

Royal United Hospitals Bath
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BLOOD SCIENCES DEPARTMENT OF CLINICAL BIOCHEMISTRY

Title of Document: PSA Summary of Assay Change Q Pulse Reference N°: BS/CB/DCB/EXDOC/13

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Assay change for PSA

From 14/11/2022 at NBT, in January 2023 at RUH and in March 2023 at UHBW, the Clinical Biochemistry departments at each Trust will be moving to a new suite of analytical equipment, produced by Beckman Coulter UK (BCUK). For most assays there will be either no, or only very small, differences in results.

In the case of PSA there are some expected method related differences that will impact on result interpretation in patients with known elevated PSA levels. These are summarised below:

Acceptable sample type

• <u>Serum</u> (yellow topped SST tubes) will be the <u>only</u> acceptable sample type for PSA analysis.

Interpretation of PSA at low levels (<10 µg/L)

- There is no clinically significant difference expected between the old and new assay at PSA concentrations of <10 μg/L.
- NICE NG12 criteria for referral will still apply:

<40 yrs: Use Clinical judgment

40 - 49 yrs: <2.5 ug/L

50 – 59 yrs: <3.5 ug/L

60 – 69 yrs: <4.5 ug/L

70 - 79 yrs: <6.5 ug/L

>79 yrs: Use clinical judgment

Interpretation of PSA at high levels (≥10 μg/L)

 At PSA concentrations ≥10 ug/L there is an expected reduction in PSA results on the new assay (mean -8%). However, there is variability around this bias in individual samples; therefore, this figure should be treated with extreme caution.

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 patient cases rather than attempts to "convert" results on the new assay to what might have been expected on the old assay.