

**BLOOD SCIENCES
DEPARTMENT OF CLINICAL BIOCHEMISTRY**

Title of Document: Thyroid Function Tests Summary of Assay Change

Q Pulse Reference N^o: BS/CB/DCB/EXDOC/15

Version N^o: 3.0

Authoriser: Michelle Young

Assay change for Thyroid Function Tests (TSH, FT4 and FT3)

From 14/11/2022 at NBT, in January 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. This is a significant step forward in our Pathology Network and we will be using the same analytical equipment and reference ranges across the three Trusts.

In the case of TFTs there are some expected method related differences that will impact on result interpretation. These are summarised below:

New Reference Ranges

Patient group	TSH (mIU/L)	FT4 (pmol/L)	FT3 (pmol/L)
0 to 14 days	0.79 – 5.85	17 – 57	4.3 – 6.9
15 days to <3 years	0.38 – 5.33	9.5 – 17.8	4.0 – 6.2
Adult range (age 3 years up)	0.38 – 5.33	7.9 – 14.4	3.8 – 6.0
Pregnant 1 st trimester	0.05 – 3.70	6.7 – 13.9	n/a
Pregnant 2 nd trimester	0.31 – 4.35	5.8 – 12.7	n/a
Pregnant 3 rd trimester	0.41 – 5.18	6.2 – 12.2	n/a

Source: BCUK for adult and pregnancy ranges, CALIPER for paediatric ranges

Assay bias

TSH: No consistent significant bias compared to current (Roche) assay

FT4: New assay has average bias of -23% compared to current assay (reflected in new RR)

FT3: More complex relationship with positive bias at low FT3 and negative bias at high FT3

Interpretation of TFTs

- Using TSH as a frontline test for possible thyroid disease remains the same. Laboratory based reflex rules for abnormal results will cascade further appropriate tests.
- Patients who have FT4 monitored will see a shift in results – interpret against new RR.
- Patients who have FT3 monitored may see a slight shift in results – interpret against new RR.

Interference in TFTs

- There is significant positive interference from biotin in the FT4 and FT3 assays, but the TSH assay is not affected by this interference.
- It is recommended that patients discontinue biotin prior to blood collection for TFT measurement.
- If there is a high clinical suspicion of interference, please contact the Duty Biochemist to discuss.

Other thyroid tests

- There is no change to anti-TSHR antibodies, TPO, thyroglobulin or Tg antibodies analysis at present.

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Assay limitations

- Due to the changes in assay platform, a higher sample volume is required for analysis of TFTs. Please ensure a full gold top SST sample is provided for adults. A full lithium heparin sample is required for TFTs in children, this is in addition to samples sent for testing of other analytes.
- The new assay is more susceptible to interference from icterus. This is based on guidance provided by the manufacturer and therefore results cannot be provided on samples with a high icteric index.