

**QDx***Path*

SPECIMEN  
COLLECTION  
MANUAL

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**Dear Clinicians and Medical Practice Professionals:**

**As required by the Centers for Medicare and Medicaid Services (CMS), all patient collection sites, including physician practice offices, must keep a Specimen Collection Manual. We provide this manual for your reference, and to comply with all state and federal regulations. Please sign below, acknowledging that you have received the manual, and intend to store it at the site where patient specimens are collected.**

**Sincerely yours,**

**M. Nasar Qureshi, M.D., Ph.D., F.C.A.P.  
President and Medical Director**

**Practice:** \_\_\_\_\_

**Practice Representative (please print):** \_\_\_\_\_

**Signature and Date:** \_\_\_\_\_

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# GENERAL SPECIMEN COLLECTION AND HANDLING

## General Purpose

The purpose of this manual is to ensure that specimen collection and submission by the facility of origin, as well as the receipt of the specimen by this laboratory, is performed correctly and appropriately. This manual outlines the procedures required to collect, transport, and submit specimens to this laboratory for processing and evaluation.

## Introduction

The quality of any laboratory test result is dependent on many variables and includes patient preparation, specimen collection and transportation. The specimen collection and handling can be completed by the healthcare staff and, in certain situations, by the patients themselves. The appropriate skill and knowledge when preparing the patient and specimen are essential to the provision of the highest quality standards for testing and services. Please contact the laboratory for clarification at (866) 909-7284, if needed, prior to specimen collection. Specific specimen requirements for each test are listed in the General Test list section of this collection guide. Specimen requirements include information such as specimen volume, collection and transport containers as well as transport temperature. It is critical that an adequate specimen volume is submitted for analysis. The volume requested in this guide is enough for initial analysis as well as any confirmatory tests that must be performed. If an inadequate specimen is submitted, the laboratory may not be able to perform the initial test or required confirmatory procedures. If repeat confirmatory tests cannot be performed, the report will indicate that specimen quantity submitted was Quantity Not Sufficient (QNS) for additional testing. When an inappropriate specimen or unclear test request has been submitted, the client will be notified with instructions for resolving the problem.

## Principle

The laboratory can accept specimens only from persons authorized by law to perform such procedures. Optimal evaluation of patient specimens requires careful control of collection technique, specimen preservation, and specimen transportation to the laboratory. Incorrect specimen collection and transportation may compromise the integrity of the specimen and lead to erroneous results. Failure to adequately label or identify a patient's specimen and failure to reject an unsuitable specimen will result in erroneous assignment of patient results.

## Responsibilities

All personnel have a team obligation to follow the procedures outlined in this manual. Persons involved with specimen collection and specimen submission to the laboratory have a responsibility to ensure:

- Appropriate collection and identification (labeling) of specimens. Specimen containers must be labeled with at least two unique patient identifiers and can include a combination of patient name, date of birth (DOB), medical record number or accession number.
- Accurate and complete information about the patient and ordering physician and practice. All test orders must include the provider's signature.
- Specimens are transported to the laboratory under appropriate conditions in a timely manner without specimen loss, undue exposure or misplacement.

Persons involved with specimen transportation and tracking must ensure that specimens are transported under appropriate conditions in a timely manner without specimen loss, undue exposure or misplacement.

Persons involved with specimen receipt and processing must ensure that specimen identification and integrity are preserved and that specimens undergo technical processing and are submitted for evaluation in a timely manner.

The general list menu performed by this laboratory includes histologic, cytologic and clinical testing evaluations performed on the following specimens:

- Aspirate, Bone Marrow
- Aspirate, Fine Needle (Non-Marrow)
- Biopsy, Surgical & Needle
- Cerebrospinal Fluid
- Cytobrushings & Washings, Endoscopic
- Cytology, Body Fluid (Pleural, Peritoneal, Pericardial)
- Cytology, Gynecologic
- Cytology, Sputum
- Cytology, Urine
- Tzanck Preparation
- Stool and Urine specimens for molecular testing
- Stool specimens for microbiology testing

Laboratory recommendations for collection of cytology specimens and bone marrow specimens are included in appendices A through K.

These specimens may possess potential biohazard risks and should be handled using standard blood and body fluid handling precautions and utilizing appropriate protective equipment (lab coat and gloves) in order to avoid contact with mucous membranes and cutaneous wounds.

### **Patient Preparation**

Some tests require specific patient preparation prior to obtaining a specimen in order to ensure accurate and clinically useful results. Some aspects pertaining to patient preparation are listed below. For some tests, there may be dietary restrictions that must be observed. For others, there are drugs that must be avoided prior to obtaining the specimen. This information is included as part of the specimen requirements for individual tests.

### **Labeling of Specimen Containers**

Each specimen must be labeled with two unique patient identifiers and include the patient's name, written exactly as it appears on the requisition (e.g., "Doe, John"), requisition number and/or date of birth.

**Failure to correctly label a specimen may result in specimen rejection.**

All specimens must be labeled with the following information:

- Patient's first and last name
- Nature, source, or body site of the specimen
- Serial number of specimen, if multiple specimens are submitted for the same patient

Optimally, the label should contain the name of the physician collecting the specimen and the office location where the biopsy was obtained.

**Requisition**

All specimens submitted to the laboratory must be accompanied by a valid requisition.

**Failure to correctly submit a valid requisition will delay specimen processing.**

A requisition *must* contain the following information:

- Patient's first and last name
- Patient's date of birth and sex
- Date of procedure
- Name of referring physician
- Clinical information and history required for professional evaluation
- A catalog of the specimens submitted, if more than one
- ICD-10 code (medical necessity)
- Tests requested
- Last menstrual period (for gynecological specimens)
- If an EMR-generated requisition is submitted in lieu of the QDx requisition, ensure the requisition information is included

Optimally, the requisition should also contain the following additional information:

- The name, phone number, fax number and address of the ordering physician's office location
- The patient's address and billing information
- A copy of the patient's insurance card may be attached to the requisition in lieu of filling in the information on the requisition
- The name of other physicians who are to receive a copy of the report

The information provided on the requisition must match the information on the specimen label.

**Failure by the submitter to match information on the specimen requisition with information on the specimen label will cause a delay in specimen processing and may result in specimen rejection.**

## Requisition for SARS-CoV-2 Laboratory Tests

Additional required requisition data specifically for SARS-CoV-2 laboratory tests are:

- Accession #/Specimen ID
- Patient age
- Patient race
- Patient ethnicity
- Patient residence county
- Ordering provider name and NPI (as applicable)
- Specimen source-using appropriate LOINC, SNOMET-CT, or SPM4 codes, or equivalently detailed alternative codes
- Date test ordered (date format)
- Date specimen collected (date format)

For SARS-CoV-2 reporting purposes, the following additional information is required:

- Test ordered-using harmonized LOINC codes provided by CDC
- Device identifier
- Test result-using harmonized LOINC and SNOMED codes, as defined by the laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 tests provided by the CDC.

## Specimen Submission:

The specimen for evaluation should be appropriately submitted to the laboratory by ensuring the following steps:

- The specimen is correctly labeled, and the requisition is completed
- The specimen container lid is tightly sealed to avoid specimen leakage or loss
- The specimen is placed in a secondary leak-proof, tightly sealed biohazard bag
- The requisition is placed in the outside pocket of the biohazard bag; and the specimen is placed inside the bag
- FROZEN specimens must be placed in a separate specimen bag along with a *separate requisition* form. Place the frozen specimen in a specimen bag with “Frozen Specimen” label applied and transport frozen. Submit a separate specimen for each frozen test requested. **Frozen specimens cannot be split for other tests.**
- Remove the protective strip and seal the specimen bag. This will protect the requisition from leakage. **Proper specimen packing helps to expedite your order.**
- The specimen biohazard bag is placed in the lockbox or specified location
- Notify the laboratory about a specimen(s) to be transported, if a routine scheduled pick-up is not already in place.

Optimally, the submitting facility should maintain a central specimen log which records:

- The reference laboratory where the specimen was sent
- The person responsible for preparing the specimen for submission
- Documentation that the courier was notified (person, date & time)
- When the specimen was received by the courier

- When the results of specimen analysis were received

A specimen receipt slip is completed by the laboratory courier, which identifies the number of specimens received from each office location. The office staff should monitor and retain these receipts to ensure a resource by which to track transfer of submitted specimens to the laboratory. Care should be taken to avoid exposure of specimens to temperatures below 32°F or exceeding 80°F. All specimens should be accompanied by a Daily Specimen Log that lists patient name, number of specimens submitted, type of specimen submitted, collection date, name of ordering physician and submitting location. Signature of the person submitting and receiving specimens and the date of specimen submission should also be included.

***Contact the laboratory regarding any exceptions, problems, or unusual circumstances.***

### **Specimen Transportation**

QDx-designated laboratory courier services are responsible for the transportation and shipping of specimens from the physician's office to the laboratory. Requests for specimen transportation received prior to 5:00 p.m. are processed during the day of notification. Requests for transportation received beyond this time will be processed on the following day unless a specific request by the office is made. STAT courier service may be available for certain areas. Specimens should be transported to the laboratory in a leak-proof, tightly sealed container without delay. The individual delivering the specimen should obtain a receipt for the specimen delivered.

### **FedEx**

Where courier services are not available clinicians may ship specimens via FedEx using a pre-printed FedEx air bill with QDx Pathology Services' account number on it.

**Materials and Supplies:** Absorbent/cushioning material (paper, foam, etc.), leak-proof/waterproof specimen containers (primary containers), FedEx Clinical Paks, plastic bag (Ziplock), etiologic agent/biomedical material label.

**Procedure:** Place specimen in a leak-proof/water-proof specimen container. If the specimen requires storage at refrigerated temperature, add an ice pack to the secondary insulated and leak-proof/water-proof container. Surround with absorbent material to absorb any potential leakage and place in a secondary leak-proof/water-proof container. Specimens requiring shipping at frozen temperatures should be frozen using a household or commercial freezer and transported to the laboratory on ice. Place in a FedEx Clinical-Pak for transportation.

**Fixed Tissue (Slides/Blocks):** Slides are to be placed in cardboard or plastic slide holders and cushioned by absorbent material to prevent breakage. Surround paraffin blocks with a layer of soft material (gauze) to prevent damage to the paraffin-embedded tissue. Place in a secondary, sealed water-proof container. Place in a FedEx Clinical Pak for shipping. No special labeling is required.

## **Specimen Receipt and Accessioning**

Specimens should be placed in the specimen box. The courier receipt should be placed in the bag containing all of the specimens from each collection location.

The accessioning clerk must frequently scan the work received in order to identify STAT specimens and improperly submitted specimens that require immediate attention. Each specimen bag must be inspected for leakage and other problems which will require special handling. If a biohazard contamination is present, institute appropriate containment procedures or contract a supervisor for specific instructions. All specimens received are assessed to ensure appropriate collection and submission instructions are followed.

- Each specimen bag must be opened individually and inspected, comparing the courier receipt for the office, the individual requisitions, and the specimen containers
- Coordinate all information, and identify discrepancies or discordant entries for immediate appropriate action
- Notify the submitting facility of significant discrepancies
- Document all discrepancies on the original requisition, and document notification and all corrective action taken on appropriate department forms

Record the following information on the Specimen Accession Log:

- Date specimen received
- Name of patient, first and last
- Name of physician
- Number of containers received and specific designations, as recorded on requisition
- Assigned accession number

Record the assigned accession number onto the requisition and onto each specimen container. If more than one specimen container is received for a single patient, an additional label should be affixed to each specimen container (A, B, etc.) according to the catalog of specimen designations present on the requisition.

## **General Criteria for Specimen Rejection**

Specimens received under the following conditions will not be tested:

- Expired collection device
- Inappropriate collection device/specimen type
- Unlabeled specimens
- Mislabeled specimens (patient ID not corresponding to test order)
- Leaking/broken specimen container
- Quantity of specimen not sufficient for test
- Specimens subjected to extensive delay or extreme temperatures
- All unacceptable specimens are documented in the laboratory computer system and reported on the patient report, stating test affected and the reason the test could not be performed
- Specimens subjected to extensive delay or extreme temperatures

## Specimen Rejection

The laboratory will not process a specimen if the identity of the specimen cannot be determined or the integrity of the specimen is compromised. The following circumstances will cause absolute rejection of the specimen:

- The specimen is received unlabeled and without requisition or any indication regarding the identity of the patient.
- Any pap smear received unlabeled, regardless of other factors.
- Excessive loss or damage to a specimen likely to render diagnosis impossible.
- Excessive contamination of the outer specimen container or biohazard bag of a sufficient nature to risk the health of laboratory workers.
- Sufficient disparity between information contained on the requisition and the specimen label which makes the integrity of the specimen questionable.

Specimens may be received and processed with reservation when the following circumstances occur:

- Minor ambiguity exists between the information on the requisition and the specimen label.
- Information not required for technical processing, but required for registration, billing or professional interpretation is incomplete or missing.
- A specimen (other than a cervical pap smear) is received unlabeled but is accompanied with a complete requisition in the same biohazard bag.

## Procedure for Handling Specimens for Potential Rejection

- Identify the specimen as meeting criteria for rejection or processing with reservation.
- Notify the appropriate supervisor and follow the instructions given.
- Record the occurrence in the specimen rejection/exceptional event log, action taken and all appropriate notifications.
- If the specimen is absolutely rejected, the pathology assistant or pathologist must notify the submitting physician.
- All specimens should be accessioned, and a report should be issued with the appropriate statement:

*Specimen rejected due to* \_\_\_\_\_

*Specimen processed with reservation due to* \_\_\_\_\_

All communications must be documented completely in the communication section of the report. All other actions should be documented in the exceptional event/specimen rejection log.

## Health and Safety Precautions

Specimens should be handled in a safe manner and according to applicable legal requirements. Information on safe specimen handling may be obtained from the U.S. Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC). In handling human specimens, the goal is to protect healthcare workers from exposure to blood and to potentially infectious body fluids.

Beside following other specimen preparation procedures included in this guide, health professional personnel should, prior to sending a specimen to the laboratory, ensure that there is no leakage or

visible contamination outside the specimen container and that no needles or other sharps are in the package that could cause injury or pathogenic exposure to anyone handling or opening the package and inner containers. Leaking containers pose a health hazard. Special precautions must be taken while using needles or disposing of biological material and contaminated specimen containers. Attention to recommendations controlling safety of patients and health care professionals should continue throughout the specimen collection and analysis procedure.

Safety regulations specify that specimens must be in proper containers for transport to the testing laboratory. Specimens in syringes, with or without needles, by law cannot be transported in standard specimen bags. Do not submit needles attached to syringes.

## **SURGICAL PATHOLOGY & CYTOPATHOLOGY SPECIMEN COLLECTION AND HANDLING**

### **A. Aspirate, Bone Marrow:**

- Collect the marrow aspirate using standard technique.
- Place a few drops of aspirate into EDTA/normal saline, which is prepared by adding 5 mL of normal saline to 5-7 mL lavender stopper Vacutainer tube.
- Inspect for marrow particles (spicules); if not present, repeat marrow aspiration.
- Prepare four to ten marrow particle smears; allow time to sufficiently air dry.
- Allow the remaining marrow to clot within the syringe for one hour; transfer the marrow clot to a 10% buffered formalin specimen container.
- Collect the marrow core biopsy using standard technique (optional).
- Discharge the core aseptically onto a clear paper towel, avoiding contamination of the biopsy bottle.
- Touch-preps pick up the core biopsy with forceps, avoiding tissue crushing, and prepare five to ten on two microscope slides; allow time to sufficiently air dry.
- Place the core biopsy into a 10% buffered formalin specimen container.
- Label all slides and specimen containers with the patient's last name; include the site of biopsy if more than one site is collected.
- Place the slides in appropriate slide containers and label these containers with the patient's full name and site of biopsy.
- Submit all slides and specimens together with the requisition according to standard policy.

### **Special handling instructions:**

- A recent CBC report should be submitted or collected.
- A reticulocyte count should be obtained if the patient displays anemia.
- Serum iron, biochemistry profile, protein, and immunoglobulin studies should be submitted.
- Peripheral blood smears (preferably two) for Wright staining should be submitted.
- Complete clinical history is required, including preoperative diagnosis and copies of prior relevant pathology reports.

## B. Aspirate, Fine Needle: (Non-Marrow)

### Preparation:

Open up the Fine Needle Aspiration kit and remove one plastic slide container with slides. Lay out four slides, frosted side up. Label the patient's name and aspiration site on the frosted portion of each slide.

### Specimen Collection

#### Guidelines for the collection of fine needle aspirations of masses, nodules or cystic lesions:

1. Insert a 22-25 gauge needle into the lesion. Apply gentle suction with a 10 cc syringe or an aspiration gun.
2. Move the needle in an up and down motion 2-3 times at different angles. Discontinue aspiration attempt when blood is visualized within the hub of the needle.
3. Gently release suction from the syringe barrel before the needle is removed from the mass. This ensures that the sample remains in the hub and needle, and is not dispersed into the barrel of the syringe.
4. Remove the needle from the syringe. Withdraw the plunger and reattach the needle.

### Specimen Fixation

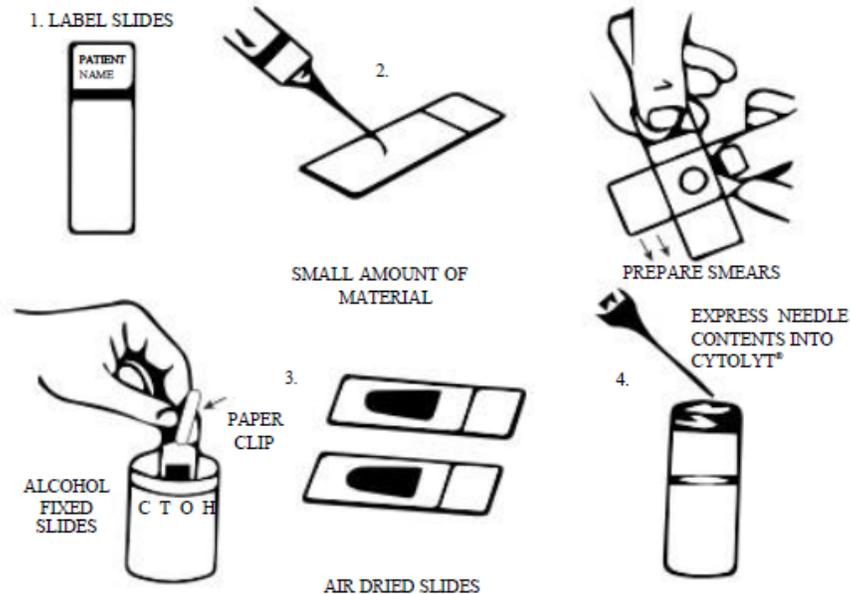
If the aspiration is fluid from a cystic lesion, do not prepare slides instead express all the material into the CytoLyt collection tube.

If a core biopsy is collected, place sample into 40 mL formalin jar.

#### Slide Preparation (prepare 2 slides at a time):

1. Label slides with patient name and aspiration site.
2. Express a small drop (1-2 drops only) of the aspirated material from the needle shaft onto the center of the frosted slide of one of the labeled glass slides. This procedure may be accomplished by removing the needle and pulling back the plunger, then reapplying forced air pressure until sufficient sample is expressed onto the slide.
3. Turn over the frosted side of the second labeled slide on top of the slide containing the aspirated material and spread/smear the material between the two slides in a circular manner.
4. Draw the slides apart in opposite directions. **Immediately** place one slide into the purple top plastic cyto-vial with alcohol fixative (do not allow the slide to air dry).
5. Take the other slide and let air dry completely for approximately one minute. Place into empty plastic slide holder.
6. If the syringe contains additional specimen from the aspirate, then a second set of slides can be prepared repeating steps 1 – 4.
7. Once a sufficient number of slides have been prepared, express any remaining material into the CytoLyt collection tube. Place the needle with the syringe attached into the CytoLyt solution, and apply back and forth suction to rinse thoroughly.
8. The fine needle aspiration procedure can be repeated up to three times from the same site in order to obtain adequate material.

9. If a lymph node or mass is aspirated and a Lymphoproliferative Disorder is suspected (i.e., Lymphoma), a separate additional aspiration should be collected and submitted in RPMI media. Pour 10 mL of RPMI medium into the blue top RPMI tube. Express the entire sample into the medium.
10. RPMI should be kept refrigerated at all times and specimen should be shipped on ice pack.



### C. Biopsy, Surgical & Needle:

- Place the biopsy into sufficient 10% buffered formalin (at least 10 parts formalin for every one part specimen).
- Label all specimen containers and submit, together with the requisition, according to standard policy.

### D. Cerebrospinal Fluid:

- Collect cerebrospinal fluid using standard technique.
- Partition CSF for culture, cell counts and chemistry tests into appropriate tubes and submit to appropriate reference laboratory providing these services.
- Place remaining CSF (collect as much as possible) into a sterile tube (no CytoLyt), preferably on ice.
- Label the specimens and submit, together with the requisition for cytologic analysis, according to standard policy.
- Submit via courier to QDx Pathology Services.

### E. Cytobrushings & Washings, Endoscopic:

- Prepare not more than two direct cytobrush smears by rolling the cytobrush onto a frosted glass slide, covering a central area not exceeding 1 cm<sup>2</sup>.

- Fix the slide by immersion into 95% ethanol within 10 seconds of preparation.
- Using wire cutters, sever the cytobrush above its attachment so that the brush freely falls into the CYTOLYT® CYTOLOGY FIXATIVE container (30 mL CytoLyt® fixative) available from the Cytology Laboratory. The purpose of the CytoLyt® Solution is for fixation and reservation of cytologic specimens. Improper fixation or delay in processing may lead to possible decreased cellular preservation and less than optimal or possible unsatisfactory diagnostic results.
- Label all slides with the last name of the patient and the site of collection.
- Label all specimen and fixative containers with the full name of the patient and the site of collection.
- Submit all slides and specimen containers together with the requisition according to standard policy.

#### **F. Cytology, Body Fluid (Pleural, Peritoneal, Pericardial):**

- Collect the fluid into a clean specimen container suitable to hold the amount of specimen collected. The container must be sterile if microbial cultures are to be performed.
- Submit the specimen for microbial studies to the appropriate reference laboratory providing microbiology reference testing ASAP. Submit an additional specimen in CytoLyt® fixative or on ice to QDx Pathology Services for cytology processing.
- Ensure that the specimen is adequately labeled and a valid cytology requisition accompanies the specimen.
- Enclose the specimen in a biohazard container or bag and arrange for courier pick up and transport to the laboratory ASAP.

#### **Standard Instructions for Use of Commercial Spray Fixative:**

- Hold the fixative spray can 10 inches away from the slide to be fixed.
- Spray the slide evenly and completely in a gentle, sweeping motion; avoid a jet effect which will alter the cellular distribution.
- Allow the slide to dry for three minutes prior to placing the slide in a holder.
- PRECAUTIONS: Use the spray in a well ventilated room. Avoid direct inhalation.

#### **G. Cytology, Sputum (Patient Instructions):**

Your physician has requested a cytological examination of sputum. Only a properly collected specimen can be satisfactorily examined. Please follow the instructions listed below for collecting a specimen. Specimens may be collected for one, two or three days, depending on your physician's request. The specimens should be collected in the morning before you brush your teeth, use mouthwash or eat.

1. Remove the lid to the sputum cytology specimen (CytoLyt® fixative) container provided to you.
2. Cough deeply and expectorate sputum (not saliva) into the container. An adequate amount of sputum is approximately one teaspoon.
3. Replace the lid tightly onto the specimen container.
4. Bring the specimen container with sputum and the requisition to your doctor's office or to QDx Pathology Services within four hours.

5. The results of your test will be forwarded to your physician, who will then discuss them with you. It is important that the sputum and fixative be mixed together without spillage. If fixative is spilled prior to use do not use that container. Instead, obtain a new specimen container which has the appropriate volume of fixative.
6. The Cytolyt® fixative in the container should not come in contact with the eyes or skin. If the fixative contacts your eyes or skin, flush the area with water. Contact your doctor if problems develop.

## **UROVYSION AND URINE CYTOLOGY SPECIMEN COLLECTION AND HANDLING SURGICENTER AND PHYSICIAN OFFICE COLLECTION**

### **H. Cytology, Urine:**

In order to enhance the urine collection process, QDx Pathology Services is providing a Urine Cytology and/or UroVysion™ FISH specimen container prefilled with 30 cc of PreservCyt® solution. The specimen container is used for the collection of urine samples for cytology and/or UroVysion™ FISH testing from the same specimen. The PreservCyt® solution is uniquely designed to act as the ideal transport and preservative solution for urine specimens sent to the laboratory for cytological examination and/or UroVysion™ FISH (fluorescence *in situ* hybridization) testing. Only a properly collected specimen can be adequately tested. Please follow the instructions listed below for collecting a urine sample.

### **Urine Cytology and/or UroVysion™ fluorescence *in situ* hybridization (FISH) Testing Profile**

The Abbott Vysis UroVysion™ FISH Assay is an FDA approved tumor marker test designed for the molecular detection of cancer in the urinary tract in patients with hematuria suspected of having bladder cancer and for following up patients with a history of bladder cancer. Physicians who request a urine specimen for both cytology and/or UroVysion™ FISH testing or just for UroVysion™ FISH testing only can use the same specimen container for these tests. The ICD-10 codes valid for UroVysion™ FISH testing include R31.9, hematuria and C67.9, bladder cancer. Please enter the appropriate ICD-10 code on the Uropathology requisition form when submitting specimens for UroVysion™ FISH and/or Cytology testing.

### **Specimen Collection Procedure: UroVysion™ FISH and/or Cytology**

**Instructions for Use:** See below Steps 1-8:

Step 1: Collect the patient's urine in the collection cup using your routine office procedure. The ideal volume of patient specimen is 35-60 cc of urine. If the patient urine volume collected exceeds 60 cc, pour off excess urine. A minimum volume of 33 cc of patient urine is required to perform the FDA approved Vysis UroVysion assay.

**Note:** Fresh urine for UroVysion™ FISH and/or Urine Cytology can be mixed with a 2:1 ratio of patient urine-to-PreservCyt® solution and stored for up to 48 hours before processing. Since the urine containers supplied by QDx Pathology Services are pre-filled with 30 cc of PreservCyt® solution, the maximum amount of patient urine that can be added to this container is 60 cc, giving a total volume of 90 cc. See below the additional specimen collection instructions for minimum and maximum urine volumes needed for urine cytology testing only at the bottom of this page.

Step 2: Open the UroVysion™ FISH and/or urine cytology specimen container.

Step 3: Thoroughly stir and mix the urine sample, and then add the urine to the pre-filled specimen container, containing the 30 cc of PreservCyt® solution (adjust the volume of PreservCyt® as needed to achieve the 2:1 urine-to-PreservCyt® volume).

Step 4: Record the patient's name and place the specimen tracking number on the specimen container. The peel off patient specimen tracking number is located on the requisition.

Step 5: Important step: Tightly secure the specimen cover on the specimen container to prevent leakage of the specimen.

Step 6: Place the patient's specimen container into a biohazard specimen bag. Tightly seal the bag.

Step 7: Fold and place the Uropathology requisition (completely filled out with patient demographics including name, physician, specimen source and test requested) into the specimen transport biohazard bag.

Step 8: The preferred storage and shipping conditions for UroVysion™ FISH specimens are on ice packs, but specimen may be stored and shipped at temperatures up to 25°C (77°F). Urine specimens stored in PreservCyt® solution under these conditions have been shown to be stable for one week. However, it is recommended that urine specimens be shipped to QDx Pathology Services within 24 hours after collection.

## **Additional Specimen Collection Instructions**

### **Urine Cytology Testing Only:**

As a general rule for urine cytology only, 35 – 60 cc of patient urine is desirable. However, it may not always be possible for some patients to void larger quantities of urine. This may be a significant factor for some patients with low volume output or difficulty passing urine. In these cases, any amount of urine for cytology testing only will be accepted and processed by the laboratory. However, lesser volumes of patient urine cannot guarantee adequate cytology results.

**Warning:** If the PreservCyt® fixative solution comes in contact with your eyes or skin, flush the area with water. Contact your physician if problems develop.

If you have any questions, please contact the Cytology/UroVysion™ FISH Laboratory at QDx Pathology Services at 1-866-909-7284.

#### **I. Tzanck Preparation:**

- Identify the vesicle for examination.
- Using aseptic technique, remove the vesicle roof with forceps and a scalpel.
- Curette the base of the vesicle with scalpel blade.
- Spread the curette sample from the blade surface onto a clean microscope slide.
- Allow the preparation to adequately dry.
- Label the slide with the patient's first and last name.
- Place the slide into a cardboard slide holder.
- Complete an appropriate cytology requisition.
- Place the slide holder and requisition into a biohazard bag.
- Submit to the laboratory in the standard manner.

#### **PRECAUTIONS**

*These specimens are likely to contain infectious Herpes virus, which can cause serious hazard of infection to health care workers handling this specimen. Use vigilant blood and bloody fluid precautions in order to avoid contact with mucous membranes or skin wounds. Always use latex gloves, gown, eye shields and mask when collecting this specimen.*

#### **J. Nipple Secretions:**

- Express nipple secretion onto a clean glass microscope slide.
- The secretions must be thin and transparent.
- If the secretions are copious or thick, gently spread thinly over the slide by applying another slide over the surface in a gliding manner without undo physical force.
- Allow the secretions to dry adequately and immediately fix with Safetex spray fixative or place in a slide transport vial of 95% ETOH. Alternatively, nipple secretions could be collected with a cotton swab and the swab broken off and immediately placed in a container of CytoLyt® solution.
- Label the specimen container vial or label the slide and place it into a cardboard slide holder.
- Complete a cytology requisition fully.
- Place the specimen and requisition into a biohazard bag and submit to the laboratory according to standard procedure.

### **Gynecologic Cytopathology – Sampling of Female Genital Tract (Guidelines for Pap Test Collection and Transport to the Laboratory)**

#### **K. Cytology, Gynecologic:**

##### **Purpose:**

Cytologic evaluation of the female genital tract requires proper technique in collecting and preserving the sample. The purpose of this policy is to provide the proper guidelines necessary to collect both Conventional Pap Smears and the Liquid-based ThinPrep® Pap Test.

**Policy:**

This policy provides guidelines in the collection, handling and transport of gynecologic (Pap) tests for cytologic evaluation and HPV/CT-NG testing.

**Specimen:**

Gynecological (Pap) specimens

- Conventional Pap Smears
- Liquid-based ThinPrep® Pap Test

**Equipment and Materials:**

1. Unlubricated vaginal speculum
2. Saline solution
3. Spatula
4. Cervical Brushes
5. Papette™ Broom Brush
6. Medscand Sample Collection Kits (Cervical Brush and Spatula)
7. Accellon® Combi bio sampler
8. Frosted-end Slides and slide folders
9. Surgipath or Safetex® spray fixative or any other approved spray fixative
10. Cytoc PreservCyt® ThinPrep® Vials
11. Cytology Gynecologic Requisition

**Principle of the Procedure**

Gynecological specimens should be obtained prior to bi-manual examination. The recommended sampling procedure is to use an unlubricated vaginal speculum moistened with warm tap water or saline solution. The examiner should inspect the entire vaginal vault noting suspicious areas in the vaginal vault for later palpation, and collect direct-scrape samples from such areas, preferably using a spatula. Lateral vaginal wall specimens may also be collected, at this time, for determination of hormonal status.

**Test Procedure**

There are currently two types of Pap tests offered by QDx Pathology Services. In addition, QDx Pathology Services offers HPV and CT/NG testing by molecular testing methodology off of the same ThinPrep® vial.

- Conventional Pap Tests (Smears)
- Liquid-based ThinPrep® Pap Test
- Liquid-based ThinPrep® Pap Test with HPV and/or CT/NG testing

### **Ancillary Tests:**

- **Candida albicans, Candida glabrata**
- **Chlamydia trachomatis/Neisseria gonorrhoea (CT/NG)**
- **Gardnerella vaginalis**
- **Human Papillomavirus (HPV)**
- **Trichomonas vaginalis**

The above-mentioned ancillary tests can be performed from the same specimen vial. The HPV test can be requested by checking off the appropriate box on the Gynecologic Pathology requisition form. The options include HPV testing by reflex (for abnormal Paps with a diagnosis of ASC-US and LSIL) or as a test for all patients over 30 years of age, regardless of the cytologic diagnosis. CT/NG can be requested up front by checking off the box for CT/NG testing. Those physicians or clinicians that would like all of their abnormal Pap's tested for HPV can submit a letter of authorization for reflex HPV testing for High and Low Risk HPV types.

### **Conventional Pap Test: (Smears)**

Evaluation of the uterine cervix requires sampling of the cervix and the endocervical canal. The following procedures are recommended for cervical and endocervical sampling.

1. Use the CytoBrush by gently inserting it into the endocervical canal, past the squamocolumnar junction. One can also use the CytoBrush for sampling the ectocervix, if desired.
2. To use a Papette™ broom brush insert the long central bristles into the endocervix and continue inserting the instrument until the short lateral bristles make firm contact with ectocervix. Rotate the instrument a minimum of three and preferably five full rotations in one direction only and then withdraw it.
3. To use a spatula, insert the extended tip into the endocervical canal until the short lip contacts the ectocervix and rotates at least three full rotations, and preferably five full rotations in one direction. Alternatively, one can use a Cyto Brush to sample the endocervix and a spatula without an extended tip to sample the ectocervix and the vagina.
4. To use an Accellon® Combi bio-sampler, insert the long central spike into the endocervical canal until the lateral brushes contact the ectocervix. Then rotate the device one full turn in each direction.
5. To use a cotton-tip swab, moisten it with saline and then insert the swab into the endocervical canal and rotate it vigorously. Withdraw the swab and then use it to make a direct-scrape collection from the ectocervix.

### **Note:**

The use of any combination of the above devices is generally acceptable and should produce adequate results. The use of a non-moistened swab is not recommended.

In sampling the ectocervix, the examiner should remember that excoriations are common, and these produce an often obscuring amount of bleeding. If the examiner plans a biopsy, then he should collect the cytological sample prior to any biopsy, loop, electrocautery or LEEP conization.

After collecting the specimen, spread the cellular material quickly and evenly onto a designated area on a properly labeled slide (**Note: Full Patient Name is required**). The Accelon® Combi bio-sampler can be collapsed by a simple forward motion of its outer sleeve in order to facilitate the spreading of the sample on the slide.

Fix the slide immediately by spraying it with SurgiPath (SurgiPath Medical Industries, Inc., Richmond, IL) or Safetex Cytology Spray Fixative (Andwin Scientific, Canoga Park, CA) or any commercially available fixative. Air-drying artifacts can distort the cellular detail within 10 seconds.

## Liquid-Based Thinprep® Pap Test

There are two methods for collecting the ThinPrep Pap tests:

- **Papette™ Collection Kit**
- **Medscan Sample Collection Kit**

### The Papette™ Collection Kit

The *PAPETTE™* is the most gentle, yet effective means of simultaneously taking both ectocervical and endocervical cell samples.

1. Contact the cervix with the *PAPETTE™* and insert the central bristles into the cervical canal deep enough to allow the shorter bristles to fully contact the ectocervix.
2. While maintaining gentle pressure in the direction of the cervix, rotate the brush five times in a clockwise direction.
3. Rinse the brush into the PreservCyt® solution for use with the ThinPrep® Pap Test™ by pushing the brush into the bottom of the vial 10 times, forcing the bristles apart. Swirl the brush vigorously to further release material. Discard the collection device.
4. Tighten the PreservCyt® Vial cap so that the torque line on the cap passes the torque line on the vial.
5. Dispose of the *PAPETTE™* in accordance with local Medical Hazardous Waste practices.

### The Medscand Sample Collection Kit

Medscand Sample Collection Kit containing Cytobrush® Plus GT cell collector gentle touch tip and Pap Perfect® plastic spatula are single use devices. Discard after use.

**Caution: For Use Only by Medical Professionals**

#### Indications for Use:

Medscand sample collection kit is used to collect specimens from the exo- and endocervix for the ThinPrep® Pap Test.

**Contraindications:**

Do not use Cytobrush® Plus GT on pregnant patients.  
Do not use Cytobrush® Plus GT for endometrial sampling.

**Warnings:**

Do not insert Cytobrush® Plus GT too far into the endocervix; brush bristles should be visible at the os of the cervix. Do not over-rotate sampling devices; avoid excessive bleeding.

**Adverse Reactions:**

No known adverse reactions.

**Sampling Instructions:**

With patient in lithotomy position, expose cervix using a vaginal speculum moistened with warm water. Visually examine vaginal mucosa and cervix for lesions, ulceration or discharge. Document findings of the examination on patient's record, and communicate the relevant clinical findings to laboratory for optimum cytological interpretation.

1. Collect specimen from the exocervix, select contoured end of plastic spatula and rotate it 360° around the entire exocervix while maintaining tight contact with exocervical surface. Remove spatula.
2. Rinse contoured end of plastic spatula in a vial of PreservCyt® Solution (supplied by Cytec Corporation) by swirling vigorously 10 times. Discard plastic spatula. Place cap on vial until step 4.
3. Insert Cytobrush® Plus GT device into the endocervix until only the bottommost bristles are exposed. Slowly rotate ¼ to ½ turn in one direction. Remove device. Do not over-rotate. Additional rotation may cause bleeding and contaminate device.
4. Rinse the Cytobrush® Plus GT device in the PreservCyt® Solution by rotating the device in the solution ten times while pushing it against the wall of the vial. Swirl the device vigorously to further release material. Discard device.
5. Tighten the PreservCyt® vial cap so that the torque line on the cap passes the torque line on the vial.

**Submission of Gynecologic Samples to Laboratory**

Once the sample has been collected (either by the Thinprep® Pap Test method or by the Conventional Pap Test method), place the collected and properly labeled Pap test along with a completely filled out gynecologic requisition (including tests requested-ThinPrep® Pap Test, HPV, CT/NG, etc.) into a biohazard bag. Place all samples in a larger collection bag and put samples in the outside collection box to be picked up by QDx Pathology Services couriers or send by overnight express delivery (DHL, FedEx, etc.).

**Warnings and Precautions:**

Read and follow all package inserts concerning any reagents or chemicals used in this test procedure.

### **Reagent Preparation and Storage:**

All chemicals and reagents used for this test are purchased fully prepared for use. These chemicals are stored in the laboratory safety cabinets or designated areas until ready for use. All testing personnel must follow safety guidelines in handling, use and proper storage of hazardous chemicals and reagents.

### **Quality Control:**

The Quality (Adequacy) of a Pap Test Sample (Conventional or ThinPrep®) is based on the presence of an adequate number of epithelial cells present in the sample. Other factors include but are not limited to labeling (Full Patient Name on slide or specimen), fixation, excessive obscuring inflammation, blood, debris, lubricant and other factors as outlined in the Bethesda 2001 guidelines. The laboratory director and/or his designee(s) shall periodically monitor compliance with both specimen collection, specimen handling and specimen adequacy in accordance with the performance improvement monitors established for the Cytopathology Service.

### **Infection Control and Safety:**

Practice universal precautions. Wear the appropriate personal protective equipment, including gown, latex gloves, and facial protective gear to protect the face and eyes. Read the safety data sheets (SDS) on all reagents and fixatives. Keep all reagent containers properly sealed when not in use.

1. Bibbo, M.: Comprehensive Cytopathology, 2<sup>nd</sup> Edition, Chapter 32, Philadelphia, W.B. Saunders and Company, 1997, pp. 881-906.
2. "Instructions for Use of the Medscand Sample Collection Kit", Hollywood, Florida: Medscand (USA), Inc.
3. "Instructions for Use of the Papette™ Collection Kit", Orange, Connecticut: Wallach Surgical Devices, Inc., 5/2000.
4. "Instructions for Use of the Accellon® Combi Cervical BioSampler". Hollywood, Florida: Medscand (USA), Incorporated, 1994.
5. "Instructions for Use of the Pap-Pak Kit", Camarillo, California: Medical Packaging Corporation, 1992.
6. "Instructions for the Use of the Cervix-Brush Cervical Samples", Wilton, Connecticut: Unimar of America, 1990.

## **MOLECULAR PATHOLOGY TESTS**

### **UROGENITAL TRACT PATHOGENS**

#### **Bacterial Vaginosis (BV)/Gardnerella vaginalis, NAA (LDT)**

**CPT code:** 87511

**Expected Turnaround Time:** 3-5 days. Turnaround time is defined as the usual number of days from the date of specimen receipt in the laboratory to when the result is released to the ordering provider.

**Use:** The intended use for the Bacterial Vaginosis (BV) LDT is for the detection of organisms associated with bacterial vaginosis/vaginitis from ThinPrep® specimens of symptomatic women.

**Limitations:** This test was developed, and its performance characteristics determined by QDx Pathology Services. It has not been cleared or approved by the Food and Drug Administration. However, such clearance/approval is not required as the laboratory is regulated and qualified under CLIA to perform high-complexity testing. The test results are not intended to be used as the sole means for clinical diagnosis or patient management. Clinical correlation and physician judgement is required when making a diagnosis or treatment decisions.

**Methodology:** Nucleic acid amplification (NAA)

**Specimen Requirements:**

**Specimen:** Clinician-collected cervical specimens in ThinPrep® vial

**Volume:** Entire ThinPrep® vial

**Container:** ThinPrep® Cytology vial

**Collection: ThinPrep® Vial:**

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Transport & Storage:** Room temperature up to 30 days

**Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted from male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen, specimen more than 30 days old in ThinPrep® vial.

**BD Affirm™ VPIII Microbial Identification Test**

**CPT codes:** 87480, 87510, 87660

**Test Includes:** Candida, Gardnerella vaginalis and Trichomonas vaginalis

**Specimen:** Vaginal fluid

**Volume:** Swab placed in Affirm™ transport system

**Container:** Affirm™ VP88 Ambient Temperature Transport System (ATTS)

**Specimen Collection & Transportation:**

Specimen collection is a critical step. Personnel collecting vaginal fluid specimens should be well trained to minimize the possibility of inadequate specimens. For specimen collection, use only the Affirm™ VP88 Ambient Temperature Transport System, the Affirm™ VP88 Sample Collection Set or the swabs provided in the Affirm™ VP88 Microbial Identification Test Kit.

**Vaginal Sample Collection:**

1. Label the Sample Collection Tube (SCT) with the patient identification information. Include the time the sample was collected.
2. Place the patient in position for a pelvic examination. Insert a speculum into the vagina to permit visualization of the posterior vaginal fornix.
3. Using the sterile swab, obtain a sample from the posterior vaginal fornix. Twist or roll the swab against the vaginal wall two or three times, ensuring the entire circumference of the swab has touched the vaginal wall. Swab the lateral vaginal wall while removing the swab.
4. Immediately place the swab into the Sample Collection Tube (SCT).
5. With the swab touching the BOTTOM of the collection tube, grasp the pre-scored handle of the swab just above the top of the tube and bend until the swab breaks. When the swab is fully inserted into the collection tube, the score mark on the swab is approximately one centimeter above the top of the collection tube. Discard the broken handle into an infectious waste container.
6. Place the cap over the exposed end of the swab and firmly press the cap onto the tube. The cap will “snap” onto the tube when it is properly seated. The total time between sample collection and proceeding with sample preparation should be no longer than 72 hours when the specimen is stored at ambient conditions (15°C to 30°C). The system has also been qualified for transport use at refrigerated conditions (2°C to 8°C).

**Storage Instructions:**

Maintain specimen at room temperature for 72 hours.

**Causes for Rejection:**

Specimen collected or transported other than previously described; specimen more than 72 hours old.

**Candida albicans & Candida glabrata, NAA (LDT)**

**CPT code:** 87481

**Expected Turnaround Time:** 3 - 5 days. Turnaround time is defined as the usual number of days from the date of specimen receipt in the laboratory to when the result is released to the ordering provider.

**Use:** The Candida Vaginosis (CV) LDT assay is used for the detection of organisms associated with Candida vaginosis/vaginitis (Candida albicans, Candida tropicalis, Candida parapsilosis, Candida dubleniensis and Candida glabrata) in ThinPrep® specimens collected from symptomatic women.

**Limitations:**

The test was developed and its performance characteristics determined by QDx Pathology Services. It has not been cleared or approved by the Food and Drug Administration. However, such clearance/approval is not required as the laboratory is regulated and qualified under CLIA to perform high-complexity testing. The test results are not intended to be used as the sole means for clinical diagnosis or patient management. Clinical correlation and physician judgement is required when making a diagnosis or treatment decisions.

**Methodology:** Nucleic acid amplification (NAA)

**Specimen Requirements:**

**Specimen:** Clinician-collected cervical specimens in ThinPrep® vial

**Volume:** Entire ThinPrep® vial

**Container:** ThinPrep® Cytology vial

**Collection: ThinPrep® Vial:**

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do not over-rotate the brush. Then rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the Thin Prep® container so that the torque line of the cap passes the torque line on the vial.

**Transport & Storage:** Room temperature up to 30 days

**Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted from male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen, specimen more than 30 days old in ThinPrep® vial.

## **Chlamydia trachomatis/Neisseria gonorrhoea, NAA**

**CPT codes:** 87491, 87591

**Use:** Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

### **Limitations:**

**Note:** Specimens cannot be collected and used for *Chlamydia/Neisseria* and routine chemistry or urine culture. *Chlamydia/Neisseria* requires use of a first catch (initial stream of urine that will wash organisms out of the urethra of men or women). Routine chemistry and bacterial or fungal culture require use of the clean catch midstream collection technique.

**Methodology:** Nucleic acid amplification (NAA)

**Special Instructions:** Specify the exact specimen source/origin (e.g., endocervical)

**Expected Turnaround Time:** 2-3 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

### **Specimen Requirements:**

**Specimen:** Endocervical, vaginal, or male urethral swab; first-void urine (patient should not have urinated for one hour prior to specimen collection); or cervical cells in liquid cytology vial.

**Volume:** Endocervical and male urethral swab specimens, vaginal swab specimens, throat and rectal swab specimens, PreservCyt Solution liquid Pap specimens, and female and male urine specimens.

**Container:** Aptima® Multitest swab, Aptima® Vaginal swab, Aptima® urine specimen transport; ThinPrep® liquid cytology vials.

### **Collection:**

#### **Option 1. Aptima® Endocervical, Male Urethral or Vaginal Swab**

**Endocervical swab:** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents. Recap the swab specimen transport tube tightly.

**Male urethral swab:** The patient should not have urinated for at least one hour prior to specimen collection. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2 to 4 cm into the urethra. Gently rotate the swab clockwise from two to three seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly.

**Vaginal swab Care provider specimen:** Collect vaginal fluid sample using the Aptima® Multitest or Vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. **Patient self-collection:** Partially open the package of the Aptima® Multitest or Vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube, and carefully break the swab shaft against the side of the tube. Tightly screw on the cap.

## Option 2. Urine Specimen

The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservative. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Female patients should **not** cleanse the labial area prior to providing the specimen. Add urine to the Aptima® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL).

## Option 3. Liquid-based Cytology Specimen

### ThinPrep® Vial – Broom or Brush/Spatula

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush  $\frac{1}{4}$  to  $\frac{1}{2}$  turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

### **Specimen Transport and Storage before Testing:**

1. **Urogenital swab specimens:** After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed with the Aptima® Combo 2 Assay within 60 days of collection.
2. **Extragenital (throat and rectal swab specimens):** After collection, transport and store swab in the swab specimen transport tube between 4°C and 30°C. Specimens must be assayed with the Aptima® Combo 2 Assay within 60 days of collection.
3. **Urine specimens:**
  - a. Urine samples that are still in the primary collection container must be transported to the lab at 2°C to 30°C. Transfer the urine sample into the Aptima® urine specimen transport tube within 24 hours of collection.
  - b. After collection, transport the processed urine specimens in the Aptima® urine specimen transport tube at 2°C to 30°C. Transfer the urine sample into the Aptima® urine specimen transport tube within 24 hours of collection.
4. **PreservCyt® Solution liquid Pap specimens:**

PreservCyt® Solution liquid Pap specimens intended for CT and/or GC testing must be processed for cytology and/or transferred to an Aptima Specimen Transfer tube within 30 days of collection when stored at 2°C to 30°C.

### **Herpes Simplex Virus Types 1 & 2, NAA**

**CPT code:** 87529x2

**Expected Turnaround Time:** 2 - 4 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Use & Methodology:** The Aptima® Herpes Simplex Viruses 1 & 2 assay (Aptima® HSV 1 & 2 assay) is an *in vitro* diagnostic nucleic acid amplification test (NAAT), using real time transcription-mediated amplification (TMA), for the qualitative detection and differentiation of herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) messenger RNA (mRNA) in clinician-collected swab specimens from anogenital skin lesions. The assay is intended for use with swab specimens placed in Aptima® specimen transport medium (STM). The Aptima® HSV 1 & 2 assay is intended for use as an aid in the diagnosis of HSV-1 and/or HSV-2 infections in symptomatic male and female patients.

### **Specimen Requirements:**

**Specimen:** Vesicular fluid, ulcerated lesions, vaginal or endocervical cells

**Volume:** One Aptima® swab

**Minimum Volume:** One Aptima® Multitest swab

**Container:** Aptima® Multitest Swab

**Collection: Lesion/vesicle swab:** Unroof or scrape the lesion with an Aptima® swab.

**Endocervical swab in Aptima®:** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shafted swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shafted swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the score line using care to avoid splashing of the contents. Recap the swab specimen transport tube tightly.

**Note:** Handle all specimens as if they contain potentially infectious agents. Use Universal Precautions. Refer to the appropriate specimen collection kit package insert for specific collection instructions (Aptima® Multitest Swab Specimen Collection Kit), for specimens collected in STM. Specimens must be tested with the Aptima® HSV 1 & 2 assay within 36 days of collection.

**Storage Instructions:** Maintain specimen at room temperature.

**Causes for Rejection:**

Urine specimen; specimen transported under inappropriate conditions; bacterial swabs; unlabeled specimen or discrepancy between specimen label and test request form; Aptima® COMBO 2 (AC2) swab specimen transport tube with two swabs or swab not supplied by Gen-Probe® or no swab; ProbeTec™ swabs; female urethral swab. Aptima® swab transports >7 days from collection.

**Limitations:**

This test is intended for use as an aid in the diagnosis of herpes simplex virus (HSV) infections with active viral shedding; it also differentiates HSV-1 from HSV-2. Negative HSV NAA results indicate lack of viral shedding, but do not confirm absence of previous infection.

**Human Papillomavirus (HPV) DNA Detection with Reflex to HPV**

**Genotypes 16 and 18/45**

**CPT code:** 87624

**Expected Turnaround Time:** 2 - 6 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Use:** High-risk HPV test is used for types 16, 18, 31, 33, 25, 39, 45, 51, 52, 56, 58, 59 and 68, without differentiation of the individual type. If the initial high-risk test is positive, then the residual specimen will be tested for HPV types 16 and 18, 45; type 18 cannot be differentiated from type 45.

**Limitations:** A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 13 most common high-risk HPV types.

**Methodology:** Nucleic acid amplification (NAA)

**Specimen Requirements:**

**Specimen:** Cervical cells in liquid-based cytology transport

**Volume:** ThinPrep® vial

**Minimum Volume:** ThinPrep® vial 2 mL (**Note:** This volume does not allow for repeat testing.)

**Container:** ThinPrep® vial

**Collection: ThinPrep® Vial – Broom or Brush/Spatula:**

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Storage Instructions:**

Maintain specimen at room temperature.

**Patient Preparation**

Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.

**Causes of Rejection**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in

vial that expired according to manufacturer's label; frozen specimen, specimen more than three months old in ThinPrep® vial.

### **Trichomonas vaginalis, NAA**

**CPT code:** 87661

**Expected Turnaround Time:** 3 - 5 days. Turnaround time is defined as the usual number of days from the date of specimen receipt in the laboratory to when the result is released to the ordering provider.

**Use:** Detection of *Trichomonas vaginalis* in clinician-collected endocervical and vaginal swab specimens and PreservCyt liquid Pap specimens.

#### **Limitations:**

- The effects of tampon use, douching and specimen collection variable have not been assessed for their impact on the detection of *Trichomonas vaginalis*.
- To ensure proper endocervical sampling, excess mucus should be removed.
- Vaginal swab and PreservCyt® Solution liquid Pap specimen sampling is not designed to replace cervical exams and endocervical specimens for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections or vaginal infections due to other causes or concurrent infections with other agents.
- This assay has been tested using only the specimen types indicated. Performance with other specimen types has not been evaluated.
- Reliable results are dependent on adequate specimen collection.

**Methodology:** Nucleic acid amplification (NAA)

#### **Specimen Requirements:**

**Specimen:** Endocervical and vaginal swab specimens and PreservCyt liquid Pap specimens

#### **Container:**

##### **A. PreservCyt® liquid Pap specimens collected in ThinPrep® vial:**

- **Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.
- **Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottom most fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over rotate the brush. Then rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Transportation and Storage:**

After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested. Specimen is stable for up to 30 days of collection.

**B. Aptima® Endocervical, Male Urethral or Vaginal Swab**

**Endocervical swab:** Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Carefully break the swab shaft at the score line; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly.

**Male urethral swab:** The patient should not have urinated for at least one hour prior to specimen collection. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2 to 4 cm into the urethra. Gently rotate the swab clockwise from two to three seconds in the urethra to ensure adequate sampling. Withdraw the swab carefully. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube. Carefully break the swab shaft at the score line; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly.

**Vaginal swab care provider specimen:** Collect vaginal fluid sample using the Aptima® Multitest or vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap.

**Transportation and Storage:**

After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested. Specimen is stable for up to 60 days of collection.

**Causes of Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted from male patient; specimen submitted in vial that expired according to manufacturer's label; specimen received beyond the stated stability duration.

**Urinary Tract Infection Pathogen Panel (UTI Panel), NAA**

**CPT code:** 87798-59x13

**Use:** Diagnosis of urinary tract infection. The QDx UTI panel includes infectious disease-associated gram-positive and gram-negative bacteria, fungi, and protozoa. The panel also tests for antibiotic

resistance gene targets. The estimated microbial load is the approximate colony forming units present in the original sample (cfu/mL) categorized as follows: LOW (10,000 – 100,000 cfus/mL); HIGH (>100,000 cfus/mL). Levels less than LOW are reported as “Not Detected”. Levels less than LOW are reported as “Not Detected”. Loads less than LOW generally represent normal flora/contaminants.

**Methodology:** Nucleic acid amplification (NAA)

#### **Specimen Requirements:**

- **Specimen:** Urine
- **Volume:** To minimum fill line (4 mL) on Vacutainer® gray-top urine culture transport tube with preservative.
- **Container:** Vacutainer® gray-top urine culture transport tube.
- **Collection:** Clean catch midstream collection. First morning specimens yield highest bacterial counts from overnight incubation in the bladder and are the best specimens. Read Patient Preparation.
- **Transportation and Storage Instructions:**  
Specimen should be transported to the laboratory within 48 hours of collection. Specimen is stable at room temperature for up to 72 hours post-collection.

#### **Causes for Rejection**

- Unpreserved specimen
- Unlabeled specimen or name discrepancy between specimen and request label
- Specimen in expired transport container
- Specimen received after prolonged delay (more than 72 hours)
- Specimen collected from a foley catheter bag
- Specimen in nonsterile or leaking container

#### **Patient Preparation**

Patient should be instructed on the proper collection of a clean catch midstream urine specimen. Avoid contamination with normal flora from skin, rectum, or vagina.

**Clean Catch Specimen:** Have patient urinate into a small clean disposable cup (Styrofoam or “Dixie”). Afterward, collection site staff can transfer the urine to the urine culture transport tube using the special collection straw-puncture device designed for use with the Vacutainer® tubes. The numbers of bacteria in a clean unused cup are so few as to be inconsequential when the urine transport stabilizer is added. Thoroughly instruct patient for proper collection of “clean catch” specimen. Patient must be instructed to thoroughly cleanse skin and collect a midstream specimen. The patient should be instructed to follow the directions provided with the urine collection kit as follows.

**Male:** Wash hands thoroughly with soap and water. Rinse them well and dry with a paper towel.

- Tear open the towelette packages so that the towels can be easily removed with one hand as they are needed. Do **not** touch any of the inside surfaces of the collection cup.
- Pull back the foreskin to expose the head of the penis completely.
- Wash the head of the penis thoroughly using first one towelette then the other. Discard the used towelettes into the toilet bowl.

- Pass a small amount of urine into the toilet bowl, then pass a sample into the container. Do not allow the container to touch the legs or penis. Keep fingers away from the rim and inner surface of the container. Fill the container half full.
- The urine specimen should be transferred to the Vacutainer® tube within 10 minutes of collection.

**Female:** Wash hands thoroughly with soap and water. Rinse them well and dry with a paper towel.

- Tear open the towelette packages so that the towels can be easily removed with one hand as they are needed. Do **not** touch any of the inside surfaces of the collection cup.
- Remove undergarments and sit on the toilet seat with legs spread widely apart.
- With one hand, spread labia apart to expose the vulva. Keep this hand in place during the washing and urinating procedure.
- Use one towelette to wash the vulva well passing the towelette only from front to back, not back and forth. Repeat this procedure using the second towelette. Discard the used towelettes into the toilet bowl.
- Begin urinating into the toilet bowl then without stopping the stream, insert the collection cup to collect the specimen. Do **not** allow the container to touch the legs, vulva, or clothing. Keep fingers away from the rim and inner surface of the container. Fill the container about half full.
- The urine specimen should be transferred to the Vacutainer® tube within 10 minutes of collection.

#### **Limitations:**

The Urinary Tract Microbiota Profiling Assay is a real-time PCR assay developed and its performance characteristics determined by QDx Pathology Services. It has not been cleared or approved by the Food and Drug Administration. However, such clearance/approval is not required as the laboratory is regulated and qualified under CLIA to perform high-complexity testing. The test results are not intended to be used as the sole means for clinical diagnosis or patient management. Clinical correlation and physician judgment is required when making a diagnosis or treatment decisions.

## **GASTROINTESTINAL PATHOLOGY TESTS**

### **Anti-Saccharomyces cerevisiae antibodies (ASCA), Stool**

**CPT code:** 83520

**Use:** The **ASCA-CHEK** test is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of human anti-*Saccharomyces cerevisiae* antibodies (ASCA) in feces. The test result is used as an aid to distinguish Crohn's disease from other gastrointestinal illnesses such as ulcerative colitis and irritable bowel syndrome in combination with clinical and other laboratory finds.

**Methodology:** Enzyme-linked immunosorbent assay (ELISA)

**Specimen Requirements:** Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool (unpreserved, random)

- **Volume:** 1.5 g
- **Container:** Clean screw-capped plastic vial
- **Collection:** Do not contaminate outside of container; do not overfill container. Loose stools are acceptable.
- **Storage instructions:** Stool specimens should be shipped on ice and received by the laboratory within 48 hours.
- Freeze specimen and send frozen if transport to the laboratory is delayed.

**Causes for Rejection:**

- Fecal specimens that have been preserved or contain barium enema.
- Improper labeling; unlabeled specimen or name discrepancy between specimen and request label.
- Specimen vial leaking.
- Specimen received after prolonged delay.

**Limitations:**

Fecal samples from the following patients should be excluded from use in the ASCA-CHEK test: patients with a history of HIV and/or Hepatitis B and C, patients with a history of infectious diarrhea (within six months), and patients having had a colostomy and/or ileostomy within one month.

- A positive **ASCA-CHEK** test indicates the presence of antibody to *S. cerevisiae* and without consideration of a patient’s clinical history or physical examination does not necessarily indicate the presence of Crohn’s disease.
- Samples from patients with chronic liver disease and hypergammaglobulinemia were not evaluated by the **ASCA-CHEK** test for potential presence of fecal ASCA.

**Calprotectin, Fecal**

**CPT code:** 83993

**Use:** QUANTA Flash® Calprotectin is a chemiluminescent immunoassay for the quantitative determination of fecal calprotectin in extracted human stool samples. Elevated levels of fecal calprotectin, in conjunction with clinical findings and other laboratory tests, can aid in the diagnosis of inflammatory bowel disease (IBD) (ulcerative colitis and Crohn’s disease), and in the differentiation of IBD from irritable bowel syndrome (IBS).

**Methodology:** Quantitative chemiluminescent immunoassay

**Reference Intervals:**

CALPROTECTIN CONCENTRATION	INTERPRETATION	FOLLOW-UP
<50 mg/kg	Normal	None
≥50 - <120 mg/kg	Borderline	Re-evaluate in 4 to 6 weeks
≥120 µg/g	Abnormal	Repeat as clinically indicated

### **Specimen Requirements:**

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool (unpreserved, random)
- **Volume:** 1.5 g
- **Container:** Clean screw-capped plastic vial
- **Collection:** Do not contaminate outside of container; do not overfill container. Loose stools are acceptable.
- **Storage Instructions:** Stool specimens should be received by the laboratory within 7 days of collection.

### **Causes of Rejection:**

Quantity not sufficient for analysis; preserved stool; improper labeling; unlabeled specimen or name discrepancy between specimen and request label; specimen vial leaking; specimen received after prolonged delay, samples taken from diapers unless portion taken has not been in contact with diaper material.

### ***Clostridium difficile* CHEK (GDH-EIA), Stool**

**CPT code:** 87449

**Use:** This test is used as a screening test to detect the cell wall associated enzyme, glutamate dehydrogenase, produced by *Clostridium difficile* strains in fecal specimens from persons suspected of having *C. difficile* disease. The test does not distinguish toxigenic from nontoxigenic strains of *C. difficile*. With the use of additional tests that detect *C. difficile* toxins, this test is to be used as an aid in the diagnosis of *C. difficile* disease. As with other *C. difficile* tests results should be considered in conjunction with patient history.

**Methodology:** Enzyme immunoassay (EIA)

### **Specimen Requirements:**

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool
- **Volume:** 5 g
- **Container:** Sterile screw-cap container or stool transport vial without preservative.
- **Storage Instructions:** Specimen should be kept refrigerated and transported to the laboratory within 24 hours of collection. If transport is delayed, the specimen should be kept **frozen**.

**Causes for Rejection:**

Quantity not sufficient for analysis; inappropriate specimen transport conditions (e.g., room temperature) or transport device; unlabeled specimen or name discrepancy between specimen and request label; specimen received after prolonged delay (usually more than 72 hours); specimens other than stool; leaking specimen.

***Clostridium difficile* Toxins A and B, EIA**

**CPT code:** 87324

**Use:** This test is an enzyme immunoassay used for the detection of toxins A and B produced by toxigenic strains of *Clostridium difficile*. It can be used to detect toxins A and B in fecal specimens from persons suspected of having *C. difficile* disease. The test is to be used as an aid in the diagnosis of *C. difficile* disease and results should be considered in conjunction with the patient history.

**Methodology:** Enzyme immunoassay (EIA) for *Clostridium difficile* toxins A and B

**Specimen Requirements:** Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool and collection and transportation kit.

- **Specimen:** Stool
- **Volume:** 5 g
- **Container:** Sterile screw-cap container or stool transport vial without preservative.
- **Storage Instructions:** Specimen should be kept refrigerated and transported to the laboratory within 24 hours of collection. If transport is delayed, the specimen should be kept **frozen**.

**Causes for Rejection:**

Inappropriate specimen transport conditions (e.g., room temperature) or transport device; unlabeled specimen or name discrepancy between specimen and request label; specimen received after prolonged delay (usually more than 72 hours); specimens other than stool; leaking specimen.

**Fecal Fat, Qualitative**

**CPT code:** 82705

**Use:** Detect the presence of neutral fat.

**Methodology:** Microscopic examination following staining with Sudan Black IV.

**Contraindications:** Administration of barium, bismuth, Metamucil®, castor oil, mineral oil or ingestion of oily salad dressing within one week prior to collection of the specimen.

**Reference Interval:** Neutral fats: Normal (<60 droplets/hpf)

**Specimen Requirements:** Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool (fresh random)
- **Volume:** Approximately 3 g
- **Container:** Plastic screw-cap vial without preservative
- **Patient Preparation:** Patient should be on a diet containing at least 60 g of fat. The patient should not use suppositories or mineral oil before the specimen is collected. Oily material (e.g., creams, lubricants, etc.) should be avoided prior to collection of the specimen.
- **Collection:** Do not contaminate outside of container, do not overfill container.
- **Storage Instructions:** Refrigerate at 2°C to 8°C
- **Stability Requirements:**

TEMPERATURE	PERIOD
Room temperature	14 days
Refrigerated	14 days
Frozen	14 days
Freeze/thaw cycles	Stable x 3

**Causes for Rejection:**

Quantity not sufficient for analysis; improper specimen transport device; improper labeling; unlabeled specimen or name discrepancy between specimen and request label; specimen received after prolonged delay; frozen specimen; rectal swab; specimen contaminated with urine and/or water; specimen on outside of container; specimen containing interfering substances (e.g., castor oil, bismuth, Metamucil®, barium).

**Gastrointestinal Pathogen Panel (GPP), Stool, PCR (14 Targets)**

**Note:** All positive *C. difficile* Toxin A/B samples will be reflexed to *C. difficile* Toxin A/B (EIA) and will incur additional charges. Please see CPT code and specimen requirements in the *C. difficile* Toxin A/B (EIA) section.

**CPT code:** 87507

**Test includes:** Adenovirus F 40/41; *Campylobacter*; *Clostridium difficile* toxin A/B; *Cryptosporidium*; *E. coli* O157; *Entamoeba histolytica*; Enterotoxigenic *E. coli* (ETEC) It/st; *Giardia lamblia*; Norovirus GI/GII; Rotavirus A; *Salmonella*; Shiga-like toxin-producing *E. coli* (STEC) stx 1/stx 2; *Shigella*; *Vibrio cholerae*.

**Use:** The Gastrointestinal Pathogen Panel (GPP) (14 targets) is multiplexed nucleic acid test intended for the simultaneous qualitative detection and identification of multiple viral, bacterial, and parasitic nucleic acids in human stool collected in Cary-Blair media from individuals with signs and symptoms of gastrointestinal infection.

**Methodology:** Polymerase chain reaction (PCR)

### Limitations:

The performance of this test has not been established for patients without signs and symptoms of gastrointestinal illness. Virus, bacteria, and parasite nucleic acid may persist *in vivo* independently of organism viability. Additionally, some organisms may be carried asymptotically. Detection of organism targets does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms. The detection of organism nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false-positive and false-negative results caused by improperly collected, transported, or handled specimens.

Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. Due to high rates of asymptomatic carriage of *Clostridium difficile*, especially in very young children and hospitalized patients, the detection of toxigenic *C. difficile* should be interpreted within the context of published guidelines (e.g., guidelines/policy statements published by The American Academy of Pediatrics or the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America).

### Specimen Requirements:

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool placed in a stool culture transport vial (C&S orange or yellow top)
- **Volume:** Add stool until level in the vial is at fill-line on vial label. Do **not** over fill.
- **Container:** C&S container with Cary-Blair preservative liquid medium
- **Collection:** If possible, allow patient to urinate before collecting stool specimen to avoid contaminating the stool specimen with urine. Catch the stool specimen in a clean, empty wide-mouthed container or place plastic wrap over the opening of the toilet bowl to prevent the stool specimen from falling into the bowl. Do **not** mix urine or water with the stool specimen.
- For diaper collected specimens, line the diaper with plastic wrap. Do **not** submit the diaper. Place small amounts of the stool specimen into the C&S vial using the spork affixed to the vial cap, taking care not to let the volume in the vial exceed the RED fill-line indicated on the vial label. Cap the vial and shake the vial 10 times to ensure complete distribution of the stool into the preservative. The stool specimen must be placed into the vial within one hour of collection. Ensure the vial cap is securely in place and that the vial is not leaking.
- **Storage Instructions:** Ship to the laboratory without delay. If there is delay, refrigerate. Room temperature storage and transport up to two days is acceptable.
- **Causes for Rejection:** Quantity not sufficient for analysis; improper specimen transport device; improper labeling; unlabeled specimen or name discrepancy between specimen and request label; specimen vial leaking; specimen received after prolonged delay; frozen specimen; rectal swab.

**Figure 3: Stool Transport Containers for Gastrointestinal Pathogen Panel**

Para-Pak C&S Vial

OR

MCC C&S Vial



### **Gastrointestinal Pathogen Panel (GPP), Stool, PCR (17 Targets)**

**Note:** All positive *C. difficile* Toxin A/B samples will be reflexed to *C. difficile* Toxin A/B (EIA) and will incur additional charges. Please see CPT code and specimen requirements in the *C. difficile* Toxin A/B (EIA) section.

**CPT code:** 87507

**Test Panel includes:**

- Adenovirus F 40/41
- *Campylobacter (C. jejuni/C. coli)*
- *Clostridium difficile (C. difficile)* toxin A/B
- *Cryptosporidium (C. hominis/C. parvum)*
- *Entamoeba histolytica*
- *Escherichia coli (E. coli)* O157
- Enterotoxigenic *E. coli* (ETEC) LT/ST
- Enteroaggregative *E. coli* (EAEC)
- *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*)
- Norovirus GI/GII
- Rotavirus A
- *Salmonella* spp.
- Shiga-like toxin-producing *E. coli* (STEC) stx1/stx2
- *Shigella (S. boydii, S. sonnei, S. flexneri, S. dysenteriae)*/ Enteroinvasive *E. coli* (EIEC)
- *Vibrio* spp. (*V. cholerae* /*V. vulnificus*), specific identification of *V. parahaemolyticus*
- *Yersinia enterocolitica*

**Use:** The Gastrointestinal Pathogen Panel (GPP) is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and identification of multiple viral, bacterial, and parasitic nucleic acids in human stool specimens in Cary-Blair media from individuals with signs and symptoms of gastrointestinal infection.

**Methodology:** Polymerase chain reaction (PCR)

**Limitations:** The performance of this test has not been established for patients without signs and symptoms of gastrointestinal illness. Virus, bacteria, and parasite nucleic acid may persist *in vivo* independently of organism viability. Additionally, some organisms may be carried asymptotically. Detection of organism targets does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms. The detection of organism nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false-positive and false-negative results caused by improperly collected, transported, or handled specimens.

Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. Due to high rates of asymptomatic carriage of *Clostridium difficile*, especially in very young children and hospitalized patients, the detection of toxigenic *C. difficile* should be interpreted within the context of published guidelines (e.g., guidelines/policy statements published by The American Academy of Pediatrics or the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America).

### **Specimen Requirements:**

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool placed in a stool culture transport vial (C&S orange or yellow top);
- **Volume:** Add stool until level in the vial is at fill-line on vial label. Do **not** over fill.
- **Container:** C&S container with Cary-Blair preservative liquid medium
- **Collection:** If possible, allow patient to urinate before collecting stool specimen so as to avoid contaminating the stool specimen with urine. Catch the stool specimen in a clean, empty wide-mouthed container or place plastic wrap over the opening of the toilet bowl to prevent the stool specimen from falling into the bowl. Do **not** mix urine or water with the stool specimen. For diaper collected specimens, line the diaper with plastic wrap. Do **not** submit the diaper. Place small amounts of the stool specimen into the C&S vial using the spoon affixed to the vial cap, taking care not to let the volume in the vial exceed the RED fill-line indicated on the vial label. Cap the vial and shake the vial 10 times to ensure complete distribution of the stool into the preservative. The stool specimen must be placed into the vial within one hour of the stools production for optimum results. Label the vial with the patient's name, date of birth and date of collection. Be sure the vial cap is securely in place and that the vial is not leaking.

### **Storage Instructions:**

Ship to the laboratory without delay. If there is delay, refrigerate. Room temperature storage and transport up to four days is acceptable.

### **Causes for Rejection:**

Quantity not sufficient for analysis; improper specimen transport device; improper labeling; unlabeled specimen or name discrepancy between specimen and request label; specimen vial leaking; specimen received after prolonged delay; frozen specimen.

**Figure 1: Stool Transport Containers for Gastrointestinal Pathogen Panel (17 Targets)**

Para-Pak C&S Vial

OR

MCC C&S Vial



### **Gastrointestinal Pathogen Panel (GPP), Stool, PCR (22 Targets)**

**Note:** All positive *C. difficile* Toxin A/B samples will be reflexed to *C. difficile* Toxin A/B (EIA) and will incur additional charges. Please see CPT code and specimen requirements in the *C. difficile* Toxin A/B (EIA) section.

**CPT code:** 87507

**Test includes:** Adenovirus F 40/41; Astrovirus; *Campylobacter*; *Clostridium difficile* toxin A/B; *Cryptosporidium*; *Cyclospora cayetanensis*; *E. coli* O157; *Entamoeba histolytica*; Enteroaggregative *E. coli* (EAEC); Enteropathogenic *E. coli* (EPAC); Enterotoxigenic *E. coli* (ETEC) lt/st; *Giardia lamblia*; norovirus GI/GII; *Plesiomonas shigelloides*; Rotavirus A; *Salmonella*; Sapovirus; Shiga-like toxin-producing *E. coli* (STEC) stx1/stx2; *Shigella*/Enteroinvasive *E. coli* (EIEC); *Vibrio cholerae*; *Yersinia enterocolitica*

**Use:** The Gastrointestinal Pathogen Panel (GPP) is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and identification of multiple viral, bacterial, and parasitic nucleic acids in human stool specimens in Cary-Blair media from individuals with signs and symptoms of gastrointestinal infection.

**Methodology:** Polymerase chain reaction (PCR)

**Limitations:** The performance of this test has not been established for patients without signs and symptoms of gastrointestinal illness. Virus, bacteria, and parasite nucleic acid may persist *in vivo* independently of organism viability. Additionally, some organisms may be carried asymptotically. Detection of organism targets does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms. The detection of organism nucleic acid is dependent upon proper sample collection, handling, transportation, storage and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false-positive and false-negative results caused by improperly collected, transported or handled specimens.

Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. Due to high rates of asymptomatic carriage of *Clostridium difficile*, especially in very young children and hospitalized patients, the detection of toxigenic *C. difficile* should be interpreted within the context of published guidelines (e.g., guidelines/policy statements published by The American Academy of Pediatrics or the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America).

### **Specimen Requirements:**

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool placed in a stool culture transport vial (C&S orange or yellow top); Copan rectal swabs.
- **Volume:** Add stool until level in the vial is at fill-line on vial label. Do **not** over fill.
- **Container:** C&S container with Cary-Blair preservative liquid medium
- **Collection:** If possible, allow patient to urinate before collecting stool specimen so as to avoid contaminating the stool specimen with urine. Catch the stool specimen in a clean, empty wide-mouthed container or place plastic wrap over the opening of the toilet bowl to prevent the stool specimen from falling into the bowl. Do **not** mix urine or water with the stool specimen. For diaper collected specimens, line the diaper with plastic wrap. Do **not** submit the diaper. Place small amounts of the stool specimen into the C&S vial using the spoon affixed to the vial cap, taking care not to let the volume in the vial exceed the RED fill-line indicated on the vial label. Cap the vial and shake the vial 10 times to ensure complete distribution of the stool into the preservative. The stool specimen must be placed into the vial within one hour of the stools production for optimum results. Label the vial with the patient's name, date of birth and date of collection. Be sure the vial cap is securely in place and that the vial is not leaking.

### **Storage Instructions:**

Ship to the laboratory without delay. If there is delay, refrigerate. Room temperature storage and transport up to four days is acceptable.

### **Causes for Rejection:**

Quantity not sufficient for analysis; improper specimen transport device; improper labeling; unlabeled specimen or name discrepancy between specimen and request label; specimen vial leaking; specimen received after prolonged delay; frozen specimen.

**Figure 1: Stool Transport Containers for Gastrointestinal Pathogen Panel (22 Targets)**

Para-Pak C&S Vial

OR

MCC C&S Vial



### ***Helicobacter pylori* Stool Antigen**

**CPT code:** 87338

**Use:** This test is used for the qualitative detection of *Helicobacter pylori* specific antigen. It is intended for use with human fecal specimens to aid in the diagnosis of *H. pylori* infection and to demonstrate loss of *H. pylori* antigen following treatment. The test can be used with unpreserved fecal specimens and fecal specimens preserved in transport media from patients suspected of *H. pylori* infection. Testing of patients to demonstrate loss of *H. pylori* antigen following treatment should be performed no sooner than four weeks after completion of the treatment regimen. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms.

**Methodology:** Immunoassay

**Limitations:** The test is used to detect *H. pylori* antigen in fecal specimens. The test confirms the presence of *H. pylori* antigen in the sample, and this information should be taken under consideration by the physician in light of the clinical history and physical examination of the patient.

A negative test result does not preclude the possibility of the presence of *H. pylori* antigen in the specimen which may occur if the level of antigen is below the detection limit of the test.

False negative results may occur if a patient has used antibiotics, proton pump inhibitors (PPIs) or bismuth compounds in the 14 days prior to fecal sample collection, as these medications are known to inhibit *H. pylori*. In these cases, a new fecal sample should be collected and tested 14 days after treatment has stopped. Positive results from patients that have used antibiotics, PPIs, or bismuth compounds in the 14 days prior to fecal sample collection are still considered accurate.

No data exists on the effects of colonic washes, barium enemas, laxatives, or bowel preparations on the performance of the test. These procedures can result in extensive dilution or the presence of additives that may affect test performance. Performance characteristics have not been established in asymptomatic populations.

**Specimen Requirements:**

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool
- **Volume:** 2 grams (thumbnail size portion of stool), 2 mL liquid stool
- **Container:** Sterile screw-cap vial without preservative or fecal specimens collected in C&S container with Cary-Blair preservative liquid medium

**Figure 2: Stool Transport Vials for *H. pylori* Stool Antigen Test**



- **Storage Instructions:**

ACCEPTABLE SAMPLE TYPE	DO NOT USE
Fresh Fecal Specimens	Fecal Specimens in Formalin-based fixative (e.g., sodium acetate formalin, 10% formalin)
Frozen Fecal Specimens	Fecal Specimens in alcohol-based fixative (e.g., polyvinyl alcohol)
Specimens in Transport Media (Cary Blair, C&S)	Concentrated Fecal Specimens
STORAGE CONDITIONS	RECOMMENDED STORAGE TIME
Fresh Unpreserved Samples and Samples in Cary Blair or C&S Transport Media Stored between 20°C and 8°C	96 hours
Fresh Unpreserved Samples and Samples in Cary Blair or C&S Transport Media Stored between 20°C and 25°C	96 hours
Frozen Unpreserved Samples Stored at ≤ 10°C	14 days

**Causes for Rejection:**

Unlabeled specimen or name discrepancy between specimen and request label; specimen received after prolonged delay; leaking specimen; specimen received in inappropriate container.

## Lactoferrin, Fecal, Quantitative

**Use:** An *in vitro* diagnostic aid to distinguish patients with active inflammatory bowel disease (IBD) from those with inactive IBD, as well as from non-inflammatory irritable bowel syndrome (IBS).

**CPT code:** 83631

### Limitations:

The LACTOFERRIN SCAN® TEST is a quantitative test that measures the level of fecal lactoferrin released from leukocytes. The test may not be appropriate in immunocompromised persons. The following patient samples should be excluded from use in the test; patients with a history of HIV and/or Hepatitis B and C, patients with a history of infectious diarrhea (within six months), and patients having had a colostomy and/or ileostomy within one month.

Fecal lactoferrin concentrations should not be interpreted as absolute evidence for the presence of a gastrointestinal illness. Prediction of active and inactive disease should be based on a complete clinical evaluation of the patient that may also include multiple fecal lactoferrin level determinations.

Other intestinal ailments, including many gastrointestinal infections and colorectal cancer, often result in elevated levels of lactoferrin in fecal specimens. Therefore, when evaluating a patient, a clinical assessment must be considered along with test results.

Fecal samples from breast fed infants should **not** be used with this assay.

**Methodology:** Enzyme-linked immunosorbent assay (ELISA)

### Reference Interval:

- Baseline (normal); 0.00-7.24 µg/mL
- Elevated: ≥7.25 µg/mL

### Specimen Requirements:

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel collection and transportation kit.

- **Specimen:** Stool (unpreserved, random)
- **Volume:** 1 gram
- **Container:** Clean, screw-capped, plastic vial with no preservatives
- **Collection:** Do **not** contaminate outside of container, do not overfill container. Loose/watery stools are acceptable.
- **Storage Instructions:** Refrigerate at 2°C to 8°C; stable for 14 days. Stable at room temperature or frozen for 14 days.

### Causes for Rejection:

Non-fecal sample received (e.g., serum, plasma, urine); stool contaminated with urine; preserved stool received (e.g., 10% formalin, sodium acetate formalin, or polyvinyl alcohol). Unlabeled specimen or name discrepancy between specimen and request label; specimen received after prolonged delay; specimens other than stool; leaking specimen.

## Pancreatic Elastase, Fecal

**CPT code:** 82656

**Use:** This test is intended for the quantitative determination of pancreatic elastase in human stool samples. The test may be used as an aid in the diagnosis or exclusion of exocrine pancreatic insufficiency associated with chronic pancreatitis, cystic fibrosis, carcinoma of the pancreas, diabetes mellitus type 1 and other etiologies of pancreatic insufficiency.

### Methodology:

Enzyme-linked immunosorbent assay (ELISA) based upon a monoclonal antibody-based detection system specific for pancreatic elastase.

### Reference Interval:

- Normal: >200 µg elastase/g fecal material
- Moderate pancreatic insufficiency: 100-200 µg elastase/g fecal material
- Severe pancreatic insufficiency: <100 µg elastase/g fecal material

### Specimen Requirements:

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool (unpreserved, random)
- **Volume:** 3 grams
- **Container:** Screw-capped plastic vial
- **Collection:** Do **not** contaminate outside of container. Do **not** overfill container. Do **not** submit watery or unformed (loose) stool. Do **not** use a preservative.
- **Storage Instructions:**

Room Temperature (15°C - 30°C)	3 days
Refrigerator (2°C - 8°C)	3 days
Freezer (up to -20°C)	12 months

### Causes for Rejection

Quantity not sufficient for analysis; improper specimen transport device; improper labeling; unlabeled specimen or name discrepancy between specimen and request label; specimen vial leaking; specimen received after prolonged delay, preserved specimen; stool contaminated with urine; watery or unformed (loose) stool submitted.

## RESPIRATORY PATHOLOGY - MOLECULAR TESTS

### BioCode® Respiratory Pathogen Panel (RPP) (17 Targets)

**CPT code:** 87633

**Test Includes:** Adenovirus, Coronavirus (229E, OC43, HKU1, and NL63), Human Metapneumovirus A/B, Influenza A (including subtypes Ha, Ha 2009 Pandemic, and H3), Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Respiratory Syncytial Virus A/B, Rhinovirus/Enterovirus, *Bordetella pertussis*, *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*.

**Use:** This is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test for the simultaneous detection and identification of nucleic acids from multiple viruses and bacteria extracted from nasopharyngeal swab (NPS) samples obtained from individuals with signs and/or symptoms of respiratory tract infection.

**Methodology:** Reverse transcription (RT) and multiplex PCR (polymerase chain reaction) amplification

**Specimen Requirements:** Nasopharyngeal swab (NPS) (flocked) in 1-3 mL viral transport media or Universal Transport Media (UTM™). A sample of 200 µL is required for testing. Samples should be tested as soon as possible.

**Storage Instructions:** Store at room temperature for 8 hours, 2 - 8°C for 7 days, or < 60° C for up to 90 days.

**Causes for Rejection:** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen exceeding storage requirements; prolonged delay in specimen transportation.

**Limitations:** This assay is qualitative and does not provide a quantitative value for the pathogen(s) present in the sample. The performance of this test has not been established for patients without signs of symptoms of respiratory infection. The performance of the BioCode® RPP is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive and false negative results caused by improperly collected, transported, or handled specimens. Negative results do not exclude the possibility of infection. Negative test results may occur from sequence variants in the region targeted by the assay, the presence of inhibitors, or an infection caused by a pathogen not detected by the panel. Test results may also be affected by concurrent antimicrobial therapy or levels of pathogen in the sample that are below the limit of detection for the test. Negative results should not be used as the sole basis for diagnosis treatment, or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with

pathogens that are not detected by this test or lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. Nucleic acid may persist independently of a pathogen's viability or pathogens may be asymptotically carried. Therefore, a positive result does not necessarily indicate the presence of viable pathogens or that the pathogen is the causative agent for the clinical symptoms. There is a risk of false positive results due to non-specific amplification and cross-reactivity with organisms found in the respiratory tract. Erroneous results due to cross-reactivity with organisms that were not evaluated or new variant sequences that emerge are possible. The performance of the test has not been established with potentially interfering medications for the treatment of influenza or cold viruses.

### **BioFire® Respiratory Panel 2.1 (RP2.a) (22 Targets)**

**CPT code:** 87633

**Test Includes:** Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Human Metapneumovirus Human Rhinovirus/Enterovirus, Influenza A (including subtypes H1, H3, and H1-2009), Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*.

**Use:** The BioFire® RP2.1 is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and differentiation of nucleic acids from multiple viral and bacterial respiratory organisms, including nucleic acid obtained from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in nasopharyngeal swabs (NPS) obtained from individual with signs and/or symptoms of respiratory infection by their healthcare provider.

The BioFire® RP2.1 is a real-time, nested multiplexed polymerase chain reaction test designed to simultaneously identify nucleic acids from 22 different viruses and bacteria associated with respiratory tract infection, including SARS-CoV-2, from a single nasopharyngeal swab (NPS) specimen. Specifically, the SARS-CoV-2 primers contained in the BioFire RP2.1 are designed to detect RNA from the SARS-CoV-2 in nasopharyngeal swabs in transport media from patients who are suspected of COVID-19.

**Methodology:** Real-time PCR (polymerase chain reaction)

**Specimen Requirements:** Nasopharyngeal Swab (NPS) collected according to standard technique and immediately placed in up to 3 mL of transport media.

**Storage Instructions:** Store at room temperature for 4 hours (15-25°C), Refrigerated for up to 3 days (2-8°C), frozen (<15°C or <70°C) for up to 30 days.

**Causes for Rejection:** Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; prolonged delay in specimen transportation.

**Limitations:** The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results are indicative of the presence of the identified organism but do not rule out co-infection with other pathogens. The agent(s) detected by the BioFire RP2.1 may not be the definite cause of disease. Negative results in the setting of a respiratory illness may be due to infection with pathogens not detected by this test, or lower respiratory tract infection that may not be detected by an NPS specimen. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative SARS-CoV-2 results must be combined with clinical observations, patient history, and epidemiological information. Negative results for other organisms identified by the test may require additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence and radiography) when evaluating a patient with possible respiratory tract infection.

### ***Bordetella pertussis* and *Bordetella parapertussis*, Real-time DNA PCR**

**CPT code:** 87798x2

**Test includes:** *Bordetella pertussis* and *Bordetella parapertussis*

**Use:** This is a real-time polymerase chain reaction (PCR) based qualitative *in vitro* diagnostic test for the direct detection and identification of *Bordetella pertussis* (*B. pertussis*) and *Bordetella parapertussis* (*B. parapertussis*) nucleic acid in nasopharyngeal swab (NPS) specimens obtained from individuals suspected of having a respiratory tract infection attributable to *B. pertussis* or *B. parapertussis*.

**Methodology:** Real-time polymerase chain reaction (PCR)

#### **Specimen Requirements:**

Nasopharyngeal swab (NPS) (flocked, Rayon or Polyester) in viral transport or Universal Transport Media (UTM™) or Nasal swab in saline. Transport samples on ice to the laboratory within 48 hours of collection. If there will be a prolonged delay, samples should be frozen at -70°C or colder and transported on dry ice.

#### **Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen exceeding storage requirements; prolonged delay in specimen transportation.

#### **Limitations:**

- The detection of bacterial nucleic acids depends on proper sample collection, handling and transportation. Failure to observe proper procedures in any one of these steps can lead to an incorrect result.
- There is a risk of false negative results due to improperly collected, transported or handled samples.

- There is a risk of false negative results due to the presence of sequence variants in the targets.
- There is a risk of false positive results due to potential cross-contamination by target organism(s), their nucleic acid or amplified product, or from non-specific signals in the assay.
- Cross-reactivity with respiratory tract organisms other than those tested can lead to erroneous results. This test cannot rule out diseases caused by other bacterial or viral pathogens.
- There is a risk of false positive results due to potential cross-contamination by target organism(s), their nucleic acid or amplified product, or from non-specific signals in the assay.
- Cross-reactivity with respiratory tract organisms other than those tested can lead to erroneous results
- This test cannot rule out diseases caused by other bacterial or viral pathogens.

### **Group A *Streptococcus*, Real-time DNA PCR**

**CPT code:** 87651

**Use:** The Group A *Streptococcus* Assay is a real-time polymerase chain reaction (PCR) based qualitative *in vitro* diagnostic test for the direct detection of *Streptococcus pyogenes* (Group A  $\beta$ -hemolytic *Streptococcus*) infections.

**Methodology:** Real-time polymerase chain reaction (PCR)

#### **Specimen Requirements:**

- **Specimen:** Collection: Nylon Flocked Throat swab samples should be obtained by appropriately trained individuals using a Nylon Flocked Swab for collection and stored in 1 mL of Liquid Amies Medium (COPAN ESwab™ 480C or BD™ equivalent).
- **Transport:** Transport samples on ice to the laboratory within 48 hours of collection.

#### **Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen exceeding storage requirements, specimen types other than those described in “Specimen Collection” section; prolonged delay in specimen transportation.

#### **Limitations:**

- The detection of bacterial nucleic acids depends on proper sample collection, handling and transportation. Failure to observe proper procedures in any one of these steps can lead to an incorrect result.
- There is a risk of false negative results due to improperly collected, transported or handled swab samples.
- There is a risk of false negative results due to the presence of sequence variants in the targets of the assay, amplification inhibitors in samples or inadequate number of organism(s) for amplification.
- False negative results may be obtained in the presence of NyQuil® (0.5% v/v) and in the presence of high concentrations of *Treponema denticola*.

- This assay does not distinguish between viable and nonviable organisms and may produce a positive result in the absence of living organisms.
- This assay does not differentiate asymptomatic carriers of Group A *Streptococcus* from those exhibiting streptococcal infection.
- There is a risk of false positive results due to potential cross-contamination by target organism(s), their nucleic acid or amplified product, or from non-specific signals in the assay.
- Additional follow-up testing by culture should be performed if the result of this assay is negative and clinical symptoms persist, or in the event of an outbreak of acute rheumatic fever (ARF).
- There is a risk of an “invalid” result if a specimen contains mucin proteins  $\geq 5$  mg/mL.

## Luminex NxTAG<sup>®</sup> Respiratory Pathogen Panel, PCR (20 Targets)

**CPT codes:** 87633, 87486, 87581

**Test Includes:** Adenovirus, Chlamydomphila pneumoniae; Coronavirus 229E; Coronavirus HKU1; Coronavirus NL63; Coronavirus OC43; Human Metapneumovirus; Human rhinovirus/Enterovirus; Influenza A; Influenza A subtype H1; Influenza A subtype H3; Influenza B; Mycoplasma pneumoniae; Parainfluenza virus; Parainfluenza virus 2; Parainfluenza virus 3; Parainfluenza virus 4; Respiratory Syncytial Virus A; Respiratory Syncytial Virus B; Human Bocavirus.

**Use:** This test provides simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs obtained from individuals suspected of respiratory tract infections.

**Methodology:** Polymerase chain reaction (PCR)

### **Specimen Requirements:**

Nasopharyngeal swab in viral transport (flocked, Rayon or Polyester) or Universal Transport Media (UTM™) or Nasal swab in saline. Swabs in viral transport media are stable for 7 days refrigerated (2°C - 8°C) and for 12 months at -70°C or below.

### **Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen exceeding storage requirements.

### **Limitations:**

- Analyte targets (viral sequences) may persist *in vivo* independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.
- All results from this test must be considered in conjunction with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- The detection of viral nucleic acids is dependent upon proper specimen collection, handling, and transportation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- There is a risk of false negative values resulting from improperly collected, transported, or handled specimens.

- There is a risk of false negative values due to the presence of sequence variants in the viral targets of the assay, amplification inhibitors in specimens or inadequate numbers of organisms for amplification.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay.
- A specimen yielding a negative result may contain respiratory viruses not probed by the assay.
- Positive influenza results obtained in a patient who received FluMist prior to sample collection may be due to detection of influenza viruses in the vaccine and may mask a true positive result due to infection by one or more of these viruses.
- The performance of the assay has not been established in individuals who received nasally administered Influenza A vaccine.

## SARS CoV-2 COVID-19 TESTS

### Aptima® SARS-CoV-2 Assay (Panther® System)

**CPT Code:** 87635

**Use:** The Aptima® SARS-CoV-2 Assay (Panther® System) is a nucleic acid amplification *in vitro* diagnostic test intended for the qualitative detection and identification of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) nucleic acids in human respiratory samples.

**Methodology:** Nucleic acid hybridization

#### Limitations:

- A. Reliable results are dependent on adequate specimen collection, transport, storage, and processing.
- B. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other management decisions.
- C. A positive result indicates the detection of nucleic acid from the relevant virus. Nucleic acid may persist even after the virus is no longer viable.
- D. Nasopharyngeal wash/aspirate or nasal aspirates and self-collected or healthcare provider collected nasal and mid-turbinate nasal swabs are additional acceptable upper respiratory specimens that can be tested with the Aptima® SARS-CoV-2 assay.

#### Specimen Requirements:

Instructions for collection and transportation are included in the QDx COVID-19 Nasal and Nasopharyngeal swab collection and transportation kit.

- **Specimen:** Clinical material collected from patient nasopharyngeal, mid-turbinate and oropharyngeal, nasopharyngeal wash/aspirate, or nasal aspirates by swab and placed in transport tubes [containers].
- **Volume:** Nasal swab tip is placed in specimen transport medium (STM).
- **Container:** Transport container or tube.

- **Collection:** Patient insert NP swab, nasal swab, and OP swab specimens according to standard technique using a polyester-, rayon-, or nylon-tipped swab. Immediately place the swab specimen into a 3 mL saline container.
- **Storage Instructions:** After collection, specimens should be shipped to the laboratory without delay.

**Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen exceeding storage requirements.

**HDPCR™ SARS-CoV-2 Assay**

**CPT code:** 87635

**Use:** This is a reverse transcription real-time polymerase chain reaction (qRT-PCR) test for the qualitative detection and identification of viral SARS-CoV-2 RNA nucleic acid in nasopharyngeal swab (NPS) specimens obtained from individuals suspected of having an upper respiratory infection attributable to COVID-19.

**Methodology:** Real-time polymerase chain reaction (PCR)

**Limitations:**

False-positive results may arise for various reasons, including, but not limited to the following:

- Contamination during specimen collection, handling or preparation
- Incorrect sample labeling
- Improper sample collection or storage
- Presence of inhibitory substance
- Negative test results do not exclude possibility of exposure to or infection with SARS-CoV-2 virus.

**Specimen Requirements:**

Nasopharyngeal swab (NPS) in viral transport or Universal Transport Media (UTM™) (Flocked, Rayon or Polyester) or Nasal swab in saline. Transport samples on ice to the laboratory within 48 hours of collection. If there will be a prolonged delay, samples should be frozen at -70°C or colder and transported on dry ice.

**Storage Instructions:**

Swabs in viral transport are stable for 7 days refrigerated (2°C - 8°C) and for 12 months at -70°C or below.

**Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis, name discrepancies; specimen exceeding storage requirements prolonged delay in specimen transportation.

**Luminex ARIES® SARS-CoV-2 Assay**

**CPT code:** 87635

**Use:** This is a real-time reverse transcriptase polymerase chain reaction (RT-PCR) qualitative *in vitro* diagnostic test for the qualitative detection and identification of viral SARS-CoV-2 in nasopharyngeal swab specimens obtained from individuals suspected of having upper respiratory tract infections.

**Methodology:** Reverse transcriptase polymerase chain reaction (RT-PCR)

**Specimen Requirements:**

Nasopharyngeal swab (NPS) in viral transport (Flocked, Rayon or Polyester) or Universal Transport Media (UTM™) or Nasal swab in saline. Transport samples on ice to the laboratory within 48 hours of collection. If there will be a prolonged delay, samples should be frozen at -70°C or colder and transported on dry ice.

**Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen exceeding storage requirements.

**Limitations:**

- Analyte targets (viral sequences) may persist *in vivo*, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) is infectious, are the causative agents for clinical symptoms.
- All results from this and other tests must be considered in conjunction with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- The detection of pathogen nucleic acids is dependent upon proper specimen collection, handling, transportation, storage and preparation (including extraction). Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false negative values resulting from improperly collected, transported or handled specimens.
- This is a qualitative test and does not provide the quantitative value of detected organisms present.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product or from non-specific signals in the assay.
- There is a risk of false positive values due to the presence of sequence variants in the pathogen targets of the assay, amplification inhibitors in specimens, or inadequate numbers of organisms for amplification.

- A specimen yielding a negative result may contain respiratory pathogens not probed by the assay.
- The performance of this assay was not established in immunocompromised patients.
- The performance for some viruses and subtypes may vary depending on the prevalence and population tested.
- This test cannot rule out infections caused by other viral or bacterial pathogens not present on this panel.
- There is a risk of false negative results when at low concentration and in the presence of a high concentration co-infection.

## **Luminex NxTAG® CoV Extended Panel Assay**

**CPT code:** 87635

**Use:** This is a qualitative multiplexed nucleic acid test for the detection and identification of the viral SARS-CoV-2 nucleic acid in nasopharyngeal swab specimens obtained from individuals suspected of upper respiratory infections.

**Methodology:** Reverse transcriptase polymerase chain reaction (PCR)

### **Specimen Requirements:**

Nasopharyngeal swab (NPS) in viral transport (Flocked, Rayon or Polyester) in Universal Transport Media (UTM®) or Nasal swab in saline. Transport samples on ice to the laboratory within 48 hours of collection. If there will be a prolonged delay, samples should be frozen at -70°C or colder and transported on dry ice.

### **Causes for Rejection:**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen exceeding storage requirements.

### **Limitations:**

- Analyte targets (viral sequences) may persist *in vivo*, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.
- All results from this and other tests must be considered in conjunction with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- The detection of pathogen nucleic acids is dependent upon proper specimen collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false negative values resulting from improperly collected, transported or handled specimens.
- The test is a qualitative test and does not provide the quantitative value of detected organisms present.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay.

- There is a risk of false negative values due to the presence of sequence variants in the pathogen targets of the assay, amplification inhibitors in specimens, or inadequate number of organisms for amplification.
- A specimen yielding a negative result may contain respiratory pathogens not probed by the assay.
- The performance of this assay was not established in immunocompromised patients.
- The performance for some viruses and subtypes may vary depending on the prevalence and population tested.
- This test cannot rule out infections caused by other viral or bacterial pathogens not present on this panel.
- The performance of this device has been evaluated for monitoring treatment of infections.

## MICROBIOLOGY

### Introduction

Quality results in microbiology depend on the combined efforts of the ordering client and the laboratory. The many factors contributing to the successful isolation of potential pathogens range from specimen selection and collection to proper transport and timely delivery to the laboratory.

### Collection of Specimens: General Information

1. Labeling. The following information is needed:
  - Patient's name
  - Source of specimen or collection site
  - Date and time of collection
  - Test requested
2. Obtain specimen correctly:
  - Explain collection procedure to the patient
  - Label correctly and send the specimen to the laboratory promptly
  - Avoid contamination of the container
3. Temperature  
Appropriate storage and transport temperatures for specimens are essential for successful isolation of organisms. Specimens may need to be stored and transported:
  - At room temperature. Avoid exposure to extreme hot or cold temperature.
  - At refrigerated temperature, using a household or commercial refrigerator and transported in a cooler on ice packs.
  - Frozen, using a household or commercial freezer and transported to the laboratory on ice.

## STOOL MICROBIOLOGY

### Ova and Parasites, General Screen

**Note:** Evaluation for *Cryptosporidium*, *Cyclospora*, *Isospora* and *Microsporidium* are not included in the routine Ova & Parasites screen and must be requested separately.

Many parasites are passed intermittently. It is recommended that a routine examination for ova and parasites before therapy, include up to three specimens collected at 1-3 day intervals to increase the probability of detecting parasites.

Each specimen must be preserved in one vial of 10% formalin (pink cap ParaPak™ vial) and in one vial of Zinc-Polyvinyl Alcohol (PVA) (gray cap ParaPak™ vial) with a minimum of 5 grams of specimen in each of the paired vials. Do not exceed the fill line on the vials. Formalin preserves helminth eggs and larvae. PVA is an excellent fixative for the preservation of trophozoite stages of protozoa.

**A comprehensive examination for parasites cannot be made unless both vials are submitted.**

**Alternatively, a stool specimen may be submitted in a single Total-Fix™ stool collection vial.**

**WARNING:** Liquid in containers is poisonous. Keep out of reach of children.

It is important to indicate specimen consistency (formed, soft, loose, or watery) by checking the appropriate box on the transport vial label.

#### Para-Pak™ Stool Collection Kit for Ova and Parasites Examination



#### Total-Fix™ Stool Collection Kit for Ova and Parasites Examination



### Collection & Transportation:

1. Collect the stool specimen in a clean, dry container (**avoid contamination with urine or toilet water**).
2. Transfer to the transport vials. **Do not** discard the liquid from the vials. This liquid is a preservative for the stool specimen.
3. Open the transport vials.
4. Using the collection spork built into the lid, obtain scoops of stool from areas which appear bloody, slimy, or watery and place them into the vial until the volume rises to the red line. If the stool is formed (hard), obtain small amounts from each end and the middle. Add up to the “fill

5. line” ensuring that the preservative completely covers the specimen. Do not over fill past the fill line.
6. Mix the contents of the vial thoroughly with the spork, twist the cap tightly closed, check the cap to be sure it is secure and shake until the contents are well mixed.

#### **Precautions:**

- Barium, antibiotics, antimalarials, mineral oil and other laxatives interfere with the detection of intestinal protozoa. Specimens submitted from patients that have been treated with the above must be collected at least seven days post treatment.
- Parasite examinations cannot be performed on specimens submitted in stool culture transport vials or any other transport media specifically designed for bacterial pathogens.
- Do not use stool collection and transport containers beyond their date of expiration.
- Store and transport preserved stool specimens at room temperature.

#### **Additional Concerns for the General Screen:**

Intestinal amebiasis should be considered in any patient with protracted diarrhea and in all patients with dysentery. Examination of fresh stool for the presence of cysts and trophozoites is important and should be carried out immediately if amebiasis is suspected.

If amoebae are not discovered on passed stool specimens, a purged stool specimen should be obtained and immediately examined. As amoebae tend to be more concentrated in the cecum in light infections, it is the second and third expulsions of the liquid portions of the stool, after administration of a purgative, which are most likely to yield amoebae.

- Purge adult patients with a Fleet™ Enema, a ready-to-use saline laxative. The use of laxatives is contraindicated under the following conditions:
- When nausea, vomiting or abdominal pain is present unless directed by a physician.
- Patients with congenital megacolon, bowel obstruction, imperforate anus or congestive heart failure.
- Use with caution for patients with impaired renal function, pre-existing electrolyte disturbances or those on diuretics or other medications that may affect electrolyte levels or where colostomy exists.
- Place the most liquid portion of the specimen into **only** the PVA (pink cap ParaPak™) or the black top Total-Fix specimen vial within 30 minutes of collection up to the fill line.
- Do not submit formed stool.
- Store and transport preserved stool specimens at room temperature.

#### **Duodenal/Gastric Aspirates:**

- Collect the duodenal/gastric aspirates and place the fluids in both 10% formalin (Pink cap Para Pak™ vial) and PVA (Gray cap Para Pak™ vial) containers within 30 minutes of collection. Fill up to the fill line. Alternatively, specimens may be transported in one Total-Fix™ vial.
- Indicate the source of the specimen on the specimen vial.
- Store and transport preserved stool specimens at room or refrigerated temperatures (stable for two months).

### **Parasite Identification: (Worm, Larvae, Insects)**

- Submit the entire organism in 70% Isopropyl alcohol in a clean screw-cap container.
- Transport at room or refrigerated temperature (stable for two months).

### **Pinworm: (Enterobius vermicularis)**

1. Pinworm Collector Vials have clear, thin, flexible plastic paddles that can be analyzed directly on a microscope slide for the presence of ova in the identification of pinworms.
2. Optimal time for obtaining sample is early in the morning immediately after the patient wakes.
3. Remove cap from vial.
4. Press sticky side of paddle (marked ADH) to perianal skin of patient with moderate pressure.
5. Carefully place paddle back in the collection vial and close the cap firmly.
6. Label vial with patient name and date of birth and date of sample collection.
7. Ship to lab at room temperature (15°C - 30°C) without delay.

### **White Blood Cells (WBC), Stool**

Synonym: Fecal Leukocytes

**CPT Code:** 89055

**Test Includes:** Evaluation of fecal material for the presence of WBC by direct smear and stain.

**Use:** Assist in the differential diagnosis of diarrheal disease.

**Limitations:** Ten percent to 15% of stools that yield an invasive bacterial pathogen have an absence of fecal leukocytes. Fecal leukocytes are present in idiopathic inflammatory bowel disease.

**Methodology:** Trichrome stain

#### **Specimen Requirements:**

Instructions for collection and transportation are included in the QDx Gastrointestinal Pathogen Panel stool collection and transportation kit.

- **Specimen:** Stool
- **Volume:** 1 gram. Add stool specimen up to the fill line.
- **Container:** Parasite (O & P) transport (PVA) or Total Fix O & P vial.
- **Storage Instructions:** Maintain specimen at room temperature.
- **Causes of Rejection:** Quantity not sufficient for analysis; improper specimen transport device; improper labeling; unlabeled specimen or name discrepancy between specimen and request label; specimen vial leaking; specimen received after prolonged delay, frozen specimen, rectal swab.

**Figure 4: Stool Specimen Transport Container for Stool White Blood Cell**

**Para-Pak PVA Vial**



**OR**

**Total-Fix Ova & Parasite Vial**



## **APPENDICES**

- I.** Critical Values Form - Positive COVID-19 Reporting
- II.** Critical Values Form - QDetect™ Gastrointestinal Pathogen Panel
- III.** Specimen Collection for COVID-19 Specimens
- IV.** Specimen Collection for Urine Cytology and/or UroVysion™ FISH
- V.** STD Testing
- VI.** Test Add-On Request Form
- VII.** Test Cancellation Request Form

**CRITICAL VALUES REPORTING  
POSITIVE COVID-19 REPORTING**

**Practice Name & Location:**

***All positive COVID-19 results will be called during business hours to:***

Name(s): \_\_\_\_\_

Phone/Backline: \_\_\_\_\_

***After hours, holidays & week-ends, call all positive results to:***

Name(s): \_\_\_\_\_

Phone/Backline: \_\_\_\_\_

**PRACTICE SIGNATURE REQUIRED:** (Representative Signature, Print Name and Date)

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Practice Name & Location:

46 Jackson Drive | Cranford, NJ 07016 | Phone 866.909.PATH (7284) | Fax 908.272.1478 | www.qdxpath.com

Practice Name & Location:

## CRITICAL VALUES REPORTING

### QDetect™ Gastrointestinal Pathogen Panel

#### Bacteria

- Campylobacter
- Salmonella
- Vibrio cholerae
- Yersenia enterocolitica
- Vibrio species
- Plesiomonas shigelloides

#### Diarrheagenic E. coli/Shigella

- Enteroaggregative E.coli (EAEC)
- Enteropathogenic E.coli (EPEC)
- Enterotoxigenic E. coli (ETEC) lt/st
- Shiga-like toxin producing E. coli (STEC)stx1/stx2
- E.coli 0157
- Shigella/Enteroinvasive E. coli (EIEC)

#### Viruses

- Adenovirus 40/41
- Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus (Genogroups I,II,IV and V)

#### Parasites

- Cryptosporidium
- Cylospora
- Entamoeba histolytica
- Giardia lamblia

**C. Difficile: All C. difficile positive by PCR (xtag or Filmarray GPP) shall be reflexed to C. difficile Toxin A/B, EIA.**

- Hold positive C. Diff PCR (GPP) and report with C. Diff antigen toxin A/B
- C. Diff antigen toxin A/B (Immunoassay)

**All information above approved by Physician Information. Check all that apply:**

\_\_\_\_\_

**All positive results will be called during business After hours, holidays & week-ends, call all positive hours to: results to:**

Name(s): \_\_\_\_\_ Name (s): \_\_\_\_\_

Phone/Backline: \_\_\_\_\_ Phone/Backline: \_\_\_\_\_

**CALL ON ALL POSITIVE RESULTS**

**DO NOT** send preliminary results for negative GPP

**NO** calls after hours

**NO** calls on weekends and holidays

**PRACTICE SIGNATURE REQUIRED:** (Representative signature, Print Name and Date)

## SPECIMEN COLLECTION AND STORAGE

Upper respiratory specimens are to be collected and transported according to the instructions provided with the QDx Pathology Services specimen collection kit.

- Samples can be stored at 2-8°C for 72 hours after collection prior to extraction. Maintain samples at 2-8°C on ice packs for overnight shipment.
- For longer term storage, unextracted samples can be stored at ≤-70°C. If samples need to be transported, maintain ≤-70°C on dry ice for overnight shipment.
- Extracted nucleic acids can be stored at ≤-70°C. If samples need to be transported, maintain ≤-70°C for overnight shipment.

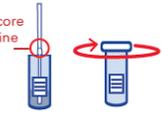
*Note: Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.*

### Nasopharyngeal Swab Instructions

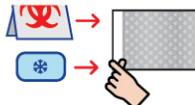
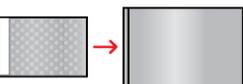
**IMPORTANT! SPECIMEN MUST SHIP THE SAME DAY OF COLLECTION**

FOLLOWING THESE STEPS ENSURES ACCURATE TESTING

#### SPECIMEN COLLECTION

1. Remove swab from its package. **Do not** touch tip of swab.  **hold here**
2. Screw off the top of the specimen container. **Do not** spill the liquid. 
3. Tilt head back, insert swab into nostril as deep as you can without excessive discomfort. Rotate in a circle at least 3 times. 
4. Remove swab and using the same swab repeat step 3 on the other nostril. 
5. After collection, insert swab in the specimen container so the swab tip sits in the liquid.  Carefully snap off the handle at score line. **Tightly** secure cap.

#### PACKAGING

1. Insert specimen container in the biohazard zip lock bag, seal and fold in it in half. 
2. Put gel pack and the folded biohazard bag in the silver padded foil pouch and seal it. 
3. Place the foil pouch in the bigger zip lock bag. 
4. Fold and place the completely filled out requisition inside the zip lock bag and seal.  **IMPORTANT! Ensure that the patient information section is completely filled including telephone number.**

Please call QDx Client Services at (866) 909-7284 with any questions.



Icons made by QDx Pathology and pixel perfect, Darius Dan, photo3idea\_studio, Smashicons, Freepik, photo3idea\_studio from www.flaticon.com

QDx Pathology Services

# Qdetect Nasal Swab Instructions

IVD, Rx only, for use under an Emergency Use Authorization (EUA) only

**IMPORTANT:** The specimen should be collected on the same day as the pickup is scheduled. Samples should only be collected Monday-Friday, as shipping services do not operate on the weekends.

These instructions should be read before beginning testing.

## FOLLOWING THESE STEPS ENSURES ACCURATE TESTING

**SAFETY FIRST**

- You must be 18+ to use this sample collection kit.

**MUST COLLECT AND SHIP ON THE SAME WEEK DAY. MONDAY-FRIDAY ONLY. DO NOT COLLECT ON WEEKENDS!**

1. Call FedEx at 800-463-3339 for same day pick up and say you have a pre-paid express label. Visit <https://www.fedex.com/en-us/shipping/dropbox.html> to view FedEx drop box locations and pickup schedules. If they cannot pick up, please go to nearest FedEx drop off location(s) and drop off package before the last express pick up. Keep a copy of your tracking number. (Tracking number can be found on reverse side of these instructions.)



2. Call QDx Client Services at (908) 349-2444 and give them the FedEx tracking number. **IMPORTANT: Please mention you are sending a CoVID kit.**



**PREPARE FOR SAMPLE COLLECTION**

1. Wash hands with soap and water and dry thoroughly.



2. Open kit and place all items on a clean, dry surface. Make sure all items shown to the right were received.



3. **PATIENT INFORMATION FORM**  
Fill out any missing information on the order form. Ensure that the patient information section is completely filled.

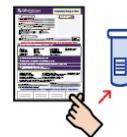


4. **LABELS**  
Fill out one label at the bottom of the order form. Make sure label is filled with date of collection, patient's name, date of birth and telephone number.



Peel off label and place it on saline collection tube.

**Note: If this step is not completed, your sample will not be processed by the lab.**



Please call QDx Client Services at (866) 909-7284 with any questions.



**QDxPath** WE LEAVE NO STONE UNTURNED IN OUR QUEST FOR *excellence*

## Specimen Collection for Urine Cytology and/or UroVysion™ FISH



**Step 1:** Record patient information in the space provided on the specimen collection cup (blue cap). Collect urine in a routine manner. If urine volume exceeds 60mL, pour off excess. A minimum of 33mL, and a maximum of 60mL of urine is needed to perform urine cytology and/or FISH testing.



**Step 2:** After urine is collected, carefully pour PreservCyt® solution (white cap) into specimen collection cup.



**Step 3:** Tightly secure blue cap on the specimen cup to prevent leakage. (Keep turning for another ¼ inch after you hear the audible click).



**Step 4:** Return specimen collection cup to urine collection kit box. Transport specimen to our laboratory in closed box.

**QDxPath** WE LEAVE NO STONE UNTURNED IN OUR QUEST FOR *excellence*.



**Thin Prep Pap Kit**  
Female HPV, CT/NG,  
Gardnerella vaginalis Candida,  
Trichomonas vaginalis



**Aptima Multitest Swab**  
Male and Female  
CT/NG, HSV 1+2,  
Trichomonas vaginalis



**Aptima Urine Collection Kit**  
Male and Female  
CT/NG



**Aptima Endocervical and  
Male Urethral Swab**  
Male and Female  
CT/NG



**BD Affirm VPiii**  
Female  
Candida, Gardnerella,  
Trichomonas vaginalis

Accession No.:

Attention: \_\_\_\_\_

Fax No.: \_\_\_\_\_

### Test Add-On Request

Top portion to be filled out by QDx Pathology Services:

- Patient Name: \_\_\_\_\_
- Date of Birth: \_\_\_\_\_
- Gender: \_\_\_\_\_
- Date of Procedure: \_\_\_\_\_
- Date Received: \_\_\_\_\_
- Submitting Location: \_\_\_\_\_
- Report Prepared by: \_\_\_\_\_
- Date/Time Faxed: \_\_\_\_\_

Comments: \_\_\_\_\_

---

**Please see below. Complete, sign and return. Thank you.**

To be completed by authorized office representative and faxed to **(908) 272-2587**:

- Test requested: \_\_\_\_\_
- ICD-10 Code: \_\_\_\_\_
- Office Representative *print* name: \_\_\_\_\_
- Office Representative *signature*: \_\_\_\_\_
- Date/Time: \_\_\_\_\_

Comments: \_\_\_\_\_

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Accession No.:

## Test Cancellation Request

To be completed by Practice:

- Patient Name: \_\_\_\_\_
- Date of Birth: \_\_\_\_\_
- Gender: \_\_\_\_\_
- Date of Procedure: \_\_\_\_\_
- Date Received: \_\_\_\_\_
- Submitting Location: \_\_\_\_\_
- Report Prepared By: \_\_\_\_\_
- Date/Time Faxed: \_\_\_\_\_

Test requested: \_\_\_\_\_

Comments: \_\_\_\_\_

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**Please see below. Complete, sign and return. Thank you.**

To be completed by authorized office representative and faxed to **(908) 272-2587**:

- Date/Time: \_\_\_\_\_
- Test requested to be cancelled: \_\_\_\_\_
- Office Representative *print* name: \_\_\_\_\_
- Office Representative *signature*: \_\_\_\_\_

Comments: \_\_\_\_\_

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