

Department of Reference Biochemistry
King's College Hospital
Denmark Hill
London SE5 9RS
customerservices@viapath.org

20nd December 2022

To whom it may concern:

Ref: IMMULITE 2000 Thyroglobulin Not Meeting Claim for Functional Sensitivity

We are writing to inform you about an **urgent field safety notice** issued by Siemens for their **Immulite 2000 thyroglobulin assay** (see attached) this December. We have identified you as a user of our thyroglobulin service.

The issue relates to increased imprecision at low thyroglobulin concentrations vs. manufacturers stated performance, and affected a number of lots of thyroglobulin reagent earlier this year. In a worst-case scenario, the increased imprecision may have led to the reporting of erroneously depressed thyroglobulin results in some patients. We used the affected lots between 27th May 2022 and 30th November 2022.

As precautionary measure, we have re-analysed 12 samples using an unaffected lot number and found no issues with thyroglobulin results that we had previously reported as <0.7 µg/L in anti-thyroglobulin antibody negative samples. Unfortunately, we were not able to re-run all affected samples, since they had already been discarded as per Reference Biochemistry protocol. For this reason, we recommend that you discuss this issue with your Endocrine team so that patients clinical management can be reviewed where there were any clinical concerns.

Siemens Healthcare Diagnostics is currently investigating the root cause of this issue.

If you wish to discuss please contact the Immunochemistry Laboratory at King's College Hospital (tel. 020 3299 4130) for further information if required or Dr Hakim Zouita (Operational Lead for Reference Biochemistry – tel. 020 3299 4141).

Yours faithfully,



Dr Hakim Zouita
Operational Lead Reference Biochemistry
Hakim.Zouita@nhs.net



David Taylor
Consultant Clinical Scientist
Reference Biochemistry



Dr Colin Stone
Service Delivery Manager
Colin.Stone@nhs.net