Assay change for AFP

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

Interpretation of AFP at low levels (<12 kU/L)

- Overall there is no statistical or clinically significant differences expected between the old and new AFP assays at AFP concentrations < 12 kU/L. However, there is a tendency for samples to run slightly positive on the new assay vs the old assay at very low concentrations.

- The quoted upper limit of normal (ULN) will change:

Current ULN (Current manufacturer (Roche) derived)	New ULN (New manufacturer (Beckman) derived)
< 5.9 kU/L	<8 kU/L

Interpretation of AFP at high levels (≥12 kU/L)

- At AFP concentrations ≥12 kU/L there is an expected reduction in AFP results on the new assay (mean -7%). 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 AFP

- We recommend establishing the new trend in AFP 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.