

Panther Fusion™ Specimen Lysis Tubes

For *in vitro* diagnostic use.

For U.S. Export Only.

Intended Use

The Panther Fusion Specimen Lysis Tube is for use with Panther Fusion assays. The Panther Fusion Specimen Lysis Tube is intended to be used for processing of specimens.

Materials Provided

Panther Fusion Specimen Lysis Tubes (Cat. No. PRD-04339)

| Component | Quantity | Description |
|------------------------------------|----------|---|
| Panther Fusion Specimen Lysis Tube | 100 each | 1 tube containing 0.71 mL of Specimen Transport Media (STM) |

Materials Required But Not Provided

P1000 pipettor and tips with hydrophobic plugs for the transfer of specimen from the primary collection container to the Panther Fusion Specimen Lysis Tube.

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 Panther Fusion Specimen Lysis Tube, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Storage Requirements

Store Panther Fusion 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 Panther Fusion assay package insert. The Panther Fusion assay package inserts may be referenced online at www.hologic.com. The table below identifies the acceptable specimen types for each of the Panther Fusion assays.

| Panther Fusion Assay | Nasopharyngeal Swab (NP) Specimens |
|-----------------------------|------------------------------------|
| Panther Fusion™ Flu A/B/RSV | Yes |
| Panther Fusion™ Paraflu | Yes |
| Panther Fusion™ AdV/hMPV/RV | Yes |
| Panther Fusion™ Bordetella | Yes |

Specimen Collection and Handling

Specimens - Clinical material collected from patient placed in an appropriate transport system. Specimen types include NP swab specimens.

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

A. Specimen collection

Panther Fusion Flu A/B/RSV, Paraflu, and AdV/hMPV/RV Assays

Collect NP swab specimens according to standard technique using a polyester-, rayon-, or nylon-tipped swab. Immediately place the swab specimen into 3mL of viral transport medium.

The following types of viral transport medium were verified for use.

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

Panther Fusion Bordetella Assay

Collect NP swab specimens according to standard technique using a polyester-, rayon-, or nylon-tipped swab. Immediately place the swab specimen into dedicated transport medium.

The following types of transport media were verified for use.

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

B. Specimen processing

1. Prior to testing on the Panther Fusion system, transfer specimen* to the Panther Fusion Specimen Lysis Tube.

- Transfer 500 µL of the NP swab specimens to a Panther Fusion Specimen Lysis Tube.

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

2. Storing specimens before testing
 - a. After collection, specimens can be stored at 2°C to 8°C up to 96 hours before transferred to the Panther Fusion Specimen Lysis Tube. Remaining specimen volumes can be stored at ≤-70°C.
 - b. Specimen in the Panther Fusion Specimen Lysis Tube may be stored under one of the following conditions:
 - 15°C to 30°C up to 6 days or
 - 2°C to 8°C up to 3 months.

Note: *It is recommended that specimens transferred to the Panther Fusion Specimen Lysis Tube are stored capped and upright in a rack.*

- C. Specimen on board the Panther Fusion system may be archived for additional testing at a later time.
- D. Storing samples after testing
 1. Samples that have been assayed should be stored upright in the rack under one of the following conditions:
 - 15°C to 30°C up to 6 days or
 - 2°C to 8°C up to 3 months.
 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, 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 lysis 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. Prior to retest, replace the non-penetrable cap with a penetrable cap. Avoid splashing and cross-contamination.

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 the Panther Fusion Specimen Lysis Tube only with the Panther Fusion assays. Performance has not been established with other products.



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