

Panther Fusion® Open Access General Purpose Reagents

Instructions for Use

For *in vitro* diagnostic use

Intended Use

The Panther Fusion® Open Access General Purpose Reagents consist of Specimen Transport Medium (STM), Urine Transport Medium (UTM), and Blood Transport Medium (BTM), Panther Fusion Oil and Oil Reagent Kit, and the Panther Fusion Open Access Diluent Additive. STM, UTM, and BTM are specimen diluents intended to be used for processing and/or storing specimens for use with the Panther Fusion system. Panther Fusion Oil Reagent and Oil Reagent Kit are used to prevent evaporation of aqueous solutions onboard the Panther Fusion system. The Panther Fusion Open Access Diluent Additive is intended to be added to STM, UTM, BTM, or Phosphate Buffered Saline (PBS) to enhance nucleic acid capture. The Panther Fusion Open Access General Purpose Reagents are intended for use on the fully automated nucleic acid detection instrument, Panther Fusion system.

Principles of the Procedure

The Urine Transport Medium (UTM) is intended to be used for processing and/or storing urine specimens for use with the Panther Fusion System. UTM releases target nucleic acid and protects them from degradation during storage.

The Specimen Transport Medium (STM) is intended to be used for processing and/or storing specimens for use with the Panther Fusion system. STM releases target nucleic acid and protects them from degradation during storage.

The Blood Transport Medium (BTM) is intended to be used for processing and/or storing whole blood specimens for the use with the Panther Fusion® System. BTM releases target nucleic acid and protects them from degradation during storage.

The Panther Fusion Open Access Diluent Additive is intended to be used as an additive to STM, UTM, BTM, and Phosphate Buffered Saline (PBS) to enhance nucleic acid capture for specimen processing.

The Panther Fusion Oil Reagent and Oil Reagent Kit are used to prevent evaporation during sample processing.

Refer to the *Panther/Panther Fusion System Operator's Manual* for information on the operation of the Panther Fusion system.

Materials Provided

Note: Hazard communication information for labeling of globally marketed products reflects the US and EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicds.com.

Panther Fusion General Purpose Reagents

Specimen Transport Medium	1 x 80 mL	PRD-04423
Urine Transport Medium	1 x 80 mL	PRD-04943
Blood Transport Medium	1 x 80 mL	PRD-04944
Panther Fusion Open Access Diluent Additive	1 x 1 mL	PRD-04945
Panther Fusion Oil	2 x 38 mL	PRD-04335
Oil Reagent	1 x 24.6 mL	PRD-04304

Warnings and Precautions

- A. Carefully read this entire package insert, the *Panther Fusion System Open Access Application Sheet*, and *Panther/Panther Fusion System Operator's Manual*. Panther Fusion General Purpose Reagents are for use on the Panther Fusion System.
- B. Use routine laboratory precautions. Do not eat, drink, or smoke in designated work areas. Wear disposable, powderless gloves, protective eyewear, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and reagents.
- C. Avoid microbial and ribonuclease contamination of reagents.
- D. Dispose of all material that has come into contact with specimens and reagents in accordance with applicable national, international, and regional regulations.
- E. Store components at the recommended storage condition. See Storage and Handling Requirements.
- F. Inspect for damage, leaking, and expiration before use. Do not use if damaged, leaking, or expired.

- G. Do not combine any assay reagents or fluids. Do not top off reagents or fluids; the Panther Fusion system verifies reagent levels.
- H. See the outer packaging for manufacture date and expiration date.

Storage and Handling Requirements

- A. Store unopened Specimen Transport Medium, Urine Transport Medium, Blood Transport Medium, Panther Fusion Oil, and Oil Reagent at 15°C to 30°C. Store unopened Panther Fusion Open Access Diluent Additive at -85°C to -15°C.
- B. Once opened, Panther Fusion Oil, and Oil Reagent are stable for 60 days when capped and stored at their intended storage conditions. Testing of the prepared working diluents, i.e., STM, UTM, or BTM, combined with the Panther Fusion Open Access Diluent Additive has demonstrated stability at room temperature up to 30 days. Customers are recommended to determine stability in consideration of a specific assay performance and use case.
- C. Discard any unused reagents that have surpassed their stability.
- D. Avoid cross-contamination during reagent handling and storage.
- E. Do not freeze the Panther Fusion Open Access General Purpose Reagents, except for the Panther Fusion Open Access Diluent Additive that must be stored frozen.

Procedure

Refer to the IVD assay Instructions for Use or the Extraction Reagents Instructions for Use for specific procedures.

Limitations

For use only on the Panther Fusion system by a trained professional.

Contact Information and Revision History

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This product is intended for use only in the field of human in vitro diagnostics.

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

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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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Revision History	Date	Description
AW-26514-001 Rev. 001	April 2022	<ul style="list-style-type: none"> Creation of new Panther Fusion Open Access General Purpose Reagents IFU AW-26514-001 Rev. 001 for regulatory compliance with IVDR