

Panther Fusion® Reconstitution Buffers

Instructions for Use
For *in vitro* diagnostic use

Intended Use

The Panther Fusion Reconstitution Buffer I and Panther Fusion Reconstitution Buffer II are used to reconstitute the lyophilized unit dose assay cartridge, in order to facilitate the *in vitro* testing of analytes.

These products are Panther Fusion general purpose reagents for use on the fully automated nucleic acid detection instrument, Panther Fusion® system.

Principles of the Procedure

The Panther Fusion Reconstitution Buffer I and Panther Fusion Reconstitution Buffer II are salt-containing buffers used to reconstitute the lyophilized unit dose assay cartridge. The reconstituted assay mix is added to the reaction tube in preparation for target amplification and detection on the Panther Fusion system.

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

Materials Provided

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

Panther Fusion Reconstitution Buffers

Panther Fusion Reconstitution Buffer I	2 x 87 mL or 1920 tests	PRD-04333
Panther Fusion Reconstitution Buffer II	2 x 87 mL or 1920 tests	PRD-04804

Warnings and Precautions

- A. Carefully read this entire package insert and the *Panther Fusion System Operator's Manual*. Panther Fusion Reconstitution Buffers I and II 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. Avoid touching the foil top or the red septum.
- H. Do not combine any assay reagents or fluids. Do not top off reagents or fluids; the Panther Fusion system verifies reagent levels.
- I. See the outer packaging for manufacture date and expiration date.

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.hologicsds.com.

Storage and Handling Requirements

- A. Store unopened the Panther Fusion Reconstitution Buffer I and the Panther Fusion Reconstitution Buffer II at 15°C to 30°C. The shelf life for the Panther Fusion Reconstitution Buffer I and the Panther Fusion Reconstitution Buffer II is 26 months.
- B. Once opened, the Panther Fusion Reconstitution Buffers I and II are stable for 60 days.
- C. Discard any unused reagents that have surpassed their stability.
- D. Avoid cross-contamination during reagent handling and storage.
- E. Do not freeze reagents.

Procedure

Replace bottles in the Fusion Universal Fluids Drawer when notified by the system. Refer to the *Panther Fusion System Operator's Manual*.

Limitations

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

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.

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-26599-001 Rev. 001	April 2022	<ul style="list-style-type: none"> Created Panther Fusion Reconstitution Buffers IFU AW-26599-001 Rev. 001 for regulatory compliance with IVDR