

Important Update on Upcoming Change to Anti-TPO Assay

This affects patients in the care of City & Hackney, Tower Hamlets, Newham and Waltham Forest GP practices and Barts Health, Homerton Healthcare and Lewisham and Greenwich NHS Trusts.

Dear colleagues,

We are writing to inform you of upcoming changes to the anti-thyroid peroxidase (TPO) assay. **These changes will be implemented from 23/09/2026.**

Rationale for change:

- The existing assay has been discontinued by the manufacturer (Roche).
- The manufacturer has released a new assay formulation, which has been developed to be less susceptible to interference from biotin and to have greater specificity for anti-TPO antibodies.

Summary of changes:

- Please note the updated interpretative cut-off. This has been updated by the manufacturer following further studies in clinically relevant populations.

	Cut-off for "Negative" interpretation	Evidence-base for cut-off
Old Assay	<34 kU/L	95% centile derived from a study of 208 healthy test subjects
New assay	<20 kU/L	Clinical cut-off derived from a study of 85 subjects with Hashimoto's thyroiditis and validated in a cohort of 148 patients with Hashimoto's thyroiditis and a cohort of 313 patients with non-autoimmune thyroid diseases or other autoimmune diseases.

- Quantitative results are not directly comparable between the two assays. However, an in-house concordance study of 75 patients showed good agreement in interpretation between the assays. Note that serial monitoring of anti-TPO antibodies is not recommended and that the laboratory applies a minimum re-testing interval of 1 year for this test.

For queries:

Duty Biochemist is available on 07821 666732 or BHNT.ClinBiochemAdvice-barts@nhs.net

Yours sincerely,

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