

**BLOOD SCIENCES
DEPARTMENT OF CLINICAL BIOCHEMISTRY**

Title of Document: CA125 Summary of Assay Change

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Assay change for CA125

From 14/11/2022 at NBT, 10/01/2023 at RUH and later in 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 CA125 there are some expected method related differences that will impact on result interpretation in patients with known elevated CA125 levels. These are summarised below:

Acceptable sample type

- Serum (yellow topped SST tubes) and Lithium Heparin (green topped tubes) will continue to be acceptable for CA125 analysis.

Interpretation of CA125 in screening for ovarian cancer

- The NICE CG122 guideline threshold for referral of patients for ultrasound of ≥ 35 kIU/L will still apply.
- Overall there is no significant difference between the current and new CA125 assays at concentrations below 100 kIU/L.

Interpretation of CA125 at high concentrations

At high CA125 concentrations (above 100 kIU/L) there is an expected increase in CA125 results on the new assay (approximately +40%). However, there is variability around this bias in individual samples; therefore this figure should be treated with caution.

Recommendation for monitoring patients with known elevated CA125 due to cancer

- We recommend establishing the new trend in CA125 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.