

Aptima® Specimen Diluent

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 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

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Aptima Specimen Diluent, Cat. No. PRD-03003

(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity
DIL	Specimen Diluent <i>Buffered solution.</i>	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

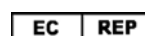
- A. For *in vitro* diagnostic use.
- B. Refer to the appropriate assay package insert for instructions for approved specimen types as well as for additional warnings and precautions.
- C. Use only supplied or specified disposable laboratory ware.
- D. Use routine laboratory precautions. Do not eat, 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 diluent after its expiration date.

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.



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