AEGIS® Sciences Corporation

Molecular Testing Solutions Infectious Disease Specimen Collection Types and Guidelines

Helping Clinicians Make Better Decisions

Aegis Sciences Corporation
501 Great Circle Road
Nashville, TN 37228

Clinical Laboratory Improvement Amendments (CLIA) - #44D2062333
College of American Pathologists (CAP) - #8853197

Client Services
615.760.2835
Clientservicesbiopharma@aegislabs.com

Billing Department
877.723.2145
billing@aegislabs.com

Contact your Regional Sales Manager to order kit/supplies

Table of Contents

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
   - Sexually Transmitted 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. Please answer all applicable highlighted fields in each section.
7. Specimen Type
   - Select the type of specimen collected.
   - There will only be one specmen type per 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.

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 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. Ship specimens ambient using the provided FedEx shipping supplies.
8. Place the sealed biohazard specimen bag(s) into the provided box. Up to 4-5 samples should be consolidated per box.
   - Place up to 5 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, 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 specimen transport tube 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 guanidinethiocyanate, which produces a dangerous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite) or other halogenated chemicals.

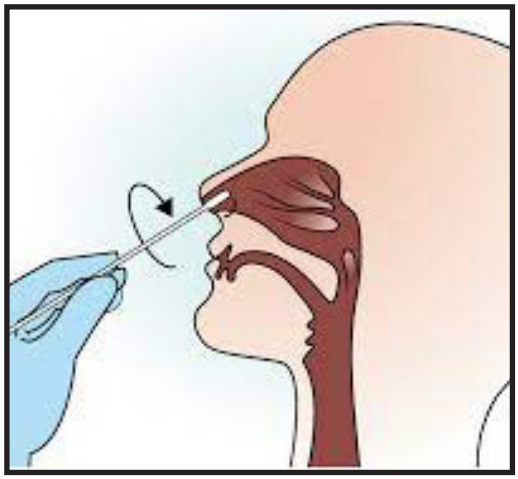
PrimeStore MTM Manufacturer Info:
Longhorn Vaccines and Diagnostics LLC
1747 Citadel Plaza Ste 206, San Antonio, TX 78209
Telephone: USA (210) 826-0910 Email: info@lhnvd.com

Respiratory Tract Infection RT-PCR Specimen Collection Guidelines

Specimen type: Nasal Swab (NS)

Collection Guidelines for Nasal Swab

1. 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.
2. 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).
3. Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.
4. 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.
5. Break swab shaft at the break point against the rim of the transport tube.
6. Replace, tighten, and seal the transport tube screw cap.
7. Label the specimen.
8. Place in biohazard bag.
9. Prepare for shipping.



Sexually Transmitted Infection (STI) RT-PCR Specimen Collection Guidelines

Collection Guidelines for Urine First Void

1. DO NOT collect within two hours of the last urination.
2. Instruct the patient to wash their hands prior to the collection.
3. Instruct the patient to collect a sample of urine "first void" in the supplied urine specimen cup.
4. Pass first urine straight into the supplied specimen collection cup, then allow the rest to pass into the toilet.
5. There should be no more than 20mL of urine collected.
6. 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.
7. Replace, tighten, and seal the transport tube screw cap.
8. Label the specimen.
9. Place in biohazard bag.
10. Prepare for shipping.

Common Reasons for Cancellation/Delay of Test Results

Cancellation:

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

Delay:

1. 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
2. Selected testing is not associated to sample type submitted (scenario dependent)
3. Testing write-ins. Writing in testing associated to a different requisition
4. Multiple providers selected
5. Not submitting a requisition with the sample (scenario dependent)
6. Selecting multiple specimen types
7. Missing demographics from requisition

515 Great Circle Road | Nashville, TN 37228 | 615.255.2400 | 800.533.7052 | AegisLabs.com