

Urgent Field Safety Notice

IMC24-02.A.OUS

IMMULITE 2000 Analyzer

IMMULITE 2000 XPi Analyzer

Title	IMMULITE 2000 and IMMULITE 2000 XPi Anti-TG Ab Potential Positive Bias with Patient Results
Date Issued	Apr-2024
Issue Description	<p>Siemens Healthineers has confirmed, through the investigation of customer complaints, the potential for falsely elevated patient sample results when using impacted kit lots of IMMULITE® 2000 and IMMULITE® 2000 XPi Anti-TG Ab.</p> <p>A positive bias may be observed when using the kit lot numbers listed in the 'Products' table below when compared to historical lots.</p> <p>See Appendix A, Figures 1, and 2, for supporting data. Figures 1 and 2 provide the biases between results generated with an unaffected lot to representative affected lots. Note: The data is representative of the lots listed in the table below compared to an unaffected lot (lot number 780).</p> <p>Siemens is currently investigating the root cause of this issue.</p>

Products	Assay	Catalog #/Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
IMMULITE 2000 Anti-TG Ab		L2KTG2/10381659/ 00630414962108	782	04-Oct-2023	31-Jul-2024
			783	18-Oct-2023	31-Jul-2024
			786	18-Oct-2023	30-Sep-2024
			787	23-Oct-2023	30-Sep-2024
			788	20-Oct-2023	30-Sep-2024
			789	19-Oct-2023	30-Sep-2024
			791	10-Nov-2023	31-Oct-2024
			792	04-Jan-2024	31-Dec-2024
		793	08-Jan-2024	31-Dec-2024	
		L2KTG6/10381655/ 00630414962115	785	18-Oct-2023	30-Sep-2024
			790	20-Oct-2023	30-Sep-2024
			791	10-Nov-2023	31-Oct-2024
			793	08-Jan-2024	31-Dec-2024

Impact to Results

- Falsely elevated Anti-TG Ab patient results may occur. The data from an internal study across the analytical measuring range shows a positive bias with representative affected kit lots. See Appendix A, Figures 1, and 2 for detailed sample data. The results would be used in conjunction with other test results, the overall clinical presentation to the physician, and other findings.

Customer Actions

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Perform the instructions provided below:
 - Discontinue use of and discard the kit lots listed in the table above ('Products' Table).
 - You may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
 - Complete and return the Field Correction Effectiveness Check and indicate product replacement needs on the form attached to this letter within 30 days.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

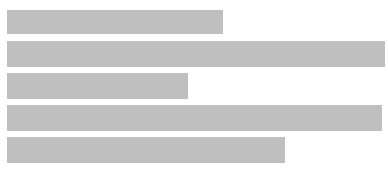
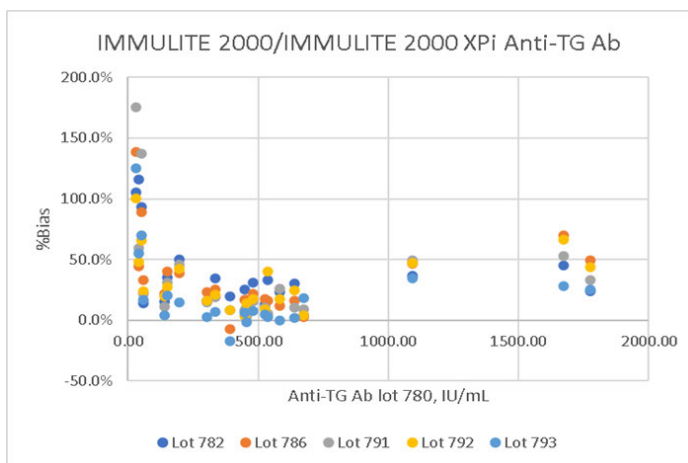
Resolution

This issue is specific to the lots listed in the 'Products' table. Assay performance has been restored with Anti-TG Ab Lot 794. Lot 794 is anticipated to start arriving at the European Distribution Center 16-Apr-2024.

Single Registration Number (SRN) GB-MF-000016339

Additional Data Describing the Product Issue

Figure 1. Bias Plot: Affected Lots 782, 786, 791, 792 and 793 versus Unaffected Lot 780 (20 – 3000 IU/mL)



Appendix

Figure 2. Bias Plot: Affected Lots 782, 786, 791, 792 and 793 versus Unaffected Lot 780 (0 – 400 IU/mL)

