Follow up Urgent Field Safety Notice
Resolution
IMC20-01.B.OUS
December 2020

IMMULITE® 2000
IMMULITE® 2000 XPi

Resolution of the IMMULITE 2000/2000 XPi systems Estradiol High Discordant Results on Some Patient Samples

Table 1. IMMULITE 2000 and IMMULITE 2000 XPi Systems Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot numbers
Estradiol	E2	L2KE22 L2KE26	10381178 10381177	601 and above

Reason for Communication

In February 2020, Siemens Healthcare Diagnostics Inc. issued an Urgent Field Safety Notice (UFSN) IMC20-01.A.OUS, to inform all customers of high discordant results for some patient samples when using kit lots 501 and above on the IMMULITE systems. Preliminary investigations indicated an unidentified interferent in some patient samples potentially causing an increase in estradiol concentration when using the IMMULITE Estradiol assay.

Investigation findings have since identified that the introduction of a new lot of raw material resulted in an increased reagent sensitivity to heterophilic antibodies with kit lots 501-557.

The assay has now been reformulated to mitigate the impact of these heterophilic interferences beginning with kit lot 601 and above on the IMMULITE 2000 and IMMULITE 2000 XPi systems. Please see “Additional Information” below.

Laboratories will not be expected to re-establish quality control ranges for the BioRad Immunoassay Plus. Each laboratory should select appropriate commercially available controls and evaluate control recovery based on their established internal laboratory quality control (QC) procedures.

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Actions to be Taken by the Customer

- Customers can now order the estradiol assay reagents for use on the IMMULITE 2000 and IMMULITE 2000 XPi systems. Please be advised that all prior customer orders have been cancelled, and new orders will have to be placed.
- Please review this letter with your Medical Director.

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

If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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Additional Information

The performance of the assay has not changed (ex: precision, sensitivity etc.). The reformulation addresses ONLY samples impacted by the observed heterophilic interference.

Siemens carried out a method comparison between the newly formulated estradiol reagent lot 601 vs lot 557 which is a lot prior to reformulation. Details in Figure 1 and Figure 2.

Testing included samples across various patient populations and age groups. The data showed that the reformulated estradiol assay on the IMMULITE 2000/2000 XPi resolved the increase in the number of discordant patient sample results due to the heterophilic interference observed with kit lots 501-557.

Figure 1: IMMULITE 2000/2000 XPi Estradiol Reagent Lot 601(reformulated, new) vs. Reagent Lot 557 (prior to reformulation)

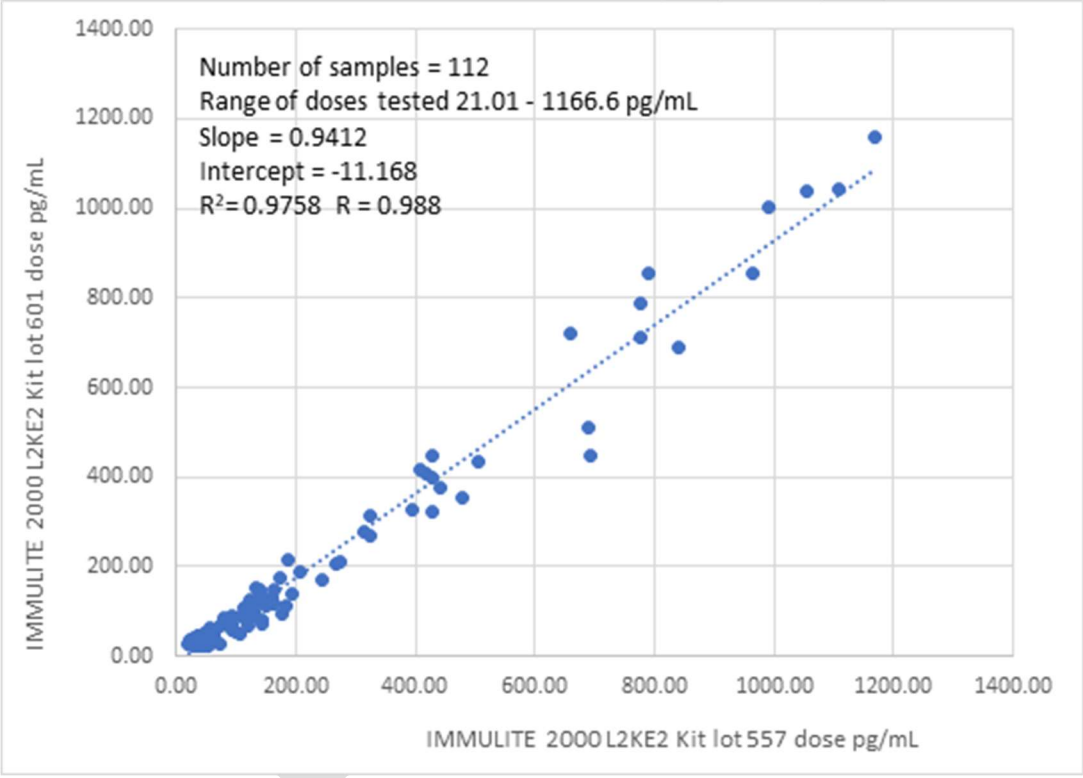
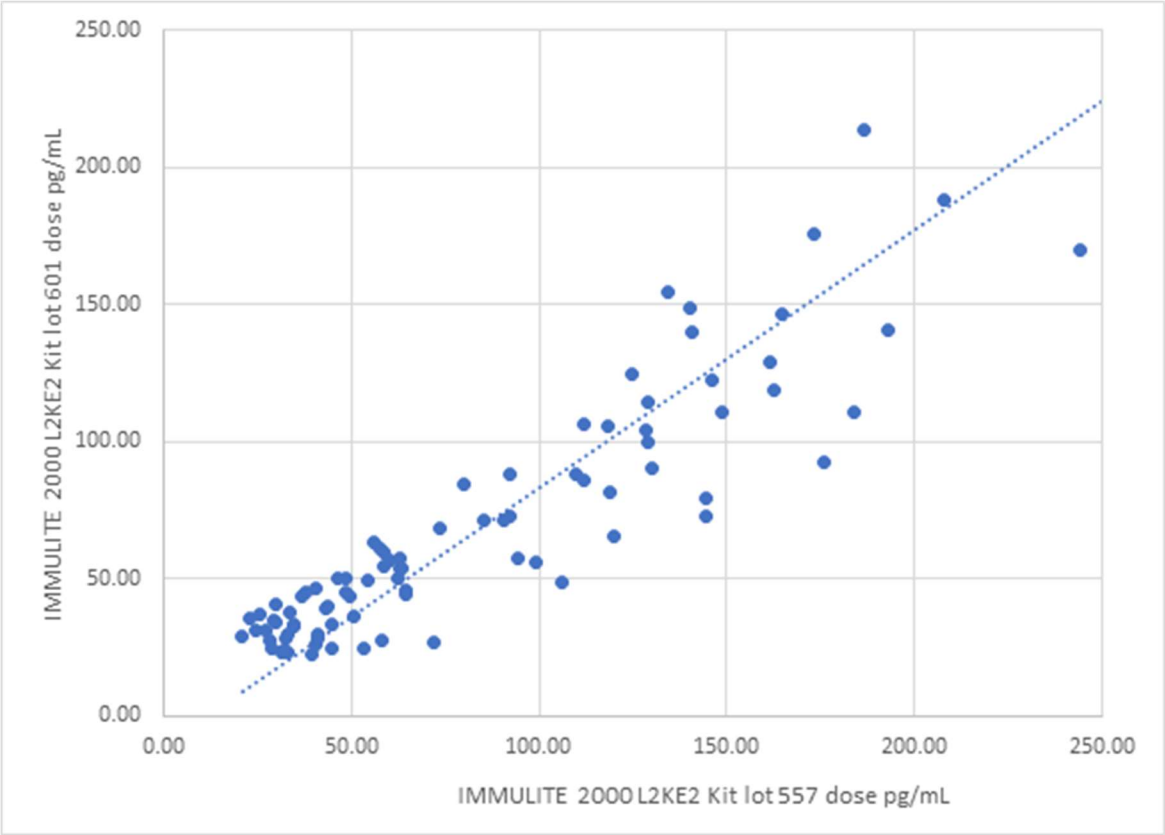


Figure 2: IMMULITE 2000/2000 XPi Estradiol Reagent Lot 601(reformulated, new) vs. Reagent Lot 557 (prior to reformulation) – Patient samples <250 pg/mL from Figure 1



Frequently Asked Questions

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Question: Are there new SMNs for the IMMULITE 2000 and IMMULITE 2000 XPi Systems Estradiol reformulated kit lots?
Answer: No. Please order reagents using the same SMNs as indicated in Table 1 above.

Question: What was the cause of the increase in high discordant Estradiol results on some patient samples?
Answer: The introduction of a new lot of raw material in kit lots 501-557 attributed to an increase in high discordant results. Siemens investigation has confirmed that this raw material lot increased the estradiol reagent sensitivity to heterophilic antibodies found in some patient samples.

Question: Will reference ranges need to be re-established?
Answer: No. The reformulated estradiol assay remains in line with the current Expected Values published in the Instructions for Use (IFU) for this assay.

Question: Will there be changes in Quality Control Material target values?
Answer: There are no expected changes to the QC material assignments resulting from the reformulation of the Estradiol assay.

Question: Have the values and ranges of IMMULITE Systems Estradiol Calibrator Verification Material (CVMs) changed?
Answer: There are no changes to the current CVM targets/ranges.

Question: When will the Estradiol assay on the IMMULITE/IMMULITE 1000 be available?
Answer: Siemens is in the process of completing final implementation and a separate communication will be issued when the IMMULITE/IMMULITE 1000 systems estradiol assay becomes available.

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