



## **Molecular Testing Solutions Infectious Disease Specimen Collection Types and Guidelines**



*Helping Clinicians Make  
Better Decisions*

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# Table of Contents

Completion of Test Request/Order Form .....	4
Specimen Labelling and Transport .....	5
Specimen Collection General Instructions .....	6
Respiratory Tract Infection RT-PCR Specimen Collection Guidelines .....	7
Collection Guidelines for Throat Swab .....	7
Collection Guidelines for Nasal Swab .....	7
Collection Guidelines for Nasopharyngeal Swab .....	8
Collection Guidelines for Sputum .....	8
Collection Guidelines for Saliva .....	9
Urinary Tract Infection RT-PCR Specimen Collection Guidelines .....	10
Collection Guidelines for Mid-stream Urine .....	10
Collection Guidelines for Catheterized Urine .....	10
Genital Health/Sexually Transmitted Infection (GH/STI) RT-PCR Specimen Collection Guidelines .....	11
Collection Guidelines for Vaginal Swab .....	11
Collection Guidelines for Endocervical Swab .....	11
Collection Guidelines for Urethral Swab .....	12
Collection Guidelines for Rectal Swab .....	12
Collection Guidelines for Lesion Swab .....	13
Collection Guidelines for Urine First Void .....	13
Gastrointestinal Infection RT-PCR Specimen Collection Guidelines .....	14
Collection Guidelines for Rectal Swab .....	14
Collection Guidelines for Fecal Swab .....	14
Common Reasons for Cancellation/Delay of Test Results .....	15

## Completion of Test Requisition/Order Form

1. The following is a list of test requisition forms and respective disease state:
  - Respiratory Tract Infection Laboratory Requisition for RT-PCR
  - Urinary Tract Infection/Genital Health/Sexually Transmitted Infection Laboratory Requisition for RT-PCR
  - Gastrointestinal Infection Laboratory Requisition for RT-PCR
2. Choose the appropriate test requisition form which reflects the disease state and the test(s) being ordered.
3. Complete all fields of the requisition.
4. Patient Information
  - Fill in patient's complete First Name, Last Name, Sex, Date of Birth, Address, City, State, Zip Code, Phone Number, and Social Security Number. Fill in Patient ID#, Race, and Ethnicity if applicable.
  - Failure to complete may delay result.
5. Following collection of sample, place initials of individual collecting the sample in the box provided. Fill in the date of service (DOS), which is the date of collection.
6. Check yes or no, "Is the patient symptomatic".
  - This is a required field and failure to complete may delay result.
7. Specimen Type
  - Each specimen type must be accompanied by a separate test requisition form and provider order.
  - Select the type of specimen collected.
  - Acceptable specimen types for the orderable tests are listed next to each test on the test requisition form.
  - Testing is limited to the acceptable types listed for the orderable test.
8. Requesting Provider
  - Select the appropriate requesting provider (choose only one).
  - Write in name legibly if not preprinted on the test requisition form.
  - Obtain the ordering provider's signature.
9. Billing Information
  - Complete all patient insurance information.
  - Insured's name and insured's social security number must be provided. Failure to complete may delay results.
  - Always validate information with the patient.
10. Requesting provider must check the desired test(s) on the test menu.
  - Tests may be ordered individually by checking the box in front of the analyte.
  - Test may be ordered as a profile when listed. Profiles are constructed for clinical relevance.
11. All test requisition forms must have a valid ICD-10 code provided by the ordering provider.
  - Diagnosis codes are 3-7 characters. First digit is alpha, 2nd and 3rd are numeric and 4-7 can be alpha and/or numeric (Example: U07.1).
  - Diagnosis codes are necessary for the documentation of medical necessity.
  - Diagnosis information must be determined by the requesting provider.

\*For the GH/STI requisition, please mark if the patient is pregnant and date of last menstrual period. These questions are required for gynecologic samples.

\*For the UTI requisition, please mark Leukocyte esterase screen result: (REQUIRED) POSITIVE or NEGATIVE.

## Specimen Labelling and Transport

1. Complete the barcode label provided on the requisition with the patient's full name and date of birth. All specimens must be labelled with the patient's first and last name, ID number and date of birth. A minimum of two identifiers are required on the specimen for testing.
2. Affix the barcode straight and vertically along the length of the specimen tube while in front of the patient. Take care not to cover the edge of the cap. Do not wrap the bar code around the specimen or apply horizontally. Never place the specimen in an unlabeled collection tube with the intent to label later.
3. Following collection, show the specimen to the patient and ask for confirmation of information on the label.
4. The specimen information must match the test requisition form information or it will be rejected.
5. Place the labeled PrimeStore MTM tube containing the patient's specimen into the provided Biohazard bag. Seal the bag. Do not place more than one specimen in a biohazard bag.
6. Place the completed test requisition form, folded, in the back pocket of the biohazard bag. Do not place the test requisition form in the bag with the specimen. It must be placed in the pocket of the biohazard bag.
7. Do not refrigerate or freeze. Ship specimens ambient using the provided FedEx shipping supplies.
8. Place the sealed biohazard specimen bag(s) into the provided kit box. Up to 4-5 samples should be consolidated per kit box. Do not place more than one specimen in a biohazard bag.
  - Provided kit box should be prelabeled with an "Exempt Human Specimens" label. If not, an appropriate label should be provided.
  - Place up to 5 kit box(es) with samples inside the clinical pack.
  - Call Aegis Client Services 800.533.7052 to schedule a FedEx or courier pickup.

# Specimen Collection

## General Instructions

1. Make sure that there is a means for washing hands and a suitable clean surface for use as a work area. Adequate personal protective equipment (PPE) must be available.
2. Guidance with respect to personal protective equipment is provided by the client. The collector must follow all requirements for PPE of the client. Gloves are to be worn at a minimum during specimen collection.
3. The collection site must have all the supplies needed to complete a specimen collection (e.g. collection kits, ink pens, Aegis Laboratory Request Forms, leak-resistant plastic bags, absorbent material, shipping containers, UN3373 Category B shipping labels (if shipping via FedEx), and appropriate personal protective equipment).
4. Ensure access to collection supplies is restricted to qualified collectors and other authorized personnel. Ensure there is a storage area for maintaining collected specimens until they are packaged and sent to Aegis for testing.
5. Make sure all staff are trained in the safe use of the specimen transport media and have proper practices in place in the event of a spill. Following a spill, take a paper towel and absorb as much of the liquid as is possible. Wash the spill with soap and water. There may be a stick residue remaining. A spill does not cause concern for microbial contamination because all organisms are killed in the transport media immediately. Do not allow the liquid to come into contact with skin.
6. Carefully read and understand all specimen collection directions.
7. Assemble all necessary supplies prior to collection (test request form, specimen label, specimen collection device, specimen transport medium (Molecular Transport Medium (MTM)).
8. Check the collection swab and viral transport media packaging to ensure the expiration date has not been exceeded. Do not use expired devices.
9. Use only Aegis validated collection devices. Failure to do so will result in rejection of the specimen
10. For best results, specimens should be collected within 3 days of and no later than 7 days from symptom onset. Ideal collection should occur prior to the initiation of antimicrobial therapy.



*NOTE: Do not allow bleach to come into contact with PrimeStore Molecular Transport Medium® (MTM). PrimeStore MTM contains guanidiniethiocyanate, which produces a dangerous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite) or other halogenated chemicals.*

*PrimeStore MTM Manufacturer Info:  
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# Respiratory Tract Infection RT-PCR Specimen Collection Guidelines

Specimen types include Throat Swab (TS), Nasal Swab (NS), Nasopharyngeal Swab (NP), Sputum (SP), Saliva (S)

Note: There are two swab types packaged in collection kits: Large Swab (VF106-80) which is used for TS and NS and small Swab (VF105-80) which is used for NP. Both swabs come in collection kits. Use the appropriate swab and discard the other.

## Collection Guidelines for Throat Swab

- Open the Large Swab VF106-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Insert the Large Swab VF106-80 into the posterior pharynx and tonsillar areas.
- Rub swab over both tonsillar pillars and posterior oropharynx. **Avoid touching the tongue, teeth, and gums.**
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Collection Guidelines for Nasal Swab

- Open the Large Swab VF106-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Tilt patient's head back 70 degrees and insert the Large Swab VF106-80 into one nostril, parallel to the palate, not upwards, until resistance is met at turbinates (about 2 cm).
- Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Collection Guidelines for Nasopharyngeal Swab

- Open the Small Swab VF105-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Tilt patient's head back 70 degrees and slowly insert the Small Swab VF105-80 into the nostril, parallel to the palate, not upwards, until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Gently roll the swab, leave in place for several seconds to absorb secretions, and slowly remove while rotating.
- Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection.
- If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Collection Guidelines for Sputum

Note: Requires the Saliva/Sputum funnel (ordered separately).

- Patient should not eat, drink, smoke, vape, or chew gum, etc for 30 minutes before providing a sample.
- Instruct the patient to wash their hands prior to specimen collection.
- Patient's mouth should be rinsed thoroughly with water.
- Retrieve Saliva/Sputum funnel (not provided in collection kit).
- Remove the screw cap from the PrimeStore MTM tube and screw the funnel on to the collection tube. Do not discard the collection tube screw cap.
- Instruct patient to take a deep breath and cough, collecting the sputum into the collection tube through the funnel.
- Repeat as necessary to ensure ~1 - 2mL of sputum enters the PrimeStore MTM tube.
- Remove the funnel from the PrimeStore MTM tube and discard. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.



## Collection Guidelines for Saliva

Note: Requires the Saliva/Sputum funnel (ordered separately).

- Patient should not eat, drink, smoke, vape, or chew gum, etc for 30 minutes before providing a sample.
- Instruct the patient to wash their hands prior to specimen collection.
- Retrieve Saliva/Sputum funnel (not provided in collection kit).
- Remove the screw cap from the PrimeStore MTM tube and screw the funnel on to the collection tube. Do not discard the collection tube screw cap.
- Instruct the patient to hold the tube and spit into the funnel until the amount of liquid (not bubbles) in the PrimeStore MTM tube reaches the 'mL' mark.
- Remove the funnel from the PrimeStore MTM tube and discard. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Urinary Tract Infection RT-PCR Specimen Collection Guidelines

Specimen types include Mid-stream Urine (UM) and Catheterized Urine (UC). The urine collection kit is used.

### Collection Guidelines for Mid-stream Urine

- Instruct the patient to wash their hands and clean the urethral area with a towelette.
- Females: Separate folds of urinary opening with thumb and forefinger and clean inside with towelettes, using front to back strokes only; keep separated during urination into container.
- Males: Clean head of penis.
- Instruct the patient to collect a sample of urine “mid-stream” in the supplied urine specimen cup. By allowing the first 2-3 seconds of urine flow into the toilet before collecting the sample.
- Fill urine specimen cup only half-way.
- Using the transfer pipette provided in the kit, transfer approximately 3 mL of urine to the labeled PrimeStore MTM tube. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

### Collection Guidelines for Catheterized Urine

- A catheterized urine sample must be collected by a health professional trained to perform the procedure. The standard practice guidelines for catheterized urines of the client should be used for collection.
- Following collection, Using the transfer pipette provided in the kit, transfer approximately 3 mL of urine to the labeled PrimeStore MTM tube. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## **Genital Health/Sexually Transmitted Infection (GH/STI) RT-PCR Specimen Collection Guidelines**

Specimen types include Vaginal Swab (VS), Urethral Swab (US), Endocervical Swab (ES), Lesion Swab (LS), Rectal Swab (RS), and Urine First Void (UF). There are two swab types in the collection kit. Large swab VF106-80 is used for vaginal, rectal and lesion swab. Small swab VF105-80 is used for urethral and endocervical swab.

### **Collection Guidelines for Vaginal Swab**

- Open the Large Swab VF106-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Insert the Large Swab VF106-80 into the opening of the vagina (approx 2 in) and gently rotate swab for 10 to 30 seconds.
- Make sure swab touches the walls of the vagina so that moisture is absorbed by swab.
- Withdraw swab from the vagina without touching skin.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

### **Collection Guidelines for Endocervical Swab**

- Open the Small Swab VF105-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Insert the Small Swab VF105-80 into the endocervical canal. Gently rotate the swab clockwise for 10-30 seconds in the endocervical canal, and withdraw the swab carefully.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

### **Collection Guidelines for Urethral Swab**

- Open the Small Swab VF105-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Insert the Small Swab VF105-80 into the urethra (approx 2-4 cm for males).
- Gently rotate the swab in one direction for a minimum of 10 seconds and withdraw.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

### **Collection Guidelines for Rectal Swab**

- Open the Large Swab VF106-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Insert the Large Swab VF106-80 approximately 2.5 cm into the anal canal.
- Move swab from side to side and remain in the anal canal for 10-30 seconds to maximize absorption of organisms onto the swab.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Collection Guidelines for Lesion Swab

- Open the Large Swab VF106-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Clean the surface of the lesion with sterile saline. The use of alcohol or iodophors to cleanse the lesions may inactivate the virus and should therefore be avoided.
- Unroof the vesicle and collect with the Large Swab VF106-80 or scrape the base of an open vesicle with a sterile scalpel blade and then rub the base vigorously with the Large Swab VF106-80 to allow epithelial cells to be collected onto the swab.
- Rotate the Large Swab VF106-80 for 30 seconds to allow the cells of the lesion to be collected onto the swab.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube. Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Collection Guidelines for Urine First Void

- DO NOT collect within two hours of the last urination.
- Instruct the patient to wash their hands prior to the collection.
- Instruct the patient to collect a sample of urine “first void” in the supplied urine specimen cup.
- Pass first urine straight into the supplied pee canter, then allow the rest to pass into the toilet.
- Fill urine specimen cup only half-way.
- Using a transfer pipette, transfer approximately 3 mL of urine to the labeled PrimeStore MTM tube. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

# Gastrointestinal Infection RT-PCR Specimen Collection Guidelines

Note: Specimen may be collected within 14 days of symptom onset. Swab type is large swab VF106-80.

## Collection Guidelines for Rectal Swab

- Open the Large Swab VF106-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Insert the Large Swab VF106-80 approximately 2.5 cm into the anal canal.
- Move swab from side to side and remain in the anal canal for 10-30 seconds to maximize absorption of organisms onto the swab.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Collection Guidelines for Fecal Swab

- Place supplied Collection Hat over the bowl of the toilet.
- Instruct the patient to wash their hands and to collect the sample in the Collection Hat.
- Open the Large Swab VF106-80 packaging and remove the swab. Do not lay the swab down or touch it to any surfaces before performing the specimen collection. Discard swab packaging.
- Insert the Large Swab VF106-80 into the sample in the Collection Hat and allow to remain there for 30 seconds to maximize absorption of organisms onto the swab.
- Place swab, tip first, into the provided transport tube containing PrimeStore MTM. Take care not to spill the contents of the transport tube. Samples received with less than the required volume of media will be canceled.
- Break swab shaft at the break point against the rim of the transport tube.
- Replace, tighten, and seal the transport tube screw cap.
- Label the specimen.
- Place in biohazard bag.
- Prepare for shipping.

## Common Reasons for Cancellation/Delay of Test Results

### Cancellation:

- Patient ID mismatch
- Only one patient identifier on collection device
  - Minimum of 2 identifiers must match from sample to requisition
- No identification on the collection device
- Sample compromised in shipping (sample leakage)
- Quantity insufficient
- Sample received in a non-Aegis validated device
- Selected testing not associated to sample type submitted
- Requisition received is not from the submitting clinic
- Sample received without a requisition
- Requisition received without a sample

### Delay:

- Line drawn down the requisition in attempt to indicate all testing or multiple tests are selected (scenario dependent)
  - Each selection box must be checked individually
- Selected testing is not associated to sample type submitted (scenario dependent)
- Selected tests do not align with selected gender
- Testing write-ins. Writing in testing associated to a different requisition
- Multiple providers selected
- Not submitting a requisition with the sample (scenario dependent)
- Selecting multiple specimen types
- Missing demographics from requisition



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