

**BLOOD SCIENCES
DEPARTMENT OF CLINICAL BIOCHEMISTRY**

Title of Document: Haematinics Summary of Assay Change
Q Pulse Reference N^o: BS/CB/DCB/EXDOC/11
Authoriser: Michelle Young

Version N^o: 1.0

Assay change for Haematinics

From 14/11/2022 at NBT, 10/01/2023 at RUH and in June 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 haematinics there are some expected method related differences that will impact on result interpretation. These are summarised below:

Vitamin B12

- B12 results may be significantly lower than with the current method
- Women taking oral contraceptives may show decreased cobalamin levels because of a decrease in cobalamin carrier protein, however, this may not result in deficiency
- Serum cobalamin levels fall in pregnant women and are less reliable in determining deficiency

B12 <100ng/L:	Likely deficiency, commence treatment
B12 100-180ng/L	Possible deficiency. If clinical findings suggest deficiency consider a trial of therapy and assessment of response
B12 180-250ng/L	May still indicate deficiency. If strong clinical suspicion suggest discussion with a clinical biochemist or haematologist
B12 >250ng/L	Vitamin B12 deficiency not likely to be present

Folate

- Folate results are indicating positive bias
- Based on two UK population studies the new reference range is 3.0 – 20.0 ug/L
- At levels 3.0 - 4.5 ug/L, consider other causes of macrocytosis but if clinical suspicion remains high, consider a trial of therapy after B12 levels have been investigated. Monitor FBC/MCV for response.

Ferritin

- There is a significant negative bias in comparison to the previous method
- The new reference ranges are: Males: 24 – 336 ug/L and Females: 11 – 307 ug/L
- In otherwise well individuals ferritin level below 30 ug/L will still be considered consistent with iron deficiency
- At levels 30-100 ug/L where deficiency is suspected we continue to suggest transferrin saturation

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Transferrin Saturation:

- The methodology for iron studies is changing whereby we will be measuring transferrin rather than measuring the unsaturated iron-binding capacity and calculating the total iron-binding capacity
- We will be moving to gender specific cut-off values; 50% for males and 40% for females

As referenced in British Journal of Haematology systematic review:

<https://onlinelibrary.wiley.com/doi/full/10.1111/bjh.15164>