

To: Departments of Urology, Oncology and primary care,

PSA Assay Update

From w/c 19th October 2026, the Clinical Biochemistry laboratories in Bristol and Bath intend to move to the WHO-traceable PSA assay (WHO IS 96/670), produced by Beckman Coulter UK (BCUK). This will be a change from the current Hybritech-traceable PSA assay, also produced by BCUK.

This change has been initiated as part of quality improvement in the provision of our PSA service. Moving to the WHO-traceable PSA assay will ensure that Bristol and Bath have results that align with other manufacturer's methods, including those produced by Roche assays offered by neighbouring Gloucester NHS Foundation Trust and Salisbury Foundation Trust. Great Western Hospital, Swindon and Somerset Foundation Trust are already running the BCUK WHO-traceable PSA assay. All neighbouring laboratories are aligned to NICE NG12 to guide primary care referrals.

Expect a negative shift of -14% at lower levels of PSA (<10 µg/L) and -20% at higher levels (>10 µg/L)

- EQA scheme data (2026) shows a mean difference in results between BCUK Hybritech and BCUK WHO assays of -14.2%.
- Patient sample comparison performed at RUH indicates a mean reduction in PSA results of -14.4% (95% CI 12-17%) in low level samples (<10 µg/L) and an average reduction in results of -20% (95% CI 17-23%) in samples with higher PSA concentrations (>10 µg/L) when measured on the WHO-traceable assay.
- NOTE: there is variability in individual samples; these figures must be treated with caution.

NICE NG12 criteria for referral will still apply

- In alignment with NICE NG12 and our neighbouring laboratories, the following limits will continue to be used to guide primary care referrals:

<40 yrs: Use clinical judgment
40 – 49 yrs: <2.5 µg/L
50 – 59 yrs: <3.5 µg/L
60 – 69 yrs: <4.5 µg/L
70 – 79 yrs: <6.5 µg/L
>79 yrs: Use clinical judgment

Recommendation for monitoring patients with known elevated PSA

- We recommend establishing a new trend in PSA results by repeat analysis on the new assay over a period appropriate for individual patients rather than attempts to "convert" results on the new assay to what might have been expected on the old assay. This change in assay standardisation should be appropriately flagged on all PSA reports from the laboratory.

If you have any queries about this change, please contact the appropriate individual below.

Yours sincerely,

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