

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

For Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use only

Rx Only

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General Information

Intended Use

The Aptima® SARS-CoV-2 assay is a nucleic acid amplification *in vitro* diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP) and oropharyngeal (OP) swab specimens, nasopharyngeal washes/aspirates or nasal aspirates (collected by a healthcare provider) and anterior nasal (nasal) and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from individuals who meet COVID-19 clinical and/or epidemiological criteria, as well as NP and OP swab specimens (collected by a healthcare provider) and nasal and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from any individual, including from individuals without symptoms or other reasons to suspect COVID-19. The Aptima SARS-CoV-2 assay is for use only under Emergency Use Authorization (EUA) in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual NP or OP swabs (collected by a healthcare provider), nasal, or mid-turbinate nasal swabs (collected under observation of or by a healthcare provider) where each specimen is collected using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. For specific patients, whose specimen(s) were the subject of pooling, a notice that pooling was used during testing must be included when reporting the result to the clinician or healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA, clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Aptima SARS-CoV-2 assay on the Panther® and Panther Fusion® system is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the operation of the Panther and Panther Fusion systems and *in vitro* diagnostic procedures. The Aptima SARS-CoV-2 assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation of the Test

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus, SARS-CoV-2, causes the associated coronavirus disease COVID-19. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.¹

The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat, new loss of taste or smell, or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. The disease can spread through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.² These droplets also can land on objects and surfaces around the person.³ Other people may acquire SARS-CoV-2 by touching these objects or surfaces, then touching their eyes, nose, or mouth.

The virus that causes COVID-19 is infecting people and spreading easily from person to person. On March 11, 2020, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization (WHO).^{4,5}

Principles of the Procedure

The Aptima SARS-CoV-2 assay combines the technologies of target capture, Transcription Mediated Amplification (TMA), and Dual Kinetic Assay (DKA).

Specimens are collected and transferred into their respective specimen transport tubes. The transport solutions in these tubes release the RNA target and protect them from degradation during storage. When the Aptima SARS-CoV-2 assay is performed in the laboratory, the target RNA molecules are isolated from specimens by use of capture oligomers via target capture that utilizes magnetic microparticles. The capture oligomers contain sequences complementary to specific regions of the target molecules as well as a string of deoxyadenosine residues. A separate capture oligomer is used for each target. During the hybridization step, the sequence specific regions of the capture oligomers bind to specific regions of the target molecules. The capture oligomer:target complex is then captured out of solution by decreasing the temperature of the reaction to room temperature. This temperature reduction allows hybridization to occur between the deoxyadenosine region on the capture oligomer and the poly-deoxythymidine molecules that are covalently attached to the magnetic particles. The microparticles, including the captured target molecules bound to them, are pulled to the side of the reaction vessel using magnets and the supernatant is aspirated. The particles are washed to remove residual specimen matrix that may contain amplification reaction inhibitors. After the target capture steps are completed, the specimens are ready for amplification.

Target amplification assays are based on the ability of complementary oligonucleotide primers to specifically anneal and allow enzymatic amplification of the target nucleic acid strands. The Aptima SARS-CoV-2 assay replicates specific regions of the RNA from SARS-CoV-2 virus. Detection of the RNA amplification product sequences (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent nucleic acid probes, which are unique and complementary to a region of each target amplicon and Internal Control (IC) amplicon, are labeled with different acridinium ester (AE) molecules. The AE labeled probes combine with

amplicon to form stable hybrids. The Selection Reagent differentiates hybridized from unhybridized probe, eliminating the generation of signal from unhybridized probe. During the detection step, light emitted from the labeled hybrids is measured as photon signals in a luminometer, and are reported as Relative Light Units (RLU). In DKA, differences in the kinetic profiles of the labeled probes allow for the differentiation of signal; kinetic profiles are derived from measurements of photon output during the detection read time. The chemiluminescent detection reaction for the IC signal has very rapid kinetics and has the “flasher” kinetic type. The chemiluminescent detection reaction for the SARS-CoV-2 signal is relatively slower and has the “glower” kinetic type. Assay results are determined by a cut-off based on the total RLU and the kinetic curve type.

The Aptima SARS-CoV-2 assay amplifies and detects two conserved regions of the ORF1ab gene in the same reaction, using the same “glower” kinetic type. The two regions are not differentiated and amplification of either or both regions leads to RLU signal. The assay results are determined by a cut-off based on the total RLU and the kinetic curve type.

Warnings and Precautions

- A. For in vitro diagnostic use. For use under an Emergency Use Authorization (EUA) only. For prescription use only. Carefully read this entire package insert and the *Panther/Panther Fusion System Operator's Manual*.
- B. The Aptima SARS-CoV-2 assay has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories.
- C. The Aptima SARS-CoV-2 assay is for use only under Emergency Use Authorization (EUA) in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- D. The emergency use of the Aptima SARS-CoV-2 assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- E. The Aptima SARS-CoV-2 assay has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- F. Only personnel adequately trained on the use of this assay and in handling potentially infectious materials should perform these procedures. If a spill occurs, immediately disinfect using appropriate site procedures.
- G. Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV. <https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>.
- H. Specimens may be infectious. Use Universal Precautions when performing this assay. Proper handling and disposal methods should be established by the laboratory director. Only personnel adequately trained in handling infectious materials should be permitted to perform this diagnostic procedure.⁶

- I. If infection with SARS-CoV-2 is suspected based on current clinical screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.
- J. Use only supplied or specified disposable laboratory ware.
- K. Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).
- L. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and reagents. Wash hands thoroughly after handling specimens and reagents.
- M. Dispose of all material that has come into contact with specimens and reagents in accordance with applicable national, international, and regional regulations.
- N. Expiration dates listed on the Panther Fusion Specimen Lysis Tubes, Hologic Specimen Lysis Tubes, the Aptima Multitest Collection Kit, the Aptima Unisex Swab Specimen Collection Kit and the Aptima Specimen Transfer Kit pertain to the transfer of sample into the tube and not to testing of the sample. Specimens collected/transferred any time prior to these expiration dates are valid for testing provided they are transported and stored in accordance with the appropriate package insert, even if these expiration dates have passed.
- O. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- P. Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of virus or other organisms. Ensure that specimen containers do not come in contact with one another, and discard used materials without passing them over any open containers. Change gloves if they come in contact with specimens.
- Q. Do not use the reagents and controls after the expiration date.
- R. Store assay components at the recommended storage condition. See *Reagent Storage and Handling Requirements* (page 6), and *Panther System Test Procedure* (page 17) for more information.
- S. Do not combine any assay reagents or fluids. Do not top off reagents or fluids; the Panther system verifies reagent levels.
- T. Avoid microbial and ribonuclease contamination of reagents.
- U. Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.
- V. Do not use material that may contain Guanidinium thiocyanate or any guanidine-containing materials on the instrument. Highly reactive and/or toxic compounds may form if combined with sodium hypochlorite.

- W. Contamination may occur if carryover of samples is not adequately controlled during sample pool preparation, handling, and processing.
- X. Testing of pooled specimens may impact the detection capability of the Aptima SARS-CoV-2 Assay and decrease sensitivity.
- Y. A reagent in this kit is labeled with risk and safety symbols.

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologicds.com.

**Selection Reagent****BORIC ACID 1-5%****WARNING**

H315 - Causes skin irritation

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P332 + P313 - If skin irritation occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

Reagent Storage and Handling Requirements

- A. The following reagents are stable when stored at 2°C to 8°C (refrigerated):
- Aptima SARS-CoV-2 Amplification Reagent
 - Aptima SARS-CoV-2 Enzyme Reagent
 - Aptima SARS-CoV-2 Probe Reagent
 - Aptima SARS-CoV-2 Internal Control
 - Aptima SARS-CoV-2 Positive Control
 - Aptima SARS-CoV-2 Negative Control
- B. The following reagents are stable when stored at 2°C to 30°C:
- Aptima SARS-CoV-2 Amplification Reconstitution Solution
 - Aptima SARS-CoV-2 Enzyme Reconstitution Solution
 - Aptima SARS-CoV-2 Probe Reconstitution Solution
 - Aptima SARS-CoV-2 Selection Reagent
- C. The following reagents are stable when stored at 15°C to 30°C (room temperature):
- Aptima SARS-CoV-2 Target Capture Reagent
 - Aptima Wash Solution
 - Aptima Buffer for Deactivation Fluid
 - Aptima Oil Reagent
- D. Working Target Capture Reagent (wTCR) is stable for 30 days when stored at 15°C to 30°C. Do not refrigerate.

- E. After reconstitution, the Enzyme Reagent, Amplification Reagent, and Probe Reagent are stable for 30 days when stored at 2°C to 8°C.
- F. Discard any unused reconstituted reagents and wTCR after 30 days or after the Master Lot expiration date, whichever comes first.
- G. Controls are stable until the date indicated on the vials.
- H. Reagents stored on-board the Panther System have 120 hours of on-board stability.
Note: *Only Panther Systems with system software version 7.2.5 or higher support 120 hours of reagent on-board stability. Panther Systems with other system software versions support 72 hours of on-board reagent stability.*
- I. The Probe Reagent and Reconstituted Probe Reagent are photosensitive. Store the reagents protected from light. The specified reconstituted stability is based on 12 hours exposure of the Reconstituted Probe Reagent to two 60W fluorescent bulbs, at a distance of 17 inches (43 cm), and temperature less than 30°C. Light exposure of the Reconstituted Probe Reagent should be limited accordingly.
- J. Upon warming to room temperature, some control tubes may appear cloudy or contain precipitates. Cloudiness or precipitation associated with controls does not affect control performance. The controls may be used whether they are clear or cloudy/precipitated. If clear controls are desired, solubilization may be expedited by incubating them at the upper end of the room temperature range (15°C to 30°C).
- K. **Do not freeze the reagents.**

Specimen Collection and Storage

Specimens - Clinical material collected from patient placed in an appropriate transport system. For the Aptima SARS-CoV-2 assay, this includes NP, nasal, mid-turbinate and OP swab specimens, or nasopharyngeal wash/aspirate and nasal aspirate specimen collection in viral transport medium (VTM/UTM), saline, Liquid Amies, or specimen transport medium (STM).

Samples - Represents a more generic term to describe any material for testing on the Panther System including specimens, specimens transferred into a Panther Fusion Specimen Lysis Tube, Hologic Specimen Lysis Tube with solid cap, Custom Specimen Lysis Tube, Aptima Specimen Transfer Tube, Aptima Multitest Transport Tube, Hologic Direct Load Tube, Hologic Direct Load Capture Cap Tube, and controls.

Note: *Handle all specimens as if they contain potentially infectious agents. Use Universal Precautions.*

Note: *Take care to avoid cross-contamination during specimen handling steps. For example, discard used material without passing over open tubes.*

Swab Specimen Collection

Collect 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 3mL of VTM or UTM. Swab specimens may alternatively be added to saline, Liquid Amies or STM. The Aptima Multitest Swab Specimen Collection Kit may be used for the collection of OP and nasal swab samples. The Hologic Direct Load Collection Kit may be used for the

collection of OP and nasal swab samples. The Hologic Direct Load Capture Cap Collection Kit - CLASSIQSwab is for the collection of OP and nasal swab samples. The Hologic Direct Load Capture Cap Collection Kit - FLOQSwab is for the collection of mid-turbinate and NP swab samples.

After collection, specimens collected in VTM/UTM can be stored at 2°C to 8°C up to 96 hours before transferring to the Specimen Lysis Tube (i.e., Panther Fusion Specimen Lysis Tube, Hologic Specimen Lysis Tube with solid cap, or Custom Specimen Lysis Tube) or Aptima Specimen Transfer Tube as described in the specimen processing section below. Remaining specimen volumes in VTM/UTM can be stored at ≤-70°C.

After collection, specimens in the Aptima Multitest Tube, the Hologic Direct Load Tube, and the Hologic Direct Load Capture Cap Tube, may be stored at 2°C to 30°C up to 6 days.

Note: *It is recommended that specimens transferred to the Aptima Multitest Tube, the Hologic Direct Load Tube, and the Hologic Direct Load Capture Cap Tube, are stored capped and upright in a rack.*

The following types of VTM/UTM can be used.

- Remel MicroTest M4, M4RT, M5 or M6 formulations
- Copan Universal Transport Medium
- BD Universal Viral Transport Medium

Note: *Do not use medium that may contain Guanidium thiocyanate or any guanidine-containing material.*

Nasopharyngeal Wash/aspirate and Nasal Aspirate Specimen Collection

Collect nasopharyngeal wash/aspirate and nasal aspirate specimens according to standard techniques.

Specimen Processing

Capped Workflow using Aptima SARS-CoV-2 Assay Software

Specimen Processing using the Panther Fusion Specimen Lysis Tube

- A. Prior to testing on the Panther system, transfer 500 µL of the collected specimen* to a Panther Fusion Specimen Lysis Tube.

***Note:** *When testing frozen specimen, allow specimen to reach room temperature prior to processing.*

Specimen Processing using the Aptima Specimen Transfer Tube

- A. Prior to testing on the Panther system, transfer 1 mL of the collected specimen* to an Aptima Specimen Transfer Tube**.

***Note:** *When testing frozen specimen, allow specimen to reach room temperature prior to processing.*

****Note:** *Alternatively, an unused Aptima Multitest Tube, Aptima Unisex Tube, or Hologic Direct Load Tube can be used.*

- B. Recap the Aptima Specimen Transfer Tube tightly.

- C. Gently invert the tube 2 to 3 times to ensure complete mixture of the specimen.

Specimen Processing for Specimen Collected with the Aptima Multitest Collection Kit

- A. After placing the collected specimen* into the Aptima Multitest Tube using the Aptima Multitest Collection Kit, no further processing is required.

****Note:*** Allow specimen to reach room temperature prior to processing.

Specimen Processing for Specimen Collected with the Hologic Direct Load Tube Collection Kit

- A. After placing the collected specimen* into the Hologic Direct Load Tube, no further processing is required.

****Note:*** Allow specimen to reach room temperature prior to processing.

Uncapped Workflow using Aptima SARS-CoV-2 Assay Software

Specimen Processing using the Panther Fusion Specimen Lysis Tube

- A. Uncap the Panther Fusion Specimen Lysis Tube with penetrable cap. The penetrable cap can be retained or a replacement solid cap can be used in the next step.
- B. Prior to testing on the Panther system, transfer 500 µL of the specimen to the Panther Fusion Specimen Lysis Tube, with penetrable cap or replacement solid cap.
- C. To avoid contact with the top of the tube, loosen the cap and place the sample tube into the sample rack.
- D. Remove and discard the cap. To avoid contamination, do not pass the cap over any other sample racks or sample tubes. Inspect the sample tube. If bubbles are present, carefully remove from the sample tube (for example, use the tip of a sterile swab or similar method).

Note: Failure to remove bubbles may affect assay processing and cause invalid results.

- E. Place the rack retainer on the sample rack and load the rack into the instrument.

Specimen Processing using the Hologic Specimen Lysis Tube with Solid Cap

- A. Uncap the Hologic Specimen Lysis Tube with solid cap and retain the cap.
- B. Prior to testing on the Panther system, transfer 500 µL of the specimen to the Hologic Specimen Lysis Tube with solid cap.
- C. It is recommended to recap the tube and gently invert three times to ensure viral inactivation and a homogeneous mixture.
- D. To avoid contact with the top of the tube, loosen the cap and place the sample tube into the sample rack.
- E. Remove and discard the cap. To avoid contamination, do not pass the cap over any other sample racks or sample tubes. Inspect the sample tube. If bubbles are present, carefully remove from the sample tube (for example, use the tip of a sterile swab or similar method).

Note: Failure to remove bubbles may affect assay processing and cause invalid results.

- F. Place the rack retainer on the sample rack and load the rack into the instrument.

Specimen Processing for Specimen Collected with the Hologic Direct Load Capture Cap Collection Kit - CLASSIQSwabs and the Hologic Direct Load Capture Cap Collection Kit - FLOQSwabs

- A. After placing the collected specimen* into the Hologic Direct Load Capture Cap Tube, no further processing is required.

****Note:*** Allow specimen to reach room temperature prior to processing.

- B. To avoid contact with the top of the tube, loosen the cap and place the sample tube into the sample rack.
- C. Remove and discard the cap and swab. To avoid contamination, do not pass the cap over any other sample racks or sample tubes. Inspect the sample tube. If bubbles are present, carefully remove from the sample tube (for example, use the tip of a sterile swab or similar method).

Note: If the swab wasn't captured by the cap, recap the tube to ensure that the swab is captured and removed from the tube. Direct Load Capture Cap tubes containing a swab should not be loaded into the Panther System.

Note: Failure to remove bubbles may affect assay processing and cause invalid results.

- D. Place the rack retainer on the sample rack and load the rack into the instrument.

Specimen Processing using a Custom Specimen Lysis Tube

- A. Using a sterile, or non-sterile (unused) generic tube made of polypropylene plastic that is 12 mm to 13 mm in outer diameter and 75 mm to 100 mm in height, aliquot 0.78 mL ± 0.07 mL of bulk STM into the tube using a pipet or repeat pipettor.

Note: This step should be conducted in an area where SARS-CoV-2 specimens are NOT processed.

Note: If tubes are prepared prior to use, recap the tube and store at 15°C to 30°C until use in specimen processing.

Note: When the filled Custom Specimen Lysis Tube is stored closed, if no contaminants were introduced during the filling of the Custom Specimen Lysis Tube, the STM should be stable until the expiration date provided for the STM.

Note: There may be an increased risk of contamination when using non-sterile (unused) tubes.

- B. Uncap the custom Specimen Lysis Tube containing STM and retain the cap.
- C. Prior to testing on the Panther system, transfer 500 µL of the specimen to the custom Specimen Lysis Tube containing STM.
- D. It is recommended to recap the sample tube and gently invert three times to ensure viral inactivation and a homogeneous mixture.
- E. To avoid contact with the top of the tube, loosen the cap and place the sample tube into the sample rack.

- F. Remove and discard the cap. To avoid contamination, do not pass the cap over any other sample racks or sample tubes. Inspect the sample tube. If bubbles are present, carefully remove from the tube (for example, use the tip of a sterile swab or similar method).

Note: Failure to remove bubbles may affect assay processing and cause invalid results.

- G. Place the rack retainer on the sample rack and load the rack into the instrument.

Specimen Processing for Specimen Collected with the Aptima Multitest Collection Kit

- A. Obtain and follow instructions for Panther Fusion Specimen Lysis Tube (Step A), Hologic Specimen Lysis Tube with Solid Cap (Step A), or Custom Specimen Lysis Tube (Step A-B).
- B. Prior to testing on the Panther system, transfer 500 µL of the collected specimen from the Aptima Multitest Tube to a Panther Fusion Specimen Lysis Tube, Hologic Specimen Lysis Tube or Custom Specimen Lysis Tube as described in the specimen processing sections above.

Sample Storage

- A. Samples on board the Panther system may be archived for additional testing at a later time.
- B. Storing samples before or after testing

1. Samples in the Aptima Multitest Tube, Aptima Specimen Transfer Tube, Panther Fusion Specimen Lysis Tube, Hologic Specimen Lysis Tube, Hologic Direct Load Tube, Hologic Direct Load Capture Cap Tube, or Custom Specimen Lysis Tube should be stored upright in the rack under the following condition:
 - 2°C to 30°C up to 6 days
2. For both capped and uncapped workflows, samples should be covered with a new, clean plastic film or foil barrier.
3. If assayed samples need to be frozen or shipped,

- Capped workflows

Remove the penetrable cap and place a new non-penetrable cap on the specimen tubes. If samples need to be shipped for testing at another facility, recommended temperatures must be maintained. Prior to uncapping, specimen transport tubes must be centrifuged for 5 minutes at 420 Relative Centrifugal Force (RCF) to bring all of the liquid down to the bottom of the tube. Avoid splashing and cross-contamination.

- Uncapped workflows

Remove the solid cap and place a new solid cap on the specimen tubes. If samples need to be shipped for testing at another facility, recommended temperatures must be maintained. Prior to uncapping, specimen transport tubes must be centrifuged for 5 minutes at 420 Relative Centrifugal Force (RCF) to bring all of the liquid down to the bottom of the tube. Avoid splashing and cross-contamination.

Note: Replacement tube closures and tube plugs should not be used to cover tubes when centrifuging, freezing, or shipping.

Specimen Transport

Maintain specimen storage conditions as described in the *Specimen Collection and Storage* section on page 7.

Note: *Specimens must be shipped in accordance with applicable national, international, and regional transportation regulations.*

Specimen Pooling - Determining Appropriate Strategy for Implementation and Monitoring

When considering specimen pooling, laboratories should evaluate the appropriateness of a pooling strategy based on the positivity rate in the testing population and the efficiency of the pooling workflow. Refer to Appendix A of these Instructions for Use for additional information **prior** to implementation of specimen pooling.

Preparing Samples for Pooling

The following upper respiratory tract specimens authorized for use under the Emergency Use Authorization of the Aptima SARS-CoV-2 assay may be tested with sample pooling: nasopharyngeal, oropharyngeal, mid-turbinate, and nasal swab specimens collected into VTM/UTM, saline, Liquid Amies and specimen transport media (STM). Only specimens collected into a single type of media may be combined for each sample pool. For example, specimens collected in VTM/UTM should not be combined into a pool with specimens collected in Liquid Amies. Additionally, both neat specimens (those not prepared with STM for testing) and specimens prepared with STM for testing may be included in sample pooling. Each sample pool must be comprised of only neat or only STM prepared specimens. Recommended sample pooling workflow options for different specimen types are provided below.

For Specimens Collected in VTM/UTM, Saline or Liquid Amies

Customers may choose from one of the following two options to perform specimen processing for pooled samples using Specimen Lysis Tubes with the Aptima SARS-CoV-2 assay.

Note: *Hologic testing was performed using pooled samples generated from samples collected in a single collection medium type (i.e., VTM/UTM). Combination of multiple transport media types (e.g., VTM/UTM, saline, and Liquid Amies) in a single pool has not been evaluated.*

Option 1:

Specimen Preparation Instructions for Neat Samples Pooled Directly into a Specimen Lysis Tube (Hologic SLT, Custom SLT, and Panther Fusion SLT)

Perform the following procedure when pooling specimens collected in VTM/UTM, saline, or Liquid Amies by transferring samples directly into a Specimen Lysis Tube (Hologic SLT, Custom SLT, or Panther Fusion SLT).

- A. Determine the appropriate volume required from each individual specimen based on the pool size being implemented. The required specimen to STM ratio in the assay test sample must

be maintained for sample pooling. For example, if a pool size of 5 specimens is being utilized, 100 µL of each individual specimen (500 µL total) is required.

- B. Uncap the Specimen Lysis Tube and retain the cap.
- C. Prior to testing on the Panther system, carefully transfer the determined volume of each individual specimen from the specimen collection container to the Specimen Lysis Tube.
- D. Ensure homogeneous mixing of each prepared sample pool.

Note: Retain the individual specimens for additional testing, if required.

Option 2:

Specimen Preparation Instructions for Samples Pooled Prior to Transferring to a Specimen Lysis Tube (Hologic SLT, Custom SLT, and Panther Fusion SLT)

Perform the following procedure when pooling specimens collected in VTM/UTM, saline, or Liquid Amies, by pooling the samples prior to transferring into a Specimen Lysis Tube (Hologic SLT, Custom SLT, or Panther Fusion SLT).

- A. Obtain a generic empty tube. This tube will not be loaded on the Panther System for testing.
- B. Determine the appropriate volume required from each individual specimen based on the pool size being implemented.

Note: The total volume of the pooled specimens must be greater than 500 µL to support transfer into a Specimen Lysis Tube.

- C. Prior to testing on the Panther system, carefully transfer 500 µL of the pooled specimens from the generic tube into a Specimen Lysis Tube (Hologic SLT, Custom SLT, or Panther Fusion SLT).
- D. Ensure homogenous mixing of each prepared sample pool.

Note: Retain the individual specimens for additional testing, if required.

Option 3:

Specimen Preparation Instructions for Specimens Previously Transferred into Specimen Lysis Tubes and Pooled into an Empty Tube

Perform the following procedure when pooling specimens from Specimen Lysis Tubes (Hologic SLT, Custom SLT, or Panther Fusion SLT) by transferring directly into an empty tube per specifications in the Panther or Panther Fusion System Operators Manual.

- A. Obtain a Panther system compatible empty tube.
- B. Determine the appropriate volume required from each individual specimen based on the pool size being implemented. Specimens previously transferred into a Specimen Lysis Tube do not require additional dilution with STM prior to testing.

Note: The recommended combined volume of each individual specimen is dependent upon the dimensions of tube being utilized. A Hologic representative can provide recommendations on minimum volume requirements for processing on the Panther system.

- C. Prior to testing on the Panther system, carefully transfer the determined volume of each individual specimen from the Specimen Lysis Tubes (Hologic SLT, Custom SLT, or Panther Fusion SLT) to the Panther system compatible empty tube.
- D. Ensure homogeneous mixing of each prepared sample pool.
- E. Retain the individual specimens for additional testing if required.

For Specimens Collected in Aptima Multitest Transport Tubes

Specimen Preparation Instructions for Samples Pooled Directly into a Generic Tube

Perform the following procedure when pooling specimens collected in Aptima Multitest Transport Tubes by transferring individual specimens directly into an empty tube per specifications in the *Panther or Panther Fusion System Operators Manual*.

- A. Obtain a Panther system compatible empty tube.
- B. Determine the appropriate volume required from each individual specimen based on the pool size being implemented. Specimens collected in an Aptima Multitest Transport Tube do not require additional dilution with STM prior to testing.

Note: *The recommended combined volume of each individual specimen is dependent upon the dimensions of tube being utilized. A Hologic representative can provide recommendations on minimum volume requirements for processing on the Panther system.*

- C. Prior to testing on the Panther system, carefully transfer the determined volume of each individual specimen from the Aptima Multitest Transport Tubes to the empty tube.
- D. Ensure homogeneous mixing of each prepared sample pool.
- E. Retain the individual specimens for additional testing if required.

Panther System

Reagents for the Aptima SARS-CoV-2 assay are listed below for the Panther System. Reagent Identification Symbols are also listed next to the reagent name.

Reagents and Materials Provided

Aptima SARS-CoV-2 Assay Kit PRD-06419

250 tests (2 boxes)

Aptima SARS-CoV-2 Refrigerated Box (Box 1 of 2)
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity 250 test kit
A	Aptima SARS-CoV-2 Amplification Reagent <i>Non-infectious nucleic acids dried in buffered solution containing < 5% bulking agent.</i>	1 vial
E	Aptima SARS-CoV-2 Enzyme Reagent <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	1 vial
P	Aptima SARS-CoV-2 Probe Reagent <i>Non-infectious chemiluminescent DNA probes dried in succinate buffered solution containing < 5% detergent.</i>	1 vial
IC	Aptima SARS-CoV-2 Internal Control	1 vial

Aptima SARS-CoV-2 Room Temperature Box (Box 2 of 2)
(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity 250 test kit
AR	Aptima SARS-CoV-2 Amplification Reconstitution Solution <i>Aqueous solution containing preservatives.</i>	1 x 27.7 mL
ER	Aptima SARS-CoV-2 Enzyme Reconstitution Solution <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 x 11.1 mL
PR	Aptima SARS-CoV-2 Probe Reconstitution Solution <i>Succinate buffered solution containing < 5% detergent.</i>	1 x 35.4 mL
S	Aptima SARS-CoV-2 Selection Reagent <i>600 mM borate buffered solution containing surfactant.</i>	1 x 108 mL
TCR	Aptima SARS-CoV-2 Target Capture Reagent <i>Buffered salt solution containing solid phase and capture oligomers.</i>	1 x 54 mL
	Reconstitution Collars	3
	Master Lot Barcode Sheet	1 sheet

Materials Required and Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

	<u>Cat. No.</u>
Panther System	303095
Aptima Assay Fluids Kit <i>(Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)</i>	303014 (1000 tests)
Aptima Auto Detect Kit	303013 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther Run Kit <i>contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects</i>	303096 (5000 tests)
Tips, 1000 µL conductive, liquid sensing	10612513 (Tecan)
Aptima SARS-CoV-2 Controls Kit <i>PC - Aptima SARS-CoV-2 Positive Control. Non-infectious nucleic acid in a buffered solution containing < 5% detergent. Quantity 5 x 1.7 mL</i> <i>NC - Aptima SARS-CoV-2 Negative Control. A buffered solution containing < 5% detergent. Quantity 5 x 1.7 mL</i>	PRD-06420
Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Hologic Direct Load Tube Collection Kit	PRD-06997
Hologic Direct Load Capture Cap Collection Kit - CLASSIQSwabs	PRD-06951
Hologic Direct Load Capture Cap Collection Kit - FLOQSwabs	PRD-06952
Aptima Specimen Transfer Kit	301154C
Aptima Specimen Transfer Kit - printable	PRD-05110
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens	301041
Panther Fusion Specimen Lysis Tubes, 100 per bag <i>tube contains 0.71 mL of STM with a penetrable cap</i>	PRD-04339
Hologic Specimen Lysis Tubes, 100 each <i>tube contains 0.71 mL of STM with a solid cap (for uncapped workflow)</i>	PRD-06554
Hologic Specimen Lysis Tubes, 1200 each <i>tube contains 0.71 mL of STM with a solid cap (for uncapped workflow)</i>	PRD-06660
Specimen Transport Medium, 1 bottle, 80 mL (for uncapped workflow)	PRD-04423
Bleach, 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution	—
Disposable gloves	—

	<u>Cat. No.</u>
Hologic Solid Cap for use with PRD-06660*, 100 caps per bag <i>*a single-use cover for the Hologic Specimen Lysis Tube (PRD-06660 only) after testing as part of the uncapped workflow</i>	PRD-06723
Hologic Solid Cap for use with PRD-06951* and PRD-06952*, 100 caps per bag <i>*a single-use cover for the Direct Load Capture Cap (PRD-06951 and PRD-06952) after testing as part of the uncapped workflow</i>	PRD-07028
Hologic Flange Cap 12/13mm, natural	PRD-06850
Fisherbrand VersaClosure Tube Closures*, 1000 per pack <i>*a single-use tube cover for the Hologic Specimen Lysis Tube (PRD-06554 only) after testing as part of the uncapped workflow</i>	02-707
Replacement Caps for the 250-test kits <i>Amplification and Probe reagent reconstitution solutions CL0041 (100 caps)</i> <i>Enzyme Reagent reconstitution solution 501616 (100 caps)</i> <i>TCR and Selection reagent CL0040 (100 caps)</i>	—

Optional Materials

	<u>Cat. No.</u>
Hologic Bleach Enhancer for Cleaning <i>for routine cleaning of surfaces and equipment</i>	302101
Generic Sample Tube (for Custom SLT) <i>*Size: 12 x 75 mm to 13 x 100 mm (including 12 x 100 mm, 13 x 75 mm, and 13 x 82 mm)</i> <i>Material: Polypropylene plastic</i> <i>Non-sterile (unused) or sterile</i> <i>Round, flat bottom, or conical (skirted conical)</i>	—
Tube rocker	—

Panther System Test Procedure

Note: Refer to the Panther/Panther System Operator's Manual for additional procedural information.

A. Work Area Preparation

Clean work surfaces where reagents and samples will be prepared. Wipe down work surfaces with 2.5% to 3.5% (0.35M to 0.5M) sodium hypochlorite solution. Allow the sodium hypochlorite solution to contact surfaces for at least 1 minute and then follow with a water rinse. Do not allow the sodium hypochlorite solution to dry. Cover the bench surface on which the reagents and samples will be prepared with clean, plastic-backed absorbent laboratory bench covers.

B. Reagent Reconstitution/Preparation of a New Kit

Note: Reagent reconstitution should be performed prior to beginning any work on the Panther System.

1. To reconstitute Amplification, Enzyme, and Probe Reagents, combine the bottles of lyophilized reagent with the reconstitution solution. If refrigerated, allow the reconstitution solutions to reach room temperature before use.
 - a. Pair each reconstitution solution with its lyophilized reagent. Ensure that the reconstitution solution and reagent have matching label colors before attaching the reconstitution collar.
 - b. Check the lot numbers on the Master Lot Barcode Sheet to ensure that the appropriate reagents are paired.
 - c. Open the lyophilized reagent vial and firmly insert the notched end of the reconstitution collar into the vial opening (Figure 1, Step 1).
 - d. Open the matching reconstitution solution, and set the cap on a clean, covered work surface.
 - e. While holding the reconstitution solution bottle on the bench, firmly insert the other end of the reconstitution collar into the bottle opening (Figure 1, Step 2).
 - f. Slowly invert the assembled bottles. Allow the solution to drain from the bottle into the glass vial (Figure 1, Step 3).
 - g. Thoroughly mix the solution in the glass vial by swirling (Figure 1, Step 4).
 - h. Wait for the lyophilized reagent to go into solution, then invert the assembled bottles again, tilting at a 45° angle to minimize foaming (Figure 1, Step 5). Allow all of the liquid to drain back into the plastic bottle.
 - i. Remove the reconstitution collar and glass vial (Figure 1, Step 6).
 - j. Recap the plastic bottle. Record operator initials and reconstitution date on the label (Figure 1, Step 7).
 - k. Discard the reconstitution collar and glass vial (Figure 1, Step 8).

Option: Additional mixing of the Amplification, Enzyme, and Probe Reagents using a tube rocker is allowed. The reagents may be mixed by placing the recapped plastic bottle on a tube rocker set to 20 RPM (or equivalent) for a minimum of 5 minutes.

Warning: Avoid creating foam when reconstituting reagents. Foam compromises the level-sensing in the Panther System.

Warning: Adequate mixing of the reagents is necessary to achieve expected assay results.

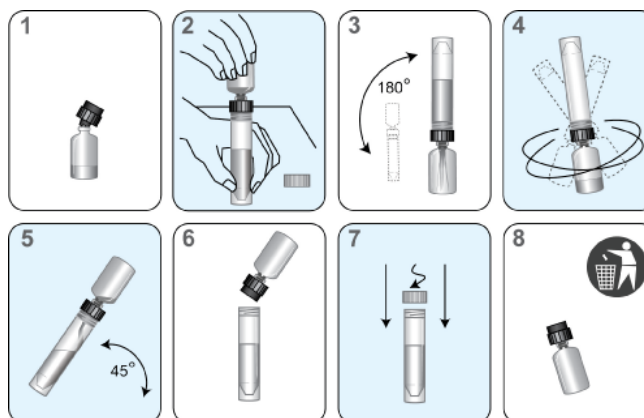


Figure 1. Panther System Reconstitution Process

2. Prepare Working Target Capture Reagent (wTCR)
 - a. Pair the appropriate bottles of TCR and IC.
 - b. Check the reagent lot numbers on the Master Lot Barcode Sheet to make sure that the appropriate reagents in the kit are paired.
 - c. Open the bottle of TCR, and set the cap on a clean, covered work surface.
 - d. Open the IC bottle and pour the entire contents into the bottle of TCR. Expect a small amount of liquid to remain in the IC bottle.
 - e. Cap the bottle of TCR and gently swirl the solution to mix the contents. Avoid creating foam during this step.
 - f. Record operator initials and the current date on the label.
 - g. Discard the IC bottle and cap.
3. Prepare Selection Reagent
 - a. Check the lot number on the reagent bottle to make sure it matches the lot number on the Master Lot Barcode Sheet.
 - b. Record operator initials and the current date on the label.

Note: Thoroughly mix by gently inverting all reagents prior to loading on the system. Avoid creating foam during inversion of reagents.

C. Reagent Preparation for Previously Reconstituted Reagents

1. Previously reconstituted Amplification, Enzyme, and Probe Reagents must reach room temperature (15°C to 30°C) prior to the start of the assay.

Option: The reagents may be brought to room temperature by placing the reconstituted Amplification, Enzyme, and Probe Reagents on a tube rocker set to 20 RPM (or equivalent) for a minimum of 25 minutes.
2. If reconstituted Probe Reagent contains precipitate that does not return to solution at room temperature, heat the capped bottle at a temperature that does not exceed 62°C for 1 to 2 minutes. After this heat step, the Probe Reagent may be used even if residual precipitate remains. Mix Probe Reagent by inversion, being careful not to induce foam, prior to loading onto the system.

3. Thoroughly mix each reagent by gently inverting prior to loading on the system. Avoid creating foam during inversion of reagents. This step is not required if reagents are loaded onto the system directly after mixing on the tube rocker.
 4. Do not top off reagent bottles. The Panther System will recognize and reject bottles that have been topped off.
 5. *Adequate mixing of the reagents is necessary to achieve expected assay results.*
- D. Specimen Handling using Panther Fusion Specimen Lysis Tube or Aptima Specimen Transfer Tube
- Note:** *Prepare specimens per the Specimen Processing instructions in the Specimen Collection and Storage section before loading specimens onto the Panther system.*
1. Inspect sample tubes before loading into the rack. If a sample tube contains bubbles or has a lower volume than is typically observed, gently tap the bottom of the tube to bring contents to the bottom.
- Note:** *For samples transferred to the Panther Fusion Specimen Lysis Tube or the Aptima Specimen Transfer Tube, to avoid a processing error, ensure adequate specimen volume is added to the tube. When adequate collected specimen is added to the tube, there is sufficient volume to perform 3 nucleic acid extractions.*
- E. Specimen Handling using Hologic Specimen Lysis Tube or Custom Specimen Lysis Tube
1. Prepare specimens per the specimen processing instructions in the *Specimen Collection and Storage* section.
- Note:** *For samples transferred to the Hologic Specimen Lysis Tube or a custom Specimen Lysis Tube, to avoid a processing error, ensure adequate specimen volume is added to the tube.*
- Note:** *When adequate collected specimen is added to the Hologic Specimen Lysis Tube (PRD-06554) or a custom Specimen Lysis Tube, there is sufficient volume to perform 2 nucleic acid extractions.*
- Note:** *When adequate collected specimen is added to the Hologic Specimen Lysis tube (PRD-06660), there is sufficient volume to perform 1 nucleic acid extraction. If an additional extraction is desired, a second Hologic Specimen Lysis Tube (PRD-06660) should be prepared using specimen from the primary collection tube (i.e. UTM, VTM, saline, etc.).*
- Note:** *When using the Aptima SARS-CoV-2 uncapped tube assay software, remove the cap from the Positive and Negative control before loading onto the Panther system.*
- F. System Preparation
1. Set up the system according to the instructions in the *Panther/Panther Fusion System Operator's Manual* and *Procedural Notes*. Make sure that the appropriately sized reagent racks and TCR adapters are used.
 2. Load samples.

Procedural Notes

A. Controls

1. To work properly with the Aptima Assay software for the Panther system, one pair of controls is required. The Aptima SARS-CoV-2 positive and negative controls can be

loaded in any rack position or in any Sample Bay Lane on the Panther system. Patient specimen pipetting will begin when one of the following two conditions has been met:

- a. A pair of controls is currently being processed by the system.
 - b. Valid results for the controls are registered on the system.
2. Once the control tubes have been pipetted and are processing for a specific reagent kit, patient specimens can be run with the associated kit up to 24 hours unless:
 - a. Controls results are invalid.
 - b. The associated assay reagent kit is removed from the system.
 - c. The associated assay reagent kit has exceeded stability limits.
 3. Each Aptima control tube can be tested once. Attempts to pipette more than once from the tube can lead to processing errors.
 4. Patient specimen pipetting begins when one of the following two conditions is met:
 - a. Valid results for the controls are registered on the system.
 - b. A pair of controls is currently in process on the system.

B. Temperature

Room temperature is defined as 15°C to 30°C.

C. Glove Powder

As in any reagent system, excess powder on some gloves may cause contamination of opened tubes. Powderless gloves are recommended.

D. Lab Contamination Monitoring Protocol for the Panther System

There are many laboratory-specific factors that may contribute to contamination, including testing volume, workflow, disease prevalence and various other laboratory activities. These factors should be taken into consideration when contamination monitoring frequency is being established. Intervals for contamination monitoring should be established based on each laboratory's practices and procedures.

To monitor for laboratory contamination, the following procedure may be performed using the Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens:

1. Label swab transport tubes with numbers corresponding to the areas to be tested.
2. Remove the specimen collection swab (blue shaft swab with green printing) from its packaging, wet the swab in the specimen transport medium (STM), and swab the designated area using a circular motion.
3. Immediately insert the swab into transport tube.
4. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.
5. Recap the swab transport tube tightly.
6. Repeat Steps 2 to 5 for each area to be swabbed.

- E. If the results are positive, see *Interpretation of Results*. For additional Panther system-specific contamination monitoring information, contact Hologic Technical Support.

Quality Control

A run or specimen result may be invalidated by the Panther system if problems occur while performing the assay. Specimens with invalid results must be retested.

Negative and Positive Controls

To generate valid results, a set of assay controls must be tested. One replicate of the negative assay control and positive assay control must be tested each time a new kit is loaded on the Panther system or when the current set of valid controls have expired.

The Panther system is configured to require assay controls run at an administrator-specified interval of up to 24 hours. Software on the Panther system alerts the operator when assay controls are required and does not start new tests until the assay controls are loaded and have started processing.

During processing, criteria for acceptance of the assay controls are automatically verified by the Panther system. To generate valid results, the assay controls must pass a series of validity checks performed by the Panther system.

If the assay controls pass all validity checks, they are considered valid for the administrator-specified time interval. When the time interval has passed, the assay controls are expired by the Panther system which requires a new set of assay controls be tested prior to starting any new samples.

If any one of the assay controls fails the validity checks, the Panther system automatically invalidates the affected samples and requires a new set of assay controls be tested prior to starting any new samples.

Internal Control

An internal control is added to each sample with the wTCR. During processing, the internal control acceptance criteria are automatically verified by the Panther system software. Detection of the internal control is not required for samples that are positive for SARS-CoV-2. The internal control must be detected in all samples that are negative for SARS-CoV-2 targets; samples that fail to meet that criteria will be reported as Invalid. Each sample with an Invalid result must be retested.

The Panther system is designed to accurately verify processes when procedures are performed following the instructions provided in this package insert and the *Panther/Panther Fusion System Operator's Manual*.

Interpretation of Results

The Panther system automatically determines the test results for samples and controls. A test result may be negative, positive, or invalid.

Table 1 shows the possible results reported in a valid run with result interpretations.

Table 1: Result Interpretation

SARS-CoV-2 Result	IC Result	Interpretation
Neg	Valid	SARS-CoV-2 not detected.
POS	Valid	SARS-CoV-2 detected.
Invalid	Invalid	Invalid. There was an error in the generation of the result; retest sample.

Note: Detection of internal control is not required for samples that are positive for SARS-CoV-2.

Interpretation of Results for Pooled Samples

Negative: Negative results from pooled sample testing should not be treated as definitive. If the patient's clinical signs and symptoms are inconsistent with a negative result and results are necessary for patient management, then the patient should be considered for individual testing. The utilization of sample pooling should be indicated for any specimens with reported negative results.

Positive: Specimens with a positive sample pool result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Invalid: Specimens with an invalid result must be tested individually prior to reporting a result. However, in instances of an invalid run, repeat testing of pooled specimens may be appropriate depending on the laboratory workflow and required result reporting time.

Limitations

- A. Use of this assay is limited to personnel who are trained in the procedure. Failure to follow these instructions may result in erroneous results.
- B. Reliable results are dependent on adequate specimen collection, transport, storage, and processing.
- C. Avoid contamination by adhering to good laboratory practices and to the procedures specified in this package insert.
- D. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other management decisions.
- E. 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.
- F. Nasopharyngeal wash/aspirate or nasal aspirates and self-collected under supervision of 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; however, performance with these specimen types have not been determined.
- G. Nasopharyngeal wash/aspirate and nasal aspirates specimen types should not be pooled.
- H. Sample pooling has only been validated using nasopharyngeal swab specimens.

- I. Samples should only be pooled when testing demand exceeds laboratory capacity and/or when testing reagents are in short supply.
- J. The Aptima SARS-CoV-2 assay may be used to test asymptomatic individuals, although performance has not been demonstrated in an asymptomatic population. This assay has been shown to exhibit high sensitivity when tested with the FDA reference panel.
- K. Use of the Aptima SARS-CoV-2 assay in a general, asymptomatic screening population is intended to be used as part of an infection control plan, that may include additional preventative measures, such as a predefined serial testing plan or directed testing of high-risk individuals. Negative results should be considered presumptive and do not preclude current or future infection obtained through community transmission or other exposures. Negative results must be considered in the context of an individual's recent exposures, history, and presence of clinical signs and symptoms consistent with COVID-19.
- L. Asymptomatic individuals infected with COVID-19 may not shed enough virus to reach the limit of detection of the test, giving a false negative result.
- M. In the absence of symptoms, it is difficult to determine if asymptomatic individuals have been tested too late or too early. Therefore, negative results in asymptomatic individuals may include individuals who were tested too early and may become positive later, individuals who were tested too late and may have serological evidence of infection, or individuals who were never infected.
- N. Evaporation of STM in the Hologic Specimen Lysis Tube, Solid Cap (1200 Tubes), PRD-06660, has been observed when stored at the upper end of the recommended temperature range (sustained storage at 28°C) near the end of the product's shelf-life (i.e., 9-months). Due to the observed evaporation, the section "Panther System Test Procedure, E" was revised to indicate that only a single extraction should be performed after an aliquot of the collected specimen has been transferred into the Hologic Specimen Lysis Tube, Solid Cap (1200 Tubes), PRD-06660. If an additional extraction is desired, a second Hologic Specimen Lysis Tube, Solid Cap should be prepared using specimen from the primary collection tube (i.e. UTM, VTM, saline, etc.).
- O. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Conditions of Authorization for Labs

The Aptima SARS-CoV-2 assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>.

However, to assist clinical laboratories using the Aptima SARS-CoV-2 assay, the relevant Conditions of Authorization are listed below.

- A. Authorized laboratories¹ using the Aptima SARS-CoV-2 assay must include with test result reports of the Aptima SARS-CoV-2 assay, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using specimen pooling strategies when testing patient specimens with the authorized test must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that “Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.”
- C. Authorized laboratories using the Aptima SARS-CoV-2 assay must perform the Aptima SARS-CoV-2 assay as outlined in the Aptima SARS-CoV-2 assay Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the Aptima SARS-CoV-2 assay are not permitted.
- D. Authorized laboratories implementing pooling strategies for testing patient specimens must use the “Appendix A: Specimen Pooling Implementation and Monitoring Guidelines” available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.
- E. Authorized laboratories that receive the Aptima SARS-CoV-2 assay must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- F. Authorized laboratories using the Aptima SARS-CoV-2 assay must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- G. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Protocol for Monitoring of Specimen Pooling Strategies. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request, and will be made available within a reasonable time after 12 months from the date of their creation.
- H. Authorized laboratories must collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Hologic (molecularsupport@hologic.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

- I. All laboratory personnel using the test must be appropriately trained in Transcription Mediated Amplification techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.
- J. Hologic, its authorized distributor(s) and authorized laboratories using the Aptima SARS-CoV-2 assay must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

¹ The letter of authorization refers to “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests” as “authorized laboratories.”

Aptima Assay Performance

Analytical Sensitivity

The analytical sensitivity (limit of detection or LoD) of the Aptima SARS-CoV-2 assay using the Panther Fusion Specimen Lysis Tube workflow was determined by testing serial dilutions of pooled negative clinical nasopharyngeal swab specimens spiked with inactivated cultured SARS-CoV-2 virus (USA-WA1/2020; BEI Resources; NR-52281). Ten replicates of each serial dilution were evaluated using each of two assay reagent lots across two Panther systems. The LoD was determined to be 0.01 TCID₅₀/mL in the test sample (0.026 TCID₅₀/mL in the neat, unprocessed sample) and verified by testing an additional 20 replicates with one assay reagent lot. The LoD was also confirmed using saline, Liquid Amies and specimen transport medium (STM) swab collection media.

The analytical sensitivity of the Aptima SARS-CoV-2 assay was additionally evaluated using nucleic acid materials from three commercial vendors. Serial dilutions of the nucleic acid materials were made in Aptima Multitest tubes (containing STM and 10,000 copies/mL HeLa cells) and 20 or more replicates at each level were tested using each of two assay reagent lots across two Panther systems. For each material, the lowest dilution resulting in $\geq 95\%$ detection was 83 copies/mL in the test sample. A test sample concentration of 83 copies/mL correlates to 323.7 copies/mL of material added to the Aptima Multitest tube or 212.5 copies/mL of material added to a neat, unprocessed Specimen Lysis Tube (SLT). The nucleic acid materials and the performance of the 83 copies/mL dilution are listed in Table 2.

Table 2: Analytical Sensitivity Evaluation of Commercial Material

Vendor and Name	Reference # and Lot #	N Valid	N Positive	% Positive	Avg kRLU	StdDev kRLU	% CV
ZeptoMetrixSAR S-CoV-2 External Run Control	NATSARS(COV2)-ERC 324332	40	39	98%	965	212	21.90%
SeraCare SARS-Cov-2 Reference Material	0505-0126 10483977	40	40	100%	728	38	5.30%
Exact Diagnostics SARS-CoV-2 Standard	COV019 20033001	40	40	100%	1032	152	14.70%

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to

confirm the LoD. The study was performed on the fully automated Panther system. The results are summarized in Table 3.

Table 3: Summary of LoD Confirmation Results using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	NP Swabs in VTM/UTM	600 NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL.

N/A = Not applicable.

ND = Not detected.

Analytical Sensitivity with the Aptima Specimen Transfer Tube Workflow

The determined 0.026 TCID₅₀/mL analytical sensitivity (limit of detection) of the Aptima SARS-CoV-2 assay in the neat, unprocessed sample was confirmed using the Aptima Specimen Transfer Tube specimen preparation workflow. Confirmation was performed using inactivated cultured SARS-CoV-2 virus (USA-QA1/2020; BEI Resources; NR-52281) in negative clinical nasopharyngeal (NP) swab, saline, Liquid Amies and specimen transport medium (STM) swab collection media by testing 20 replicates with one reagent lot.

Precision/Reproducibility

The Aptima SARS-CoV-2 assay precision/reproducibility was evaluated on three Panther systems at a single site using four panel members. Testing was performed using three lots of assay reagents with two operators over six days. Two runs were performed per operator per day for a total of 36 runs. Each of the four panels was tested in three replicates per run for a total of 108 replicates per panel.

Positive and negative panel members consisted of pooled clinical nasopharyngeal (NP) swab matrix combined with Solution Transport Media (STM) in a ratio of 1:1.56. Positive panel members spiked with inactivated cultured SARS-CoV-2 virus at 0.1x LoD (High Negative), 1x LoD (Low Positive) and 5x LoD (Moderate Positive).

The agreement with expected results was 100% in the Negative, Low Positive and Moderate Positive panel members. The High Negative panel member was 10x below the assay LoD, therefore a mix of positive and negative results were expected. This panel gave 68/108 (63%) positive results. Agreement with expected results for all four panels is shown in Table 4.

Table 4: Agreement of Aptima SARS-CoV-2 Assay Results with Expected Results

Panel Description	Panel Composition	Panel Conc. TCID ₅₀ /mL	Expected Result	N Positive	N Tested	Mean kRLU	Agreement w/Expected (95% CI)
Negative	N/A	N/A	Negative	0	108	289	100% (96.6-100)
High Negative	0.1x LoD	0.001	N/A	68	108	627	N/A
Low Positive	1.0x LoD	0.01	Positive	108	108	1131	100% (96.6-100)
Moderate Positive	5.0x LoD	0.05	Positive	108	108	1147	100% (96.6-100)

The total SARS-CoV-2 signal variability measured as %CV ranged from 2.75% to 3.84% in Negative, Low Positive, and Moderate Positive panel members. For the sources of variation all six factors evaluated had %CV values <3.0% as shown in Table 5. The High Negative panel member is 10x below the assay LoD and the %CV for this panel is expected to be higher than the others. The highest source of variability for this panel was within-run variability.

Table 5: kRLU Signal Variability of the Aptima SARS-CoV-2 Assay by Panel Member

Panel	Between Days		Between Instruments		Between Operators		Between Lots		Between Runs		Within Runs		Total	
	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Negative	0.91	0.31	4.97	1.72	0.0	0.0	4.04	1.40	0.0	0.0	6.75	2.33	9.35	3.23
High Negative*	30.45	4.85	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	244.08	38.91	245.97	39.21
Low Positive	6.46	0.57	6.74	0.60	0.0	0.0	28.10	2.48	0.0	0.0	31.77	2.81	43.43	3.84
Moderate Positive	8.53	0.74	5.59	0.49	0.0	0.0	22.98	2.00	11.06	0.96	15.59	1.36	31.59	2.75

*Panel was built to 10x below the assay LoD. Higher variability is expected in this panel.

Note: In the event that variability from some factors is numerically negative, SD and CV are shown as 0.0.

Inclusivity

The inclusivity of the Aptima SARS-CoV-2 assay was evaluated using *in silico* analysis of the assay target capture oligos, amplification primers, and detection probes in relation to 49,741 SARS-CoV-2 sequences available in the NCBI and GISAID gene databases as of July 16th, 2020. Any sequence with missing or ambiguous sequence information was removed from the analysis for that region, resulting in 49,659 sequences evaluated for the first target region of the assay and 49,514 for the second target region. The *in silico* analysis showed 100% homology to the assay oligos of both target systems for 48,180 (96.9%) of the evaluated sequences and 100% homology to the assay oligos of at least one target system for 49,730 (99.98%) of sequences. There were no evaluated sequences with identified mismatches predicted to impact binding or performance of both target systems.

Analytical Specificity and Microbial Interference

The analytical specificity of the Aptima SARS-CoV-2 assay was evaluated by testing 30 microorganisms representing common respiratory pathogens or closely related species (Table 6). Bacteria were tested at 10^6 CFU/mL and viruses were tested at 10^5 TCID₅₀/mL, except where noted. Microorganisms were tested with and without the presence of SARS-CoV-2 inactivated virus at 3x LoD. Analytical specificity of the Aptima SARS-CoV-2 assay was 100% with no evidence of microbial interference.

In addition to microorganism testing, *in silico* analysis was performed to assess the specificity of the assay in relation to the microorganisms listed in Table 6. The *in silico* analysis showed no probable cross reactivity to any of the 112 GenBank sequences evaluated.

Table 6: Aptima SARS-CoV-2 Analytical Specificity and Microbial Interference Microorganisms

Microorganism	Concentration	Microorganism	Concentration
Human coronavirus 229E	1E+5 TCID ₅₀ /mL	Parainfluenza virus 1	1E+5 TCID ₅₀ /mL
Human coronavirus OC43	1E+5 TCID ₅₀ /mL	Parainfluenza virus 2	1E+5 TCID ₅₀ /mL
Human coronavirus HKU1 ¹	1E+6 copies/mL	Parainfluenza virus 3	1E+5 TCID ₅₀ /mL
Human coronavirus NL63	1E+4 TCID ₅₀ /mL	Parainfluenza virus 4	1E+3 TCID ₅₀ /mL
SARS-coronavirus ¹	1E+6 copies/mL	Influenza A	1E+5 TCID ₅₀ /mL
MERS-coronavirus	1E+4 TCID ₅₀ /mL	Influenza B	2E+3 TCID ₅₀ /mL
Adenovirus (e.g. C1 Ad. 71)	1E+5 TCID ₅₀ /mL	Enterovirus (e.g. EV68)	1E+5 TCID ₅₀ /mL
Human Metapneumovirus (hMPV)	1E+6 TCID ₅₀ /mL	Rhinovirus	1E+4 TCID ₅₀ /mL
Respiratory syncytial virus	1E+5 TCID ₅₀ /mL	<i>Legionella pneumophila</i>	1E+6 CFU/mL
<i>Chlamydia pneumoniae</i>	1E+6 IFU/mL	<i>Mycobacterium tuberculosis</i>	1E+6 TCID ₅₀ /mL
<i>Haemophilus influenzae</i>	1E+6 CFU/mL	<i>Streptococcus pneumoniae</i>	1E+6 CFU/mL
<i>Bordetella pertussis</i>	1E+6 CFU/mL	<i>Streptococcus pyogenes</i>	1E+6 CFU/mL
<i>Pneumocystis jirovecii</i> (PJP)	1E+6 nuc/mL	<i>Streptococcus salivarius</i>	1E+6 CFU/mL
<i>Candida albicans</i>	1E+6 CFU/mL	<i>Mycoplasma pneumoniae</i>	1E+6 CFU/mL
<i>Staphylococcus epidermidis</i>	1E+6 CFU/mL	<i>Pseudomonas aeruginosa</i>	1E+6 CFU/mL
Pooled human nasal wash ² - to represent diverse microbial flora in human respiratory tract	N/A		

¹ Cultured virus and whole genome purified nucleic acid for Human coronavirus HKU1 and SARS-coronavirus are not readily available. HKU1 and SARS-coronavirus IVTs corresponding to the ORF1ab gene regions targeted by the assay were used to evaluate cross-reactivity and microbial interference.

² In place of evaluating pooled human nasal wash, testing of 30 individual negative clinical NP swab specimens was performed to represent diverse microbial flora in the human respiratory tract.

Carryover Contamination

The carryover contamination rate of the Aptima SARS-CoV-2 assay for samples tested with the capped tube and uncapped tube workflows was determined. The evaluation consisted of testing high titer SARS-CoV-2 target panels spiked at over 10,000 times the assay LoD in a checkerboard pattern with negative panels in four runs on three Panther systems. The capped

tube workflow had an observed carryover rate of 0%, whereas the uncapped tube workflow carryover rate was 0.67% with 5 of 744 negative samples evaluated giving a false positive result.

Uncapped Workflow Performance

The performance of the Aptima SARS-CoV-2 assay using the uncapped tube workflow was evaluated under variable factors including multiple operators, runs per day, and testing days. The uncapped workflow was evaluated with two tube types prefilled to 0.780 mL with specimen transport medium (STM) as representative of Hologic supplied Specimen Lysis Tubes (SLTs) and with two empty tube types as representative of custom SLTs. A variety of tube sizes covering the recommended tube dimensions and materials were included in the evaluation. The workflow evaluation included both high concentration SARS-CoV-2 positive and negative panels processed using the uncapped tube workflow.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) was calculated in relation to the expected result of the panel, as shown in Table 7. The uncapped tube workflow showed positive and negative agreements of 100% (99.4% - 100%) and 99.7% (98.9% - 99.9%) respectively.

Table 7: Aptima SARS-CoV-2 Uncapped Workflow Performance

		Expected SARS-CoV-2 Result		
		Positive	Negative	Total
Aptima SARS-CoV-2 Result	Positive	639	2	641
	Negative	0	638	638
	Total	639	640	1279

Overall Agreement: 99.8% (99.4% - 100%)

Positive Agreement: 100% (99.4% - 100%)

Negative Agreement: 99.7% (98.9% - 99.9%)

Uncapped Tube Workflow Specimen and STM Volume Guardbands

The performance of the Aptima SARS-CoV-2 assay was evaluated under specimen and STM volume variance conditions of up to $\pm 20\%$ of those specified for processing specimens with the custom SLT workflow. Positive SARS-CoV-2 positive panels at the LoD of the assay (i.e., 0.010 TCID₅₀/mL) and negative panels were evaluated at each volume guardband variance condition. Agreement to expected result was 100% for the Aptima SARS-CoV-2 assay.

Clinical Performance

The clinical performance of the Aptima SARS-CoV-2 assay was evaluated in comparison to the Panther Fusion SARS-CoV-2 assay (Hologic, Inc.) using a panel of remnant clinical specimens. For the study, remnant clinical nasopharyngeal specimens were collected from US patients with signs and symptoms of respiratory infection.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) was calculated in relation to the Panther Fusion assay as the reference result, as shown in Table 8. The Aptima SARS-CoV-2 assay showed positive and negative agreements of 100% and 98.2%, respectively.

Nasopharyngeal wash/aspirate, nasal aspirates, nasal swabs (self collected under supervision of, or healthcare provider-collected) and mid-turbinate nasal swabs are acceptable specimens to test for viral respiratory infections. However, performance with these specimen types has not been specifically evaluated with the Aptima SARS-CoV-2 assay.

Table 8: Aptima SARS-CoV-2 Clinical Agreement

		Panther Fusion SARS-CoV-2 Assay	
		Positive	Negative
Aptima SARS-CoV-2 Assay	Positive	50	1
	Negative	0	54

Overall Agreement: (95% CI): 99.0% (94.8% – 99.8%)

Positive Percent Agreement: (95% CI): 100% (92.9% – 100%)

Negative Percent Agreement: (95% CI): 98.2% (90.4% – 99.7%)

Clinical Performance with Contrived Panel

The clinical performance of the Aptima SARS-CoV-2 assay using the Aptima Specimen Transfer tube specimen preparation workflow was evaluated by testing contrived specimens. For the study, a panel of 115 remnant clinical nasopharyngeal specimens was tested using both the Panther Fusion Specimen Lysis Tube (Specimen Lysis Tube) and Aptima Specimen Transfer tube workflows. All specimens were collected from US patients with signs and symptoms of respiratory infection. The panel consisted of 65 SARS-CoV-2 positive and 50 SARS-CoV-2 negative specimens. Of the 65 positive specimens, 40 were at concentrations 0.5-2x LoD and 25 were at concentrations 3-5x LoD using inactivated cultured SARS-CoV-2 virus (USA-QA1/2020; BEI Resources; NR-52281) as the target. Due to limitations in available clinical specimens, reduced specimen/media volumes were utilized, while maintaining the Aptima Specimen Transfer workflow ratio of 1 mL specimen into 2.9 mL STM.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for both specimen preparation workflows were calculated in relation to the expected result of the contrived specimen panel, as shown in Table 9 for the Specimen Lysis Tube and Table 10 for the Aptima Specimen Transfer Tube. Detection characteristics for the contrived specimens were calculated by target concentration, as shown in Table 11, in addition to a breakdown of the positive specimens by concentration in relation to the assay LoD. Both specimen preparation workflows showed 100% agreement for the evaluated panels.

Table 9: Performance of the Specimen Lysis Tube Workflow Relative to Expected Results

Specimen Lysis Tube Result	Expected Result		
		Positive	Negative
	Total		
Positive	65	0	65
Negative	0	50	50
Total	65	50	115

Overall Agreement: 100% (96.8% – 100%)

Positive Agreement: 100% (94.4% – 100%)

Negative Agreement: 100% (92.9% – 100%)

Table 10: Performance of the Aptima Specimen Transfer Tube Workflow Relative to Expected Results

Aptima Specimen Transfer Result	Expected Result		
		Positive	Negative
	Total		
Positive	65	0	65
Negative	0	50	50
Total	65	50	115

Overall Agreement: 100% (96.8% – 100%)

Positive Agreement: 100% (94.4% – 100%)

Negative Agreement: 100% (92.9% – 100%)

Table 11: Detection Characteristics for Contrived Nasopharyngeal Swab Specimens

Aptima Specimen Transfer Sample Workflow							Specimen Lysis Tube Sample Workflow					
Target Conc.	n Valid	n Positive	% Positive	Average kRLU	St Dev kRLU	%CV	n Valid	n Positive	% Positive	Average kRLU	St Dev kRLU	%CV
Neg	50	0	0	299	9.7	3.2	50	0	0	300	9.3	3.1
0.5x LoD	10	10	100	1050	208.5	19.9	10	10	100	1153	113.0	9.8
1.0x LoD	10	10	100	1176	102.1	8.7	10	10	100	1205	24.3	2.0
1.5x LoD	10	10	100	1222	31.6	2.6	10	10	100	1223	21.9	1.8
2.0x LoD	10	10	100	1225	22.6	1.8	10	10	100	1237	26.0	2.1
3.0x LoD	10	10	100	1228	13.6	1.1	10	10	100	1215	25.5	2.1
4.0x LoD	5	5	100	1238	16.7	1.4	5	5	100	1212	12.5	1.0
5.0x LoD	10	10	100	1237	18.2	1.5	10	10	100	1246	28.3	2.3

Clinical Performance with Naturally Infected Positive Specimens

The clinical performance of the Aptima SARS-CoV-2 assay using the Aptima Specimen Transfer (AST) tube specimen preparation workflow was evaluated in comparison to the Specimen Lysis Tube (SLT) workflow tested with both the Aptima and Panther Fusion SARS-CoV-2 assays. For the study, three dilutions of 15 unique SARS-CoV-2 positive nasopharyngeal swab specimens were prepared and processed using both workflows. SARS-CoV-2 samples were previously determined to be positive using a non-Hologic molecular assay.

The positive percent agreement between the Aptima SARS-CoV-2 assay using the AST tube and the SLT workflows were 97.5% (87.1% – 99.6%) and 100% (91.0% – 100%), respectively, when compared to the Panther Fusion SARS-CoV-2 assay using the SLT workflow as reference (Table 10). The positive percent agreement of the Aptima Specimen Transfer tube workflow was 95.0% (83.5% – 98.6%) when compared to the SLT workflow as reference Table 12.

Table 12: Aptima Specimen Transfer Tube and Specimen Lysis Tube Workflow Comparison with Positive Specimens

	AST workflow tested with the Aptima assay as compared to the SLT workflow tested with the Panther Fusion assay	SLT workflow tested with the Aptima assay as compared to the SLT workflow tested with the Panther Fusion assay	AST workflow tested with the Aptima assay as compared to the SLT workflow tested with the Aptima assay
N Positive	39	39	38
N Negative	1 ¹	0	2 ²
N Total	40	39	40
% Agreement	97.5% (87.1% - 99.6%)	100% (91.0% - 100%)	95.0% (83.5% - 98.6%)

¹ Specimen was negative in the AST workflow tested with the Aptima assay and positive in the SLT workflow tested with the Panther Fusion assay. The same specimen was also positive in the SLT workflow tested with the Aptima assay.

² Specimens were negative in the AST workflow tested with the Aptima assay and positive with the SLT workflow tested with the Aptima assay. One of these specimens was positive with the SLT workflow tested with the Panther Fusion assay and the other was negative.

Uncapped Workflow Clinical Performance

The clinical performance of the Aptima SARS-CoV-2 assay using the uncapped tube workflow in comparison to the capped tube workflow was evaluated using natural clinical specimens. The evaluation included testing 200 SARS-CoV-2 negative, and 50 SARS-CoV-2 positive specimens. Two test samples were prepared for each specimen, one for the capped tube workflow and one for the uncapped tube workflow.

The observed Positive Percent Agreement (PPA) between specimens tested using the uncapped tube workflow as compared to the same specimens tested using the capped workflow was 98.0% (89.7% - 99.7%). The Negative Percent Agreement (NPA) was 100% (98.1% - 100%). Refer to Table 13.

Table 13: Uncapped Clinical Agreement to Capped Results

		Capped Results		
		Positive	Negative	Total
Uncapped Results	Positive	50	0	50
	Negative	1	199	200
	Total	51	199	250

Overall Agreement: 99.6% (97.8% – 99.9%)

Positive Agreement: 98.0% (89.7% – 99.7%)

Negative Agreement: 100% (98.1% – 100%)

Clinical Performance of Pooling up to 5 Specimens Prior to Testing

The clinical performance of the Aptima SARS-CoV-2 assay was evaluated in pools consisting of up to 5 specimens. For the study, a pool size of 5 specimens was evaluated and included positive and negative specimen pools. Each positive specimen pool consisted of one positive specimen with the remaining specimens being negative, whereas the negative specimen pools consisted only of negative specimens. For the study, 50 positive and 20 negative specimen pools were evaluated. The positive specimens used in the study covered the detectable range of the assay and included low positive specimens. Specimens for inclusion in the clinical performance of pooling study were chosen based on Ct results obtained with the Panther Fusion SARS-CoV-2 assay. The Panther Fusion SARS-CoV-2 assay was used for this purpose because the Panther Fusion SARS-CoV-2 and Aptima SARS-CoV-2 assays have the same LoD when evaluated with the FDA reference panel (i.e., 600 NDU/mL). Low positive specimens included in the study were defined as having a Ct value within 1-2 Ct of the LoD of the Panther Fusion SARS-CoV-2 assay. Both the pooled and individual specimens were evaluated with the Aptima SARS-CoV-2 assay.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated in relation to the expected (individual) result, as shown in Table 14. All evaluated positive specimens yielded a positive result in the pool. Since the kRLU values for the Aptima assay do not correspond to target concentration, signal and in silico sensitivity analysis was not performed.

Table 14: Individual and Pooled Specimen Agreement with a Pool Size of 5

		Individual Specimen Result		
		Positive	Negative	Total
Pool of 5 Result	Positive	50	0	50
	Negative	0	20	20
	Total	50	20	70

Overall Agreement: 100% (94.8% – 100.0%)

Positive Agreement: 100% (92.9% – 100.0%)

Negative Agreement: 100% (83.9% – 100.0%)

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Appendix A: Specimen Pooling Implementation and Monitoring Guidelines

Before Implementation of Pooling: Determine Appropriate Pool Size

Before a pooling strategy is implemented, a laboratory should determine the appropriate pool size based on percent positivity rate and desired testing efficiency. The Aptima SARS-CoV-2 assay has been validated for n-sample pool sizes up to five samples per pool.

If historical laboratory data for individual specimens is available:

- If historical data for individual specimens from the previous 7-10* days is available, estimate the percent positivity rate ($P_{\text{individual}}$) based on individual results.

$$(P_{\text{individual}}) = (\text{Number of positive specimen over chosen date range} \div \text{Total number of specimen tested over chosen date range}) \times 100.$$
- Using the calculated $P_{\text{individual}}$ and Table 15, identify the appropriate n number of samples to pool.
 - If $P_{\text{individual}}$ is less than 5%, the maximum pool size validated, ($n=5$), should be selected to maximize the efficiency of specimen pooling. Pooling with greater than 5 samples has not been validated and should not be performed.
 - If $P_{\text{individual}}$ is greater than 25%, Dorfman pooling of patient specimens is not efficient and should not be implemented.

If historical laboratory data for individual specimens is unavailable:

- If historical data from the previous 7-10* days is unavailable, 5, 4, or 3-specimen pooling may still implemented as the Aptima SARS-CoV-2 assay has been validated for 5-specimen pooling.
- Note: Without calculating $P_{\text{individual}}$ the pooling size implemented may not maximize pooling efficiency.

Table 15: Result Interpretation

<i>P, percent of positive subjects in the tested population</i>	<i>n max efficiency (n corresponding to the maximal efficiency)</i>	<i>Efficiency of n-sample pooling (a maximum increase in the number of tested patients when Dorfman n-pooling strategy used)</i>
5%-6%	5	2.15-2.35
7%-12%	4	1.54-1.99
13%-25%	3	1.10-1.48

Because a positive pool requires individual retesting of each sample in the pool, the efficiency of any pooling strategy depends on the positivity rate. The efficiency (F) of n -sample pooling for positivity rate (P) can be calculated with the following formula $F = 1 / (1 + 1/n - (1-P)^n)$. The efficiency (F) indicates how many more patients can be tested with n -sample pools compared to individual testing. For example, a 5-sample pooling strategy increases the number of tested patients by 2.15 times for positivity rate P of 6% ($F=2.15$). At $F=2.15$, 1,000 tests can on average cover testing of 2,150 patients.

Implementation of Pooling

See above section titled *Specimen Pooling: Preparing Samples for Pooling* and perform pooling procedure as outlined.

After Implementation of Pooling: Ongoing Monitoring of Pooling Strategy

If historical laboratory data for individual specimens is available:

- After implementing a pooling strategy, evaluate the performance of pooled testing by comparing the percent positivity rate of pooled testing to that of individual testing.
- Calculate the percent positivity rate among patient specimens during specimen pooling (P_{pools}) on a daily basis using a moving average of the data from the previous 7-10* days of testing.

$$(P_{\text{pools}}) = (\text{Number of patient specimens with a positive result as determined by individual specimen reflex testing of positive pools over chosen date range} \div \text{Total number of patient specimens tested in pools over chosen date range}) * 100$$
- Compare P_{pools} to $P_{\text{individual}}$. If P_{pools} is less than 85% of $P_{\text{individual}}$. ($P_{\text{pools}} < 0.85 \times P_{\text{individual}}$), it is recommended that the pool size be reassessed and adjusted to maximize pooling efficiency (if necessary), according to the criteria in Table 15.
- To ensure maximum pooling efficiency, it is recommended that $\eta_{\text{maxefficiency}}$ be reassessed periodically while sample pooling is implemented by the laboratory.

If historical laboratory data for individual specimens is unavailable:

- After initiating a pooling strategy, evaluate the performance of pooled testing by calculating the initial percent positivity rate for pooled specimens ($P_{\text{pools-initial}}$). ($P_{\text{pools-initial}}$ is the percent positivity rate for pooled specimens for the first 7-10* days of pooled testing.
- Calculate the initial percent positivity rate for individual specimens from pool testing ($P_{\text{pools-initial}}$) from the first 7-10* days of testing.

$$P_{\text{pools-initial}} = (\text{Number of patient specimens with a positive result as determined by individual specimen reflex testing of positive pools in first 7-10* days} \div \text{Total number of patient specimens tested in pools in the first 7-10* days}) * 100$$
 - If $P_{\text{pools-initial}}$ is greater than 25%, pooling of patient specimens is not efficient and should be discontinued until the percent positivity rate decreases.
 - If $P_{\text{pools-initial}}$ is less than or equal to 25%, pooling of patient specimens can be continued.
- Continue to monitor pooling strategy by calculating the percent positivity rate among patient specimens during specimen pooling ($P_{\text{pools-x}}$) for subsequent 7-10* day periods. ($P_{\text{pools-x}}$) should be updated daily using a moving average.

- Compare $P_{\text{pools-x}}$ to $P_{\text{pools-initial}}$. If $P_{\text{pools-x}}$ is less than 90% of $P_{\text{pools-initial}}$ ($P_{\text{pools-x}} < 0.90 \times P_{\text{pools-initial}}$), it is recommended that the pool size be reassessed and potentially adjusted to maximize pooling efficiency.
- To ensure maximum pooling efficiency, it is recommended that $\eta_{\text{maxefficiency}}$ be reassessed periodically while sample pooling is implemented by the laboratory.

*7-10 days is recommended for calculating $P_{\text{individual}}$, P_{pools} , $P_{\text{pools-initial}}$, and $P_{\text{pools-x}}$.

Laboratories should determine if 7-10 days is appropriate by taking into consideration laboratory testing volume and percent positivity. If the number of individual or pooled positive results collected during a given time frame is less than 10, $P_{\text{individual}}$, P_{pools} , $P_{\text{pools-initial}}$, and $P_{\text{pools-x}}$ may not be representative of the percent positivity in the testing population. Consider extending the data collection time period to increase the number of positives evaluated.

Hologic® Direct Load Capture Cap Collection Kit — CLASSIQSwabs®

For Emergency Use Authorization (EUA) Only

IVD

Rx only

Intended Use

The Hologic® Direct Load Capture Cap Collection Kit – CLASSIQSwabs® is intended to be used for clinician collection of oropharyngeal and anterior nasal (nasal) swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima® SARS-CoV-2 assay to detect the presence of RNA for SARS-CoV-2. The kit is also intended to be used for clinician collection of nasal swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima SARS-CoV-2/Flu assay to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A) and/or influenza B virus (Flu B). The Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs has not been evaluated for home use.

Materials Provided

100 Hologic Direct Load Capture Cap Collection Kit—CLASSIQSwabs® (Cat. No. PRD-06951)

Each kit contains:

Component	Quantity	Description
Swab	1	Individually wrapped, sterile swab
Direct Load Capture Cap tube	1	Tube containing Specimen Transport Medium (STM), 2.9 mL

Warnings and Precautions

- A. Wash hands with soap before opening collection kit.
- B. Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- C. Do not use if the swab is visibly damaged (i.e., if the swab tip or shaft is broken, or pouch is damaged or open).
- D. Do not bend or shape the swab before collection. Do not use excessive force, pressure or bending when collecting the specimen as this may result in accidental breakage of the swab.
- E. Fiber adhesion to the shaft has been tested for instantaneous specimen collection: longer contact between the swab and the collection area may cause fiber detachment.
- F. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- G. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- H. This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

- I. When used with the Aptima SARS-CoV-2 assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- J. When used with the Aptima SARS-CoV-2/Flu assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.
- K. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- L. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- M. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs. Failure to use a new kit may invalidate the test results.
- N. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- O. Do not use the kit after its expiration date to collect specimens.

Kit Storage Requirements

Store collection kit at room temperature (15 °C to 30 °C).

Direct Load Capture Cap Collection Kit – CLASSIQSwabs Performance

The Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs contains the same media and volume as the Aptima Multitest Specimen Collection Kit. Performance data for the Multitest Specimen Collection Kit, evaluated with the Aptima SARS-CoV-2 assay, was used to support the Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs. Assay performance characteristics using the Multitest swab specimens are provided in the Aptima SARS-CoV-2 package insert. Performance of the Direct Load Capture Cap Collection Kit – CLASSIQSwabs with the Aptima SARS-CoV-2/Flu assay can be found in the Analytical Sensitivity section of the Aptima SARS-CoV-2/Flu assay package insert. Package inserts for both the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay may be referenced online at www.hologic.com.

When collecting multiple specimens from the same patient, the tube label includes a field to record each unique specimen source.

Oropharyngeal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay only

Instructions for oropharyngeal swab specimen collection (clinician collection only):

1. Partially peel open the swab package. Remove the swab. 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 Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.

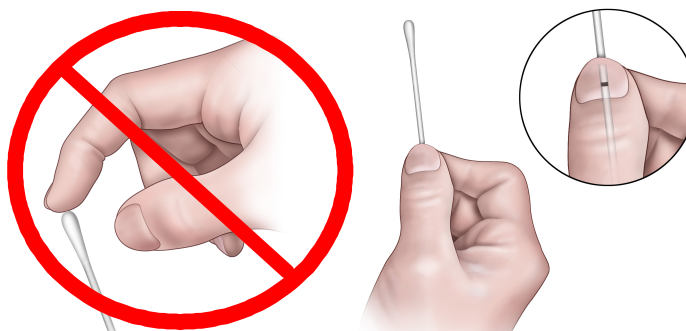
3. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Anterior Nasal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 and Aptima SARS-CoV-2/Flu Assays

Note to Patient: If you have any questions about this procedure, please ask your healthcare provider.

Instructions for anterior nasal swab specimen collection: clinician collection and patient self-collection

1. Wash hands with soap and water for 30 seconds before starting.
2. Partially peel open the swab package. Remove the swab. 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 Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.

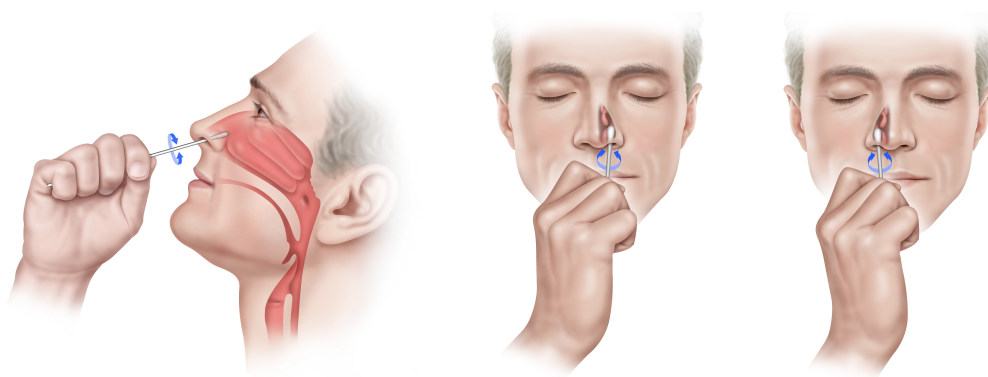


4. Carefully insert the swab into the first nostril until the swab **tip** is no longer visible, i.e. $\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril. Rotate the swab with moderate pressure against as much of the wall of the nostril as possible in a large circular path inside the nose at least 4 times (approximately 10-15 seconds per nostril) against the nasal wall and remove from nostril.

Note: Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample.

5. Using the same swab, carefully insert the swab into the second nostril until the swab **tip** is no longer visible, i.e. $\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril. Rotate the swab with moderate pressure against as much of the wall of the nostril as possible in a large circular path inside the nose at least 4 times (approximately 10-15 seconds per nostril) and remove from nostril. **Do not force the swab any further up and into nose at any point.**

Note: You must collect the sample from both nostrils!

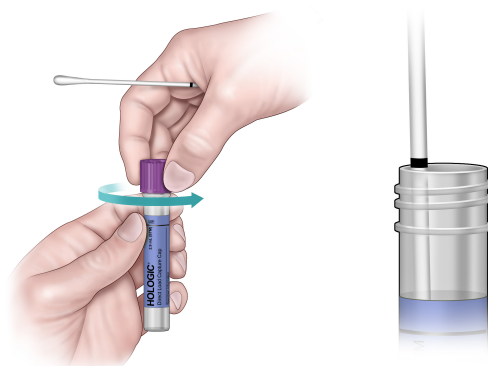


6. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.

Note to Patient: Inform your doctor or healthcare worker if liquid is spilled and a new kit is required.

Warning: If you come into contact with liquid from the tube, wash your hands with soap and water for 30 seconds.

7. Immediately place the swab into the transport tube so that the score line is at the top of the tube.



8. Carefully break the swab shaft at the score line against the side of the tube.
9. Immediately discard the top portion of the swab shaft.
10. Tightly screw the cap onto the tube.

Note to Patient: Return the collection kit to your doctor or healthcare worker.



Specimen Transport and Storage

Swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube for use with the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay. Refer to the Aptima SARS-CoV-2 assay package insert and the Aptima SARS-CoV-2/Flu assay package insert for proper specimen storage conditions.

Note: Specimens must be shipped in accordance with applicable national and international regulations.

Limitations

- A. Use this collection kit only with the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay. Performance has not been established with other products.
- B. Use appropriate personal protective equipment (PPE) when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).
- C. The patient-collected Direct Load Tube Kit nasal swab application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.
- D. Oropharyngeal swabs are authorized for use with the Aptima SARS-CoV-2 assay only.



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2022-03

Hologic® Direct Load Capture Cap Collection Kit — FLOQSwabs™

US: For Emergency Use Authorization (EUA) Only

IVD

Rx only

Intended Use

The Hologic® Direct Load Capture Cap Collection Kit – FLOQSwabs™ is intended to be used for clinician collection of mid-turbinate nasal and nasopharyngeal (NP) swab specimens for testing with the Aptima SARS-CoV-2 assay to detect the presence of RNA for SARS-CoV-2. The kit is also intended to be used for clinician collection of NP swab specimens for testing with the Aptima SARS-CoV-2/Flu assay to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A) and/or influenza B virus (Flu B). The Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs has not been evaluated for home use.

Materials Provided

100 Hologic Direct Load Capture Cap Collection Kit—FLOQSwabs™ (Cat. No. PRD-06952)

Each kit contains:

Component	Quantity	Description
Swab	1	Individually wrapped, sterile swab
Direct Load Capture Cap tube	1	Tube containing Specimen Transport Medium (STM), 2.9 mL

Warnings and Precautions

- A. Wash hands with soap before opening collection kit.
- B. Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- C. Do not use if the swab is visibly damaged (i.e., if the swab tip or shaft is broken, or pouch is damaged or open).
- D. Do not bend or shape the swab before collection. Do not use excessive force, pressure or bending when collecting the specimen as this may result in accidental breakage of the swab.
- E. Fiber adhesion to the shaft has been tested for instantaneous specimen collection: longer contact between the swab and the collection area may cause fiber detachment.
- F. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- G. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- H. This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

- I. When used with the Aptima SARS-CoV-2 assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- J. When used with the Aptima SARS-CoV-2/Flu assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.
- K. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- L. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- M. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs. Failure to use a new kit may invalidate the test results.
- N. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- O. Do not use the kit after its expiration date to collect specimens.

Kit Storage Requirements

Store collection kit at room temperature (15 °C to 30 °C).

Direct Load Capture Cap Collection Kit – FLOQSwabs™ Performance

Assay performance characteristics for the types of specimens (e.g., NP swabs) collected with the Direct Load Capture Cap Collection Kit – FLOQSwabs is provided in the clinical performance section of the Aptima SARS-CoV-2 assay package insert. Performance of the Direct Load Capture Cap Collection Kit – FLOQSwabs with the Aptima SARS-CoV-2/Flu assay can be found in the Analytical Sensitivity section of the Aptima SARS-CoV-2/Flu assay package insert. Package inserts for both the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay may be referenced online at www.hologic.com.

When collecting multiple specimens from the same patient, the tube label includes a field to record each unique specimen source.

Nasal Mid-Turbinate (NMT) Specimen Collection and Handling – Aptima SARS-CoV-2 Assay only

Instructions for nasal mid-turbinate (NMT) swab specimen collection (clinician collection only):

1. Partially peel open the swab package. Remove the swab. 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 Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the mid-turbinate region. Rotate the swab several times against nasal wall.

4. Remove swab, insert it into the other nostril and repeat the process.
5. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit. - FLOQSwabs.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
7. Carefully break the swab shaft at the score line against the side of the tube.
8. Immediately discard the top portion of the swab shaft.
9. Tightly screw the cap onto the tube.

Nasopharyngeal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay and Aptima SARS-CoV-2/Flu Assay

Instructions for nasopharyngeal swab specimen collection (clinician collection only):

1. Partially peel open the swab package. Remove the swab. 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 Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Tilt patient's head back 70 degrees. Gently and slowly insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.¹

Note: Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit. – FLOQSwabs.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Specimen Transport and Storage

Swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube for use with the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay. Refer to the Aptima SARS-CoV-2 assay package insert and the Aptima SARS-CoV-2/Flu assay package insert for proper specimen storage conditions.

Note: Specimens must be shipped in accordance with applicable national and international regulations.

¹ <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Limitations

- A. Use this collection kit only with the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay. Performance has not been established with other products.
- B. Use appropriate personal protective equipment (PPE) when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).² Mid-Turbinate Swabs are authorized for use with the Aptima SARS-CoV-2 assay only.



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2022-03

² World Health Organization's (WHO) Laboratory biosafety guidance related to coronavirus disease (COVID-19): interim guidance. [https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-\(covid-19\)](https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19)).

Hologic® Direct Load Tube Collection Kit**For Emergency Use Authorization (EUA) Only****Rx only-****IVD****Intended Use**

The Hologic® Direct Load Tube Collection Kit is intended to be used for clinician collection of oropharyngeal and anterior nasal (nasal) swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima SARS-CoV-2 assay to detect the presence of RNA for SARS-CoV-2. The kit is also intended to be used for clinician collection of nasal swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima SARS-CoV-2/Flu assay to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A), and/or influenza B virus (Flu B). The Hologic Direct Load Tube Collection Kit has not been evaluated for home use.

Materials Provided**100 Hologic Direct Load Tube Collection Kits (Cat. No. PRD-06997)**

Each kit contains:

Component	Quantity	Description
Swab	1	Individually wrapped, sterile swab
Transport tube	1	Tube containing Specimen Transport Medium (STM), 2.9 mL

Warnings and Precautions

- A. Wash hands with soap before opening collection kit.
- B. Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- C. Do not use if the swab is visibly damaged (i.e., if the swab tip or shaft is broken, or pouch is damaged or open).
- D. Do not bend or shape the swab before collection. Do not use excessive force, pressure or bending when collecting the specimen as this may result in accidental breakage of the swab.
- E. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- F. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- G. This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- H. When used with the Aptima SARS-CoV-2 assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

- I. When used with the Aptima SARS-CoV-2/Flu assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.
- J. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- K. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- L. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Hologic Direct Load Tube Collection Kit. Failure to use a new kit may invalidate the test results.
- M. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- N. Do not use the kit after its expiration date to collect specimens.

Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

Direct Load Tube Collection Kit Performance

The Hologic Direct Load Tube Collection Kit contains the same media and volume as the Aptima Multitest Specimen Collection Kit. Performance data for the Multitest Specimen Collection Kit was used to support the Hologic Direct Load Tube Collection Kit. Assay performance characteristics using the Multitest swab specimens are provided in the Aptima SARS-CoV-2 assay package insert and the Aptima SARS-CoV-2/Flu assay package insert. Package inserts for both the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay may be referenced online at www.hologic.com.

When collecting multiple specimens from the same patient, the tube label includes a field to record each unique specimen source.

Oropharyngeal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay only

Instructions for oropharyngeal swab specimen collection (clinician collection only):

1. Partially peel open the swab package. Remove the swab. 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 Hologic Direct Load Tube Collection Kit.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Tube Collection Kit.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.

7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Anterior Nasal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay and Aptima SARS-CoV-2/Flu Assay

Note to Patient: If you have any questions about this procedure, please ask your healthcare provider.

Instructions for anterior nasal swab specimen collection: clinician collection and patient self-collection

1. Wash hands with soap and water for 30 seconds before starting.
2. Partially peel open the swab package. Remove the swab. 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 Hologic Direct Load Tube Collection Kit.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.

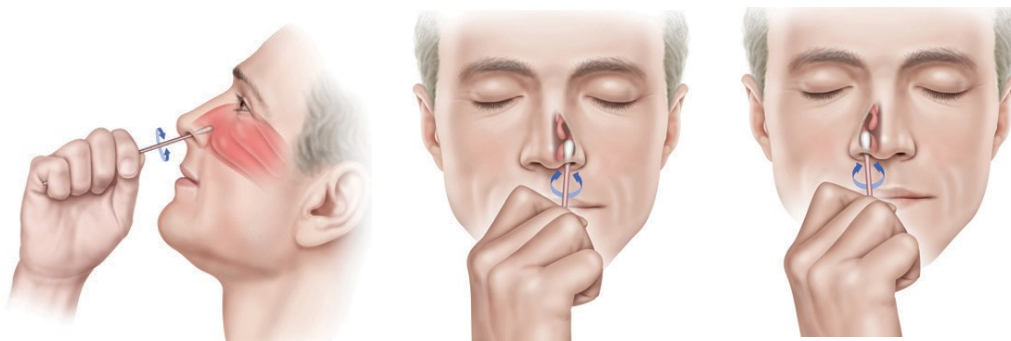


4. Carefully insert the swab into the first nostril until the swab **tip** is no longer visible, i.e. $\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril. Rotate the swab with moderate pressure against as much of the wall of the nostril as possible in a large circular path inside the nose at least 4 times (approximately 10-15 seconds per nostril) against the nasal wall and remove from nostril.

Note: Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample.

5. Using the same swab, carefully insert the swab into the second nostril until the swab **tip** is no longer visible, i.e., $\frac{1}{2}$ to $\frac{3}{4}$ of an inch into the nostril. Rotate the swab with moderate pressure against as much of the wall of the nostril as possible in a large circular path inside the nose at least 4 times (approximately 10-15 seconds per nostril) and remove from nostril. **Do not force the swab any further up and into nose at any point.**

Note: You must collect the sample from both nostrils!

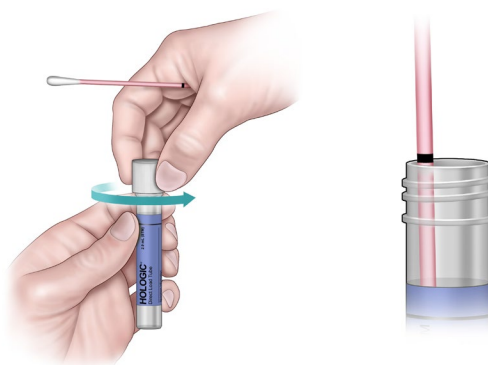


6. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Tube Collection Kit.

Note to Patient: Inform your doctor or healthcare worker if liquid is spilled and a new kit is required.

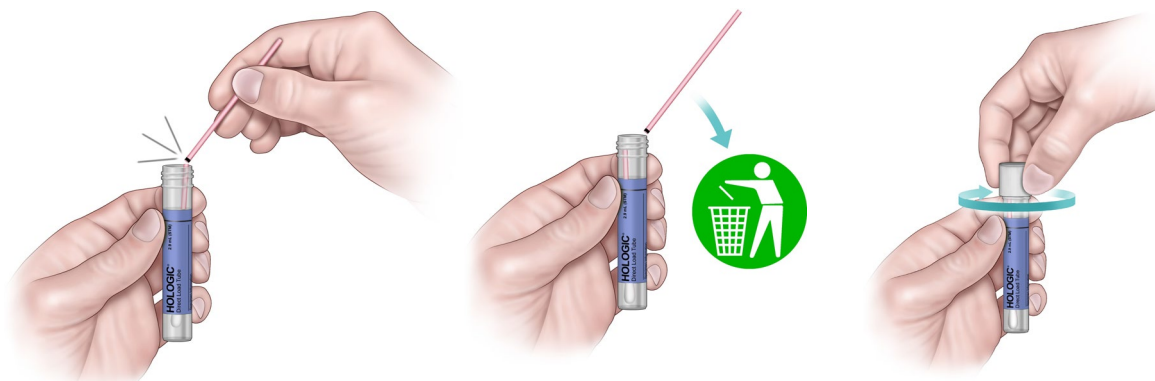
Warning: *If you come into contact with liquid from the tube, wash your hands with soap and water for 30 seconds.*

7. Immediately place the swab into the transport tube so that the score line is at the top of the tube.



8. Carefully break the swab shaft at the score line against the side of the tube.
9. Immediately discard the top portion of the swab shaft.
10. Tightly screw the cap onto the tube.

Note to Patient: Return the collection kit to your doctor or healthcare worker.



Specimen Transport and Storage

Swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube for use with the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay. Refer to the Aptima SARS-CoV-2 assay package insert and the Aptima SARS-CoV-2/Flu assay package insert for proper specimen storage conditions.

Note: Specimens must be shipped in accordance with applicable national and international regulations.

Limitations

- A. Use this collection kit only with the Aptima SARS-CoV-2 assay and Aptima SARS-CoV-2/Flu assay. Performance has not been established with other products.
- B. Use appropriate personal protective equipment (PPE) when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).
- C. The patient-collected Direct Load Tube Kit nasal swab application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.
- D. Oropharyngeal swabs are authorized for use with the Aptima SARS-CoV-2 assay only.



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2021-11

Aptima® Multitest Swab Specimen Collection Kit

US Only: For Emergency Use Authorization (EUA) Only

Rx Only

IVD

Instructions for SARS-CoV-2 Specimen Collection

The Aptima® Multitest Swab Specimen Collection Kit is intended to be used for clinician collection of oropharyngeal and anterior nasal (nasal) swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima® SARS-CoV-2 assay and Panther Fusion® SARS-CoV-2 assay to detect the presence of RNA for SARS-CoV-2. The kit is also intended to be used for clinician collection of nasal swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima® SARS-CoV-2/Flu assay to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A), and/or influenza B virus (Flu B). The Aptima Multitest Swab Specimen Collection Kit has not been evaluated for home use.

Warnings and Precautions

- A. Wash hands with soap before opening collection kit.
- B. Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- C. Do not use if the swab is visibly damaged (i.e., if the swab tip or shaft is broken or pouch is damaged or open).
- D. Do not bend or shape the swab before collection. Do not use excessive force, pressure or bending when collecting the specimen as this may result in accidental breakage of the swab.
- E. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- F. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- G. This product has not been FDA cleared or approved for use with the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, and Panther Fusion SARS-CoV-2 assay, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- H. When used with the Aptima SARS-CoV-2 assay and/or Panther Fusion SARS-CoV-2 assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- I. When used with the Aptima SARS-CoV-2/Flu assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.
- J. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection

and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

- K. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- L. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Aptima Multitest Swab Specimen Collection Kit. Failure to use a new kit may invalidate the test results.
- M. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- N. Do not use the kit after its expiration date to collect specimens.

Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

Multitest Swab Specimen Performance

Assay performance characteristics using the Multitest swab specimens are provided in the Aptima SARS-CoV-2 assay package insert, Aptima SARS-CoV-2/Flu assay package insert, and Panther Fusion SARS-CoV-2 assay package insert. Package inserts for the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, and Panther Fusion SARS-CoV-2 assay may be referenced online at www.hologic.com.

When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification of each specimen.

Oropharyngeal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay and Panther Fusion SARS-CoV-2 Assay

Instructions for oropharyngeal swab specimen collection (clinician collection only):

1. Partially peel open the swab package. Remove the swab. 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 Multitest Swab Specimen Collection Kit.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Nasal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay, Aptima SARS-CoV-2/Flu Assay, and Panther Fusion SARS-CoV-2 Assay

Note to Patient: If you have any questions about this procedure, please ask your healthcare provider.

Instructions for nasal swab specimen collection: clinician collection and patient self-collection

1. Wash hands with soap and water for 30 seconds before starting.
2. Partially peel open the swab package. Remove the swab. 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 Multitest Swab Specimen Collection Kit.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.



4. Carefully insert the swab into the first nostril until the swab tip is no longer visible, i.e. $\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril. Rotate the swab with moderate pressure against as much of the wall of the nostril as possible in a large circular path inside the nose at least 4 times (approximately 10-15 seconds per nostril) against the nasal wall and remove from nostril.

Note: Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample.

5. Using the same swab, carefully insert the swab into the second nostril until the swab **tip** is no longer visible, i.e., $\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril. Rotate the swab with moderate pressure against as much of the wall of the nostril as possible in a large circular path inside the nose at least 4 times (approximately 10-15 seconds per nostril) and remove from nostril. **Do not force the swab any further up and into nose at any point.**

Note: You must collect the sample from both nostrils!.



6. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.

Note to Patient: Inform your doctor or healthcare worker if liquid is spilled and a new kit is required.

Warning: If you come into contact with liquid from the tube, wash your hands with soap and water for 30 seconds.

7. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
8. Carefully break the swab shaft at the score line against the side of the tube.
9. Immediately discard the top portion of the swab shaft.
10. Tightly screw the cap onto the tube.

Note: Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample.

Note to Patient: Return the collection kit to your doctor or healthcare worker.

Specimen Transport and Storage

Multitest swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube for use with the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, and Panther Fusion SARS-CoV-2 assay. Refer to the Aptima SARS-CoV-2 assay package insert, Aptima SARS-CoV-2/Flu assay package insert, and Panther Fusion SARS-CoV-2 assay package insert for proper specimen storage conditions.

Note: Specimens must be shipped in accordance with applicable national and international regulations.

Limitations

- A. Use this collection kit only with the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, Panther Fusion SARS-CoV-2 assay, and other Hologic products. Performance has not been established with other products.
- B. Use appropriate personal protective equipment (PPE) when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).
- C. The patient-collected Aptima Multitest Swab Specimen Collection Kit nasal swab application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.
- D. Oropharyngeal swabs are authorized for use with the Aptima SARS-CoV-2 assay and Panther Fusion SARS-CoV-2 assay only.



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For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.

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This product may be covered by one or more U.S. patents identified at www.hologic.com/patents.

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2022-01

HOLOGIC®

Aptima® SARS-CoV-2 Assay For the detection of RNA from SARS-CoV-2
US: For Use Under an Emergency Use Authorization (EUA) Only
This product may be covered by one or more U.S. patents identified at www.hologic.com/patents
Consult Package Insert for hazard information
The text in the box on this insert applies to US Customers only
Box 1 of 2:
Amplification Reagent (Nucleic Acids) 1 EA / Enzyme Reagent (Enzyme) 1 EA / Probe Reagent (Chemiluminescent probes) 1 EA / Internal Control (Non-infectious nucleic acid in a buffered solution) 1 EA
Box 2 of 2:
Amplification Reconstitution Solution (Aqueous solution containing preservatives) 1 EA / Enzyme Reconstitution Solution (HEPES buffered solution) 1 EA / Probe Reconstitution Solution (Succinate buffered solution) 1 EA / Selection Reagent (600 mM borate buffered solution) 1 EA / Target Capture Reagent (Buffered salt solution containing solid-phase and capture oligomers) 1 EA / Reconstitution Collars 1 Package / WARNING
Controls:
Non-infectious nucleic acid in a buffered solution 5 x 1.7 mL / Buffered solution 5 x 1.7 mL

AW-25564 Rev. 001

The text in the box on this insert applies to US Customers only

- Rx Only.
- For in vitro diagnostic use.
- For use under an Emergency Use Authorization (EUA) only.
- This translation insert does not contain the full instructions for use.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 354(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- The current electronic instructions for use are available at <https://www.hologic.com/package-inserts>
- To request a paper copy of the instructions for use free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com

Bulgarian

Aptima SARS-CoV-2 Assay За откриване на РНК от SARS-CoV-2
САЩ: Само за употреба с разрешение за специен случай (EUA)
Този продукт може да се ползва от един или повече пациенти в САЩ, посочени на www.hologic.com/patents
Консултирайте се с листовката в опаковката за информация за опасностите
Текстът в полето на тази вложка важи само за клиенти от САЩ
Кутия 1 от 2:
Амплификационен реагент (нуклеинови киселини) 1 EA / Ензимен реагент (ензим) 1 EA / Реагент за сонда (хемилуминесцентна сонда) 1 EA / Внутрен контрол (неинфекциозна нуклеинова киселина в буферен разтвор) 1 EA
Кутия 2 от 2:
Разтвор за приготвяне на амплификационен агент (еден разтвор с консерванти) 1 EA / Разтвор за приготвяне на ензимен реагент (HEPES буферен разтвор) 1 EA / Разтвор за приготвяне на реагент за сонда (сукцинат буферен разтвор) 1 EA / Реагент за избиране (600 mM борат буферен разтвор) 1 EA / Реагент за целено прихващане (буферен солен разтвор, съдържа олигомери в твърда фаза и за прихващане) 1 EA / Общи за разтваряне 1 опаковка / ПРЕДУПРЕЖДЕНИЕ
Controls: Неинфекциозна нуклеинова киселина в буферен разтвор 5 x 1,7 mL / Комплект контроли

Croatian

Aptima SARS-CoV-2 Assay Za detekciju RNA iz SARS-CoV-2
SAD: Za uporabu samo uz Odobrenje za hitnu uporabu (EUA)
Ovaj je proizvod možda zaštićen jednim ili više američkih patenata identificiranih na www.hologic.com/patents
Podatke o opasnostima potražite u Umetku pakiranja
Tekst u kutiji na ovom umetku primjenjuje se samo za kupce u SAD
Kutija 1 od 2:
Pojacičani reagensi (nukleinske kiseline) 1 EA / Enzimski reagensi (enzimi) 1 EA / Reagens sonde (hemiluminescentne sonde) 1 EA / Interna kontrola (neinfektivna nukleinska kiselina u puferiranoj otopini) 1 EA
Kutija 2 od 2:
Otopina za pojačavanje rekonstitucije (vodena otopina koja sadrži konzervanse) 1 EA / Otopina za rekonstituciju enzima (puferirana otopina HEPES) 1 EA / Otopina za rekonstitucijsku sondu (sukcinatna puferirana otopina) 1 EA / Selektivni reagens (puferirana otopina 600 mM borata) 1 EA / Reagens za hvatanje (puferirana otopina soli koja se sastoji od čvrste faze i hvatajućih oligomera) 1 EA / Ovatnici za rekonstrukciju 1 paket / UPOZORENJE
Kontrolni komplet:
Neinfektivna nukleinska kiselina u puferiranoj otopini 5 x 1,7 mL / Kontrolni komplet

Czech

Aptima SARS-CoV-2 Assay Pro detekci RNA viru SARS-CoV-2
USA: K použití pouze v režimu povolení k nouzovému použití (Emergency Use Authorization – EUA)
Tento produkt může být chráněn jedním nebo více patenty Spojených států, které jsou uvedeny na webové stránce www.hologic.com/patents
Pro informace o nebezpečnosti viz příbalový létek
Tato část textu příbalového letáku uvedená v rámciku se týká pouze zákazníků v USA.
Box 1 ze 2:
Amplifikační reagencie (nukleová kyselina) 1 EA / Enzymová reagencie (enzym) 1 EA / Reagencie sondy (chemiluminescentní sondy) 1 EA / Vnitřní kontrola (neinfekční nukleová kyselina v pufovaném roztoku) 1 EA
Box 2 ze 2:
Rekonstituční roztok pro amplifikační reagenci (vodný roztok obsahující konzervanty) 1 EA / Rekonstituční roztok pro enzymovou reagenci (roztok pufovaný HEPES) 1 EA / Rekonstituční roztok pro reagenci sondy (roztok pufovaný sukcinátem) 1 EA / Selektivní reagencie (roztok pufovaný 600mM boritanem) 1 EA / Reagencie pro zachytí cíle (pufovaný solný rotok obsahující pevnou fázi a zachytivé oligomery) 1 EA / Rekonstituční obálky 1 balení / VAROVÁNÍ
Sada kontrol:
Neinfekční nukleová kyselina v pufovaném roztoku 5 x 1,7 ml / Pufovaný roztok 5 x 1,7 ml

Danish

Aptima SARS-CoV-2 Assay Til detektion af RNA fra SARS-CoV-2
USA: Kun til brug under en Emergency Use Authorization (EUA), en særlig godkendelse til nedsituation
Dette produkt kan muligvis være dækket af et eller flere amerikanske patenter, der kan findes på www.hologic.com/patents
Konsumer indlægsedelen for lægepersonaler
Teksten i feltet på denne indlægsedel gælder kun for kunder i USA
Æske 1 af 2 æsker:
Amplifikationsreagens (nukleinsyre) 1 EA / Enzymreagens (enzym) 1 EA / Proberagens (kemiluminescerende prober) 1 EA / Intern kontrol (ikke-infektive nukleinsyre i en bufferopløsning) 1 EA
Æske 2 af 2 æsker:
Amplifikationsrekonstitutionsopløsning (vandsopløsning, som indeholder konserveringsmidler) 1 EA / Enzymrekonstitutionsopløsning (HEPES bufferopløsning) 1 EA / Proberkonstitutionsopløsning (sukcinatbufferopløsning) 1 EA / Selektionsreagens (600 mM boratbufferopløsning) 1 EA / Target capture reagens (buffersaltopløsning, som indeholder fastfase og capture-oligomere) 1 EA / Rekonstitutionscollars 1 pakke / ADVARSEL
Kontrolkit:
Ikke-infektive nukleinsyre i en bufferopløsning 5 x 1,7 ml / Bufferopløsning 5 x 1,7 ml

Front

Dutch

Aptima SARS-CoV-2 Assay Voor de detectie van RNA uit SARS-CoV-2
VS: Alleen voor gebruik onder een Emergency Use Authorization (EUA)
Dit product maakt mogelijk deel uit van een of meer Amerikaanse octrooien vermeld op www.hologic.com/patents
Raadpleeg de bijlufte voor informatie over gevaren
De omkleedende tekst in deze bijlufte geldt alleen voor klanten in de VS
Doos 1 van 2:
Amplificatiereagens (nucleinezuren) 1 EA / Enzymreagens (enzym) 1 EA / Probereagens (chemiluminescente probes) 1 EA / Interne controle (niet-infectieuze nucleinezuren in gebufferde oplossing) 1 EA
Doos 2 van 2:
Amplificatiereconstitutieoplossing (waterige oplossing met conserveermiddelen) 1 EA / Enzymreconstitutieoplossing (HEPES gebufferde oplossing) 1 EA / Probereconstitutieoplossing (met succinaat gebufferde oplossing) 1 EA / Selectiereagens (600 mM in boraat gebufferde oplossing) 1 EA / Target Capture Reagent (gebufferde zoutoplossing met vaste drager en capture-oligomeren) 1 EA / Reconstitutiekraag 1 pakket / WAARSCHUWING
Kontrolkit:
Niet-infectieuze nucleinezuren in gebufferde oplossing 5 x 1,7 mL / Gebufferde oplossing 5 x 1,7 mL

Estonian

Aptima SARS-CoV-2 Assay SARS-CoV-2 RNA määramiseks
USA: kasutamiseks ainult erakorralise kasutamise vältimiseks (EUA)
Seda toodet võib hõlmata üks või rohkem USA patendidest, mis on toodud veebilehel www.hologic.com/patents
Ohutusteabe saamiseks lugege pakendi infolehte
Vahelehel olev raamiga ümbritsetud tekst kehtib üksnes USA klientidele
Karp 1/2:
Amplifikatsioonireaktiiv (nukleiinhapped) 1 tk / Ensüümireaktiiv (ensüüm) 1 tk / Sond reaktiiv (kemoluminesentsentsondid) 1 tk / Sisemine kontroll (mitteinfektsioosne nukleiinhape puhverlahuses) 1 tk
Karp 2/2:
Amplifikatsiooni rekonstitutsiooni lahus (vedel lahus, mis sisaldab säilitusaineid) 1 tk / Ensüümi rekonstitutsiooni lahus (HEPES-puhverlahus) 1 tk / Sondi rekonstitutsiooni lahus (suktsinaat puhverlahus) 1 tk / Selektiooni reaktiiv (600 mM booradi puhverlahus) 1 tk / Sihtmärgi sidumise reaktiiv (Puhveratud soolalahus, mis sisaldab tahkes faasis ja siduva oligomeeri) 1 tk / Rekonstitutsiooni võrud 1 pak / HOIATUS!
Kontrolide komplekt:
Mitteinfektsioosne nukleiinhape puhverlahuses 5 x 1,7 ml / Puhverlahus 5 x 1,7 ml

Finnish

Aptima SARS-CoV-2 Assay RNA:n havaitsemiseen SARS-CoV-2:sta
USA: Saa käyttää vain hätäkäyttökäytävällä (Emergency Use Authorization, EUA)
Yksi tai useampi sivustossa www.hologic.com/patents mainittuista US-patenteista voi kattaa tämän tuotteen.
Käytä hallituslupakirjoitusta pakkausohjeesta
Tämän selosteen ruudussa oleva teksti koskee vain USA:ssa olevia asiakkaita
Pakkaus 1/2:
Monistusrageenssi (nukleiinihapot) 1 kpl / Entsyymirageenssi (entsyym) 1 kpl / Koetinrageenssi (kemiluminesenssikoet-timet) 1 kpl / Sisäinen kontrolli (ei-infektiova nukleiinihappo puskuroidussa liuoksessa) 1 kpl
Pakkaus 2/2:
Monistusekskultuussu (säilytysainetta sisältävä vesiliuos) 1 kpl / Entsyymiekkskultuussu (HEPES-puskuroitu liuos) 1 kpl / Koetinsekkskultuussu (sukksinaattipuskuroitu liuos) 1 kpl / Valintareageenssi (600 mM boratipuskuroitu liuos) 1 kpl / Kohleen pöimintareageenssi (puskuroitu suolaliuos, joka sisältää kiinteän faasin ja pöimintaoiigomeeria) 1 kpl / Sekoitusvälikappaleet 1 pakkaus / VAROITUS
Kontrolipakkaus:
Ei-infektiova nukleiinihappo puskuroidussa liuoksessa 5 x 1,7 ml / Puskuroitu lios 5 x 1,7 ml

French - European

Aptima SARS-CoV-2 Assay Pour la détection de l'ARN du SARS-CoV-2
ÉTATS-UNIS : À n'utiliser que sous autorisation d'utilisation d'urgence (EUA) seulement
Ce produit peut être protégé par un ou plusieurs brevets américains identifiés à l'adresse www.hologic.com/patents
Consultez la notice pour plus d'informations sur les dangers
Le texte encadré sur cette notice s'applique uniquement aux clients des États-Unis
Boîte 1 de 2:
Réactif d'amplification (acides nucléiques) 1 / Réactif enzymatique (enzyme) 1 / Réactif sonde (sondes chimiluminescentes) 1 / Contrôle interne (acide nucléique non infectieux dans une solution tampon) 1
Boîte 2 de 2:
Solution de reconstitution pour amplification (solution aqueuse contenant des agents de conservation) 1 / Solution de reconstitution d'enzyme (solution tampon HEPES) 1 / Solution de reconstitution de sonde (solution tampon succinate) 1 / Réactif de sélection (solution tampon borate à 600 mM) 1 / Réactif de capture de cible (A/solution saline tamponnée contenant des oligomères en phase solide et de capture) 1 / Collets de reconstitution 1 emballage / AVERTISSEMENT
Kit de contrôles:
Acide nucléique non infectieux dans une solution tamponnée 5 x 1,7 mL / Solution tamponnée 5 x 1,7 mL

German

Aptima SARS-CoV-2 Assay Zum RNA-Nachweis von SARS-CoV-2
USA: Nur für die Anwendung gemäß einer Emergency Use Authorization (EUA)
Dieses Produkt kann unter einem oder mehreren US-amerikanischen Patent(en) geschützt sein, die unter www.hologic.com/patents zu finden sind
Gefahrenhinweise der Packungsbeilage entnehmen
Der eingerahmte Text in der Packungsbeilage betrifft nur Kunden in den USA
Packung 1 von 2:
Amplifikationsreagenz (Nukleinsäuren) 1 Stk / Enzymreagenz (Enzyme) 1 Stk / Sondenreagenz (Chemolumineszenzsonden) 1 Stk / Interne Kontrolle (nicht-infektiöse Nukleinsäure in gepufferter Lösung) 1 Stk
Packung 2 von 2:
Rekonstitutionslösung (Wässrige Lösung mit Konservierungsmitteln) 1 EA / Enzymrekonstitutionslösung (HEPES-gepufferte Lösung) 1 Stk / Sondenrekonstitutionslösung (sukzinatgepufferte Lösung) 1 Stk / Selektionsreagenz (600 mM boratgepufferte Lösung) 1 Stk / Target Capture-Reagenz (gepufferte Salzlösung mit Festphasen-und Finger-Oligomeren) 1 Stk / Rekonstitutions-collars 1 Packung / WARNUNG
Kontrollen-Kit:
Nicht-infektiöse Nukleinsäure in gepufferter Lösung 5 x 1,7 mL / Gepufferte Lösung 5 x 1,7 mL

Greek

Aptima SARS-CoV-2 Assay Για την ανίχνευση RNA από SARS-CoV-2
Η.Π.Α.: Αποκλειστικά για χρήση υπό εξουσιοδότηση χρήσης έκτακτης ανάγκης (EUA)
Το παρόν προϊόν ενδέχεται να καλύπτεται από ένα ή περισσότερα πατέντια των Η.Π.Α. που προσδιορίζονται στη διεύθυνση www.hologic.com/patents
Συμβουλευτείτε τις οδηγίες χρήσης στη συσκευασία για πληροφορίες σχετικά με τους κινδύνους
Το κείμενο στο πλαίσιο σε αυτό το ένθετο αφορά μόνο για πελάτες των Ηνωμένων Πολιτειών
Πλαίσιο 1 από 2:
Αντιδραστήριο ενίσχυσης (Νουκλεϊκά οξέα) 1 EA / Αντιδραστήριο ενζύμου (Ενζύμο) 1 EA / Αντιδραστήριο ανίχνευσης (Ανιχνευτές χημειοφωτισμού) 1 EA / Εσωτερικός έλεγχος (Μη μολυσματικό νουκλεϊκό οξύ σε ρυθμιστικό διάλυμα) 1 EA
Πλαίσιο 2 από 2:
Διάλυμα αναοξείωσης ενίσχυσης Α/Υδατικό διάλυμα που περιέχει συντηρητικά) 1 EA / Διάλυμα αναοξείωσης ενζύμου (Ρυθμιστικό διάλυμα HEPES) 1 EA / Διάλυμα αναοξείωσης ανίχνευσης (Ηλεκτρικό ρυθμιστικό διάλυμα) 1 EA / Αντιδραστήριο επιλογής (600 mM βορικό ρυθμιστικό διάλυμα) 1 EA / Αντιδραστήριο δέσμευσης στόχου (Ρυθμιστικό διάλυμα άλατος που περιέχει ολιγομερή στερεάς φάσης και δέσμευσης) 1 EA / Κολάρ αναοξείωσης 1 πακέτο / ΠΡΟΕΙΔΟΠΟΙΗΣΗ
Kit ελέγχου:
Μη μολυσματικό νουκλεϊκό οξύ σε ρυθμιστικό διάλυμα 5 x 1,7 mL / Ρυθμιστικό διάλυμα 5 x 1,7 mL

Front

Back

Hungarian

Aptima SARS-CoV-2 Assay A SARS-CoV-2 RNS kimutatására
Amerikai Egyesült Államok: Kizárólag sürgősségi használatra szóló engedély (Emergency Use Authorization, EUA) alapján használható! Ez a termék egy vagy több amerikai szabadalmi oltalom alá tartozik, amely szabadalmak megtalálhatók a www.hologic.com/patents oldalon
A veszélyekkel kapcsolatos információkért olvassa el a termékétájékoztatót
A betegétájékoztatót a keretben lévő szöveg csak az amerikai ügyfelekre vonatkozik
2/1. doboz:
Amplifikációs reagens (nukleinsavak) 1 EA / Enzim reagens (enzim) 1 EA / Próba reagens (kemilumineszcsoans próbák) 1 EA / Belső kontroll (nem fertőző nukleinsav pufferooldatban) 1 EA
2/2. doboz:
Amplifikációs rekonstitúciós oldat (tartósítozáert tartalmazó vizes oldat) 1 EA / Enzim rekonstitúciós oldat (HEPES pufferooldat) 1 EA / Próba rekonstitúciós oldat (szukcinát pufferooldat) 1 EA / Szekelciós reagens (600 mM borát pufferooldat) 1 EA / Célmegkötő reagens (szilárd fázist és megkötő oligomereket tartalmazó puffert oldat) 1 EA / Rekonstitúciós gallérok 1 csomag / FIGYELMEZTETÉS
Kontrolit készlet:
Nem fertőző nukleinsav pufferooldatban 5 x 1,7 ml / Pufferoldat 5 x 1,7 ml

Italian

Aptima SARS-CoV-2 Assay Per il rilevamento dell'RNA del SARS-CoV-2
Stati Uniti: utilizzo consentito solo autorizzazione all'uso in emergenza (EUA)
Questo prodotto potrebbe essere protetto da uno o più brevetti USA identificati nel sito www.hologic.com/patents
Consultare il foglietto illustrativo per informazioni sui pericoli
Il testo nella casella in questo inserto si applica solo ai clienti statunitensi
Scatola 1 di 2:
Reagente di amplificazione (acidi nucleici) 1 EA / Reagente enzimatico E (enzima) 1 EA / Reagente sonda (sonde chemiluminescenti) 1 EA / Controllo interno (acido nucleico non infettivo in soluzione tamponata) 1 EA
Scatola 2 di 2:
Soluzione di ricostituzione e amplificazione (soluzione acquosa contenente conservanti) 1 EA / Soluzione di ricostituzione enzimatica (soluzione tamponata HEPES) 1 EA / Soluzione di ricostituzione sonda (soluzione tampone succinato) 1 EA / Reagente di selezione (600 mM di soluzione tampone borato) 1 EA / Reagente di cattura del target (soluzione salina tamponata contenente oligomeri in fase solida di cattura) 1 EA / Collari di ricostituzione 1 confezione / AVVERTENZA
Kit dei controlli:
Acido nucleico non infettivo in soluzione tamponata 5 x 1,7 mL / Soluzione tamponata 5 x 1,7 mL

Latvian

Aptima SARS-CoV-2 Assay SARS-CoV-2 RNA noteikšana
ASV: lietošanai tikai ārkārtas situācijās saskaņā ar plinvaru (EUA)
Uz šo izstrādājumu var attiekties viens vai vairāki ASV patenti, kas norādīti vietnē www.hologic.com/patents
Informāciju par bīstamību skatiet pavadlappi
Šajā instrukcijā izziēmātas teksta attiecas tikai uz ASV klientiem.
1. Iepakojums no 2:
Amplifikācijas reāģents (nukleīnskābes) 1 gab. viena vieniā / Fermentu reāģents (ferments) 1 gab. viena vieniā / Zonžu reāģents (hemiluminescences zondes) 1 gab. viena vieniā / Iekšējā kontrolē (neinfektīva nukleīnskābe buferšķīdumā) 1 gab. viena vieniā
2. Iepakojums no 2:
Amplifikācijas šķīdināšanas šķīdums (dzens šķīdums, kas satur konservantus) 1 gab. viena vieniā / Fermentu šķīdināšanas šķīdums (HEPES buferis šķīdums) 1 gab. viena vieniā / Zonžu šķīdināšanas šķīdums (sukcināta buferis šķīdums) 1 gab. viena vieniā / Atlasas reāģents (600 mM borāta buferis šķīdums) 1 gab. viena vieniā / Mērķa saistīšanas reāģents (buferis sāls šķīdums, kas satur cietuvi un saistīsmas oligomērus) 1 gab. viena vieniā / Šķīdināšanas maršlētis 1 iepakojums / BRĪDINĀJUMS
Kontrolu komplekts:
Neinfektīva nukleīnskābe buferšķīdumā 5 x 1,7 ml / Buferšķīdums 5 x 1,7 ml

Lithuanian

Aptima SARS-CoV-2 Assay Aptikti SARS-CoV-2 viruso RNR
JAV: Galima naudoti tik gavus leidimą naudoti kritiniu atveju (angl. „Emergency Use Authorization“ (EUA))
Šiam produktui gali būti taikomas vienas ar daugiau JAV patentų, jų galima rasti adresu www.hologic.com/patents
Informacija apie pavojus pateikiama naudojimo instrukcijoje
Šio įrašo langelio tekstas taikomas tik JAV klientams
1 dėžė iš 2:
Amplifikacijos reagentas (nukleino rūgštys) 1 vnt. / Fermentinis reagentas (fermentas) 1 vnt. / Zondavimo reagentas (chemiluminescenciali zondai) 1 vnt. / Vidinė kontrolė (neinfekcinė nukleino rūgštis tirpale) 1 vnt.
2 dėžė iš 2:
Amplifikacijos atskiedimo tirpalas (vandeninis tirpalas su konservantais) 1 vnt. / Fermentų atskiedimo tirpalas (HEPES tirpalas) 1 vnt. / Zondo atskiedimo tirpalas (sukcinato įspalis) 1 vnt. / Selekcijos reagentas (600 mM boratinis tirpalas) 1 vnt. / Objektų sugavimo reagentas (druskos tirpalas su kietosios fazės ir sugavimo oligomerais) 1 vnt. / Atskiedimo žiedai 1 pakuotė / ĮSPĖJIMAS
Kontrolinis rinkinys:
Neinfekcinė nukleino rūgštis tirpale 5 x 1,7 ml / Tirpalas 5 x 1,7 ml

Norwegian

Aptima SARS-CoV-2 Assay Til deteksjon av RNA fra SARS-CoV-2
USA: Kun til bruk med autorisasjon for nødbruk (EUA)
Dette produktet kan være dekket av et eller flere amerikanske patenter som identifiseres på www.hologic.com/patents
Se pakningsvedlegget for å finne informasjon om farer.
Teksten i denne esken på dette vedlegget gjelder bare kunder i USA
Eske 1 av 2:
Amplifiseringsreagens (nukleinsyrer) 1 EA / Enzymreagens (enzyme) 1 EA / Probereagens (kemiluminescent probe) 1 EA / Intern kontroll (ikke-infektive nukleinsyre i en buffer løsning) 1 EA
Eske 2 av 2:
Amplifiseringsrekonstitueringsløsning (vannholdig løsning som inneholder konserveringsmidler) 1 EA / Enzymrekonstitueringsløsning (HEPES-buffert løsning) 1 EA / Proberkonstitueringsløsning (suksinatbuffert løsning) 1 EA / Selektionsreagens (600 mM boratbuffert løsning) 1 EA / Måltareagens (buffert saltløsning som inneholder fastfase og fangstoligomere) 1 EA / Rekonstitueringscollare 1 pakke / ADVARSEL
Kontrolsett:
Ikke-infektiske nukleinsyre i en buffert løsning 5 x 1,7 ml / Buffert løsning 5 x 1,7 ml

Polish

Aptima SARS-CoV-2 Assay Do wykrywania RNA z/w SARS-CoV-2
USA: Do użytku wyłącznie na podstawie pozwolenia na użytkowanie w trybie awaryjnym (EUA)
Ten produkt może być objęty jednym lub kilkoma patentami amerykańskimi/USA określonymi na stronie www.hologic.com/patents
Informacje na temat zagrożeń znajdują się w ulotce dołączonej do opakowania.
Tekst umieszczony w ramce na tej wkładce dotyczy tylko klientów z USA
Pudełko 1 z 2:
Odczynnik do amplifikacji (kwasy nukleinowe) 1 EA / Odczynnik enzymatyczny (enzym) 1 EA / Odczynnik sondy (sondy chemiluminescencyjne) 1 EA / Kontrola Wewnętrzna (niezakazany kwas nukleinowy w roztworze buforowym) 1 EA
Pudełko 2 z 2:
Roztwór do uzupełniania odczynnika amplifikacji (wodny roztwór zawierający środki konserwujące) 1 EA / Roztwór do uzupełniania odczynnika enzymatycznego (roztwór buforowany HEPES) 1 EA / Roztwór do uzupełniania odczynnika sondy (roztwór buforowany bursztyniany) 1 EA / Odczynnik selekcyj (600 mM roztwór buforowany boranem) 1 EA / Odczynnik celowego wychwytywania (buforowany roztwór soli zawierający fazę stałą i oligomery wychwytywające) 1 EA / Kolierze do uzupełniania 1 Pakiet / OSTRZEŻENIE
Zestaw kontrolny: Niezakazany kwas nukleinowy w roztworze buforowym 5 x 1,7 mL / Roztwór buforowany 5 x 1,7 mL

Portuguese

Aptima SARS-CoV-2 Assay Para a deteção de RNA de SARS-CoV-2
Estados Unidos: Apenas para utilização ao abrigo da Autorização de utilização de emergência (EUA)
Este produto pode estar abrangido por uma ou mais patentes nos Estados Unidos, as quais estão identificadas em www.hologic.com/patents
O texto na caixa deste folheto aplica-se apenas aos clientes dos EUA
Caixa 1 de 2:
Consulte o folheto informativo para obter informações sobre perigos.
Reagente de amplificação (Ácidos nucleicos) 1 unidade / Reagente enzimático (Enzima) 1 unidade / Reagente de sonda (Sondas quimiluminescentes) / 1 unidade Controle interno (Ácido nucleico não infeccioso em solução tamponada) 1 unidade
Caixa 2 de 2:
Solução de reconstituição da amplificação (Solução aquosa com conservantes) 1 unidade / Solução de reconstituição enzimática (Solução tamponada com HEPES) 1 unidade / Solução de reconstituição de sonda (Solução tamponada com succinato) 1 unidade / Reagente de seleção (Solução tamponada com borato a 600 mM) 1 unidade / Reagente de captura do alvo (Solução salina tamponada com fase sólida e oligómeros de captura) 1 unidade / Arcos de reconstituição 1 embalagem / AVERTÊNCIA
Kit de controles: Ácido nucleico não infeccioso em solução tamponada 5 x 1,7 ml / Solução tamponada 5 x 1,7 ml

Romanian

Aptima SARS-CoV-2 Assay Pentru detectarea ARN-ului din SARS-CoV-2
SUA: Pentru utilizare doar cu autorizatie de utilizare de urgenta (EUA)
Acest produs poate fi vizat de unul sau mai multe brevete din SUA identificate la www.hologic.com/patents
Consultati prospectul din pachet pentru informatii despre pericole.
Textul din caseta din acest prospect se aplica exclusiv clientilor din SUA.
Cutia 1 din 2:
Reactiv de amplificare (acizi nucleici) 1 flacon / Reactiv enzimatic (enzima) 1 flacon / Reactiv al sondei (sonde chemiluminescente) 1 flacon / Control intern (acid nucleic neinfectios in solutie tamponata) 1 flacon
Cutia 2 din 2:
Solutie de reconstituire amplificarea (solutie apoasa continand conservanti) 1 flacon / Solutie de reconstituire enzimatica (solutie tamponata HEPES) 1 flacon / Solutie de reconstituire a probei (solutie tamponata de succinat) 1 flacon / Reactiv de selectare (solutie tamponata borat 600 mM) 1 flacon / Reactiv de captura a firme (solutie salina tamponata continand faza solida si oligomeri de captura) 1 flacon / Coliere reconstituire 1 pachet / AVERTISMENT
Kit de control:
Acid nucleic neinfectios in solutie tamponata 5 x 1,7 mL / Solutie tamponata 5 x 1,7 mL

Slovak

Aptima SARS-CoV-2 Assay Na detekciu RNA SARS-CoV-2
USA: Na použitie výhradne pod Schválením pre núdzové použitie (EUA)
Tento produkt môže byť chránený jedným alebo viacerými patentami USA uvedenými na stránkach www.hologic.com/patents
Informácie o rizikách nájdete v príbalovej informácii.
Táto časť textu písomnej informácie pre používateľov uvedená v rámciku sa týka len zákazníkov v USA.
Box 1 z 2:
Amplifikačné činidlo (nukleové kyseliny) 1 EA / Enzymatické činidlo (Enzyme) 1 EA / Sondové činidlo (chemiluminescentné sondy) 1 EA / Interná kontrola (neinfekčná nukleová kyselina v pufovanom roztoku) 1 EA
Box 2 z 2:
Amplifikačný roztok na rekonštitúciu (vodný roztok obsahujúci stabilizátory) 1 EA / Roztok na rekonštitúciu enzýmu (roztok pufovaný HEPES) 1 EA / Roztok na rekonštitúciu sondy (Succinate buffered solution) 1 EA / Výberové činidlo (600 mM roztoku pufovaného borátom) 1 EA / Činidlo na cieľový zachyt (pufovaný solný roztok obsahujúci oligoméry pevnej fázy a zachytávajúce oligoméry) 1 EA / Rekonštitučné obálky 1 balenie / VAROVANIE
Súprava kontrol:
Neinfekčná nukleová kyselina v pufovanom roztoku 5 x 1,7 ml / Pufovaný roztok 5 x 1,7 ml

Slovene

Aptima SARS-CoV-2 Assay Za odkrivanje RNA v SARS-CoV-2
ZDA: Za uporabo samo ob odobritvi Emergency Use Authorization (EUA)
Ta izdelek morda krije eden ali več patentov ZDA, ki so navedeni na www.hologic.com/patents
Za informacije glede nevarnosti glejte navodila, priložena pakiranju.
Besedilo v okencu tega vstavka velja samo za kupce v ZDA.
Škatla 1 od 2:
Amplifikacijski reagent (nukleinske kisline) 1 EA / Encimski reagent (encim) 1 EA / Reagent z sonde (kemoluminescentne sonde) 1 EA / Notranja kontrola (nealezivje nukleinske kisline v puferirani raztopini) 1 EA
Škatla 2 od 2:
Amplifikacijska rekonstitucijska raztopina (vodna raztopina, ki vsebuje konzervanse) 1 EA / Encimska rekonstitucijska raztopina (raztopina s puferom HEPES) 1 EA / Rekonstitucijska raztopina za sonde (raztopina s sukcinatnim puferom) 1 EA / Izbrni reagent (raztopina s 600 mM boratnega pufr) 1 EA / Reagent za ciljno zajemanje (puferirana solna raztopina, ki vsebuje oligomere v trdni fazi in oligomere za zajemanje) 1 EA / Rekonstitucijski obročki 1 paket / OPOZORILO
Komplet kontrol:
Nalezljiva nukleinska kislina v puferirani raztopini 5 x 1,7 ml / Puferirana raztopina 5 x 1,7 ml

Spanish - Universal

Aptima SARS-CoV-2 Assay Para la detección del RNA de SARS-CoV-2
EE. UU.: Para uso exclusivo bajo una autorización de uso de emergencia (EUA)
Este producto puede estar cubierto por una o más patentes estadounidenses identificadas en www.hologic.com/patents
Consulte el prospecto para obtener la información sobre riesgos.
El texto contenido en el cuadro de este prospecto se aplica únicamente a los clientes de EE. UU.
Caja 1 de 2:
Reactivo de amplificación (ácidos nucleicos), 1 ud / Reactivo enzimático (enzima), 1 ud / Reactivo de sonda (sondas quimiluminescentes), 1 ud / Control interno (ácido nucleico no infeccioso en una solución de tampón), 1 ud
Caja 2 de 2:
Solución de reconstitución de amplificación (solución acuosa con conservantes), 1 ud / Solución de reconstitución enzimática (solución de tampón HEPES), 1 ud / Solución de reconstitución de sonda (solución de tampón succinato), 1 ud / Reactivo de selección (600 mM de solución de tampón de borato), 1 ud / Reactivo de captura (solución salina de tampón con fase sólida y oligómeros de captura), 1 ud / Collares de reconstitución, 1 paquete / ADVERTENCIA
Kit de controles:
Ácido nucleico no infeccioso en una solución de tampón, 5 x 1,7 mL / Solución de tampón, 5 x 1,7 mL

Swedish

Aptima SARS-CoV-2 Assay För detektering av RNA från SARS-CoV-2
USA: Endast för användning genom Emergency Use Authorization (EUA) (särskild nöddispens)
Denna produkt kan täckas av ett eller fler amerikanska patent som anges på www.hologic.com/patents
Se bipacksedeln för information om riskbedömning
Texten i rutan på denna bipacksedel gäller endast för kunder i USA.
Box 1 av 2:
Amplification Reagent (nukleinsyror) 1 st / Enzyme Reagent (enzym) 1 st / Probe Reagent (kemiluminescenta prober) 1 st / Internal Control (icke smittföreande nukleinsyra i buffrad lösning) 1 st
Box 2 av 2:
Amplification Reconstitution Solution (vattenbaserad med konserveringsmedel) 1 st / Enzyme Reconstitution Solution (buffrad HEPES-lösning) 1 st / Probe Reconstitution Solution (buffrad sukcinatlösning) 1 st / Selection Reagent (600 mM buffrad boratlösning) 1 st / Target Capture Reagent (buffrad saltlösning med solida partiklar och oligonukleotider) 1 st / Rekonstitutionskragar 1 förpackning / VARNING
Kontroller:
Icke smittföreande nukleinsyra i buffrad lösning 5 x 1,7 mL / Buffrad lösning 5 x 1,7 mL

The text in the box on this insert applies to US Customers only

bg Текстът в полето на тази вложка важи само за клиенти от САЩ

hr Teks u kutiji na ovom umetku primjenjuje se samo za kupce u SAD

cz Tato část textu příbalového letáku uvedená v rámečku se týká pouze zákazníků v USA.

da Teksten i feltet på denne indlægsseddel gælder kun for kunder i USA

nl De omkaderde tekst in deze bijsluiter geldt alleen voor klanten in de VS

et Vahelehel olev raamiga ümbritsetud tekst kehtib üksnes USA klientidele

fi Tämän selosteen ruudussa oleva teksti koskee vain USA:ssa olevia asiakkaita

fr Le texte encadré sur cette notice s'applique uniquement aux clients des États-Unis

de Der eingerahmte Text in der Packungsbeilage betrifft nur Kunden in den USA

el Το κείμενο στο πλαίσιο σε αυτό το ένθετο ισχύει μόνο για πελάτες των Ηνωμένων Πολιτειών

hu A betegájékoztatón a keretben lévő szöveg csak az amerikai ügyfelekre vonatkozik

it Il testo nella casella in questo inserto si applica solo ai clienti statunitensi

lv Šajā instrukcijā iezīmētais teksts attiecas tikai uz ASV klientiem.

lt Šio intarpo langelio tekstas taikomas tik JAV klientams

no Teksten i denne esken på dette vedlegget gjelder bare kunder i USA

pl Tekst umieszczony w ramce na tej wkładce dotyczy tylko klientów z USA

pt O texto na caixa deste folheto aplica-se apenas aos clientes dos EUA **ro** Textul din caseta din acest prospect se aplică exclusiv clienților din SUA.

sk Táto časť textu písomnej informácie pre používateľov uvedená v rámečku sa týka len zákazníkov v USA.

sl Besedilo v okencu tega vstavka velja samo za kupce v ZDA..

ei El texto contenido en el cuadro de este prospecto se aplica únicamente a los clientes de EE. UU.

sv Texten i rutan på denna bipacksedel gäller endast för kunder i USA.

- Rx Only.
- For in vitro diagnostic use.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- The Aptima SARS-CoV-2 controls kit is for use with the Aptima SARS-CoV-2 assay only. The Aptima SARS-CoV-2 assay instructions for use describe how to perform controls testing. The current electronic instructions for use for the Aptima SARS-CoV-2 assay are available at <https://www.hologic.com/package-inserts>
- To request a paper copy of the instructions for use of the Aptima SARS-CoV-2 assay, free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com
- This product information card does not contain the full instructions for use.

Hologic, Inc.

Direct Load Capture Cap Collection Kit - CLASSIQSwabs™

The text in the box on this insert applies to US Customers only

bg Текстът в полето на тази вложка важи само за клиенти от САЩ **hr** Tekst u kutiji na ovom umetku primjenjuje se samo za kupce u SAD **cz** Tato část textu příbalového letáku uvedená v rámečku se týká pouze zákazníků v USA. **da** Teksten i feltet på denne indlægsseddel gælder kun for kunder i USA **nl** De omkaderde tekst in deze bijsluiter geldt alleen voor klanten in de VS **et** Infolehel olev raamiga ümbritsetud tekst kehtib üksnes USA klientidele **fi** Tämän selosteen ruudussa oleva teksti koskee vain USA:ssa olevia asiakkaita **fr** Le texte encadré sur cette notice s'applique uniquement aux clients des États-Unis **de** Der eingerahmte Text in der Packungsbeilage betrifft nur Kunden in den USA **el** Το κείμενο στο πλαίσιο σε αυτό το ένθετο ισχύει μόνο για πελάτες των Ηνωμένων Πολιτειών **hu** A betegtájékoztatón a keretben lévő szöveg csak az amerikai ügyfelekre vonatkozik **it** Il testo nella casella in questo inserto si applica solo ai clienti statunitensi **lv** Šajā instrukcijā iezīmētais teksts attiecas tikai uz ASV klientiem. **lt** Šio intarpo langelio tekstas taikomas tik JAV klientams **no** Teksten i i feltet på denne innleggsseddelen gjelder bare kunder i USA **pl** Tekst umieszczony w ramce na tej wkładce dotyczy tylko klientów z USA **pt** O texto na caixa deste folheto aplica-se apenas aos clientes dos EUA **ro** Textul din caseta din acest prospect este valabil exclusiv pentru clienții din SUA. **sk** Táto časť textu písomnej informácie pre používateľov uvedená v rámčeku sa týka len zákazníkov v USA. **sl** Besedilo v okvirčku tega priloženega navodila velja samo za kupce v ZDA. **ei** El texto contenido en el cuadro de este prospecto se aplica únicamente a los clientes de EE. UU. **sv** Texten i rutan på denna bipacksedel gäller endast för kunder i USA.

- Rx Only
- For *in vitro* diagnostic use
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories
- For use under an Emergency Use Authorization (EUA) Only
- When used with the Aptima SARS-CoV-2 assay, this product has been authorized for the collection and maintenance of anterior nasal (nasal) and oropharyngeal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens
- When used with the Aptima SARS-CoV-2/Flu assay, this product has been authorized for the collection and maintenance of anterior nasal (nasal) swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner
- The Direct Load Capture Cap Collection Kit - CLASSIQSwabs™ is for use with the Aptima SARS-CoV-2 assay and Aptima SARS-CoV-2/Flu assay only.
The collection kit instructions for use describe how to perform specimen collection. The current electronic instructions for use for the Direct Load Capture Cap Collection Kit -CLASSIQSwabs™ are available at <https://www.hologic.com/package-inserts>
- To request a paper copy of the instructions for use of the Direct Load Capture Cap Collection Kit - CLASSIQSwabs™, free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com
- This product information card does not contain the full instructions for use

Hologic, Inc.

Direct Load Capture Cap Collection Kit - FLOQSwabs®

The text in the box on this insert applies to US Customers only

bg Текстът в полето на тази вложка важи само за клиенти от САЩ **hr** Tekst u kutiji na ovom umetku primjenjuje se samo za kupce u SAD **cz** Tato část textu příbalového letáku uvedená v rámečku se týká pouze zákazníků v USA. **da** Teksten i feltet på denne indlægsseddel gælder kun for kunder i USA **nl** De omkaderde tekst in deze bijsluiter geldt alleen voor klanten in de VS **et** Infolehel olev raamiga ümbritsetud tekst kehtib üksnes USA klientidele **fi** Tämän selosteen ruudussa oleva teksti koskee vain USA:ssa olevia asiakkaita **fr** Le texte encadré sur cette notice s'applique uniquement aux clients des États-Unis **de** Der eingerahmte Text in der Packungsbeilage betrifft nur Kunden in den USA **el** Το κείμενο στο πλαίσιο σε αυτό το ένθετο ισχύει μόνο για πελάτες των Ηνωμένων Πολιτειών **hu** A betegtájékoztatón a keretben lévő szöveg csak az amerikai ügyfelekre vonatkozik **it** Il testo nella casella in questo inserto si applica solo ai clienti statunitensi **lv** Šajā instrukcijā iezīmētais teksts attiecas tikai uz ASV klientiem. **lt** Šio intarpo langelio tekstas taikomas tik JAV klientams **no** Teksten i i feltet på denne innleggsseddelen gjelder bare kunder i USA **pl** Tekst umieszczony w ramce na tej wkładce dotyczy tylko klientów z USA **pt** O texto na caixa deste folheto aplica-se apenas aos clientes dos EUA **ro** Textul din caseta din acest prospect este valabil exclusiv pentru clienții din SUA. **sk** Táto časť textu písomnej informácie pre používateľov uvedená v rámečku sa týka len zákazníkov v USA. **sl** Besedilo v okvirčku tega priloženega navodila velja samo za kupce v ZDA. **ei** El texto contenido en el cuadro de este prospecto se aplica únicamente a los clientes de EE. UU. **sv** Texten i rutan på denna bipacksedel gäller endast för kunder i USA.

- Rx Only
- For *in vitro* diagnostic use
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories
- For use under an Emergency Use Authorization (EUA) Only
- When used with the Aptima SARS-CoV-2 assay, this product has been authorized for the collection and maintenance of mid-turbinate nasal and nasopharyngeal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens
- When used with the Aptima SARS-CoV-2/Flu assay, this product has been authorized for the collection and maintenance of nasopharyngeal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner
- The Direct Load Capture Cap Collection Kit - FLOQSwabs® is for use with the Aptima SARS-CoV-2 assay and Aptima SARS-CoV-2/Flu assay only.
The collection kit instructions for use describe how to perform specimen collection. The current electronic instructions for use for the Direct Load Capture Cap Collection Kit-FLOQSwabs® are available at <https://www.hologic.com/package-inserts>
- To request a paper copy of the instructions for use of the Direct Load Capture Cap Collection Kit - FLOQSwabs®, free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com
- This product information card does not contain the full instructions for use

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HOLOGIC® Direct Load Tube Collection Kit

Hologic, Inc.

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- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories
- When used with the Aptima SARS-CoV-2 assay, this product has been authorized for the collection and maintenance of anterior nasal (nasal) and oropharyngeal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- When used with the Aptima SARS-CoV-2/Flu assay, this product has been authorized for the collection and maintenance of anterior nasal (nasal) swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner
- The Direct Load Tube collection kit is for use with the Aptima SARS-CoV-2 assay and Aptima SARS-CoV-2/Flu assay only. The collection kit instructions for use describe how to perform specimen collection. The current electronic instructions for use for the Direct Load Tube collection kit are available at <https://www.hologic.com/package-inserts>
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