

Aptima™ DBS Extraction Buffer

Instructions for Use
For *in vitro* diagnostic use
For US export only

Intended Use

The Aptima™ DBS Extraction Buffer is intended for extraction of HIV viral nucleic acid from Dried Blood Spot (DBS) specimens for testing with an Aptima HIV-1 Quant Dx assay (PRD-03000).

Principles of the Procedure

Dried blood spots are added in the Aptima Specimen Aliquot Tubes (SATs) containing Aptima DBS Extraction Buffer. During the incubation step, viral nucleic acid is released from the dried blood spot. Refer to the appropriate assay package insert for instructions on preparation and handling of the DBS specimen types.

Reagents

Aptima DBS Extraction Buffer, Cat. No. PRD-04772

(store at 15°C to 40°C upon receipt)

Symbol	Component	Quantity
DEB	DBS Extraction Buffer <i>Phosphate Buffered solution containing detergent.</i>	1 X 104 mL

Materials Required But Available Separately

Note: Materials available from Hologic have catalog numbers listed.

Note: Aptima Specimen Aliquot Tubes and Transport Tube Caps are for general laboratory use and are not specifically intended for a particular IVD test.

Material	Cat. No.
Aptima Specimen Aliquot Tubes (100 pack)	503762
Transport Tube Caps (100 pack)	504415
Calibrated pipettors	—
Aerosol-barrier pipette tips	—

Warnings and Precautions

- A. For *in vitro* diagnostic use.
- B. Do not use Aptima Specimen Diluent or other buffers to extract DBS specimens.
- C. Use only supplied or specified disposable laboratory ware.
- D. Use routine laboratory precautions. Do not eat, drink or smoke in designated work areas. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and reagents. Wash hands thoroughly after handling specimens and reagents.
- E. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain high levels of target. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- F. Do not use this buffer after its expiration date.

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.hologicsds.com.

Storage and Handling Requirements

Store Aptima DBS Extraction Buffer at 15°C to 40°C. Once an extraction buffer bottle is opened, it can be used for up to 30 days. Cap the extraction buffer bottle immediately after use.

Specimen Extraction and Test Procedure

Refer to the appropriate assay package insert for extraction and test procedures.

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-26507-001 Rev. 001	May 2022	<ul style="list-style-type: none"> Created Aptima DBS Extraction Buffer IFU AW-26507-001 Rev. 001 based on AW-17270-001 Rev. 001 for regulatory compliance with IVDR Added Instructions for Use Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support
AW-26507-001 Rev. 002	May 2022	<ul style="list-style-type: none"> Editorial change - no change to content