Test Definition: FPCA3

PCA3 Assay

Reporting Title: PCA3 Assay
Performing Location: DIANON Systems, Inc

Specimen Requirements:

Urine
Collect specimen using PROGENSA Urine Specimen Transport Tube (supply T695) as follows:
1. Patient should undergo a thorough digital rectal exam (DRE) (3 strokes per lobe). Collect the first 20-30 mL urine of the patient's next void immediately following the DRE. If more than 30 mL collected, do not discard, mix thoroughly.
2. Mix to re-suspend cells, pipette 2.5 mL of urine to PROGENSA tube. The maximum time between collection and transfer to the PROGENSA tube is 20 minutes. The correct volume of urine has been added when the fluid level is between the black fill lines on the PROGENSA urine transport tube. Invert tube 5 times to mix the urine and the transport medium.
3. Send PROGENSA transport tube ambient.

Specimen Type	Temperature	Time
Urine	Ambient (preferred)	5 days
	Frozen	5 days
	Refrigerated	5 days

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
Z2997	Specimen type	Alphanumeric		In Process
Z2998	Result (PCA3 Score)	Alphanumeric		In Process
Z2999	Interpretation	Alphanumeric		In Process

CPT Code: 1 × 81479

Reference Values:

Reference Range:
<25 negative
> or = 25 positive

Comment: Due to normal assay variability, specimens with PCA3 scores near the cut-off of 25 (i.e. 18-31) could yield a different overall interpretation of positive or negative upon repeat testing. PCA3 scores in the range from 18 to 31 should, therefore, be interpreted with caution.

The testing method is target capture, transcription-mediated amplification (TMA) and hybrid protection assay (HPA), manufactured by Gen-Probe and performed using the Gen-Probe PROGENSA assay kit.

Test Performed by: DIANON Systems, Inc.
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