

**BLOOD SCIENCES
DEPARTMENT OF CLINICAL BIOCHEMISTRY**

Title of Document: CA199 Summary of Assay Change

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Assay change for CA199

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 CA199 there are some expected method related differences that will impact on result interpretation in patients with known elevated CA199 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 CA199 analysis.

Interpretation of CA199 at low levels (<35 kU/L)

- There is no statistical or clinically significant differences expected between the old and new CA199 assays at concentrations < 35 kU/L.

Interpretation of CA199 at high levels (≥35 kU/L)

- At CA199 concentrations ≥35 kU/L there is an expected increase in CA199 results on the new assay (mean +20%). However, there is large variability around this bias in individual samples; therefore this figure should be treated with extreme caution.

Recommendation for monitoring patients with known elevated CA199

- We recommend establishing the new trend in CA199 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.