HOLOGIC®

Panther Fusion® Extraction Reagents-X

Instructions for Use

For *in vitro* diagnostic use.

Intended Use

The Panther Fusion® Extraction Reagents-X are intended for extraction of DNA from nasopharyngeal, lower respiratory tract (bronchial wash and bronchoalveolar lavage), EDTA plasma, serum, EDTA whole blood, stool, urine, cerebral spinal fluid (CSF), ThinPrep samples, vaginal swabs, endocervical swabs, rectal swabs, throat swabs, skin lesions, Lim broth cultures, and Carrot broth cultures 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-X (IC-X) reagent is added to each test specimen via the working Panther Fusion Capture Reagent-X (wFCR-X). The IC-X 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, DNA 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 Fusion Operator's Manual* for information on the operation of the Panther Fusion System.

Materials Provided

Panther Fusion Extraction Reagents-X (Cat No. PRD-04477)

Component	Quantity	Volume	Description
Panther Fusion Capture Reagent-X	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-X	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.*

	Cat. No.
Panther System	303095
Panther Fusion Module	PRD-04173
Panther Fusion System	PRD-04172
Panther Fusion Internal Control-X 960 Tests *Panther Fusion Internal Control-X tube, 4 per box*	PRD-04476
Panther Fusion Specimen Lysis Tubes (SLT), 100 per bag	PRD-04339
Aptima Penetrable Caps	105668
Transport Tube, Polypropylene, 50 per bag	401457
Specimen Aliquot Tubes (SAT), 100 pack	503762

Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Aptima Specimen Transfer Kit	301154C
Specimen Transport Medium (STM)	PRD-04423
Urine Transport Medium (UTM)	PRD-04943
Viral Transport Medium (VTM) *VTM verified for use:* *Remel MicroTest M4, M4RT, M5 or M6 formulation* *Copan Universal Transport Medium* *BD Universal Viral Transport Medium*	
Blood Transport Medium (BTM)	PRD-04944
Panther Fusion Open Access Diluent Additive	PRD-04945
Proteinase K	—
Phosphate Buffered Saline (PBS)	—

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-X (FER-X) 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.hologicsds.com.

US Hazard Information

Panther Fusion Enhancer Rgt (FER-X)
LITHIUM HYDROXIDE, MONOHYDRATE 5 – 10%
DANGER
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
P310 - Immediately call a POISON CENTER or doctor/physician
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

EU Hazard Information

Panther Fusion Enhancer Rgt (FER-X)
LITHIUM HYDROXIDE, MONOHYDRATE 5 – 10%
DANGER
H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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
P280 - Wear eye protection/ face protection

Storage and Handling Requirements

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

Reagent	Unopened Storage	On-board/Open Stability*	Opened Storage**
Panther Fusion Capture Reagent-X	15 °C to 30 °C	30 days	15 °C to 30 °C
Panther Fusion Enhancer Reagent-X	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-X and FER-X.
**Working Panther Fusion Capture Reagent-X (Panther Fusion Capture Reagent-X that has been mixed with Internal Control-X on the Panther Fusion system) and Panther Fusion Enhancer Reagent-X are stable for 60 days when capped and stored at 15ºC to 30ºC. Do not refrigerate.

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.

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 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.
- 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 volumes needed based on the chosen tube type, number of extractions needed, and sample aspiration height.

Table 1. Minimum Sample Volumes

					FCR/FER-X	
Sample Tube	**Part Number**	**Sample Aspiration Height**	**Cap**	**Required Dead Volume (µL)**	**Minimum Volume for a Single Extraction (µL)**	**Additional Volume for Each Additional Extraction (µL)**
Aptima Specimen Aliquot Tubes (SATs) 100 Tubes (tapered)	503762	Low	Pierceable	200	550	350
		Medium	Pierceable	800	1150	350
		High-Level Sensing	No Cap	200	550	350
Transport Tube Polypropylene 50 per bag	401457	Low	Pierceable	900	1250	350
		Medium	Pierceable	1300	1650	350
		High-Level Sensing	No Cap	1300	1650	350
Note: *The minimum volume may vary by sample type. Each sample type will need to be validated.*						

Preparation of Working Diluents

Specimens with high nucleic acid or cellular content will demonstrate greater extraction efficiency if diluted with a diluent (STM, UTM, PBS, or BTM) containing Panther Fusion Open Access Diluent Additive.

1. Prepare working diluent stocks by pipetting 1.0 mL of Panther Fusion Open Access Diluent Additive into 80 mL of STM, UTM, and BTM. To prepare a PBS working diluent stock, pipette 1.0 mL of Panther Fusion Open Access Diluent Additive into 25 mL of PBS.
2. Mix by gently swirling the bottle or gently inverting. Do not vortex.
3. Label the bottle as Working Diluent-XXX where XXX = STM, UTM, PBS, or BTM.
4. Once prepared, the working diluents may be stored at room temperature (15°C to 30°C) for up to 30 days.

Nasopharyngeal (NP) Swab in VTM and Nasal Swab in Liquid Amies Specimen Processing

1. Transfer 500 µL of the NP or nasal swab specimen to an SLT.
2. Affix the provided penetrable cap or a new penetrable cap.

Alternatively,

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.
2. Dilute the NP or nasal swab specimen in a 1:1.56 ratio with STM (e.g. combine 500 µL specimen with 780 µL of STM).
3. Affix the provided penetrable cap or a new penetrable cap.

Lower Respiratory Tract (LRT) Specimen Processing

1. Transfer 250 µL of the LRT specimen (avoid transferring mucus) and 250 µL of VTM to an SLT.
2. Affix the provided penetrable cap or a new penetrable cap.

Alternatively,

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.
2. Dilute the LRT specimen in a 1:1 ratio with VTM (e.g. combine 250 µL of specimen with 250 µL of VTM).
3. Dilute the LRT/VTM mixture in a 1:1.56 ratio with STM (e.g. combine 500 µL of the mixture with 780 µL of STM).
4. Affix the provided penetrable cap or a new penetrable cap.

EDTA Plasma and Serum Specimen Processing

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.
2. Dilute the plasma or serum specimen in a 1:0.2 ratio with Working Diluent-PBS (e.g. combine 500 µL of plasma or serum with 100 µL of Working Diluent-PBS).
3. Add Proteinase K to a final concentration of 0.5 mg/mL.

4. Incubate 30 minutes at room temperature (15°C to 30°C).
5. Affix the provided penetrable cap or a new penetrable cap.

EDTA Whole Blood Specimen Processing

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.

   Note: *Processing of whole blood requires the use of the medium sample aspiration height.*
2. Dilute the whole blood specimen in a 1:2 ratio with Working Diluent-BTM (e.g. combine 400 µL of whole blood with 800 µL of Working Diluent-BTM).
3. Add Proteinase K to a final concentration of 1 mg/mL.
4. Incubate 30 minutes at room temperature (15°C to 30°C).
5. Affix the provided penetrable cap or a new penetrable cap.

Stool Specimen Processing

Prior to loading on the Panther Fusion System, stool samples must be transferred to the transport tube of an Aptima Multitest Swab Specimen Collection Kit.

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. Submerge the swab in the unformed or liquid stool specimen.
2. Uncap the transport tube containing 2.9 mL of STM. Place the swab in the transport tube and gently swirl the swab in the tube for 5 seconds to release material.
3. Carefully break the swab shaft at the score line against the side of the tube and discard the swab shaft.
4. Affix the provided penetrable cap or a new penetrable cap.

Note: *To avoid the aspiration of flocculent material, stool specimen processing requires the use of medium sample aspiration height.*

Urine Specimen Processing

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.
2. Dilute the urine specimen in a 1:1 ratio with Working Diluent-UTM (e.g. combine 300 µL of urine with 300 µL of Working Diluent-UTM).
3. Affix the provided penetrable cap or a new penetrable cap.

Cerebrospinal Fluid (CSF) Specimen Processing

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.
2. Dilute the CSF specimen in a 1:1 ratio with Working Diluent-STM (e.g. combine 300 µL of CSF with 300 µL of Working Diluent-STM).
3. Affix the provided penetrable cap or a new penetrable cap.

ThinPrep Specimen Processing

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.

2. Dilute the ThinPrep specimen in a 1:1 ratio with Working Diluent-STM (e.g. combine 300 µL of ThinPrep specimen with 300 µL of Working Diluent-STM.
3. Affix the provided penetrable cap or a new penetrable cap.

Vaginal, Endocervical, Rectal, Throat, and Lesion Swab Specimen Processing

Note: *Swab collection kits containing STM, VTM, or liquid Amies are acceptable for use.*

1. Refer to Table 1 for the minimal volume required for the intended number of extractions for the sample tube being used.
2. Dilute the swab specimen in a 1:1 ratio with Working Diluent-STM (e.g. combine 300 µL of swab specimen with 300 µL of Working Diluent-STM).
3. Affix the provided penetrable cap or a new penetrable cap.

Lim or Carrot Broth Culture Specimen Processing

1. Prior to testing on the Panther Fusion System, resuspend the culture specimen and transfer 1 mL of the specimen to the Aptima Specimen Transfer Tube containing 2.9 mL of Specimen Transport Medium (STM).
2. Affix the provided penetrable cap or a new penetrable cap.

Panther Fusion System Test Procedure

Note: *Refer to the* 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-X, FCR-X and FER-X from storage.
2. Open the bottles of IC-X, FCR-X and FER-X, and discard the caps. Open the TCR door on the upper bay of the Panther Fusion system.
3. Place the IC-X, FCR-X and FER-X bottles in the appropriate positions on the TCR carousel.
4. Close the TCR door.

Note: *The Panther Fusion system adds the IC-X to the FCR-X. After the IC-X is added to the FCR-X, it is referred to as wFCR-X (working FCR-X). If the FCR-X and FER-X 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 Fusion System Operator's Manual*.

Limitations

A. Only use on Panther Fusion system by a trained professional.

B. Use of Panther Fusion Extraction Reagents-X for clinical specimen types not mentioned has not been validated.

Contact Information and Revision History

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For country-specific Technical Support and Customer Service email addresses and telephone numbers, 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.

AW-26512-001 Rev. 001

2022-04

Revision History	Date	Description
AW-26512-001 Rev. 001	April 2022	• Created Panther Fusion Extraction Reagents-X IFU AW-26512-001 based on AW-18173-001 Rev. 002 for regulatory compliance with IVDR • Updated contact information including EC Rep, CE Mark, Australian Rep information, and technical support • Added Panther Fusion preceding instances of Open Access Diluent Additive