

Overview
Method Name

Transcription Mediated Amplification (TMA) and Hybrid Protection Assay (HPA)

NY State Available

Yes

Specimen
Specimen Type

Urine

Specimen Required

Urine

Collect specimen using PROGENSA Urine Specimen Transport Tube (T695) as follows:

1. Perform an attentive digital rectal exam (DRE) immediately prior to specimen collection (specimen should be collected within approximately 1 hour of DRE).
2. Patient should collect the first 20-30 mL voided urine following the DRE.
3. Process specimen within 4 hours of collection (if specimen cannot be processed within 15 minutes, store refrigerated or on ice and process within 4 hours)
 1. Invert specimen cup 5 times to re-suspend cells
 2. Add 2.5 mL of urine to each of the two GEN-PROBE PROGENSA PSA3 Urine Specimen Transport Tubes. (Do NOT puncture the foil seal on the cape of the transport tube; the specimen 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.
4. Send both GEN_PROBE PROGENSA transport tubes frozen.

Specimen Minimum Volume

5 mL

Reject Due To

| | |
|------------|--|
| Hemolysis: | Urine |
| Thawing: | Warm OK; Cold OK |
| Lipemia: | NA |
| Icterus: | NA |
| Other: | Volume <2 mL; incorrect collection kit; Aptima media |

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|--------------------|---------|-------------------|
| Urine | Frozen (preferred) | 90 days | PROGENSA VIAL |
| | Refrigerated | 5 days | PROGENSA VIAL |

| Specimen Type | Temperature | Time | Special Container |
|---------------|-------------|----------|-------------------|
| | Ambient | 24 hours | PROGENSA VIAL |

Clinical and Interpretive

Clinical Information

Prostate cancer antigen 3 (PCA3, also known as Differential Display Code 3 or DD3) is a prostate-specific gene that was present in 95% of prostate cancer samples initially studied, and significantly over-expressed in cancer versus benign tissue. PCA3 is known to be a non-coding messenger ribonucleic acid (mRNA) with no resultant protein. Clinically, PCA3 mRNA is detectable in the urine and appears to be independent of prostate volume and serum PSA. The PCA3 urinary assay is reported out as a ratio of PCA3 mRNA to PSA mRNA.

Reference Values

A score less than 25 is considered negative

A score greater than or equal to 25 is considered positive

Performance

Method Description

The PCA3 test is a molecular assay that detects the mRNA of the DD3 gene expressed in prostate cells. The cells are obtained from patient urine samples after digital rectal exam (DRE). The PCA3 test is the ratio of PCA3 mRNA to PSA mRNA multiplied by 1,000. In recent studies it was shown to have a specificity of 78% and a sensitivity of 57% in cancer vs. non-cancer. This test was approved by FDA in February 2012 to aid in the decision for a repeat biopsy.

PDF Report

No

Day(s) and Time(s) Test Performed

Monday, Wednesday, Friday

Analytic Time

4 - 7 days

Maximum Laboratory Time

6 - 9 days

Performing Laboratory Location

University of Michigan (MLabs)

Fees and Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This testing was performed at the University of Michigan Health System, Michigan Center of Translational Pathology, Ann Arbor, Michigan. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

CPT Code Information

81313

LOINC® Information

| Test ID | Test Order Name | Order LOINC Value |
|---------|-----------------|-------------------|
| FPPCA | PCA3 | Not Provided |

| Result ID | Test Result Name | Result LOINC Value |
|-----------|------------------|--------------------|
| Z4886 | Result | Not Provided |
| Z4887 | Interpretation | Not Provided |