

Specimen Lysis Tubes

Instructions for Use

For *in vitro* diagnostic use.

Rx Only

Intended Use

Specimen Lysis Tubes are intended to be used for processing specimens for use with Hologic® assays. Refer to the applicable assay package insert for appropriate Specimen Lysis Tubes and specimen types authorized for use with each assay.

Materials Provided

Available Products

| Component | Quantity | Description | Cat. No. |
|--|----------|---|-----------|
| Panther Fusion® Specimen Lysis Tube | 100 each | 1 tube containing 0.71 mL of Specimen Transport Media (STM) with a penetrable cap | PRD-04339 |
| Hologic® Specimen Lysis Tube | 100 each | 1 tube containing 0.71 mL of Specimen Transport Media (STM) with a solid cap | PRD-06554 |

Materials Required but not Provided

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

| | <u>Cat. No.</u> |
|---|-----------------|
| 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 preparation of Custom Specimen Lysis Tubes only | — |
| Hologic Solid Cap for use with PRD-06554*, 100 caps per bag <small>*a single-use cover for the Hologic Specimen Lysis Tube (PRD-06554 only) after testing as part of the uncapped workflow</small> | PRD-06744 |
| Fisherbrand VersaClosure Tube Closures*, 1000 per pack <small>*a single-use tube cover for the Hologic Specimen Lysis Tube (PRD-06554 only) after testing as part of the uncapped workflow</small> | 02-707 |

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.hologicsds.com.

Storage Requirements

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

Specimen Performance

The assay performance characteristics of the specimens are provided in the appropriate Hologic assay package insert. The Hologic assay package inserts may be referenced online at www.hologic.com.

Specimen Collection and Handling

Specimens - Clinical material collected from patient placed in an appropriate transport system.

Samples - Represents a more generic term to describe any material for testing on the Panther® or Panther Fusion® System including specimens and specimens transferred into Specimen Lysis Tubes.

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. Avoid touching tops of caps of specimens during preparation. Discard used material without passing over open tubes.

Collect specimens according to standard technique. Refer to the assay package insert for the specific sample types compatible with each assay.

Specimen Processing using the Panther Fusion Specimen Lysis Tube

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

***Note:** For Panther Fusion SARS-CoV-2 assay, transfer 250 µL of the LRT specimen and 250 µL of VTM/UTM.

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

- B. Refer to the respective assay package insert for information on storage of specimens before and after transferring to the Panther Fusion Specimen Lysis Tube.

Specimen Processing using the Hologic Specimen Lysis Tube with Solid Cap

Note: Specimen processing using the Hologic Specimen Lysis Tube with solid cap is for use with the Aptima® SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay only.

- 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 sample tube and gently invert three times to ensure viral inactivation and 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.

Sample Storage

- A. Samples on board the Panther system may be archived for additional testing at a later time.
 - B. Storing samples after testing
 1. Samples that have been assayed should be stored upright in the rack. Refer to the assay package insert for the appropriate storage conditions.
 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,
 - 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 Handling section*.

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

Limitations

Use Specimen Lysis Tubes only with the Hologic assays. Performance has not been established with other products.

Contact Information and Revision History



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

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

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AW-26255-001 Rev.001
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| Revision History | Date | Description |
|-----------------------|------------|--|
| AW-26255-001 Rev. 001 | April 2022 | <ul style="list-style-type: none"> Created Specimen Lysis Tubes IFU, AW-26255-001 Rev. 001 based on AW-21688-001 Rev. 004 for regulatory compliance with IVDR Updated Intended Use statement, Available Products and Specimen Processing sections Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support |