Cleveland Diagnostics IsoPSA Post-Approval Study (CDx2025-03) Synopsis

Study Title:
A Prospective, Non-Randomized, Single-Blind, Multi-Site Post-Approval Study of the IsoPSA Assay in an African American Population.

Sponsor: Cleveland Diagnostics, Inc.

Study Design:

- Prospective
- Post-approval study
- Observational study evaluating the performance and safety of the IsoPSA assay in African American men undergoing standard-of-care prostate biopsy.

Primary Objective:
To demonstrate the performance and safety of the IsoPSA assay in an African American population that meets the FDA-approved intended use criteria.

Target Enrollment:

- Approximately 500 participants
- 250 African American men
- 250 Non-African American men

Study Procedures:

- One study visit
- Informed consent
- 5 mL blood draw (prior to standard-of-care prostate biopsy)
- Medical record review
- Brief race-identification questionnaire
- No investigational treatment or intervention.

Potential Enrollment Considerations for Solaris/Urology Alliance Sites

The ideal patient is:

- Male ≥50 years old

- PSA between 4–10 ng/mL
- Scheduled for initial or repeat standard-of-care prostate biopsy

Particularly valuable if African American, since the primary purpose of the study is to validate IsoPSA performance in that population

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Key Inclusion Criteria

Cohort A – African American Men and Cohort B – Non-African American Men

- Male
- Age ≥ 50 years
- Self-identify as Black/African American (Cohort A- African American Men)
- Self-identify as: (Cohort B- Non African American Men)
    - White/Caucasian
    - Asian
    - American Indian/Alaska Native
    - Native Hawaiian/Other Pacific Islander
- Scheduled for a standard-of-care prostate biopsy
- PSA ≥4 ng/mL and ≤10 ng/mL (most recent PSA documented in medical record)
- Able and willing to provide informed consent
    - Native Hawaiian/Other Pacific Islander
- Scheduled for a standard-of-care prostate biopsy
- PSA ≥4 ng/mL and ≤10 ng/mL
- Able and willing to provide informed consent

Key Exclusion Criteria

Applies to both cohorts:

- Previous prostate biopsy within the last 3 months

- Recent prostate manipulation within the last 3 days
- Recent urinary tract infection and/or prostatitis within the last 2 weeks
- Recent prostate surgery, urinary catheterization, prostate infarction, or urinary endoscopy within the last 3 months
- Hormonal ablation surgery within the last 90 days
- History/documentation of another urinary tract malignancy
- Prior IsoPSA test within the last year.
