Uncapped Workflow for the Aptima® SARS-CoV-2 Assay on the Panther® System and Panther Fusion® System

For US/Australia/New Zealand Distribution

US only: This workflow for the test has not been reviewed by the FDA. This workflow is being distributed in accordance with Section IV.C. of the FDA's policy for diagnostic tests for Coronavirus disease – 2019 during the public health emergency at *https://www.fda.gov/media/135659/download [fda.gov]*.

Purpose

The purpose of this Customer Technical Bulletin (CTB) is to notify our customers of the uncapped workflow for testing with the Aptima SARS-CoV-2 assay on the Panther system and Panther Fusion system.

The uncapped workflow introduces two new tube options for implementation with the Aptima SARS-CoV-2 assay on the Panther system and Panther Fusion system.

The following information is included in this CTB:

A. Implementation Information
B. Materials Required and Available Separately
C. Materials Required but not Provided
D. Warnings and Precautions
E. Storage Requirements
F. Specimen Collection and Storage
G. Panther System Test Procedure
H. Troubleshooting

Scope

Hologic has an unwavering commitment to providing solutions to meet customer needs under current constrained conditions in today's supply chain. To continue to accommodate the high demand for COVID-19 testing, as well as to enable continued support for assay testing associated with our Sexual Health and Women's Health Portfolios, Hologic acted immediately and developed uncapped workflows for the Aptima SARS-CoV-2 assay that incorporate two new tube options.

This CTB is effective upon receipt and is intended for site administrators, laboratory supervisors, and users of the Aptima SARS-CoV-2 assay on the Panther system and Panther Fusion system.

This CTB will serve to provide all information and instructions associated with implementation and performance of the uncapped workflow for testing with the Aptima SARS-CoV-2 assay.

Information contained in this CTB will be incorporated into future revisions of the appropriate Aptima SARS-CoV-2 assay associated package inserts.

New Tube Options

1) **Custom Specimen Lysis Tube (Custom SLT)** – Lab selects and purchases generic tube and cap within specifications

- Lab acquires bulk Specimen Transport Medium (STM) (Cat. No. PRD-04423 or PRD-06657) from Hologic and adds to each tube

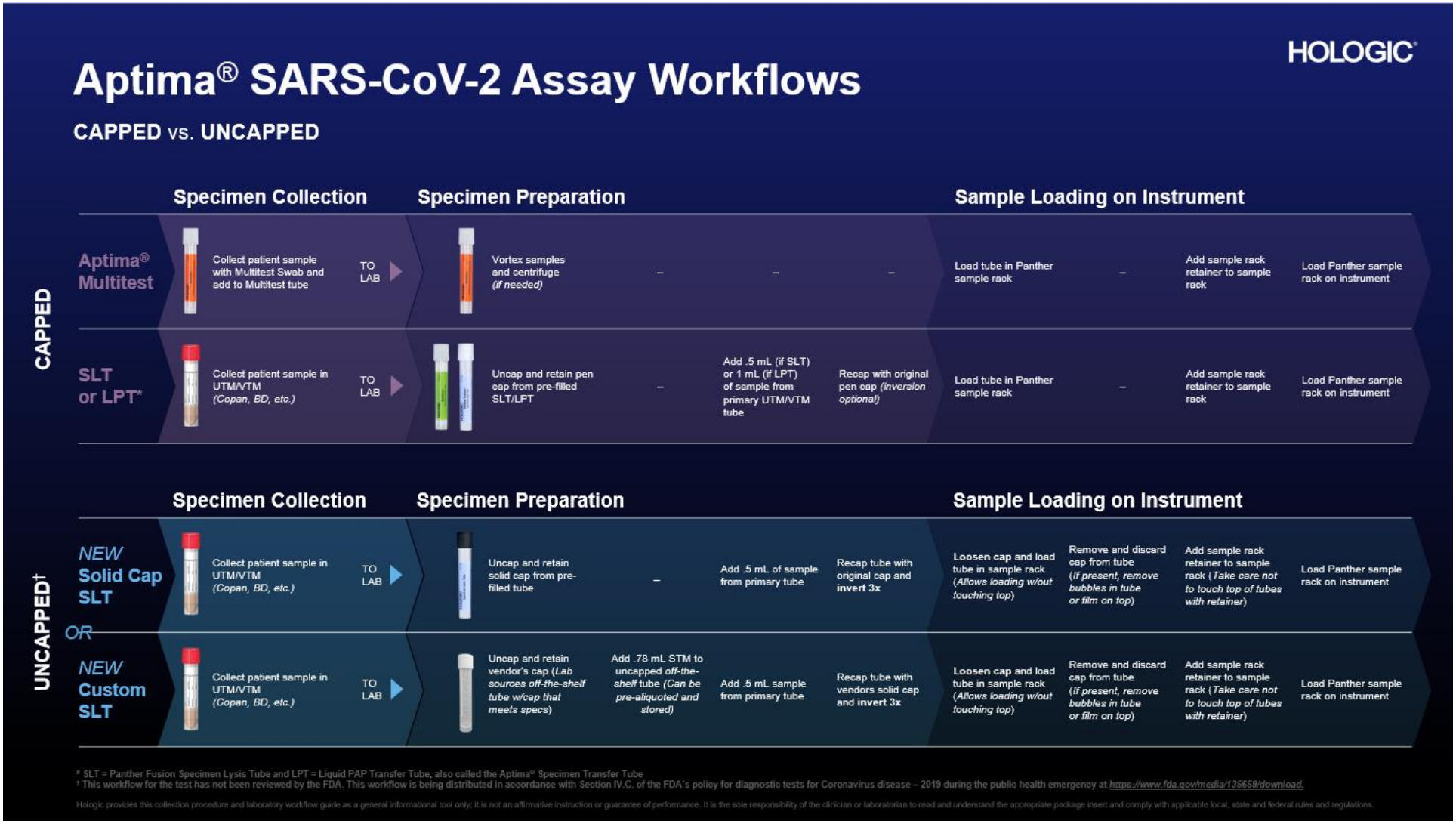
2) **Solid Cap Specimen Lysis Tube (Solid Cap SLT)**

- New tube provided by Hologic labeled as Hologic Specimen Lysis Tube (Cat. No. PRD-06554 or PRD-06660) with a solid cap
- Pre-filled tubes with STM that includes non-penetrable, dark colored solid caps

Uncapped Workflows with New Tube Options

Both the Custom SLT and the Solid Cap SLT utilize the uncapped workflow on the Panther or Panther Fusion system for the Aptima SARS-CoV-2 assay. An overview of the new uncapped workflow can be found in the graphic on the following page:

Aptima SARS-CoV-2 Assay Workflows with New Tube Options



What is Affected

In response to the high demand for COVID-19 testing and to enable continued support for assay testing associated with our Sexual Health and Women's Health Portfolios, Hologic quickly addressed a shortage in tubes and penetrable caps by developing a solution that offers an alternative uncapped workflow for testing with the Aptima SARS-CoV-2 assay.

A. Implementation Information

A Hologic representative will be in contact to discuss and assist with transition activities and customer adoption of the uncapped workflow and new tube options.

A newly released Aptima SARS-CoV-2 uncapped tube assay software is required to be installed on the Panther or Panther Fusion system prior to adoption of the uncapped workflows and new tube options. The Aptima SARS-CoV-2 uncapped tube assay software is compatible with all commercially available versions (v5.3, v6.2, and v7.1) of Panther and Panther Fusion system software. A Hologic representative will be in contact to assist and provide instructions associated with the installation of the Aptima SARS-CoV-2 uncapped tube assay software on the Panther or Panther Fusion system.

Once the Aptima SARS-CoV-2 uncapped tube assay software is installed on a Panther or Panther Fusion system, testing for the Aptima SARS-CoV-2 assay can only be performed with the uncapped workflow on the Panther or Panther Fusion system. The Panther or Panther Fusion system can only have one version of the Aptima SARS-CoV-2 assay installed (either the current commercially available assay software for testing with the capped workflow or the Aptima SARS-CoV-2 uncapped tube assay software for testing with the uncapped workflow).

The Panther or Panther Fusion system will automatically be configured to require the use of Sample Retainers on the Sample Racks with the uncapped workflow once the Aptima SARS-CoV-2 uncapped tube assay software is installed. Labs must not disable the required setting to use Sample Retainers on the Sample Racks with the uncapped workflow.

Panther or Panther Fusion systems with the Aptima SARS-CoV-2 uncapped tube assay software for the uncapped workflow with the Aptima SARS-CoV-2 assay will still be able to perform testing of samples with penetrable caps for all other commercially available assays.

For labs that are operating multiple Panther or Panther Fusion systems and testing with both the capped workflow and the uncapped workflow, it is important to identify which systems are testing with the uncapped workflow for use with the Aptima SARS-CoV-2 assay. Refer to *Appendix A (Attachment)* in this CTB for a printable visual aid to place on the Panther systems with the Aptima SARS-CoV-2 uncapped tube assay software [Version 1.102.6 (v5.3), Version 2.102.11 (v6.2), or Version 3.1.11.5 (v7.1)]. Place the visual aid in a plastic sleeve and apply to the front canopy of the Panther or Panther Fusion systems that are used to test with the uncapped workflows with the Aptima SARS-CoV-2 assay. Replace the visual aid periodically if it becomes worn due to cleaning of the instrument.

No additional Performance Qualification (PQ) activities or verification testing activities are required by Hologic upon installation of the Aptima SARS-CoV-2 uncapped tube assay software to begin testing with the uncapped workflow for the Aptima SARS-CoV-2 assay.

No additional operator proficiencies are required by Hologic, for operators who have previously been deemed proficient to test with the Aptima SARS-CoV-2 assay, to begin testing with the uncapped workflow for the Aptima SARS-CoV-2 assay.

The uncapped workflow with the Custom SLT will require labs to source generic tubes and caps to use with the Aptima SARS-CoV-2 assay. A list of possible suppliers and associated part numbers will be provided by a Hologic representative.

Aptima SARS-CoV-2 assay kits previously tested with the current commercially available assay software may still be used for testing with the uncapped workflow after installation of the Aptima SARS-CoV-2 uncapped tube assay software.

There are no additions or changes to maintenance task requirements or to the recommended frequency when testing with the uncapped workflow for the Aptima SARS-CoV-2 assay. Perform maintenance activities as outlined in the Panther System and Panther Fusion System Operator's Manual. Labs must regularly inspect sample racks and clean within 7 days or as needed.

B. Materials Required and Available Separately

Specimen Lysis Tubes, Specimen Transport Medium, and Caps

Component	Quantity	Component Description	Cat. No.
Hologic® Specimen Lysis Tube	100 each	1 tube containing 0.71 mL of Specimen Transport Media (STM) with a solid cap (Solid Cap SLT)	PRD-06554
Hologic® Specimen Lysis Tube	1200 each	1 tube containing 0.71 mL of Specimen Transport Media (STM) with a solid cap (Solid Cap SLT)	PRD-06660
Specimen Transport Medium	1 bottle	Bottle containing 80 mL of Specimen Transport Media (STM) for preparing Custom SLT	PRD-04423
Specimen Transport Medium	1 bottle	Bottle containing 120 mL of Specimen Transport Media (STM) for preparing Custom SLT	PRD-06657

Component	Quantity	Component Description	Cat. No.
Fisherbrand™ VersaClosure™ tube closures	1000 per pack	A single-use tube cover for the Hologic Specimen Lysis Tube (Cat. No. PRD-06554 only) after testing	02-707
Hologic Solid Cap	100 per bag	A single-use tube cap for the Hologic Specimen Lysis Tube (Cat. No. PRD-06554 only) after testing	PRD-06720

C. Materials Required but not Provided

- P1000 pipettor and tips with hydrophobic plugs for the transfer of specimen from the primary collection container to the Specimen Lysis Tube.
- Pipet or repeat pipettor capable of 0.78 mL ± 0.07 mL dispense for preparing Custom SLT.

Generic Sample Tube Requirements (for Custom SLT)

Type	Size	Material
Specimen	12 x 75 mm to 13 x 100 mm (including 12 x 100 mm, 13 x 75 mm, and 13 x 82mm)	Polypropylene plastic, siliconized glass, or similar material Non-sterile or sterile Round, flat bottom, or conical (skirted conical)

Note: A list of possible suppliers and associated part numbers will be provided by Hologic.

D. Warnings and Precautions

- Do not apply the transport medium directly to skin or mucous membranes or take internally. For information on any hazards and precautionary statements that may be associated with the Specimen Lysis Tube, refer to the Safety Data Sheet Library at www.hologic.com/sds.

- Expiration dates listed on the Hologic Specimen Lysis Tubes 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.

- Contamination may occur if carryover of samples is not adequately controlled during sample handling and processing.

E. Storage Requirements

Store Specimen Lysis Tubes prior to use at room temperature (15°C to 30°C).

F. Specimen Collection and Storage

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 3 mL of VTM or UTM. Swab specimens may alternatively be added to saline, Liquid Amies, or STM.

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 as described in the specimen processing section below. Remaining specimen volumes can be stored at ≤-70°C.

The following types of VTM/UTM can be used.

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

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

Nasopharyngeal wash/aspirate and nasal aspirate specimen collection

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

Specimen Processing using the Hologic Specimen Lysis Tube with Solid Cap (Solid Cap SLT)

A. Uncap the Hologic Specimen Lysis Tube and retain the cap.

B. Prior to testing on the Panther system, transfer 500 uL of the specimen to the Hologic Specimen Lysis Tube.

C. It is recommended to recap the sample tube and gently invert three times to ensure viral inactivation and homogenous 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. 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).

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

Note: *Specimen processing using the Hologic Specimen Lysis Tube is for use with the Aptima SARS-CoV-2 uncapped tube assay software.*

Note: *The Panther Fusion Specimen Lysis Tube may be used with the Aptima SARS-Cov-2 uncapped tube assay software. Prepare the Panther Fusion Specimen Lysis Tube as described above in the Specimen Processing using the Hologic Specimen Lysis Tube with Solid Cap section.*

Note: *For specimens collected with an Aptima Multitest Tube, transfer the collected specimen from the Aptima Multitest Tube to a Hologic Specimen Lysis Tube as described above in the Specimen Processing using the Hologic Specimen Lysis Tube with Solid Cap section.*

Specimen processing using a Custom Specimen Lysis Tube (Custom SLT)

A. Using a sterile or non-sterile generic tube made of siliconized glass, polypropylene plastic, or similar material 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: *If tubes are prepared prior to use, recap the tube and store at 15°C to 30°C until use in specimen processing.*

B. Uncap the custom Specimen Lysis Tube containing STM and retain the cap.

C. Prior to testing on the Panther system, transfer 500 uL 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 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. 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).

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

Note: *Specimen processing using the Custom Specimen Lysis Tube is for use with the Aptima SARS-CoV-2 uncapped tube assay software.*

Note: *For specimens collected with an Aptima Multitest Tube, transfer the collected specimen from the Aptima Multitest Tube to a Custom Specimen Lysis Tube as described above in the Specimen Processing using the Custom Specimen Lysis Tube section.*

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 Specimen Lysis Tubes should be stored upright in a rack under the following condition:
    - 2°C to 30°C up to 6 days

2. The samples should be covered with a new, clean plastic film or foil barrier.

3. If assayed samples need to be frozen or shipped, 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.

    Note: *The Fisherbrand™ VersaClosure™ tube closure should not be used to cover tubes for freezing or shipping.*

G. Panther System Test Procedure

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. When adequate collected specimen is added to the tube, there is sufficient volume to perform 2 nucleic acid extractions.*

Note: *When using the Aptima SARS-CoV-2 uncapped tube assay software, remove the cap from the Positive and Negative controls before loading onto the Panther system.*

H. Troubleshooting

The following table provides information on scenarios that may be encountered and flags that can appear if an error occurs during assay processing.

Scenario	Description / Flags	User Action Required
Running the uncapped workflow and Controls are inadvertently loaded with penetrable caps	Sample pipettor fails to pierce the penetrable cap. Controls are invalidated with VVFS/RDFS flags. Specimen will not be pipetted and no test orders will be lost.	Operator unloads and uncaps and reloads controls without caps.
Running the uncapped workflow and a tube with a penetrable cap is inadvertently loaded	Sample pipettor fails to pierce the penetrable cap for samples. Samples are invalidated with VVFS/RDFS flags.	Operator inspects samples, removes penetrable cap, and reloads sample.
Running the uncapped workflow and a tube with a solid cap is inadvertently loaded	Sample pipettor hits the top of the solid cap and sample is invalidated with a PMFS flag. Sample pipetting is stopped and no additional samples will be pipetted. Samples already pipetted will continue processing.	Allow instrument to complete assay processing. Once complete, restart instrument to reset pipettor. It is important to ensure solid caps are removed before loading on to the instrument.

What is Required

Ensure that appropriate personnel (laboratory, clinic, supply chain/inventory, purchasing, and accounting) are notified of the information documented in this CTB.

If there are any questions or concerns regarding this communication, please contact your local Hologic support representative. In the U.S., Hologic Technical Support may be reached at +1 888 484 4747 or +1 858 410 8511, or by e-mail at molecularsupport@hologic.com.

APPENDIX A (Attachment). Aptima SARS-CoV-2 Assay Uncapped Workflow Sign

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