

Panther Fusion® Elution Buffer

Instructions for Use For *in vitro* diagnostic use

Intended Use

The Panther Fusion Elution Buffer is a low ionic strength reagent used to elute the captured target nucleic acid in preparation for downstream analyte amplification and detection on the Panther Fusion® system.

This product is a Panther Fusion general purpose reagent for use on the fully automated nucleic acid detection system (Panther Fusion system).

Principles of the Procedure

The Panther Fusion Elution Buffer is used to elute purified nucleic acid after target capture occurs, resulting in isolated total nucleic acid ready to be transferred for target amplification and detection on the Panther Fusion system.

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

Materials Provided

Panther Fusion Elution Buffer

Panther Fusion Elution Buffer	2 x 89 mL or 2400 tests	PRD-04334
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Warnings and Precautions

- A. Carefully read this entire package insert, the *Panther/Panther Fusion System Operator's Manual*. Panther Fusion Elution Buffer is 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.
- J. 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 Panther Fusion Elution Buffer at 15°C to 30°C.
- B. Once opened, Elution buffer is stable for 60 days.
- C. Discard any unused reagents that have surpassed on-board 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/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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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-26594-001 Rev. 001	April 2022	New Panther Fusion Elution Buffer assay IFU AW-26594-001 Rev. 001 for regulatory compliance with IVDR