

Panther Fusion® Open Access™ RNA/DNA Enzyme Cartridge

Instructions for Use

For Laboratory Use

Intended Use

The Open Access RNA/DNA Enzyme Cartridge is intended for general amplification of RNA and DNA templates. The cartridge contains dNTPs, enzymes, and PCR buffer and is intended for use on the Panther Fusion® system.

Materials Provided

Note: Hazard Communication reflects the 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.

Catalog Number: PRD-04303

Open Access Refrigerated Reagents (2° to 8°C):

Open Access RNA/DNA Enzyme Cartridge (12 tests per cartridge) <i>Reverse transcriptase and DNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	12 x 0.024 mL lyophilized
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Storage and Handling Requirements

A. The following table provides storage and handling requirements for the cartridge.

Reagent	Unopened Storage	On-board/Open Stability ¹	Opened Storage
Open Access RNA/DNA Enzyme Cartridge	2°C to 8°C	60 days	2°C to 8°C ²

When reagents are removed from the Panther Fusion System, return them immediately to their appropriate storage temperatures.

¹ On-board stability starts at the time the reagent is placed on the Panther Fusion System.

² If removed from the Panther Fusion System, store the cartridge in an air-tight container with desiccant at the recommended storage temperature.

- B. Discard any unused reagents that have surpassed their on-board stability.
- C. Avoid cross-contamination during reagent handling and storage.
- D. Do not freeze reagents.
- E. Do not use the cartridge if the storage pouch has lost its seal or if the enzyme cartridge foil is not intact.
- F. Do not use the reagents after the expiration date.

Reagent and Enzyme Cartridge Preparation

Refer to the *Panther Fusion System Operator's Manual* for instructions on preparing and loading reagents and loading/unloading cartridges.

Warnings and Precautions

- A. For Laboratory Developed Test use only.
- B. Carefully read this entire package insert and the Panther Fusion System Open Access Application Sheet and Panther Fusion System Operator's Manual.
- C. Use routine laboratory precautions. Do not eat, drink, or smoke in designated work areas. Wear disposable, powderless gloves and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and reagents.
- D. Avoid microbial and ribonuclease contamination of reagents.
- E. Dispose of all material that has come into contact with specimens and reagents in accordance with applicable national, international, and regional regulations.
- F. Store components at the recommended storage condition. See Storage and Handling Requirements.
- G. Do not use the cartridge if the storage pouch has lost its seal or if the cartridge foil is not intact. Contact Hologic if either occurs.
- H. Handle the Open Access Enzyme Cartridge with care. Do not drop or invert cartridge. Avoid prolonged exposure to ambient light.

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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Revision History	Date	Description
AW-26511-001 Rev. 001	May 2022	<ul style="list-style-type: none"> Created Panther Fusion Open Access RNA/DNA Enzyme Cartridge for Laboratory Use IFU AW-26511-001 Rev. 001 based on AW-16080-001 Rev. 001 for regulatory compliance with IVDR Updated intended use statement Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support