

**BLOOD SCIENCES  
DEPARTMENT OF CLINICAL BIOCHEMISTRY**

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### Assay change for CEA

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 CEA there are some method related differences that will impact on result interpretation in patients, particularly those with known elevated CEA levels. These are summarised below:

#### Acceptable sample type

- Serum (yellow topped SST tubes) are the preferred sample type for CEA analysis.

#### Interpretation of CEA at levels <10 µg/L

- There is an expected negative bias in samples with CEA concentration <10 µg/L on the new CEA assay, with a reduction in the quoted upper limit of normal (ULN):

Current NBT ULN manufacturer (Roche) derived	New ULN manufacturer (BCUK) derived
<5 µg/L	<3.0 µg/L

#### Interpretation of CEA at levels ≥10 µg/L

- At high CEA concentrations there is tendency for a positive bias overall on the new assay. However, there is large variability around this bias in individual samples; with some samples running significantly higher on the new assay and some significantly lower, this is due to differences in assay reagents and specificity.

#### Recommendation for monitoring patients with known elevated CEA due to cancer

- We recommend establishing the new trend in CEA results by repeat analysis on the new assay over a period appropriate for individual patient cases.