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1 INTRODUCTION

Prostate-specific antigen (PSA) is a prostate-derived biomarker extensively used for screening and longitudinal monitoring of prostate cancer (Feltes Benitez et al., 2025). We quantified serum PSA by sandwich ELISA - using a standard curve to interpolate unknowns -to evaluate response to radiation therapy in a 60-year-old patient across pre-, 6-, and 12-month samples (Ramos et al., 2001). Tracking PSA trends post-radiotherapy - such as PSA bounce or sustained rises above nadir - provides critical insights into treatment response and recurrence risk (Liaqat et al., 2023). See Figure 1 for the clinical rationale for PSA screening and monitoring.

METHODS

96-well sandwich ELISA on anti-PSA—coated strips. After blocking, standards (1.5–12 ng/mL) and patient sera (duplicate wells) were incubated, followed by HRP-conjugated detector. TMB was developed and stopped with 1 M HCl; OD450 with 540-nm reference was blank-subtracted. A 4-point nonlinear (4PL) standard curve was fitted and unknowns interpolated. Assay performance was monitored with Levey–Jennings charts and Westgard rules using historical QC mean ± SD. Graphs (standard curve, longitudinal PSA, QC) were produced in GraphPad from plate-reader exports.

Notation: error bars = SD; n = replicates; 4PL = four-parameter logistic; QC = quality control.

RESULTS

Corrected OD450–540 from PSA standards (1.5–12 ng/mL) generated a 4PL calibration curve (Figure 2A). Patient absorbances were interpolated to concentrations (Figure 2B). PSA fell from ~9.3 ng/mL pre-treatment to ~5.1 ng/mL at 6 months, then rose to ~6.9 ng/mL at 12 months (positivity threshold 5 ng/mL). The

5. PSA trends monitored over 2. Elevated PSA 3. Blood in circulation sample collected 1. Prostate Tumor 4. PSA releases PSA into Results quide quantified blood treatment by ELISA decisions

Figure 1. PSA screening schematic. Prostate releases PSA into blood, measured by ELISA, enabling monitoring of treatment response.

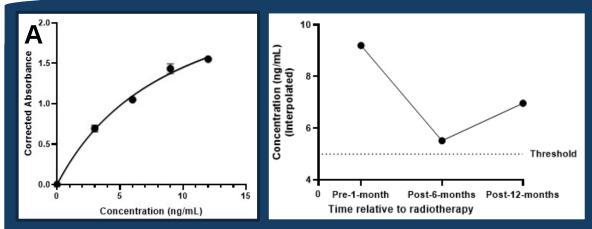


Figure 2. (A) PSA standard curve (1.5, 3.0, 6.0, 12.0 ng/mL. ng/mL), mean \pm SD; 4PL fit for interpolation. (B) Patient PSA (mean \pm SD) versus radiotherapy timeline; dotted 5 ng/mL threshold.

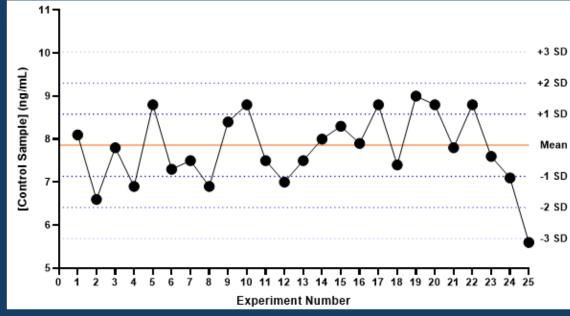


Figure 3. Levey–Jennings QC: historical mean 7.86 \pm 0.72 ng/mL; run 25 = 5.6 ng/mL (-3 SD, 1_3 s breach).

concurrent QC control was 5.6 ng/mL versus historical 7.86 \pm 0.72 ng/mL, breaching the 1₃s rule on the Levey–Jennings chart (Figure 3). Thus, this batch is out-of-control and patient values are not reportable pending repeat QC.

CONCLUSION

Because QC failed (1₃s), this batch is invalid; therapy effectiveness cannot be concluded. If confirmed after repeat testing, PSA fell from ~9.3 to ~5.1 ng/mL at 6 months, then rose to ~6.9 at 12 months—remaining above the 5 ng/mL threshold—suggesting partial response with persistent disease. Next steps: repeat QC and remeasure; trend PSA every 3 months; confirm with an independent assay; consider imaging and urology review.

REFERENCES

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