

Combined Collection Instructions 2024



Respiratory Specimen Collection Instructions	3
Urinary Tract Infection and Genitourinary Specimen Collection Instructions	4
Gastrointestinal Tract Infection Specimen Collection Instructions	6
Ophthalmology Specimen Collection Instructions	7
Otolaryngology Specimen Collection Instructions	8
Wound Specimen Collection Instructions	9
Nail/Paronychial Specimen Collection Instructions	11
Instructions for Specimen Packaging and Transport	12
Specimen Acceptance Criteria	13
Collection Guide	14

Respiratory Specimen Collection Instructions

Supplies

- ▶ 1 sterile thin swab
- ▶ 1 sterile thick swab
- ▶ 1 sterile collection cup
- ▶ 1 molecular transport tube
- ▶ 1 specimen bag

To ensure safety and validity of the sample it is important to follow these instructions. Ensure all proper Personal Protective Equipment (PPE) measures are taken.

Oropharynx or Throat Swab

Recommended sample type when suspecting pharyngitis or when a sputum sample for a lower respiratory infection is not possible.

- 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 with the swab remaining in the tube.

Nasopharynx or Nasal Swab

Recommended sample type when suspecting a primarily upper respiratory tract infection.

- 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 with the swab remaining in the tube.

Cough Sputum Samples

Recommended sample type when suspecting a lower respiratory tract infection.

- 1. Have the patient take three deep breaths, cough, and then spit phlegm into the specimen cup. Do not spit only saliva and avoid the sputum from being swirled in the mouth.
- 2. Place the swab directly into the sputum sample and swirl 4-5 times to saturate the swab.
- **3.** Immediately place the swab in the molecular transport tube.
- 4. Break the swab at the indention mark and secure cap on the tube with the swab remaining in the tube.

DO NOT send the collection cup. If cup is received, specimen will immediately be discarded!

Urinary Tract Infection and Genitourinary Specimen Collection Instructions

Supplies

- ▶ 1 sterile thin swab
- ▶ 1 sterile thick swab
- ▶ 1 sterile collection cup
- ▶ 1 transfer pipette
- ▶ 1 molecular transport tube
- ▶ 1 specimen bag

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

Voided Urine Specimens

A first morning sample or sample collected longer than 1–2 hours since prior urination maximizes sensitivity of detecting urinary system pathogens.

Patient Collection Instructions - Female

- 1. Wash hands thoroughly with warm water and soap.
- 2. Collection
 - **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.
- 3. Securely place cap on urine cup and return to the medical assistant or provider.

Patient Collection Instructions - Male

- 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 medical assistant or provider.

Medical Assistant / Provider Instructions

- 1. Don gloves and select one of the following options for specimen preparation.
- 2. Open the urine collection cup, molecular transport tube, and the plastic transfer pipette.
- 3. With the lid on, swirl the urine in the collection cup 10 times to ensure the sample is thoroughly mixed.
- 4. Transfer 1 mL of urine from the collection cup to the molecular transport tube.
- 5. Securely tighten the cap of the transport tube.

Catheterized Urine Specimen

- 1. Don gloves.
- 2. Clamp catheter tubing above the port to allow collection of freshly voided urine (minimum 2 mL urine required).
- 3. Vigorously clean the catheter port or wall of the tubing with 70% ethanol.
- **4.** Aspirate approximately 1 mL of urine via sterile needle (direct tubing puncture and aspiration), or syringe (if port has a Luer lock type fitting).
- 5. Eject the 1 mL of aspirated urine directly into a molecular transport tube.

Genital Lesions

Open Ulcer/Ulcerated Lesion

- 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 with the swab remaining in the tube.

Vesicular Lesion

- 1. Carefully open the lesion with a scalpel blade.
- 2. Collect fluid contents on the swab. The 'roof tissue' of the vesicle can be carefully removed and submitted in same MTM tube.
- 3. Thoroughly swab the base.
- **4.** Place all material in the molecular collection tube.
- 5. Snap off excess handle and securely tighten tube cap with the swab remaining in the tube.



Urinary Tract Infection and Genitourinary Specimen Collection Instructions (continued)

Endocervical / Ectocervical Specimen

- 1. Visualize cervix via speculum examination.
- 2. Wipe away excess mucus with sterile gauze.
- 3. Insert sterile 'endocervical brush' (not provided) 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. Swirl brush in the tube 5 times, remove the brush, and securely tighten tube cap.

Endocervical / Parametrial Specimen

Trans-cervical Endometrial Aspirate

- 1. Collect via an appropriate catheter device (not provided).
- **2.** Place approximately 0.5 1 mL of aspirated material into the molecular transport tube.
- 3. Securely tighten the tube cap.

Ultrasound-guided Needle Aspirates for Pelvic Inflammatory Disease Lesions

- 1. Place approximately 0.5 1 mL of aspirated material into the molecular transport tube.
- 2. Securely tighten the tube cap.

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 with the swab remaining in the tube.

Internal Urethral Swab

- 1. Insert a thin 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.** Place the swab into the molecular transport tube.
- **4.** Securely tighten the tube cap with the swab remaining in the tube.

Gastrointestinal Tract Infection Specimen Collection Instructions

Supplies

- ▶ 1 sterile thick swab
- 1 molecular transport tube
- ▶ 1 specimen bag

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

Rectal Swab

- **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 eraser size) is required.
- **4.** Place the swab in the transport tube. Snap off excess handle and securely tighten top of the transport tube with the swab remaining in the tube.

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.

Stool Sample from Toilet Hat

- 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 the swab is saturated with fecal material, ~0.5 mL (pencil eraser 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.

Ophthalmology Specimen Collection Instructions

Supplies

- ▶ 1 sterile thick swab
- ▶ 1 molecular transport tube
- ▶ 1 specimen bag

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

Eyelid / Conjunctival / Corneal / Other Orbital Area Swab

If using a swab:

- 1. Thoroughly swab the area(s) of interest by rotating the swab 5 10 times (fully saturate the swab).
- 2. For conjunctival or eyelid swabs, separate swabs can be obtained from both eyes, and placed in the same collection tube, or into "Right" and/or "Left" side designated tubes, IF clinically indicated.
- 3. Immediately place the swab in the molecular transport tube.
- 4. Snap off excess handle and securely tighten the tube cap with the swab remaining in the tube.

If using a corneal spatula:

- 1. Using a sterile spatula, collect corneal scrapings.
- 2. Transfer material directly into MTM tube. A new sterile spatula will be required for any additional passes with the spatula.
- 3. After transferring material into the MTM tube, securely tighten the tube cap.

Ocular (Anterior / Posterior Chamber Fluid, Vitreous Fluid) or Lacrimal Aspirates

- 1. Collect fluid/material per standard sterile aspiration method.
- 2. Eject 0.2 0.5 mL of aspirated fluid/material directly into molecular transport tube.
- 3. Securely tighten cap on molecular collection tube.



Otolaryngology Specimen Collection Instructions

Supplies

- ▶ 1 sterile thick swab
- ▶ 1 molecular transport tube

▶ 1 specimen bag

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

Ear

Ear Swab (External)

Use for otitis externa, perforated otitis media, other external ear/ear canal lesions.

- 1. Carefully insert the swab into the external ear canal, ensuring swab contacts area of interest.
- 2. Thoroughly swab the affected area by rotating the swab 5 10 times, saturating the swab with any drainage.
- **3.** Place the swab into the molecular transport tube.
- 4. Snap off excess handle and securely tighten the tube cap with the swab remaining in the tube.

Tympanocentesis Fluid

For otitis media

- 1. Collect fluid per standard sterile tympanocentesis aspiration method.
- 2. Eject 0.2 0.5 mL of tympanocentesis fluid directly into molecular transport tube.
- 3. Securely tighten the tube cap.

Oropharyngeal

- 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 with the swab remaining in the tube.

Nasopharyngeal / Nares

- 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 with the swab remaining in the tube.

Wound Specimen Collection Instructions

Supplies

- ▶ 1 sterile thick swab
- ▶ 1 molecular transport tube
- ▶ 1 specimen bag

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

Wound Swab

Decubitis Ulcer or Other Open Wounds

- 1. Debride 1 cm² of the wound.
- 2. Roll the swab directly across the affected area with enough force to produce fluid or blood and until the swab saturated, approximately 5 seconds.
- 3. Place the swab in the molecular transport tube.
- 4. Swirl the swab in the solution 5 times.
- 5. Break the swab handle at the indentation mark and recap the tube retaining the swab in the tube.
- 6. Snap off excess handle and securely tighten top of the transport tube with the swab remaining in the tube.

Abscess with Intact Skin

- 1. Disinfect the area. Using a sterile needle/syringe, aspirate purulent material from abscess.
- 2. Transfer 0.3 0.5 mL of purulent material directly into molecular transport tube.
- 3. Securely tighten the top of the transport tube.

Abscess with Open Skin

- 1. Debride 1 cm² of the wound.
- 2. Roll sterile swab within abscess/sinus with purulent material and ensure the swab is fully saturated. Enough force should be applied to produce blood or fluid from the wound.
- 3. Place the swab in the molecular transport tube.
- 4. Swirl the swab in the solution 5 times.
- 5. Break the swab handle at the indentation mark and recap the tube retaining the swab in the tube.
- 6. Snap off excess handle and securely tighten top of the transport tube with the swab remaining in the tube.

Vesicular Dermatitis Lesion

- 1. Carefully open the lesion with a scalpel blade.
- 2. Collect fluid contents on the swab.
- 3. Thoroughly swab the base. The 'roof tissue' of the vesicle can be carefully removed and submitted in same MTM tube.
- **4.** Place all material in the molecular collection tube.
- 5. Snap off excess handle and securely tighten tube cap with the swab remaining in the tube.

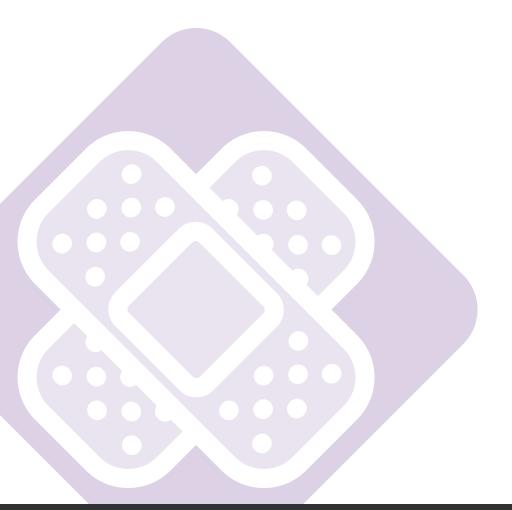
Cellulitis/Tinea/Skin Rash

- 1. Gently scrape the affected area with a sterile scalpel blade.
- 2. Vigorously swab the scraped/affected area with the swab.
- 3. Using the same swab, collect any material on the scalpel blade.
- **4.** Place the swab in the molecular transport tube.
- 5. Swirl the swab in the solution 5 times.
- 6. Break the swab handle at the indentation mark and recap the tube retaining the swab in the tube.
- 7. Snap off excess handle and securely tighten top of the transport tube.

Wound Specimen Collection Instructions (continued)

Nail

- 1. Don gloves. Clip the affected nail(s). Collect clippings on sterile gauze/paper (or equivalent).
- 2. Transfer nail(s) to provided molecular transport tube.
- 3. Optional: Using an appropriately sized sterile surgical blade, scrape affected subungual/periungual debris/tissue from the site directly into the molecular transport tube (or collect on sterile gauze/paper, and then transfer to transport tube). Collection of BOTH nail material and periungual material maximizes diagnostic yield and ensures that both pathogenic fungi and pathogenic bacteria are detected.
- **4.** Securely tighten the tube top and ensure all material is submerged in transport fluid.



Nail/Paronychial Specimen Collection Instructions

Supplies

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

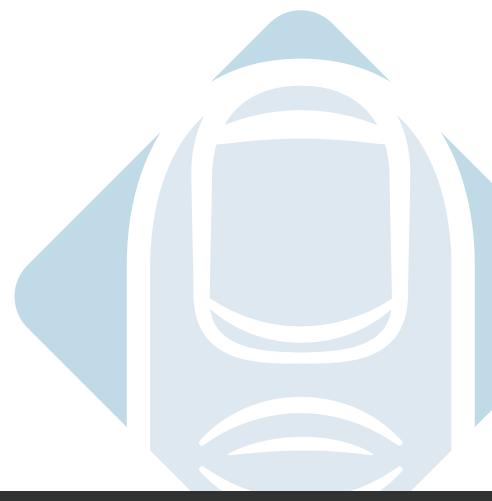
To ensure safety and validity of the sample it is important to follow these instructions.

Collect affected nail(s) and paronychial soft tissue/debris samples using standard aseptic/sterile technique currently in use at your practice. For nail clippers utilized directly from an autoclave pouch, no sterile saline rinse is required prior to nail clipping.

For nail clippers which have been autoclaved, and then placed in a cold, sterile holding container, rinse clippers with sterile saline prior to clipping nails.

Nail and Paronychial Specimen Collection

- 1. Don gloves. Clip the affected nail(s). Collect clippings on sterile gauze/paper (or equivalent).
- 2. Transfer nail(s) to provided molecular transport tube.
- **3.** (**Preferred/Optional**) Using an appropriately sized sterile surgical blade, scrape affected subungual/periungual debris/tissue from the site directly into the molecular transport tube (or collect on sterile gauze/paper, and then transfer to transport tube). Collection of BOTH nail material and periungual material maximizes diagnostic yield and ensures that both pathogenic fungi and pathogenic bacteria are detected.
- 4. Securely tighten the tube top and ensure all material is submerged in transport fluid.
- **5.** Keep the tube in an upright position for 10 15 minutes.



Instructions for Specimen Packaging and Transport

Electronic Ordering

- 1. Label the specimen tube using a fine-tip, permanent (non-smudging) pen or marker:
 - **a.** If not set up for external barcode process: Fill out the patient's first name, last name, AND date of birth on the molecular transport tube.
 - **b.** If set up for external barcodes: Add 1 or 2 patient identifiers to the pre-labeled tube.
- 2. Place the labeled molecular transport tube containing the sample into the provided specimen bag.
- 3. Seal the specimen bag.
- 4. Add any additional insurance/demographic information to the outside pocket of the specimen bag.
- 5. Add the sample to the UPS/FedEx Mailer. You can have more than one sample in the mailer.
- 6. When the UPS/FedEx Mailer is ready for pick up, seal the shipping container and place shipping label on Mailer.

If you are interested in being set up with external barcodes, contact your Sales Representative for additional information.

Paper Ordering

- 1. Fill out the patient's first name, last name, AND date of birth on the molecular transport tube label using a fine-tip, permanent (non-smudging) pen or marker.
- 2. Peel and stick the patient label on the molecular transport tube.
- 3. Place the labeled molecular transport tube containing the sample into the provided specimen bag.
- 4. Seal the specimen bag.
- **5.** Add the paper requisition and any additional insurance/demographic information to the outside pocket of the specimen bag.
- 6. Add the sample to the UPS/FedEx Mailer. You can have more than one sample in the mailer.
- 7. When the UPS/FedEx Mailer is ready for pick up, seal the shipping container and place shipping label on Mailer.

Specimen Acceptance Criteria

To provide high quality test results, HealthTrackRx company requires specimen meet all the minimum criteria outlined below. If you have questions, please contact HealthTrackRx Customer Care at 866-287-3218.

Specimen Labeling

Use a fine-tip permanent (non-smudging) pen or marker whenever labeling a specimen tube. This will ensure samples are easily identifiable.

Specimen Identification

Specimens must be clearly labeled with two unique patient identifiers or have patient identifier embedded in a barcoded label. Patient identifiers used must exactly match the information provided on the accompanying requisition or e-order.

Specimen Integrity Disclosure

Samples are stable in HealthTrackRx, PrimeStore™ MTM for 7 days post collection and at temperature ranges from -20°C to 50°C. Samples received outside of the viability window will be rejected as the integrity of the specimen cannot be determined.

Broken or Leaked Specimens

Samples received which have leaked due to the tube being cracked or broken, or samples which are received without a cap will be rejected, as there will not be enough sample nucleic acid for definitive testing.

Want Faster ? Here are Results some reminders!

Use the Right Device:

Always use the correct collection tubes and containers provided for each specific test.



ONE Universal Collection Device

Please reference the Syndromic Menu Ordering Reference Guide for available panels - these tests can only be run using the ONE Universal Collection Device.

FDA menus CANNOT be run using the ONE Universal Collection Device.





Label Correctly:

Ensure all specimens are clearly labeled with the patient's first and last name and date of birth. Include the specimen collection site on ALL tubes.

Example: Jane Doe, 01/01/1999 or J. Doe, 01/01/1999

Seal and Store Properly:

- Secure sample lid tightly
- Seal specimen bag
- Seal courier/carrier bag (once all samples have been collected for the day)
- Place shipping label on courier/carrier bag

