

ProgenSA PCA3 Urine Specimen Transport Kit

► Physician Instructions

For *in vitro* diagnostic use.

Rx only

For additional details, see the *ProgenSA PCA3 Assay package insert*, the *Physician Brochure*, and the *Physician Instructions* which are on the website:

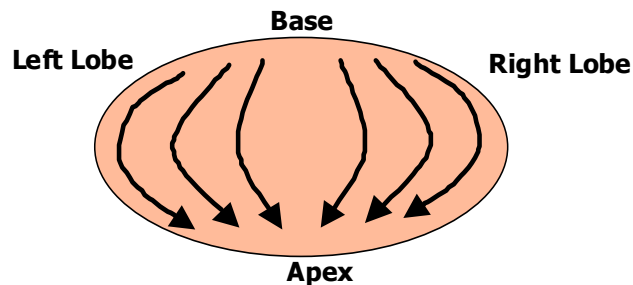
www.hologic.com/package-inserts

Warning:

The ProgenSA PCA3 Assay should not be used for men with atypical small acinar proliferation (ASAP) on their most recent biopsy. Men with ASAP on their most recent biopsy should be treated in accordance with current medical guidelines.

Instructions

1. Conduct a DRE as described below immediately prior to urine collection. Apply enough pressure to slightly depress the prostate surface from the base to the apex and from the lateral to the median line for each lobe as shown in the figure below. **Perform exactly three strokes for each lobe. This is not intended to be a prostatic massage.**



2. Following the DRE, direct the patient to provide first catch urine (approximately 20 to 30 mL of the initial urine stream) in an appropriately labeled urine collection cup. This must be the first voided urine specimen following the DRE. Use a collection cup free of any preservatives. If a patient cannot stop his urine flow and provides more urine than the requested 20 to 30 mL, keep the entire volume. If the patient is unable to provide the requested volume of urine, at least 2.5 mL is required to run the ProgenSA PCA3 Assay. Otherwise, the specimen must be rejected.

Note: Very high urine volumes can lower PCA3 and PSA analyte concentrations, and may infrequently result in an invalid specimen. Thus, the patient should try to avoid filling the urine collection cup.

3. Unprocessed urine specimens, if not immediately processed, must be maintained at 2°C to 8°C or kept on ice. The chilled, unprocessed urine specimen must be transferred into the urine specimen transport tube within 4 hours of collection (see *Specimen Handling Instructions* for further instructions). Otherwise, the specimen must be rejected and the urologist must collect a new specimen. **Do not freeze unprocessed urine specimens.**

ProgenSA PCA3 Urine Specimen Transport Kit**Warnings and Precautions**

- A. For *in vitro* diagnostic use.
- B. See the *Specimen Handling Instructions* for further warnings and precautions.

► Specimen Handling Instructions

For *in vitro* diagnostic use.

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Intended Use

The Progensa PCA3 Urine Specimen Transport Kit is for the collection and transport of male urine specimens that will be tested with the Progensa PCA3 Assay.

Contents

Progensa PCA3 Urine Specimen Transport Kit, Cat. No. 302352

Each box contains 50 Progensa PCA3 Urine Specimen Transport Kits each containing:

Component	Quantity
Progensa PCA3 Urine Specimen Transport Tube <i>PCA3 urine transport medium.</i>	1 X 2.3 mL
Disposable Transfer Pipette <i>For the transfer of 2.5 mL of urine from the primary collection container to the Progensa PCA3 urine specimen transport tube.</i>	1

Warnings and Precautions

- A. For *in vitro* diagnostic use.
- B. Use this kit only with the Progensa PCA3 Assay. Performance has not been established with other products.
- C. Do not apply the urine transport medium directly to skin or mucous membranes or take internally.
- 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 RNA target. Ensure that urine specimen containers do not contact one another, and discard used materials without passing over any 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.

Note: For hazard communication information, refer to the Safety Data Sheet Library at www.hologicsds.com.

Storage Requirements

Store the Progensa PCA3 Urine Specimen Transport Kit at room temperature (15°C to 30°C).

Urine Specimen Collection and Handling

1. Obtain a post-digital rectal exam urine specimen in a urine collection cup (see *Instructions* for detailed instructions). Unprocessed urine specimens, if not immediately processed, must be maintained at 2°C to 8°C or kept on ice. The chilled, unprocessed urine specimen must be transferred into the urine specimen transport tube within 4 hours of collection. **Do not freeze unprocessed urine specimens.**
2. To process urine specimens, tightly cap and invert the unprocessed urine specimens 5 times to resuspend cells. Remove the cap of the urine specimen transport tube and transfer 2.5 mL of the collected urine into the tube using the disposable transfer pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.

Note: *If less than 2.5 mL of urine is available, the specimen must be rejected.*

3. Re-cap the urine specimen transport tube tightly and invert the urine specimen 5 times to mix. This is now known as the processed urine specimen.
4. Store as described in *Processed Urine Specimen Transport and Storage before Testing* below.

Processed Urine Specimen Transport and Storage before Testing

Processed urine specimens must be transported to the laboratory in the urine specimen transport tube. They may be shipped under ambient conditions (without temperature control) or frozen. **Shipping arrangements must be made to ensure processed urine specimens are received by the testing site within 5 days of collection.**

Upon receipt of the shipment, the laboratory should verify the date of specimen collection on the tube. If specimens were shipped under ambient conditions and are received more than 5 days after specimen collection, the specimen must be rejected and a request for a new specimen should be made. The laboratory may store the specimen at 2°C to 8°C for up to 14 days before disposal is required. If longer time periods are needed, refer to the table below for the allowable storage times at different temperatures.

Storage Temperature	Time
Processed specimen storage and shipment:	<i>Up to 5 days*</i>
After receipt at testing site:	
2°C to 8°C	<i>Up to 14 days</i>
-35°C to -15°C	<i>Up to 11 months**</i>
At or below -65°C	<i>Up to 36 months**</i>

*Time allowed for shipment under ambient conditions or frozen.

**Time allowed after refrigerated storage.

Processed urine specimens may be subjected to up to 5 freeze–thaw cycles.

Note: *Specimens must be shipped in accordance with applicable national and international transportation regulations.*



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2019-05