PCA3 AND MIPS
SPECIMEN COLLECTION
AND PROCESSING

Specimen Collection

1. Perform an attentive DRE immediately prior to specimen collection (the specimen should be collected within approximately 1 hour of DRE):
   a. Apply firm pressure from the base to the apex and from the lateral to the medial line of the prostate.
   b. Apply enough pressure to depress the surface slightly.
   c. Perform 3 strokes for each lobe.

2. Instruct patient to collect the FIRST 20 - 30 mL of voided urine (do not catheterize) following the DRE.

3. Process the specimen within 4 hours of collection (if specimen cannot be processed within 15 minutes, store refrigerated or on ice and process within 4 hours).

Specimen Processing

1. Invert specimen cup 5 times to re-suspend cells.

2. Add 2.5 mL of urine to each of two GEN-PROBE PROGENSA PCA3 Urine Specimen Transport Tubes. Do not puncture the foil seal on the cap of the Transport Tube. The specimen volume must fall between the two black fill lines on the Transport Tube.

3. Tightly re-cap each Urine Transport Tube and gently invert 5 times to mix; do not shake or vortex. The specimen is now a "processed" urine specimen. Refrigerate. Refrigerated specimens must be received by MLabs within 5 days of collection. (Specimens stored at ambient or room temperature are stable for 24 hours). For longer storage, freeze specimen at -20º C and ship specimen on dry ice. Frozen specimens are stable for 90 days at -20º C.

4. Label each Transport Tube with the patient’s first and last names as well as a second identifier such as the patient’s date of birth or medical record number.

5. Include serum PSA result and patient history with the specimens.

Shipping

1. Place the processed Transport Tubes into the Ziploc bag with absorbent sheet and seal.

2. Place the Ziploc bag containing the Transport Tubes and frozen gel pack into the “cool shield bubble” silver pouch.

3. Place the silver pouch and completed test requisition form into the PCA3/MiPS Kit box. Place closed box inside Clinical Pak and seal according to instructions on the Clinical Pak. Call Federal Express at 800-463-3339 to schedule pick up. For Friday specimens, clearly indicate Saturday Delivery required.

Billing

1. MLabs will bill the client or referring institution or the patient’s insurance carrier if appropriate and MLabs is able to do so successfully. Please indicate Client/Referring Institution or Patient/Insurance in the “Bill To:” section of the test
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requisition form.

2. If the patient has Medicare, please check the Medicare box and indicate if the patient was an In Patient, Out Patient, or Non Patient on the date of service. If your facility is part of a hospital or health system that is billing the patient’s insurance for an office visit, Medicare patients are considered registered Out Patients and MLabs cannot bill Medicare for laboratory testing. In these cases, MLabs can bill either your facility or the patient directly (please note “self-pay” on the requisition). A Medicare ABN signed by the patient is required for MLabs to bill Medicare (Option 1) or to bill a Medicare patient self-pay (Option 2).

3. If the patient does not have Medicare, note that most insurance carriers require prior authorization for PCA3 or MiPS testing. Please contact the patient’s insurance plan to obtain prior authorization before collecting the specimen. Include a copy of the prior authorization with the test requisition.

4. Refer to MLabs Billing Policies for additional information.

Questions
Call 800.862.7284 or mlabs.umich.edu