

Panther Fusion® Extraction Reagents-B

Instructions for Use

For *in vitro* diagnostic use.

Intended Use2
Principles of the Procedure2
Materials Provided2
Materials Required and Available Separately2
Warnings and Precautions3
Storage and Handling Requirements4
Sample Preparation5
 Definitions5
 Notes5
 EDTA Plasma Specimen Processing6
 EDTA Whole Blood Specimen Processing6
Panther Fusion System Test Procedure7
 Work Area Preparation7
 Reagent Preparation7
 Specimen Handling7
 System Preparation8
Limitations8
Contact Information and Revision History9

Intended Use

The Panther Fusion® Extraction Reagents-B are intended for extraction of RNA and DNA from EDTA whole blood, EDTA plasma, and urine using upstream sample extraction capabilities of the Panther Fusion system.

Principles of the Procedure

Prior to processing and testing on the Panther Fusion system, prepare specimens as described in this document. The internal control target present in the Internal Control-B (IC-B) reagent is added to each test specimen via the working Panther Fusion Capture Reagent-B (wFCR-B). The IC-B in the reagent may be used to monitor specimen processing, amplification and detection. Capture oligonucleotides hybridize to nucleic acid in the test specimen. Hybridized nucleic acid is then separated from the specimen in a magnetic field. Wash steps remove extraneous components from the reaction tube. The elution step elutes purified nucleic acid. During the nucleic acid capture and elution step, total nucleic acid is isolated from specimens.

Refer to the Panther Fusion assay package inserts for specific information on sample preparation for approved assays. Refer to the *Panther/Panther Fusion System Operator's Manual* for information on the operation of the Panther Fusion system.

Materials Provided

Panther Fusion Extraction Reagents-B (Cat No. PRD-06232)

Component	Quantity	Volume	Description
Panther Fusion Capture Reagent-B	4 x 240 test bottles	173 mL/bottle	A buffered salt solution containing solid phase (magnetic particles) and non-infectious nucleic acids
Panther Fusion Enhancer Reagent-B	4 x 240 test bottles	70 mL/bottle	An alkaline solution of lithium hydroxide

Materials Required and Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.





	<u>Cat. No.</u>
Panther System	303095
Panther Fusion Module	PRD-04173
Panther Fusion System	PRD-04172
Panther Fusion Internal Control-B 960 Tests <i>Panther Fusion Internal Control-B tube, 4 per box</i>	PRD-06234
Aptima Whole Blood Diluent Tubes	PRD-06783
Transport Tube Cap, 100 pack	504415
Specimen Aliquot Tubes (SAT), 100 pack	503762
Blood Transport Medium (BTM)	PRD-04994
Replacement Caps for Extraction Reagent Bottles	CL0040

Warnings and Precautions

- A. Use routine laboratory precautions. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling reagents.
- B. For professional use.
- 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 reagents at the recommended storage condition. See Storage and Handling Requirements.
- F. The Panther Fusion Enhancer Reagent-B (FER-B) is corrosive, harmful if swallowed and causes severe skin burns and eye damage.
- G. Specimens may be infectious. Use Universal Precautions when performing this assay. Proper handling and disposal methods should be established by the laboratory director. Only personnel adequately trained in handling infectious materials should be permitted to perform this diagnostic procedure.
- H. Do not use the reagents after the expiration date.
- I. Do not combine any assay reagents or fluids. Do not top off reagents or fluids; the Panther Fusion system verifies reagent levels.
- J. Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.
- K. Some reagents of this kit may be labeled with risk and safety symbols.

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.

Storage and Handling Requirements

US Hazard Information	
 	<p>Panther Fusion Enhancer Rgt (FER-B) LITHIUM HYDROXIDE, MONOHYDRATE 5 – 10% DANGER</p> <p>H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage P264 - Wash face, hands and any exposed skin thoroughly after handling P270 - Do not eat, drink or smoke when using this product P260 - Do not breathe dust/fume/gas/mist/vapors/spray P280 - Wear protective gloves/protective clothing/eye protection/face protection P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a POISON CENTER or doctor/physician P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower P363 - Wash contaminated clothing before reuse P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell P330 - Rinse mouth P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting P405 - Store locked up</p>
EU Hazard Information	
 	<p>Panther Fusion Enhancer Rgt (FER-B) LITHIUM HYDROXIDE, MONOHYDRATE 5 – 10% DANGER</p> <p>H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage P280 - Wear protective gloves/protective clothing/eye protection/face protection P260 - Do not breathe dust/fume/gas/mist/vapours/spray P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a POISON CENTER or doctor/physician</p>

Storage and Handling Requirements

- A. The following table provides storage and handling requirements for the Panther Fusion Extraction Reagents-B.

Reagent	Unopened Storage	On-board/Open Stability*	Opened Storage**
Panther Fusion Capture Reagent-B	15 °C to 30 °C	30 days	15 °C to 30 °C
Panther Fusion Enhancer Reagent-B	15 °C to 30 °C	30 days	15 °C to 30 °C

*On board stability starts at the time the reagent is placed on the Panther Fusion system for the Panther Fusion FCR-B and FER-B.

**Working Panther Fusion Capture Reagent-B (Panther Fusion Capture Reagent-B that has been mixed with Internal Control-B on the Panther Fusion system) and Panther Fusion Enhancer Reagent-B are stable for 60 days when capped and stored at 15°C to 30°C. Do not refrigerate.

- B. Discard any unused reagents that have surpassed their stability.
- C. Avoid cross-contamination during reagent handling and storage.
- D. Do not freeze reagents.

Sample Preparation

Definitions

- Specimens—Clinical material collected from a patient and placed in an appropriate transport system.
- Samples—Represents a more generic term to describe any material for testing on the Panther Fusion system including specimens, specimens transferred into a Panther Fusion compatible sample tube and controls.

Notes

- Refer to the *Panther/Panther Fusion System Operator's Manual* for complete instructions on how to load samples onto the system.
- Handle all specimens as if they contain potentially infectious agents. Use Universal Precautions.
- Take care to avoid cross-contamination during specimen handling steps. For example, discard used material without passing over tubes.
- When testing frozen specimens, allow specimen to reach room temperature prior to processing.
- Whole blood specimens collected in tubes with EDTA anticoagulants may be used for subsequent dilution in the Whole Blood Diluent tube or with BTM in the Sample Aliquot Tube (SAT).
- Whole blood specimens collected in the following glass or plastic tubes may be used to prepare plasma:
 - Tubes containing EDTA anticoagulants
 - Plasma preparation tubes (PPTs). Separate the plasma from the red blood cells following the manufacturer's instructions.
- The following procedures are provided as guidance. Test specific sample preparation procedures should be developed and validated by the user.

Table 1 lists the minimum sample dead volumes needed based on the chosen tube type.

Table 1. Minimum Dead Volume by Tube Type

Tube (Size and Type)	Dead Volume on Panther Fusion System
Sample Aliquot Tube (SAT)	0.2 mL
12 x 75 mm	0.5 mL
13 x 100 mm	0.5 mL
13 x 100 mm with Gel	0.3 mL
16 x 100 mm with Gel	0.7 mL

EDTA Plasma Specimen Processing

1. Refer to Table 1 for the required sample dead volume by tube type.
2. Plasma can be tested on the Panther Fusion system in a primary tube or transferred to a secondary tube such as the Specimen Aliquot Tube (SAT). To obtain the 400 μL sample volume, the minimum volume of plasma for primary collection tubes is up to 1100 μL . For secondary tubes, the minimum volume is 600 μL to obtain the 400 μL sample volume.
3. For primary tubes, just prior to loading specimens into a Sample Rack, centrifuge each specimen at 1000g to 3000g for 10 minutes. Do not remove caps at this step.
4. Load samples into the Sample Rack. Perform the following steps for each sample tube:
 - a. Loosen one sample tube cap, but do not remove it yet.

Note: *Be especially careful to avoid contamination by the spread of aerosols. Gently loosen caps on samples.*
 - b. Load the sample tube into the Sample Rack.
 - c. Repeat Steps 4.a and 4.b for each remaining sample.
 - d. After the samples have been loaded into the Sample Rack, remove and discard each sample tube cap in one Sample Rack. To avoid contamination, do not pass a cap over any other Sample Racks or sample tubes.
 - e. If necessary, use a new, disposable transfer pipet to remove any bubbles or foam. Bubbles in the tube compromise the level-sensing by the Panther Fusion system.
 - f. When the last cap has been removed, load the Sample Rack into the Sample Bay.

EDTA Whole Blood Specimen Processing

Note: *Ensure frozen specimens are thoroughly thawed. Allow the specimens to reach 15°C to 30°C prior to processing.*

1. Gently invert whole blood tubes at least 3 times, or mix gently on a rocker, until blood is homogeneous.
2. Before sample processing, perform the following procedure on each specimen.
 - a. Blood in the primary tubes should be mixed thoroughly by inversion and the sample should be immediately transferred into the tube containing whole blood diluent.
 - b. Add 500 μL whole blood specimen to the pre-filled Whole Blood Diluent tube. Alternatively, add 400 μL of whole blood to a SAT tube containing 1200 μL of Blood Transport Medium.
 - c. Replace the cap and vortex the sample for at least 5 seconds.
 - d. Loosen one sample tube cap, but do not remove it yet.

Note: *Be especially careful to avoid contamination by the spread of aerosols. Gently loosen caps on samples.*
 - e. Load the sample tube into the Sample Rack.
 - f. After the samples have been loaded into the Sample Rack, remove and discard each sample tube cap in one Sample Rack. To avoid contamination, do not pass a cap over any other Sample Racks or sample tubes.

- g. If necessary, use a new, disposable transfer pipet to remove any bubbles or foam. Bubbles in the tube compromise the level-sensing by the Panther Fusion system.
- h. When the last cap has been removed, load the Sample Rack into the Sample Bay.

Note: Diluted whole blood samples may remain in the Sample Bay for up to 8 hours.

Panther Fusion System Test Procedure

Note: Refer to the Panther/Panther Fusion System Operator's Manual for additional procedural information.

Work Area Preparation

1. Wipe down work surfaces with 2.5% to 3.5% (0.35 M to 0.5 M) sodium hypochlorite solution. Allow the sodium hypochlorite solution to contact surfaces for at least 1 minute and follow with a deionized (DI) water rinse. Do not allow the sodium hypochlorite solution to dry. Cover the bench surface with clean, plastic-backed absorbent laboratory bench covers.
2. Clean a separate work surface where samples will be prepared using the procedure described in step 1.

Reagent Preparation

1. Remove the bottles of IC-B, FCR-B and FER-B from storage. **Mix the FCR-B by swirling by hand until beads are in full resuspension.**
2. Open the bottles of IC-B, FCR-B and FER-B, and discard the caps. Open the TCR door on the upper bay of the Panther Fusion system.
3. Place the IC-B, FCR-B and FER-B bottles in the appropriate positions on the TCR carousel.
4. Close the TCR door.

Note: The Panther Fusion system adds the IC-B to the FCR-B. After the IC-B is added to the FCR-B, it is referred to as wFCR-B (working FCR-B). If the FCR-B and FER-B are removed from the system, use new caps and immediately store according to the proper storage conditions.

Specimen Handling

Note: Prepare specimens per instructions in the Sample Preparation section before loading specimens onto the Panther Fusion system.

1. Do not vortex samples.
2. Inspect sample tubes before loading into the rack. If a sample tube contains bubbles or has a lower volume than is typically observed, gently tap the bottom of the tube to bring contents to the bottom.

System Preparation

For instructions on setting up the Panther Fusion system including loading samples, reagents, assay cartridges and universal fluids, refer to the *Panther/Panther Fusion System Operator's Manual*.

Limitations

- A. Only use on Panther Fusion system by a trained professional.
- B. Use of Panther Fusion Extraction Reagents-B for clinical specimen types not mentioned has not been validated. Use with urine specimens has only been validated for use with the Panther Fusion BKV Quant assay.

Contact Information and Revision History



Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA



Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

Australian Sponsor Address:

Hologic (Australia & New Zealand) Pty Ltd
Macquarie Park NSW 2113

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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AW-23990-001 Rev. 004
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Revision History	Date	Description
AW-23990-001 Rev. 001	January 2022	<ul style="list-style-type: none">• New release.
AW-23990-001 Rev. 002	April 2022	<ul style="list-style-type: none">• Removed a Note from Reagent Preparation section.
AW-23990-001 Rev. 003	April 2022	<ul style="list-style-type: none">• Added urine claim.• Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support.• Added Revision History table.
AW-23990-001 Rev. 004	April 2022	<ul style="list-style-type: none">• Removed second bullet from Notes under Sample Preparation section.