

**BLOOD SCIENCES  
DEPARTMENT OF CLINICAL BIOCHEMISTRY**

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### Assay change for HCG

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

#### Interpretation of HCG at low levels (<5 IU/L)

- There is a tendency for a slight positive bias (<1 IU/L) when samples are run on the new HCG assay at low concentrations, however, the cut-off to determine likely pregnancy in pre-menopausal females will remain at 5 IU/L.
- Post-menopausal females and male quoted upper limit of normal (ULN) on reports will be updated in line with the ULN derived by the new manufacturer (Beckman):

Patient group	New ULN
Non-pregnant pre-menopausal females (Literature derived)	<5 IU/L
Post-menopausal females (assay manufacturer derived)	<12 IU/L
Males (assay manufacturer derived)	<2 IU/L

#### Interpretation of HCG at high levels (≥5 IU/L)

- At HCG concentrations ≥5 IU/L there is an expected increase in HCG results on the new assay (mean +36%). However, there is variability around this bias in individual samples; therefore this figure should be treated with caution.

#### Monitoring of patients with suspected ectopic pregnancy during switching of assays

- The laboratories will ensure samples sent for cases querying an ectopic pregnancy, where continued monitoring of HCG over a number of days is required, that samples sent in the week immediately prior to go-live are analysed on the new system to allow appropriate trending of results post-go-live. Individual contact from laboratory clinicians with the gynaecology specialists to discuss results will occur on a case-by-case basis where necessary.

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

- We recommend establishing the new trend in HCG 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.