

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

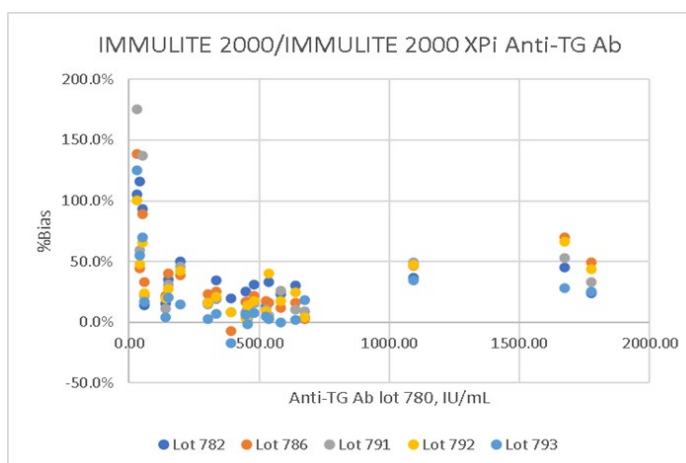
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Perform the instructions provided below:
 - Discontinue use of and discard the kit lots listed in the table above ('Products' Table).
 - 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

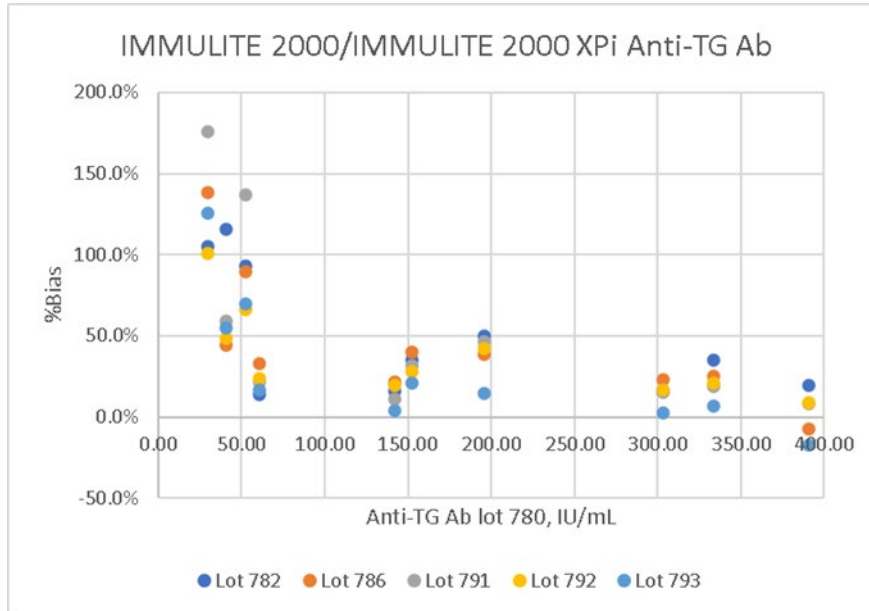
Additional Data Describing the Product Issue

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)



IMMULITE is a registered trademark of Siemens Healthcare Diagnostics Inc. © Siemens Healthcare Diagnostics Inc. 2024