SIEMENS Healthineers

Urgent Field Safety Notice

IMC 23-02.A.OUS

October 2022

IMMULITE®
IMMULITE® 1000

IMMULITE and IMMULITE 1000 Total Testosterone Positive Bias

Our records indicate that your facility may have received the following product:

Table 1. IMMULITE®/IMMULITE® 1000 Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot	Expiration Date (YYYY-MM-DD)	Date of Manufacture (YYYY-MM-DD)
Total Testosterone Assay (100 Test)	10381156	(01)00630414964782(10)0515(17)20221130	515	2022-11-30	2022-07-04
		(01)00630414964782(10)0516(17)20221231	516	2022-12-31	2022-08-06

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed an average positive bias of 40% for testosterone concentrations of approximately 660 ng/dL (22.9 nmol/L) and above with the IMMULITE/IMMULITE 1000 Total Testosterone Assay when compared to the IMMULITE 2000/IMMULITE 2000 XPi Total Testosterone Assay. The observed bias is not proportional across the assay range; biases below a dose of approximately 660 ng/dL are equivalent to historical performance. See Additional Information section below for details.

Siemens' investigation verified the Instructions for Use (IFU) reference ranges remain intact.

Alignment to the IMMULITE 2000/IMMULITE 2000 XPi Total Testosterone Assay has been restored with IMMULITE/IMMULITE 1000 Total Testosterone Assay Kit Lots 550 and above (available in October 2022).

Customers will observe a negative shift when transitioning from the kit lots listed in Table 1 to the restored Kit Lots 550 and above. See Additional Information section below for details on the expected shift.

Siemens is currently investigating root cause.

Risk to Health

There is negligible risk to health due to the biases observed at testosterone concentrations above 660 ng/dL (22.9 nmol/L). Testosterone concentrations above 660 ng/dL (22.9 nmol/L) for adult females are considered abnormal and would lead to further investigation. For adult males, the potential exists to report a concentration above the reference interval when truly normal. Such differences, however, would not lead to a clinically significant change in patient management as

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testosterone levels above the reference interval for adult males are generally not indicative of a pathological condition. For these reasons, Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- You may continue use of the IMMULITE/IMMULITE 1000 Total Testosterone Assay kit lots listed in Table 1 to report values below 660 ng/dL (22.9 nmol/L) until you receive replacement product in your laboratory. Refer to Figures 1 and 2 for IMMULITE/IMMULITE 1000 Total Testosterone bias information.
- If you are currently using IMMULITE/IMMULITE 1000 Total Testosterone Assay kit lots listed in Table 1, review your inventory needs of these products, and order replacement products by completing the Field Correction Effectiveness Check Form attached to this letter.
- Upon acceptance of the re-aligned replacement lots, discontinue use of and discard the products listed in Table 1. Refer to Figures 3 - 6 for expected results with replacement lots.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Additional Information

Current Lot Performance of the IMMULITE/IMMULITE 1000 Total Testosterone Assay Compared to IMMULITE 2000/IMMULITE 2000 XPi.

IMMULITE/IMMULITE 1000 Total Testosterone performance compared to IMMULITE 2000/IMMULITE 2000 XPi was evaluated with 100 serum samples across the assay calibration range (20 – 1600 ng/dL; 0.7 – 55 nmol/L) and two kit lots per platform. Figure 1 shows the biases observed for results within the assay calibration range when comparing representative lots (516 and below) of IMMULITE/IMMULITE 1000 Total Testosterone Assay to the IMMULITE 2000/IMMULITE 2000 XPi Total Testosterone Assay.

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Figure 1. Current IMMULITE/IMMULITE 1000 Total Testosterone vs. IMMULITE 2000/IMMULITE 2000 XPI Total Testosterone Graph

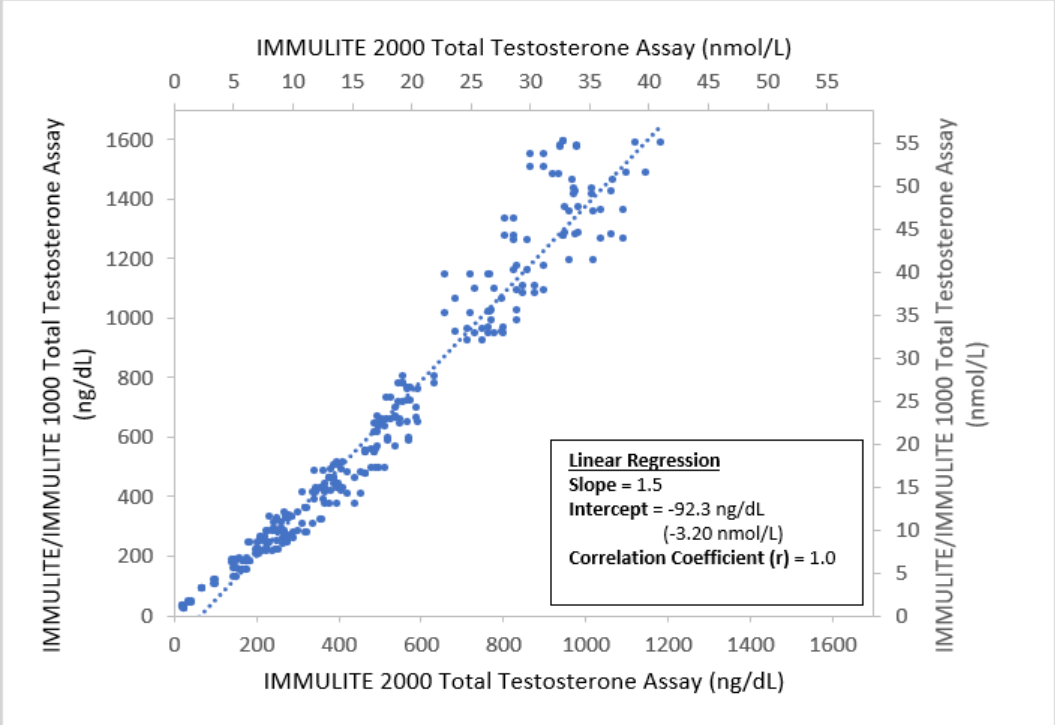
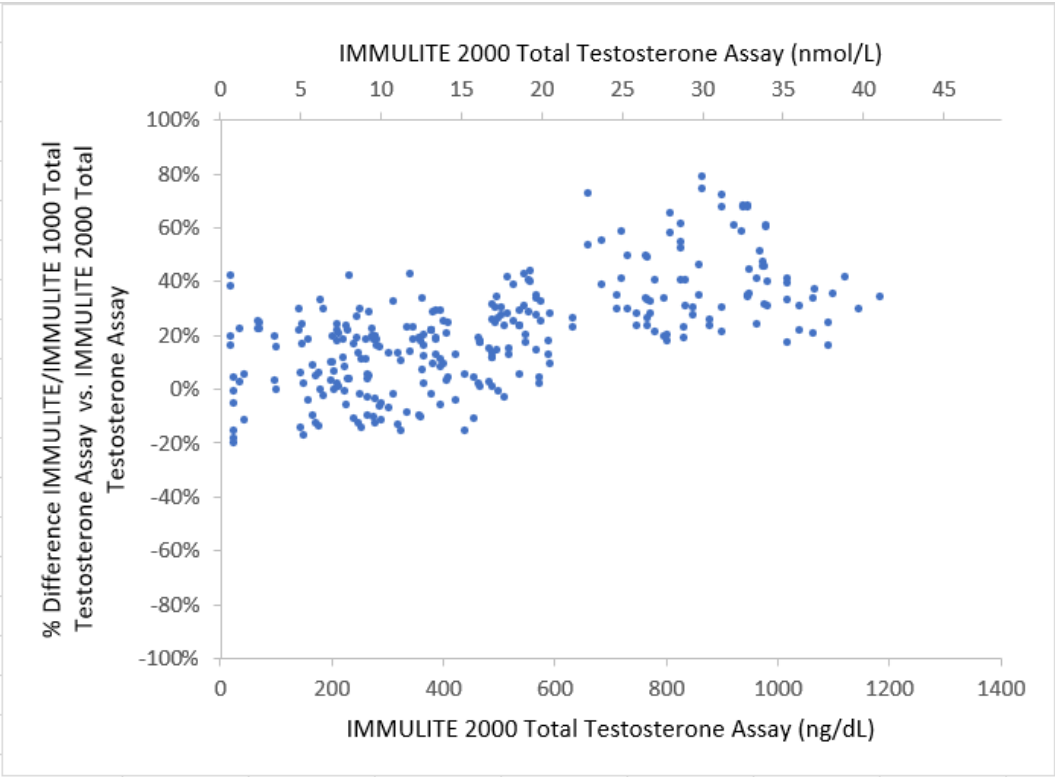


Figure 2. Current IMMULITE/IMMULITE 1000 Total Testosterone vs. IMMULITE 2000/IMMULITE 2000 XPI Total Testosterone % Difference Plot



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Restoration with IMMULITE/IMMULITE 1000 Total Testosterone Assay Kit Lot 550 and above

Siemens restored the IMMULITE/IMMULITE 1000 Total Testosterone assay method comparison alignment to the IMMULITE 2000/IMMULITE 2000 XPi. In addition, the Instructions for Use (IFU) performance claims were verified, including the reference ranges.

New Bio-Rad quality control (QC) material targets and ranges for use with IMMULITE/IMMULITE 1000 Total Testosterone Assay Kit Lot 550 and above will be made available on the Bio-Rad website (http://myeinserts.qcnet.com/) in October 2022.

IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 Bias to IMMULITE 2000/IMMULITE 2000 XPi

Evaluation of the IMMULITE/IMMULITE 1000 Total Testosterone assay compared to IMMULITE 2000/IMMULITE 2000 XPi utilized 123 patient samples covering the assay calibration range (20 – 1600 ng/dL; 0.7 – 55 nmol/L) with IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 versus IMMULITE 2000/IMMULITE 2000 XPi Total Testosterone Kit Lots 635, 638, and 639.

Figures 3 and 4 demonstrate Total Testosterone result alignment between the IMMULITE/IMMULITE 1000 and IMMULITE 2000/IMMULITE 2000 XPi Systems has been restored.

Figure 3. IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 vs. IMMULITE 2000/IMMULITE 2000 XPi Total Testosterone Kit Lots 635, 638, and 639 Graph

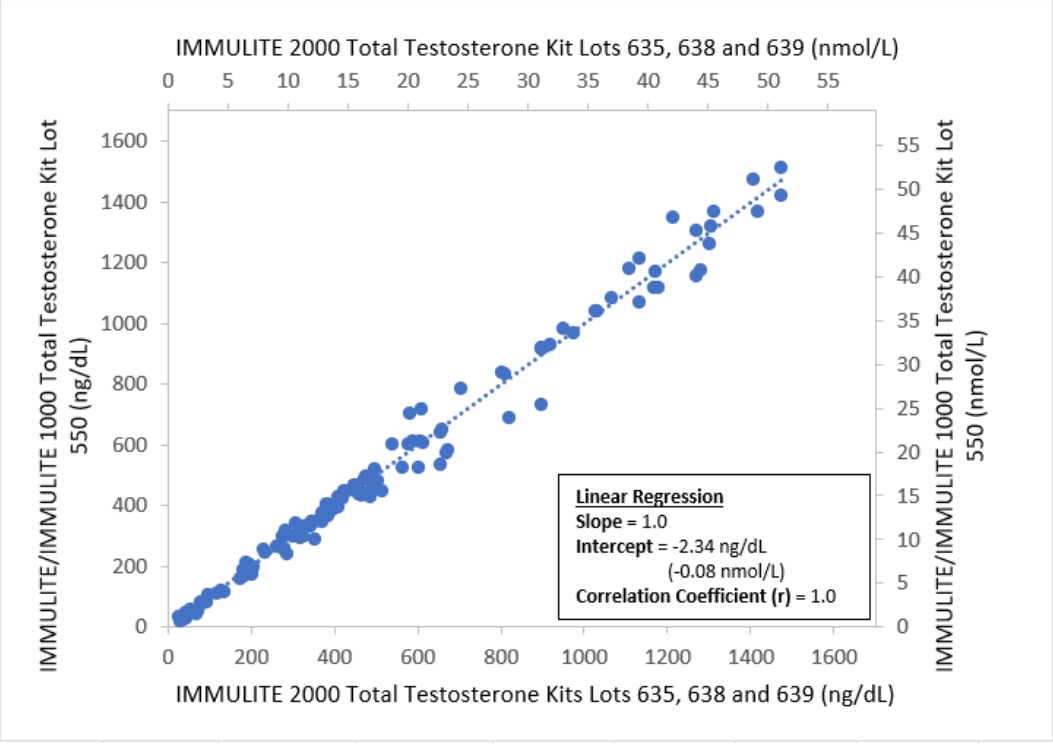

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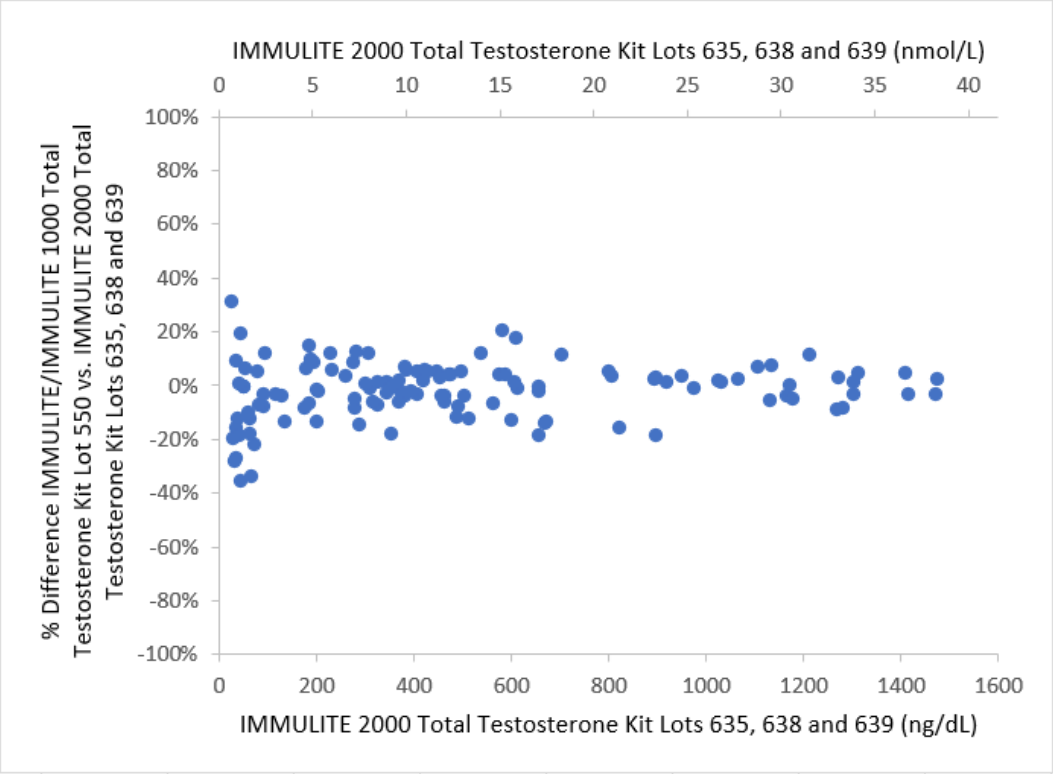
Figure 4. IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 vs. IMMULITE 2000/IMMULITE 2000 XPi Total Testosterone Kit Lots 635, 638, and 639 % Difference Plot



IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 Comparison to Kit Lot 515

After restoring alignment to the IMMULITE 2000/IMMULITE 2000 XPi, Siemens completed internal testing to evaluate the performance of IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 compared to IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 515. Method comparison studies included 65 samples across the assay calibration range (20 – 1600 ng/dL; 0.7 – 55 nmol/L) to evaluate the performance. The observed method comparison results are representative of IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 compared to IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 515.

Figures 5 and 6 show the approximate overall average negative 7% shift that is expected when transitioning to Kit Lot 550 and above.

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Figure 5. IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 vs. Kit Lot 515 Graph

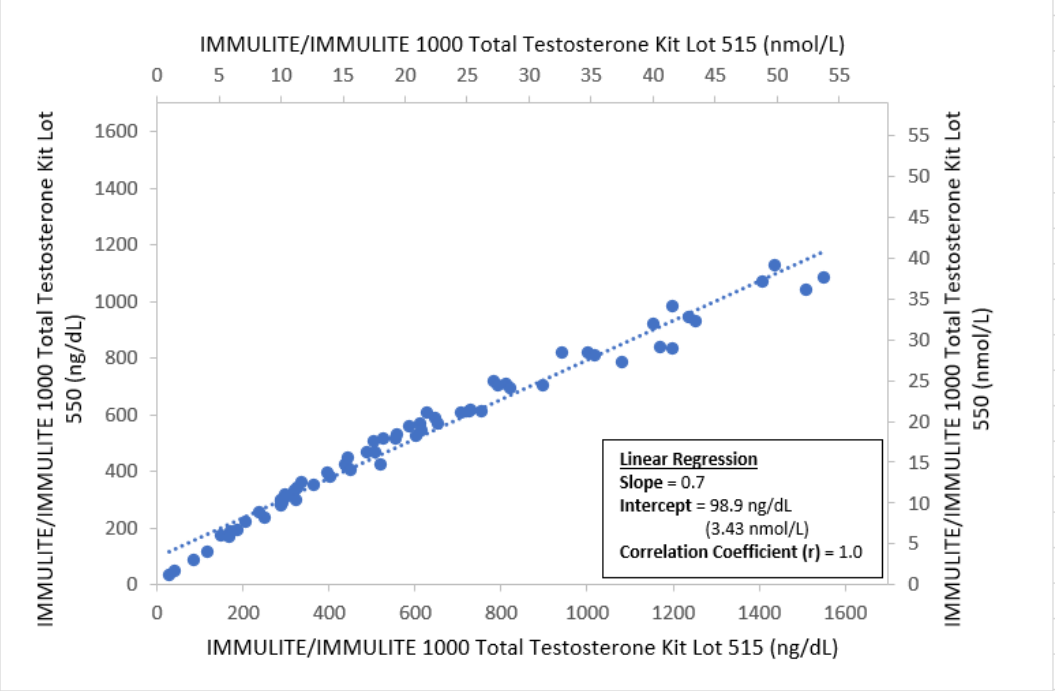
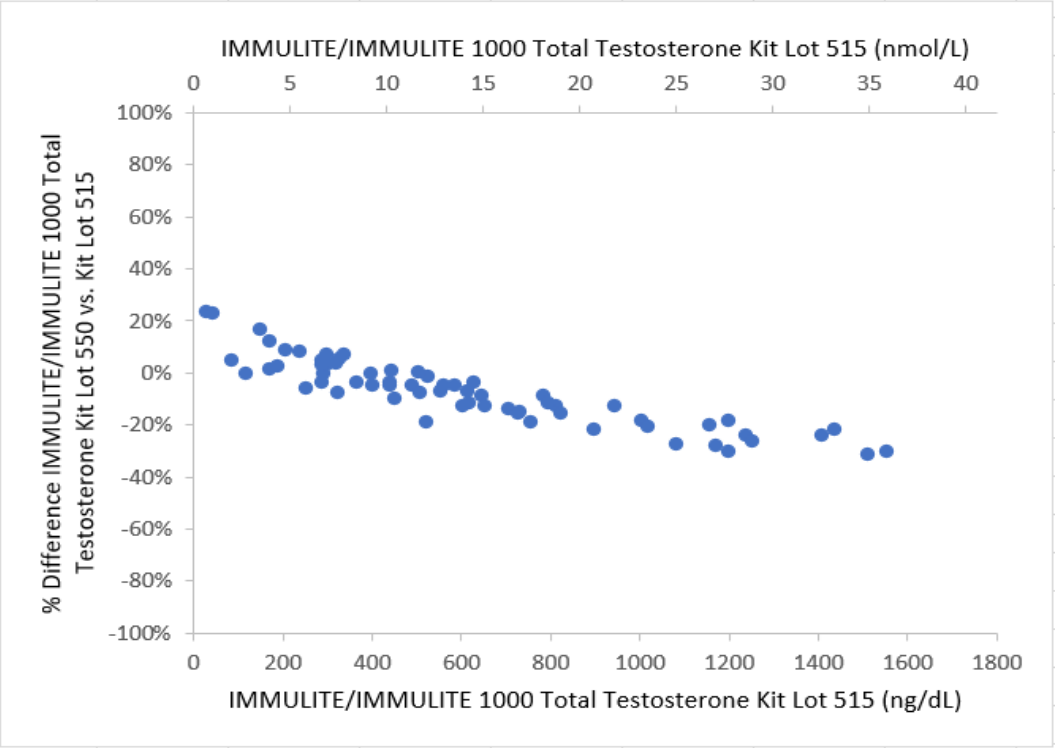


Figure 6. IMMULITE/IMMULITE 1000 Total Testosterone Kit Lot 550 vs Kit Lot 515 % Difference Plot



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FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE and IMMULITE 1000 Total Testosterone Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC 23-02.A.OUS dated October 2022 regarding IMMULITE and IMMULITE 1000 Total Testosterone Bias. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

   If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description **Product Catalog #/SMN #/Lot #**	**Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required**
IMMULITE and IMMULITE 1000 Total Testosterone Assay (100 Test) SMN: 10381156 Kit Lot: 515	
IMMULITE and IMMULITE 1000 Total Testosterone Assay (100 Test) SMN: 10381156 Kit Lot: 516	

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

If you have any questions, contact your local Siemens Healthineers technical support representative.

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