Inclusion and Reporting of Race and Ethnicity in Studies of Commercial Pre-biopsy Biomarkers for Prostate Cancer

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Abstract

Introduction
Pre-biopsy urine- and blood-based biomarkers are increasingly used to guide prostate cancer diagnostic decision-making, particularly in patients with elevated prostate-specific antigen levels or equivocal multiparametric MRI findings. However, the reliability and generalizability of these assays depend on the populations in which they were developed and validated. We evaluated the inclusion and reporting of race and ethnicity within the evidence supporting FDA-approved pre-biopsy prostate cancer biomarkers.

Methods
FDA Summary of Safety and Effectiveness Data documents were reviewed for four FDA-approved pre-biopsy biomarkers: Access Hybritech p2PSA, 4Kscore Test, PROGENSA PCA3 Assay, and IsoPSA Assay. Extracted variables included study design, sample size, clinical setting, demographic reporting, and race-stratified subgroup analyses. Representation ratio was calculated by comparing study participant demographics with 2020 United States Census benchmarks.

Results
Four biomarkers involving 2,883 participants were identified. Across studies, 80.54% of participants were White, 12.76% African American, 1.35% Asian, 0.14% Native American, and 0.03% Native Islander. White participants were consistently overrepresented, whereas Asian, Native American, and Native Islander populations were markedly underrepresented. African American representation varied substantially between studies. Reporting practices for race and ethnicity were inconsistent across studies. Only the IsoPSA assay included race-stratified performance analyses, which suggested reduced diagnostic performance in African American patients and prompted an FDA-mandated post approval study.

Conclusion
FDA-approved pre-biopsy prostate cancer biomarkers demonstrate substantial variability in racial and ethnic representation and limited subgroup validation across diverse populations. Future validation studies and regulatory evaluations should incorporate standardized demographic reporting and adequately powered race-stratified analyses to support equitable implementation of biomarker-guided prostate cancer diagnosis.

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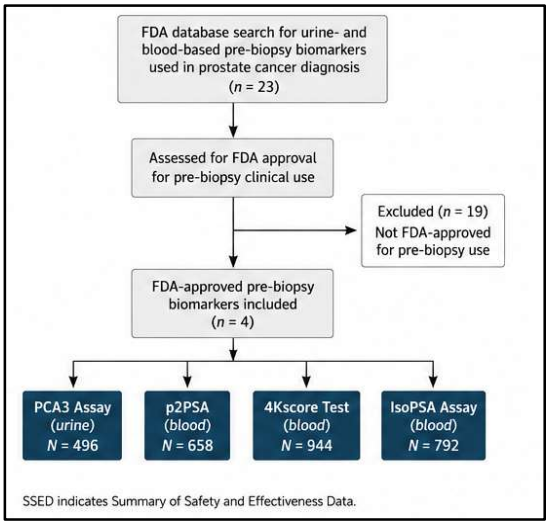

Figure 1. Study selection and included biomarkers

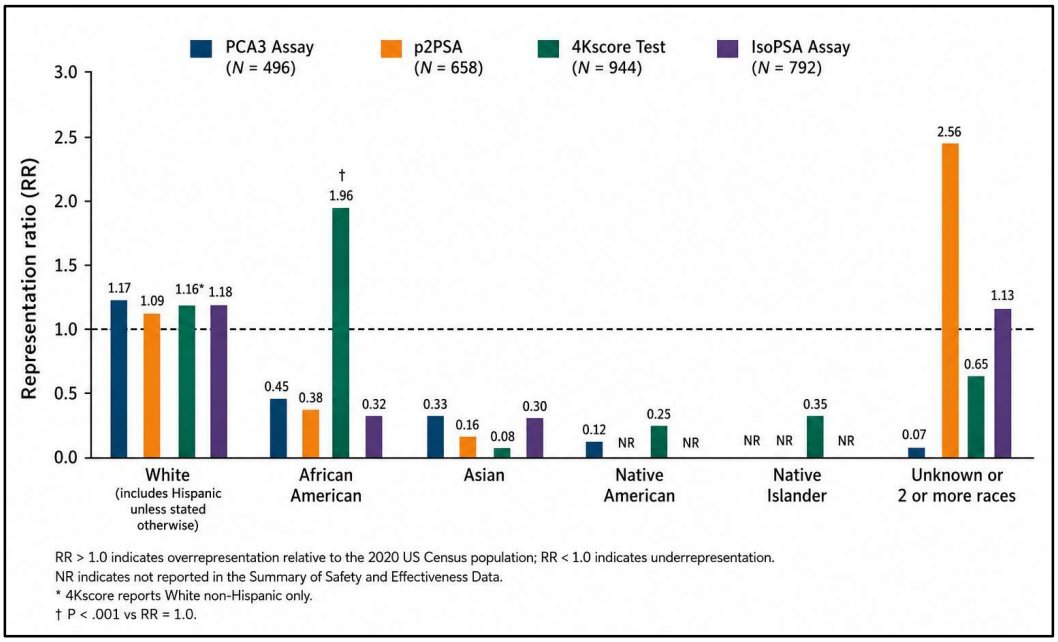

Figure 2. Representation ratio (RR) by race/ethnicity for four FDA-approved pre-biopsy biomarkers for prostate cancer.

Table 1. Summary of reporting and analysis of race/ethnicity in the FDA Summary of Safety and Effectiveness Data for each biomarker

Feature	PCA3 Assay (2012)	p2PSA (2012)	4Kscore Test (2021)	IsoPSA Assay (2025)
Race/ethnicity reported	Yes	Yes	Yes	Yes
Hispanic ethnicity reported separately	No (Combined with race)	No (Combined with race)	Yes	No (Combined with race)
Race-stratified performance analysis	No	No	No	Yes (African American vs non–African American)
Subgroup analyses by race/ethnicity	No	No	No	Yes (African American vs non–African American)
FDA post-approval study requirement	No	No	No	Yes (Focused on African American population; completion within 59 months)