause damage to nasal mucosa.
 - c. Once inserted, hold in place for three seconds then slowly rotate for five seconds.
 - d. Withdraw the swab and repeat the process in the other nostril. After completion of both nostrils, place into the tube with media. Break at the break point.
 - e. Ensure that you do not contaminate the swab while placing into the transport medium.
 - f. Close the lid but do not overtighten. Overtightening of the transport medium may increase chance of specimen leak out. Specimens that leak out will not be processed
6. Ensure transport tube is labeled with name and date of birth of patient (CLIA requires two positive identifiers) and place into specimen shipping bag with absorbent sheet.
7. Complete the test requisition and provide billing information as required. Place this sheet into the requisition pocket. Do not place in same section of bag as the specimen.
8. Place plastic bag with tubes into Federal Express Clinical Box labeled with UN3373 label.
9. Affix shipping label to Fed Ex box and call for pick up.
10. Call 901-348-5774 with any questions.
11. Stability is 7 days in UTM. **Ship at ambient temperature.**
12. Expected turnaround time is 48 hours from receipt in the laboratory.

TEST PANELS

RESPIRATORY VIRUS PANEL

- SARS CoV2
 - Influenza A
 - Influenza B
 - Respiratory Syncytial Virus (RSV)
-

SARS-COV2 WITH VARIANT REFLEX

- SARS CoV2
 - If SARS CoV2 is positive, then variant testing will be reflexively added to the order and reported
-

INFLEUNZA PANEL

- Influenza A and B
-

RESPIRATORY BACTERIA PANEL

- *Bordetella pertussis*
 - *Bordetella parapertussis*
 - *Haemophilus influenzae*
 - *Klebsiella pneumoniae*
 - *Moraxella catarrhalis*
 - *Mycoplasma pneumoniae*
 - *Streptococcus pneumoniae*
 - *Streptococcus pyogenes*
-

PEDIATRIC RESPIRATORY PANEL

- RSV
 - Influenza (A, B, C, A/H3, A/H1-2009)
 - Parainfluenza
 - Coronavirus (OC43, 229E, NL63, HKU1)
 - Human Enterovirus, Adenovirus, Parechovirus, Bocavirus, Rhinovirus, and Metapneumonia virus
 - Respiratory Bacteria Panel
-

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

ORAL HUMAN PAPILLOMA VIRUS (HPV)**Oral Rinse Collection Instructions**

1. Gather collection kit and required supplies
2. Wash hands prior to collecting sample.
3. Wear personal protective equipment as required
 - a. Gloves
 - b. Face mask
 - c. Eye protection
4. Verify patient identity by confirming name and date of birth. Label the collection container with the name and date of birth
5. Instruct the patient to empty contents of oral rinse agent into their mouth and vigorously swirl around all oral surfaces for approximately 60 seconds.
6. Expel the oral rinse agent back into collection container after 60 second vigorous rinse.
7. Close container.
8. Ensure transport tube is labeled with name and date of birth of patient (CLIA requires two positive identifiers) and place into specimen shipping bag with absorbent sheet.
9. Complete the test requisition and provide billing information as required. Place this sheet into the requisition pocket. Do not place in same section of bag as the specimen.
10. Place plastic bag with tubes into supplied shipping box.
11. Place individual shipping boxes into Fed Ex Clinical Over Wrap.
12. Affix shipping label to Fed Ex box and call for pick up.
13. Call 901-348-5774 with any questions.
14. Stability is 7 days. **Ship at ambient temperature.**
15. Expected turnaround time is 48 hours from receipt in the laboratory.

CERVICAL HUMAN PAPILLOMA VIRUS (HPV)**COLLECTION PROCEDURE****Sample Type:** Endocervical**Preferred Container:** ThinPrep PreservCyt media

Sample stability is 7 days. **Ship at ambient temperature.** Expected turnaround time is 48 hours from receipt in the laboratory.

Collection Instructions:**Brush/ Spatula Kit**

1. Assemble all required supplies and equipment prior to collecting sample.
2. Obtain ectocervical sample using plastic spatula.
3. Rinse plastic spatula into PreservCyt media vial by vigorously swirling in vial 10 times. Discard spatula when complete.
4. Insert brush into cervix until bottommost fibers are exposed. Rotate broom slowly in one direction. Do not over rotate.
5. Rinse brush as quickly as possible in PreservCyt media by rotating device in solution while pushing against vial wall. Swirl brush vigorously to release cellular material. Discard brush.
6. Tighten cap on container so that torque line on the cap passes torque line on vial.
7. Ensure that the specimen container is labeled with two patient identifiers that match the requisition form.
8. Place the labeled specimen in provided biohazard bag with absorbent sheet.
9. Place completed sample requisition form along with demographic information in pocket of specimen bag
10. Specimens should be shipped without delay. Specimens received after 72 hours after collection will be rejected.

TESTS

HUMAN PAPILLOMA VIRUS

- HPV 16
- HPV 18
- Other high risk HPV subtypes

VAGINOSIS/ VAGINITIS

COLLECTION PROCEDURES

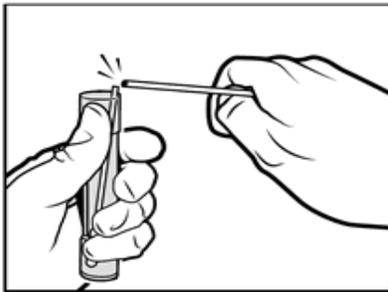
Sample Type: Vaginal Swab

Preferred Container: Universal Transport Medium

Sample stability is 72 hours. **Ship at ambient temperature.** Expected turnaround time is 48 hours from receipt in the laboratory.

Collection Instructions:

1. Collect sample prior to performing a vaginal examination with lubricant.
2. Assemble all required supplies including collection kit and gloves.
3. Insert the flocked swab approximately 2 inches into the vaginal introitus and rotate 2-3 times and hold for 5 seconds to absorb vaginal secretions.
4. Withdraw the swab, be careful not to touch the labia while withdrawing the swab.
5. Insert the swab into the universal transport medium, snap off the excess shaft of the swab at break point.
6. Do not over-tighten the cap as specimen leakage may occur.
7. Ensure that the specimen container is labeled with two patient identifiers that match the requisition form.
8. Place the labeled specimen in provided biohazard bag with absorbent sheet.
9. Place completed sample requisition form along with demographic information in pocket of specimen bag
10. Specimens should be shipped without delay. Specimens received after 72 hours after collection will be rejected.



Self-Collection Instructions:

1. Ensure that patient is given all required supplies.
2. Wash hands with soap and water prior to collecting sample. Rinse and dry.
3. Open the swab carefully and avoid touching the swab portion. Hold the end of the swab shaft in one hand.
4. With your other hand, gently spread the skin outside of your vagina and insert the tip of the swab 2 inches. Point the swab towards the lower back.
5. Rotate swab for 10-15 seconds to absorb vaginal secretions.
6. Withdraw the swab, be careful not to touch the skin outside of the vagina while withdrawing the swab.
7. Insert the swab into the sample tube, snap off the excess shaft of the swab at break point.
8. Label the tube with your name and date of birth.
9. Give the collection tube to your health care provider.
10. After collection, wash your hand with soap and water.

TEST PANELS

AEROBIC VAGINITIS

- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Staphylococcus aureus*
- *Streptococcus agalactiae*

BACTERIAL VAGINOSIS

- *Atopobium vaginae*
- *Bacteroides fragilis*
- *Gardnerella vaginalis*
- *Mobiluncus curtisii*
- *Mobiluncus mulieris*
- *Prevotella bivia*

LACTOBACILLUS PROFILE

- *Lactobacillus crispatus*
- *Lactobacillus iners*
- *Lactobacillus jensenii*

CANDIDIASIS

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

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

HERPES SIMPLEX VIRUS TESTING**COLLECTION PROCEDURE****Sample Type:** Swab of lesion**Preferred Container:** Universal Transport Medium (UTM)

Sample stability is 72 hours. **Ship at ambient temperature.** Expected turnaround time is 48 hours from receipt in the laboratory.

Collection Instructions:

1. Assemble all required supplies and equipment prior to collecting sample.
2. Select a lesion or lesions that appear to be fluid filled to be sampled.
 - a. In the absence of fluid filled lesions, scrape the crusts of lesions and place into UTM container and move to Step 3.
 - b. If site is ulcerated, remove crust if applicable, collect pus with provided swab and move to Step 3.
3. Using provided sterile swab, collect fluid and swab base of lesion/ ulcer to collect cellular material where virus is at its highest concentration.
 - a. If multiple sites are present, collect sites and submit into one container.
4. Place swab into UTM container and screw cap on container.
5. Ensure that the specimen container is labeled with two patient identifiers that match the requisition form.
6. Place the labeled specimen in provided biohazard bag with absorbent sheet.
7. Place completed sample requisition form along with demographic information in pocket of specimen bag
8. Specimens should be shipped without delay. Specimens received after 72 hours after collection will be rejected.

TESTS

HERPES SIMPLEX VIRUS

- Herpes Simplex Virus I
- Herpes Simplex Virus II

INDIVIDUAL ASSAYS OR CUSTOM PANELS

Providers can always order desired assays individually or design a custom panel based upon their needs. Ordering provider is responsible for ensuring that the appropriate testing panel or individual tests are medically needed for their patients.

PHARMACOGENOMICS (PGX)**COLLECTION PROCEDURE**

Sample Type: Dry flocked swab shipped in provided envelope. Stability 30 days. Expected turnaround time is 30 days from receipt in the laboratory.

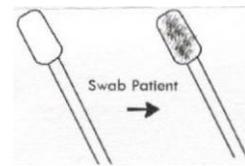
Collection Instructions:

1. Ensure that the patient did not smoke, eat, drink, or use mouth wash within **30 minutes of sample collection**.
2. Ensure that the patient is not currently chewing food or gum.
3. Request the patient to rinse out their mouth twice with water.
4. Using gloves, remove swab from its plastic packaging and discard the packaging.
5. Have patient collect sample by scraping/rolling the collection swab firmly on the **inside of both cheeks** for approximately 30 seconds; ensure that the swab is moved over the entire surface of the cheek.

Note: If sample collection is not completed as instructed, there

will not be sufficient DNA available for testing.

6. Take swab from patient and place the swab, flocked end first, into the provided envelope. Break the swab at the perforation, leaving the flocked end in the envelope. Discard the non-flocked end.
7. Affix the barcode label (from the BARCODED REQUISITION FORM) with 2 patient identifiers to the envelope and place the envelope into the SPECIMEN POUCH (small front sleeve) of plastic specimen bag.
Note: Barcode # is considered 1 identifier.
8. Place the PGX Requisition form and all other paperwork, including copy of insurance card, into the paperwork sleeve (large back sleeve) of plastic specimen bag
9. Peel away the plastic film on the stripe, fold over, and then press firmly to seal the plastic specimen bag (ensure sleeves and bag are sealed). **Store samples at room temperature until ready for shipment to the lab. Ship at ambient temperature.**
10. The package is now ready for shipment via FedEx or courier.



TESTS

- *Complete PGX*
- *CYP2C19, CYP2C9, CYP2D6*
- *CYP2D6*
- *CYP2C19*
- *CYP2C9*
- *CYP3A4*
- *CYP3A5*
- *Factor V Leiden*
- *Factor II*
- *MTHFR*
- *SLCO1B1*
- *VKORC1*
- *COMT*
- *APOE*

Clinical Samples, Biological Substance Category B (UN3373) Shipping Instructions

1. After collecting the sample, ensure the cap is securely tightened on the leakproof tube. Place the tube and absorbent material into the specimen bag, pull off the liner, and press to seal. Use the patient name on the requisition to fill out the attached itemized list of samples. Neatly fold and insert the requisition paperwork into the outside pocket. Ensure requisition is tucked under flap. Please reference picture sequence below for details.



2. Once sealed, place the specimen bag and its contents into the FedEx UN3373 Pak. You may insert multiple specimen bags and tubes into one FedEx UN3373 Pak. Once all samples are in the FedEx UN3373 Pak, remove the adhesive strip and securely seal the FedEx UN3373 Pak. Please reference picture sequence below for details.



3. Place the sealed FedEx UN3373 Pak inside the FedEx Medium Clinical Box. Fill out and insert the attached itemized list of contents into the FedEx Medium Clinical Box. Remove the adhesive strip and securely seal the FedEx Medium Clinical Box as shown in the picture sequence below.



4. On the outside of the package you must include the name and address of the shipper and of the receiver. You must also include the name and telephone number of a person responsible for the shipment. Proper packaging is the shipper's responsibility. Please reference IATA packing instruction 650 for further guidance.

Itemized List of Contents

This list must be placed between the FedEx UN3373 Pak and the FedEx Medium Clinical Box. Please fill out the itemized list of patient samples below. You must include this list of samples to ensure the receiver can reconcile the shipment. You may also print out an itemized list of samples to serve as the shipment manifest.

Date/Initials: _____ Account Number: _____

List Patient Names Below:	
1	21
2	22
3	23
4	24
5	25
6	26
7	27
8	28
9	29
10	30
11	31
12	32
13	33
14	34
15	35
16	36
17	37
18	38
19	39
20	40

Drop-off Options

- Go to <https://www.fedex.com/locate/> (see below) or call 1-800-GoFedEx to find the nearest FedEx Ship Center or Drop Box location.
- Place UN 3373 shipments in on-site Drop Boxes.
- FedEx Office Stores without Drop Boxes must accept UN3373 shipments over the counter.

