COLLEGE of AMERICAN PATHOLOGISTS

February 9, 2026

Via email: Arthur.ellis@senate.maryland.gov

Senator Arthur Carr Ellis
James Senate Office Building, Room 301
11 Bladen St.
Annapolis, MD 21401

Re: Opposition to Senate Bill 78 (PSA Testing)

Dear Senator Ellis:

I am writing on behalf of the College of American Pathologists (CAP) and the Maryland Society of Pathologists (MSP) in strong opposition to your Senate Bill 78.

This legislation runs counter to the utility and widespread medical use of the Prostate Specific Antigen (PSA) laboratory test. It creates unintentional consequences that would be unproductive and therefore detrimental to the functionality of PSA testing.

For decades, this cancer screening test has proven to be highly useful and highly effective in saving patient lives with early detection and efficacious treatment when cancer is confirmed with a subsequent biopsy. Our paramount goal in opposition to this legislation (SB 78) is to preserve Maryland patient access to high quality PSA testing in parity with the laws of every other state. No other state has requirements similar to what is contemplated under SB 78.

While CAP notes that the legislation includes a provision compelling laboratory participation in our CAP proficiency testing, this provision does not address the issue of concern we are raising with the public policy basis for the prescribed methodological requirements in the conduct of PSA testing as set forth in the legislation, including to "document and disclose to the ordering provider the test methodology, manufacturer, and lot number of the testing assay used."

CAP specific concerns and comments regarding provisions affecting clinical laboratories include the following:

- 17-803(1): Requiring the exclusive use of FDA-approved assays is overly restrictive, is not required under existing regulatory frameworks, and may reduce test availability without improving quality or patient outcomes.

- 17-803(2): Mandating the use of specific reference standards for calibration, in and of itself, does not guarantee improved inter-method comparability or superior analytical performance of PSA assays.

- 17-803(3): Most PSA results in the United States are already reported in nanograms per milliliter. While the SI unit for PSA is micrograms per liter, these units are equivalent. Reference interval reporting is already required for clinical laboratories under federal CLIA regulations.

Qihui "Jim" Zhai MD, FACP
CAP President

T: 800-323-4040

325 Waukegan Road
Northfield IL 60093
800-323-4040 | cap.org

COLLEGE of AMERICAN PATHOLOGISTS

- 17-803(4): Reagent lot numbers are an internal quality management tool and do not represent clinically meaningful or actionable information for ordering providers.
- 17-803(5): Participation in PT programs is mandatory for non-waived testing under the federal Clinical Laboratory Improvement Amendments (CLIA) law of 1988. PT is valuable to ensure a clinical laboratory's diagnostic process and assays are consistent with quality protocols and ensure machines are properly calibrated; however, inherent clinical limitations in the diagnostic accuracy of this widely respected cancer screening test are not enhanced by the performance of PT.

Overall, the proposed legislation (SB 78) includes administrative requirements that are unlikely to meaningfully address the inherent limitations of PSA as a prostate cancer biomarker. Instead, it would compel an unnecessary administrative burden, operational complexity, and potential barriers to patient care.

The limitations of PSA testing—most notably its lack of cancer specificity and imperfect sensitivity—are well established and already addressed in existing clinical guidelines through shared decision-making, risk stratification, and judicious follow-up strategies. The proposed bill will not alter the intrinsic biological characteristics of PSA, nor will it improve the analytical or clinical performance of assays used for its measurement.

Accordingly, the mandated disclosures and restrictions do not mitigate the fundamental challenges of PSA interpretation and may unintentionally convey a false sense of added clinical value. For these many reasons, we therefore respectfully oppose Senate Bill 78.

Sincerely,

Qihui "Jim" Zhai, MD, FCAP
President, College of American Pathologists

cc: Eric Wargotz, MD, FCAP, President MedChi
Michael Kallen, MD, FCAP, President, Maryland Society of Pathologists
Barry Ziman, Director, Legislation and Political Action, CAP

Qihui "Jim" Zhai MD, FACP
CAP President
T: 800-323-4040
325 Waukegan Road
Northfield IL 60093
800-323-4040 | cap.org