Aptima™ Specimen Diluent

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

Intended Use

Aptima™ Specimen Diluent can be added to plasma and serum specimens that will be tested with an Aptima or other Hologic quantitative assay. Refer to the appropriate assay package insert for instructions for approved specimen types. Diluent may be added in specified amounts to low-volume specimens to obtain the minimum required sample volume or to specimens with analyte levels above the upper limit of quantitation to obtain a quantitative result.

Principles of the Procedure

Aptima specimen diluent is used to dilute plasma specimens in the secondary Aptima Specimen Aliquot Tube (SAT). Refer to the appropriate assay package insert for instructions on the specimen types that can be diluted and the preparation of diluted specimens.

Reagents

Aptima Specimen Diluent, Cat. No. PRD-03003

(**store at 15°C to 30°C upon receipt)**

Symbol	Component	Quantity
DIL	**Specimen Diluent** *Buffered solution.*	4 X 30 mL

Materials Required But Available Separately

Note: *Materials available from Hologic have catalog numbers listed.*

Note: *Aptima Specimen Aliquot Tubes (SATs) 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 (SATs) (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. For professional use.

C. Refer to the appropriate assay package insert for instructions for approved specimen types as well as 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 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.*

	EU Hazard Information
—	**Aptima Specimen Diluent** ***HEPES 15 – 20%*** ***LAURYL SULFATE LITHIUM SALT 5 – 10%*** ***LITHIUM HYDROXIDE, MONOHYDRATE 5 – 10%*** ***SUCCINIC ACID 1 – 5%*** **—** H412 – Harmful to aquatic life with long lasting effects P273 – Avoid release to the environment P280 – Wear eye protection/ face protection

Storage and Handling Requirements

Store Aptima Specimen Diluent at 15°C to 30°C. Once a diluent bottle is opened, it can be used for up to 30 days. Cap the diluent bottle immediately after use.

Specimen Dilution and Test Procedure

Refer to the appropriate assay package insert for dilution 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.

AW-26506-001 Rev. 001
2022-05

Revision History	Date	Description
AW-26506-001 Rev. 001	May 2022	• Created Aptima Specimen Diluent IFU AW-26506-001 Rev. 001 based on AW-12051-001 Rev. 006 for regulatory compliance with IVDR • Added Instructions for Use • Updated the Intended Use section • Added EU GHS notification • Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support