

Progensa PCA3 Specimen Diluent Kit

For *in vitro* diagnostic use.

Intended Use

The Progensa PCA3 Specimen Diluent Kit is used to dilute urine specimens for use in the Progensa PCA3 Assay.

Principles of the Procedure

The Progensa PCA3 Specimen Diluent Kit provides a diluent for Progensa PCA3 Assay urine specimens that test out of range high (greater than Calibrator 5) in the initial Progensa PCA3 Assay test. For more detailed information about the Progensa PCA3 Assay, refer to the Progensa PCA3 Assay package insert. The Progensa PCA3 Specimen Diluent Kit can only be used with processed urine specimens in conjunction with the Progensa PCA3 Urine Specimen Transport Kit for testing in the Progensa PCA3 Assay.

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.

Progensa PCA3 Specimen Diluent Kit, Cat. No. 302351

Symbol	Component	Quantity
STM	PCA3/PSA Specimen Transport Medium <i>Phosphate buffered solution containing 110 mM LLS</i>	1 X 26 mL

Warnings and Precautions

- A. For *in vitro* diagnostic use.
- B. See the Progensa PCA3 Assay package insert for additional warnings and precautions relating to the Progensa PCA3 Assay.
- 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 and laboratory coats when handling urine specimens and kit reagents. Wash hands thoroughly after handling urine specimens and kit reagents.
- E. Take care to avoid cross-contamination during the urine specimen handling steps. Urine specimens can contain high levels of mRNA target. Ensure that urine specimen containers do not contact one another, and discard used materials without passing over open containers. If gloves come in contact with urine specimen, change gloves to avoid cross-contamination.

- F. Do not use this kit after its expiration date.
- G. Maintain proper storage conditions during urine specimen shipping to ensure the integrity of the urine specimen. Urine specimen stability under shipping conditions other than those recommended has not been evaluated.

Storage and Handling Requirements

Store the Progensa PCA3 Specimen Diluent Kit at 2°C to 30°C.

Specimen Transport and Storage

Transport and store processed urine specimens according to the Progensa PCA3 Assay package insert.

Specimen Dilution and Test Procedure

1. Ensure the processed urine specimen to be diluted and retested was stored properly. Refer to the Progensa PCA3 Assay package insert for transport and storage requirements.
2. Invert the processed urine specimen to mix it prior to dilution of the specimen. A recommended, but not required, dilution is 1:10 using specimen diluent: In an appropriately sized vial, add 1800 µL specimen diluent and 200 µL processed urine specimen; cap tube and invert five times to mix completely. If both PCA3 and PSA analytes are to be retested, double the volumes (use 3600 µL specimen diluent and 400 µL processed urine specimen) prior to inversion.
3. Test the diluted processed urine specimen with the Progensa PCA3 Assay as described in the Progensa PCA3 Assay package insert.
4. Repeat the procedure as necessary until the diluted processed urine specimen interpolates within range of the calibrators. The initial dilution may be further diluted following the instructions in Step 2.



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