Respiratory Pathogens (Including COVID-19) Collection Instructions

southwest labs
Excellence • Reliability • Ethics • Unity

SAMPLE TYPE: Cough Sputum, Nares, Nasopharyngeal, Oral, Oropharynx, Throat

MATERIALS PROVIDED

- 1 sterile swab
- 1 sterile collection cup (upon request)
- 1 molecular transport tube
- 1 specimen bag

To ensure safety and validity of the sample, it is important to follow these instructions.

OROPHARYNX SWAB OR THROAT SWAB

1. Guide the swab tip toward the tonsillar area of the posterior oropharynx.
2. Thoroughly and firmly swab the tonsillar area, posterior oropharynx, as well as any area of abnormal redness, inflammation, white patches, or pus.
3. Immediately place the swab in the molecular transport tube.
4. Break the swab at the indention mark and secure cap on the tube.
5. Keep the tube in the upright position for 10 - 15 minutes.

NASOPHARYNX SWAB

1. Insert the swab into the nose parallel to the palate until resistance is encountered or the distance is equivalent to that from the patient's ear to nostril, indicating contact with the nasopharynx.
2. Thoroughly swab the nasal passage by rotating the swab 5-10 times.
3. Immediately place the swab in the collection tube, break the swab at the indention mark, and secure cap on the tube.
4. Keep the tube in the upright position for 10 - 15 minutes.

COUGH SPUTUM SWAB

1. Ensure all proper Personal Protective Equipment (PPE) measures are taken.
2. Have the patient take three deep breaths, cough, and then spit phlegm into the specimen cup (do not spit only saliva.)
3. Place the swab directly into the sputum sample and swirl 4-5 times to collect.
4. Immediately place the swab in the molecular transport tube.
5. Break the swab at the indention mark and secure cap on the tube.
6. Keep the tube in an upright for 10 - 15 minutes.

⚠ **DO NOT SEND THE COLLECTION CUP. IF CUP IS RECEIVED, SPECIMEN WILL IMMEDIATELY BE DISCARDED!**

This product has not been FDA cleared or approved by FDA, but has been authorized by FDA under an EUA for use by authorized laboratories;
This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Wound Specimen Collection Instructions

southwest labs
Excellence • Reliability • Ethics • Unity

SAMPLE TYPE: Wound Swab

MATERIALS PROVIDED

- 1 sterile swab
- 1 specimen bag
- 1 molecular transport tube
- 1 UPS/FedEx Lab Pak mailer

To ensure safety and validity of the sample, it is important to follow these instructions.

⚠ **DO NOT DISINFECT THE WOUND PRIOR TO SAMPLING UNLESS OTHERWISE NOTED**

1. Don gloves and follow one of the sample collection methods below based upon the type of wound:

Decubitus ulcer and other open wounds:

a. Roll the swab directly across the affected area until saturated.
b. Proceed to step 2.

Abscess with intact skin:

a. Disinfect the area. Using a sterile needle/syringe, aspirate purulent material from abscess.
b. Transfer 0.3-0.5 mL of purulent material directly into molecular transport tube.
c. Proceed to step 5.

Abscess with open skin/sinus tract:

a. Roll sterile swab within abscess/sinus with purulent material and ensure the swab is fully saturated.
b. Proceed to step 2.

Joint Fluid:

a. Disinfect the area. Using a sterile needle/syringe, aspirate joint fluid.
b. Eject 0.3-0.5 mL of joint fluid directly into molecular transport tube.
c. Proceed to step 5.

Vesicular dermatitis lesions:

a. Carefully open the lesion with a scalpel blade.
b. Collect fluid contents on the swab.
c. Thoroughly swab the base. The 'roof tissue' of the vesicle can be carefully removed, and submitted in same MTM tube.
d. Place all material in the molecular collection tube.
e. Snap off excess handle and securely tighten tube cap. f. Keep the tube in an upright position for 10-15 minutes.

Cellulitis/Skin Rashes:

a. Preferred/Optional: Gently scrape the affected area with a sterile scalpel blade (not provided).
b. Vigorously swab the scraped/affected area with the swab.
c. Using the same swab, collect any material on the scalpel blade.
d. Proceed to step 2.

2. Place the swab in the molecular transport tube.
3. Swirl the swab in the solution 5 times.
4. Break the swab handle at the indentation mark and recap the tube retaining the swab in the tube.
5. Snap off excess handle and securely tighten top of the transport tube.
6. Keep the tube in an upright position for 10 - 15 minutes.

Gastrointestinal Tract Collection Instructions

southwest labs
Excellence • Reliability • Ethics • Unity

SAMPLE TYPE: Rectal (fecal), Stool

MATERIALS PROVIDED

- 1 sterile swab
- 1 specimen bag
- 1 molecular transport tube
- 1 UPS/FedEx Lab Pak mailer

To ensure safety and validity of the sample, it is important to follow these instructions.

RECTAL COLLECTION

1. Don gloves.
2. Insert the tip of the swab at least 1 inch beyond the sphincter, and rotate the swab 5 – 10 times within an anal pocket/groove.
3. Visually confirm the swab is saturated with fecal material. ~0.5 mL (pencil erase size) is required.
4. Place the swab in the transport tube. Snap off excess handle and securely tighten top of the transport tube.
5. Keep the tube in an upright position for 10 – 15 minutes.

STOOL SAMPLE FROM BEDPAN

1. Don gloves. Do not handle the bedpan, collection tubes, etc. without gloves.
2. Open sterile bag and wrap around bedpan.
3. Collect the stool sample in a wrapped bedpan. Verify that the stool sample is not contaminated with urine.
4. Remove sterile swab from collection kit.
5. Insert the tip of the swab into the stool sample and rotate the swab 5 – 10 times.
6. Visually confirm swab is saturated with fecal material. ~0.5 mL (pencil eraser size) is required.
7. Place the swab in the transport tube. Snap off excess handle and securely tighten top of the transport tube.
8. Keep the tube in an upright position for 10 – 15 minutes.

STOOL SAMPLE FROM TOILET HAT (IN-HOME-COLLECTION)

1. Wash hands before touching toilet hat.
2. Place toilet hat with the round end at the back of the toilet seat (instructions available on the inside of the hat itself).
3. Collect the stool sample in the toilet hat ensuring that the stool sample is not contaminated with urine.
4. Remove sterile swab from collection kit.
5. Insert the tip of the swab into the stool sample and rotate the swab 5 – 10 times.
6. Visually confirm swab is saturated with fecal materia. ~0.5 mL (pencil erase size) is required. If sample is frankly diarrheal, ensure swab is fully saturated with liquid fecal material.
7. Place the swab in the transport tube. Snap off excess handle and securely tighten top of the transport tube.
8. 8. Keep the tube in an upright position for 10 – 15 minutes.

Genito-STI
Collection Instructions (Female)

SAMPLE TYPE: Anal, Cervical, Cervicovaginal, Endometrial, Genital Skin, Labia, Oral, Oropharynx, Perineal, Rectal, Throat, Urethral Swab, Urine (Catheter), Urine (Voided), Vaginal, Vestibule, Vulva

MATERIALS PROVIDED

- 1 sterile swab
- Endocervical brush (upon request)
- Small urethral swab (upon request)
- 1 molecular transport tube
- 1 specimen bag
- 1 UPS/FedEx Lab Pak mailer

To ensure safety and validity of the sample, it is important to follow these instructions.

CLEAN CATCH AND NON-CLEAN CATCH URINE COLLECTION PROCEDURE

A first morning sample or sample collected longer than 1-2 hours since prior urination maximizes the sensitivity of detection for urinary system pathogens.

PATIENT INSTRUCTIONS

1. Wash hands thoroughly with warm water and soap.
   A. **Clean Catch:** Urinate a small amount into the toilet. Collect ~10 – 15 mL of midstream sample. Finish urinating into the toilet.
   B. **Non-Clean Catch:** Holding labia apart, collect first ~10 – 15 mL urine into sterile urine cup.

CLINICAL TECHNICIAN INSTRUCTIONS

Don gloves and choose one of the following options for specimen preparation.

URINE SPECIMEN PREPARATION INSTRUCTIONS

Option 1: Using the Sterile swab

a. Open the urine collection cup, molecular transport tube and swab.
b. Using a circular motion, completely saturate swab with 10-15 circular sweeps of the collection cup.
c. Place the swab in the molecular transport tube.
d. Snap off excess handle and securely tighten tube cap.
e. Keep the tube in an upright position for 10 - 15 minutes.

Option 2: Using a sterile plastic transfer pipette

a. Open the urine collection cup, molecular transport tube and the plastic transfer pipette.
b. Using the pipette, stir the urine 10-15 times to mix the sample.
c. Transfer no more than 0.5 mL of urine from the collection cup to the molecular transport tube.
d. Securely tighten the cap of the molecular transport tube.
e. Keep the tube in an upright position for 10 - 15 minutes.

Genito-STI
Collection Instructions (Female) continued

southwest labs
Excellence • Reliability • Ethics • Unity

ENDOCERVICAL/ECTOCERVICAL SAMPLE

1. Visualize cervix via speculum examination.
2. Wipe away excess mucus with sterile gauze.
3. Insert sterile 'endocervical brush' into endocervical canal.
4. Rotate the brush 3-5 times, ensuring adequate sampling of the endocervical and squamocolumnar junction areas.
5. Sample ectocervix and any vaginal lesions prior to removing brush from vaginal canal.
6. Place the brush into the molecular transport tube.
7. Snap off excess handle and securely tighten tube cap.
8. Keep the tube in an upright position for 10 - 15 minutes.

Additional lesions (cervical/vaginal/introital ulcers, etc...):

1. Sample lesion with the endocervical brush or swab.
2. Place the brush or swab into the molecular transport tube.
3. Snap off excess handle and securely tighten the tube cap.
4. Keep the tube in an upright position for 10 - 15 minutes.

Open ulcers:

1. Thoroughly swab the ulcer(s).
2. Place the swab into the molecular transport tube.
3. Snap off excess handle and securely tighten the tube cap.
4. Keep the tube in an upright position for 10 - 15 minutes.

Vesicular lesions:

1. Carefully open the lesion with a scalpel blade.
2. Collect fluid contents on the swab.
3. Thoroughly swab the base.
4. Place all material in the molecular collection tube.
5. Snap off excess handle and securely tighten tube cap.
6. Keep the tube in an upright position for 10 - 15 minutes.

VAGINAL SAMPLE

Vaginal Swab:

1. Insert the swab approximately 2 inches into the vagina and rotate the swab for a minimum of 10 seconds, ensuring that the swab has contact with the vaginal wall. Ensure that the any visible lesions are swabbed.
2. Visually confirm the swab is fully saturated.
3. Place the swab in the transport tube. Snap off excess handle and securely tighten top of the transport tube.
4. Keep the tube in the upright position for 10 – 15 minutes.

ENDOMETRIAL/PARAMETRIAL SAMPLE

Trans-cervical endometrial aspirate material:

1. Collect via an appropriate catheter device (not provided).
2. Place approximately 0.5 mL of aspirated material into the molecular transport tube.
3. Securely tighten the tube cap.
4. Keep the tube in an upright position for 10 - 15 minutes.

Ultrasound guided needle aspirates from pelvic inflammatory disease lesions:

1. Place approximately 0.5 mL of aspirated material into the molecular transport tube.
2. Securely tighten the tube cap.
3. Keep the tube in an upright position for 10 - 15 minutes.

Genito-STI
Collection Instructions (Male)

SAMPLE TYPE: Anal, Endometrial, Genital Skin, Oral, Oropharynx, Penile, Perineal, Rectal, Throat, Urethral Swab, Urine (Catheter), Urine (Voided), Vestibule

MATERIALS PROVIDED

- 1 sterile swab
- Small urethral swab (upon request)
- 1 molecular transport tube
- 1 specimen bag
- 1 UPS/FedEx Lab Pak mailer

To ensure safety and validity of the sample, it is important to follow these instructions.

NON-CLEAN-CATCH URINE COLLECTION PROCEDURE

A first morning sample or sample collected longer than 1-2 hours since prior urination maximizes the sensitivity of detection for urinary system pathogens.

PATIENT INSTRUCTIONS

1. Wash hands thoroughly with warm water and soap.
2. Retract foreskin (if present), collect first ~10-15 mL urine into sterile urine cup.
3. Securely place cap on urine cup and return to the clinical technician.

CLINICAL TECHNICIAN INSTRUCTIONS

Don gloves and choose one of the following options for specimen preparation.

URINE SPECIMEN PREPARATION INSTRUCTIONS

Option 1: Using the Sterile swab

a. Open the urine collection cup, molecular transport tube and swab.
b. Using a circular motion, completely saturate swab with 10-15 circular sweeps of the collection cup.
c. Place the swab in the molecular transport tube.
d. Snap off excess handle and securely tighten tube cap.
e. Keep the tube in an upright position for 10 - 15 minutes.

Option 2: Using a sterile plastic transfer pipette

a. Open the urine collection cup, molecular transport tube and the plastic transfer pipette
b. Using the pipette, stir the urine 10-15 times to mix the sample.
c. Transfer no more than 0.5 mL of urine from the collection cup to the molecular transport tube.
d. Securely tighten the cap of the molecular transport tube.
e. Keep the tube in an upright position for 10 - 15 minutes.

Genito-STI
Collection Instructions (Male) continued

southwest labs
Excellence • Reliability • Ethics • Unity

URETHRA
1. Insert a small urethral swab 3-4 cm into the urethra.
2. Leave the swab in place for 5 seconds then slowly withdraw the swab using a twirling motion. This ensures epithelial cells are well sampled.
3. Bend the swab wire in half.
4. Place the swab into the molecular transport tube.
5. Securely tighten the tube cap.
6. Keep the tube in an upright position for 10 - 15 minutes.

PENILE LESIONS
Ulcerated lesions:
1. Thoroughly swab the base of lesion.
2. Place the swab into the molecular transport tube.
3. Snap off excess handle and securely tighten tube cap.
4. Keep the tube in an upright position for 10 - 15 minutes.

Vesicular lesions:
1. Carefully open the lesion with a scalpel blade.
2. Collect fluid contents on the swab.
3. Thoroughly swab the base.
4. Place all material in the molecular collection tube.
5. Snap off excess handle and securely tighten tube cap.
6. Keep the tube in an upright position for 10 - 15 minutes.

PROSTATE
Trans-rectal prostate massage sample can be considered in possible chronic prostatitis. The patient should not have urinated for at least 1-2 hours prior to collection.

Specimen Collection
1. Have patient retract foreskin (if present) with one hand and hold the open collection cup in place with opposite hand.
2. The clinician should massage the prostate while the patient collects any expressed prostatic fluid into the urine collection cup.
3. The patient should then collect approximately 10 mL urine in same collection cup.
4. Securely tighten the cap on the cup.
5. Keep the tube in an upright position for 10 - 15 minutes.

Specimen Preparation

Don gloves and choose one of the following options for specimen preparation.

Option 1: Using the sterile swab
a. Open the urine collection cup, molecular transport tube and swab.
b. Using a circular motion, completely saturate swab with 10-15 circular sweeps of the collection cup.
c. Place the swab in the molecular transport tube.
d. Snap off excess handle and securely tighten tube cap.
e. Keep the tube in an upright position for 10 - 15 minutes.

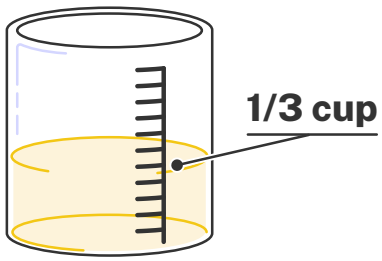
Option 2: Using a sterile plastic transfer pipette
a. Open the urine collection cup, molecular transport tube, and plastic transfer pipette.
b. Transfer approximately 0.5 mL of urine/prostatic fluid from the collection cup to the molecular transport tube.
c. Securely tighten the cap of the transport tube.
d. Keep the tube in an upright position for 10 - 15 minutes.

URINE SPECIMEN COLLECTION
BEST PRACTICES

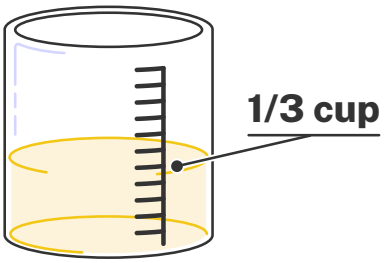
southwest labs
Excellence • Reliability • Ethics • Unity

To ensure integrity and validity of the sample, it is important to follow these instructions.

♀ FEMALES

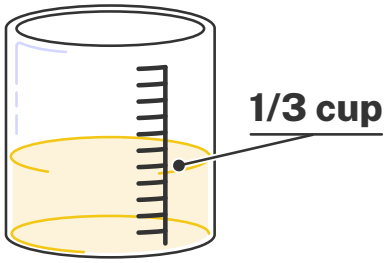


a. *Clean catch:* Urinate a small amount into the toilet. Collect midstream sample, filling urine cup no more than a 1/3 full.

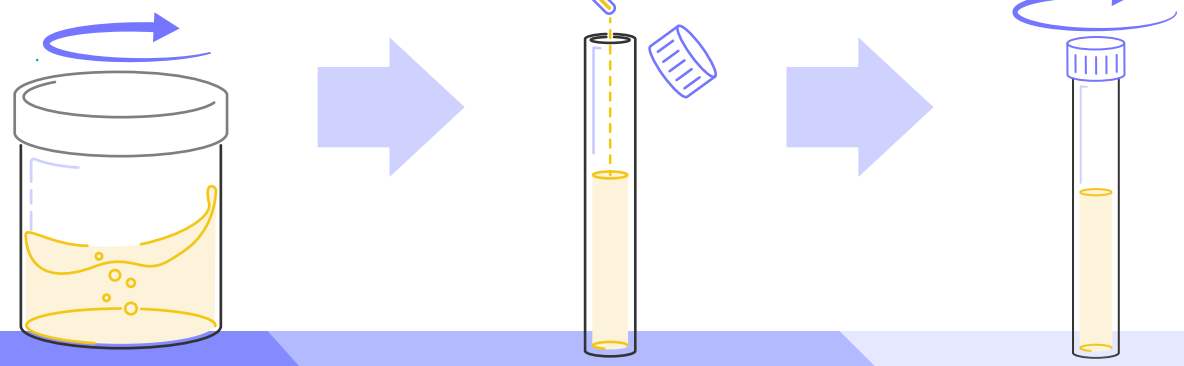


b. *Non-clean catch:* Holding labia apart, collect first ~10 – 15 mL urine, limiting total collection volume to a 1/3 of sterile urine cup.

♂ MALES



Retract foreskin (as applicable), collect first ~10 – 15 mL urine into sterile urine cup, limiting total collection volume to a 1/3 of urine cup.



With the lid on, swirl the urine cup on the counter 10 times to ensure the sample is thorougly mixed

Remove the lid and transfer no more than 1mL of urine (as marked on the pipette) from the collection cup to the molecular transport tube

Securely tighten the cap of the transport tube

southwest labs
Excellence • Reliability • Ethics • Unity

CLINICAL BULLETIN

Southwest Labs Microbial Load Reporting Update

Getting People Healthier Faster is what we do every day. To simplify and improve test report comprehension, the following changes are being implemented to our microbial load reporting.

Urinary Tract Infection Reporting

Aerobic bacterial pathogens included on the Urinary Tract Infection menus have recently been revalidated to correlate the microbial load detected by PCR to a CFU/mL microbial load from culture.

To align with how healthcare providers are accustomed to reading urine culture results, these organisms on the UTI menu will now be reported as "**> 100,000 CFU/mL equivalent" or "< 100,000 CFU/mL equivalent".**

Qualitative Reporting

Pathogens included on the HealthTrackRx test menu that are always considered pathogenic will now be reported as either "Detected" or "Not Detected" only and not include a specified microbial load. This is because these organisms are never considered normal flora or part of the human microbiome and are pathogenic at all detected microbial loads.

- All Respiratory Viruses
- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas Vaginalis
- Treponema pallidum (Syphilis)
- Herpes simplex virus 1 (HSV 1)
- Herpes simplex virus 2 (HSV 2)
- Varicella zoster virus (VZV)
- Cytomegalovirus (CMV)
- Monkeypox (Mpox)
- All Gastrointestinal pathogens (excluding Clostridium perfringens)
- Acanthamoeba castellani, polyphaga; Vermamoeba (Hartmannella) vermiformis

Semi-Quantitative Reporting

All other organisms included on HealthTrackRx menus will continue to be reported with the **"Low," "Moderate,"** and **"High"** microbial loads in use today. However, we will no longer list a specific Copies/mL value associated with that microbial load.

We look forward to continuing to serve your facility with next-morning test results and accelerated answers to your patients.