

Aptima® Whole Blood Diluent Tubes

Instructions for Use For *In Vitro* Diagnostic Use

Intended Use

The Aptima® Whole Blood Diluent (WBD) Tube is intended to be used for processing of whole blood specimens.

Principles of the Procedure

The Aptima WBD is used to process whole blood specimens in the pre-filled WBD Tubes. Refer to the appropriate assay package insert for whole blood specimen handling and preparation instructions.

Materials Provided

Aptima WBD Tubes (Cat. No. PRD-06783)

Component	Description	Quantity
WBD Tubes	1 tube containing 1.425 mL of WBD	100 each

Materials Required But Available Separately

Calibrated pipettor and tips with hydrophobic plugs for the transfer of specimen from the primary collection container to the WBD Tube.

Warnings and Precautions

- A. For in vitro diagnostic use.
- B. For professional use.
- C. See the appropriate assay package insert for additional warnings and precautions.
- D. Use only supplied or specified disposable laboratory ware.
- E. 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.
- F. 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.
- G. Do not use this diluent after its expiration date.

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.

Storage and Handling Requirements

Upon receipt, store Aptima WBD Tubes prior to use at room temperature (15°C to 30°C).

Specimen Performance

The assay performance characteristics of the specimens are provided in the appropriate assay package insert. The assay package inserts are available online at www.hologic.com.

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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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-26508-001 Rev. 001	May 2022	 Created Aptima Whole Blood Diluent Tubes IFU AW-26508-001 Rev. 001 based on AW-21090-001 Rev. 001 for regulatory compliance with IVDR Added Instructions for Use Updated Warnings and Precautions section Added Global GHS notification Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support
AW-26508-001 Rev. 002	May 2022	Editorial change - no change to content