SIEMENS Healthineers

Follow Up
Urgent Field Safety Notice

IMC20-01.C.OUS

June 2021

IMMULITE®
IMMULITE® 1000

Resolution of the IMMULITE/IMMULITE 1000 Systems Estradiol High Discordant Results on Some Patient Samples

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

Table 1. IMMULITE and IMMULITE 1000 Affected Product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Estradiol	E2	LKE21	10381132	602 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. 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 501-553.

The assay has now been reformulated to mitigate the impact of these heterophilic interferences beginning with kit lot 602 and above on the IMMULITE and IMMULITE 1000 systems. Please see “Additional Information” below.

Laboratories will be expected to re-establish quality control ranges. New BioRad control targets and ranges for use with IMMULITE and IMMULITE 1000 Estradiol kit lots 602 and above are available on the BioRad website: http://myeinserts.qcnet.com/

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Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Customers can now order the estradiol assay reagents for use on the IMMULITE and IMMULITE 1000 systems. Please be advised that new orders will have to be placed.
- Laboratories will be expected to re-establish quality control ranges. New BioRad control targets and ranges for use with IMMULITE and IMMULITE 1000 Estradiol kit lots 602 and above are available on the BioRad website.

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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics Inc.

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.

In addition, Siemens took this opportunity to improve alignment between the IMMULITE/IMMULITE 1000 Estradiol assay and the reformulated IMMULITE 2000/IMMULITE 2000 XPi Estradiol assay.

Siemens carried out a method comparison study between the newly formulated IMMULITE 2000 Estradiol reagent lot 602 vs the newly formulated IMMULITE 1000 kit lot 602. Details in Figures 1 and 2.

Testing included samples across various patient populations and age groups. The reformulated estradiol assay on the IMMULITE/IMMULITE 1000 is in alignment with the IMMULITE 2000/IMMULITE 2000 XPi and resolves the increase in the number of discordant patient sample results due to the heterophilic interference.

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Figure 1: IMMULITE/IMMULITE 1000 Estradiol Reagent Lot 602 (reformulated, new) vs. IMMULITE 2000/IMMULITE 2000 XPi Estradiol Reagent Lot 602 (reformulated, new)

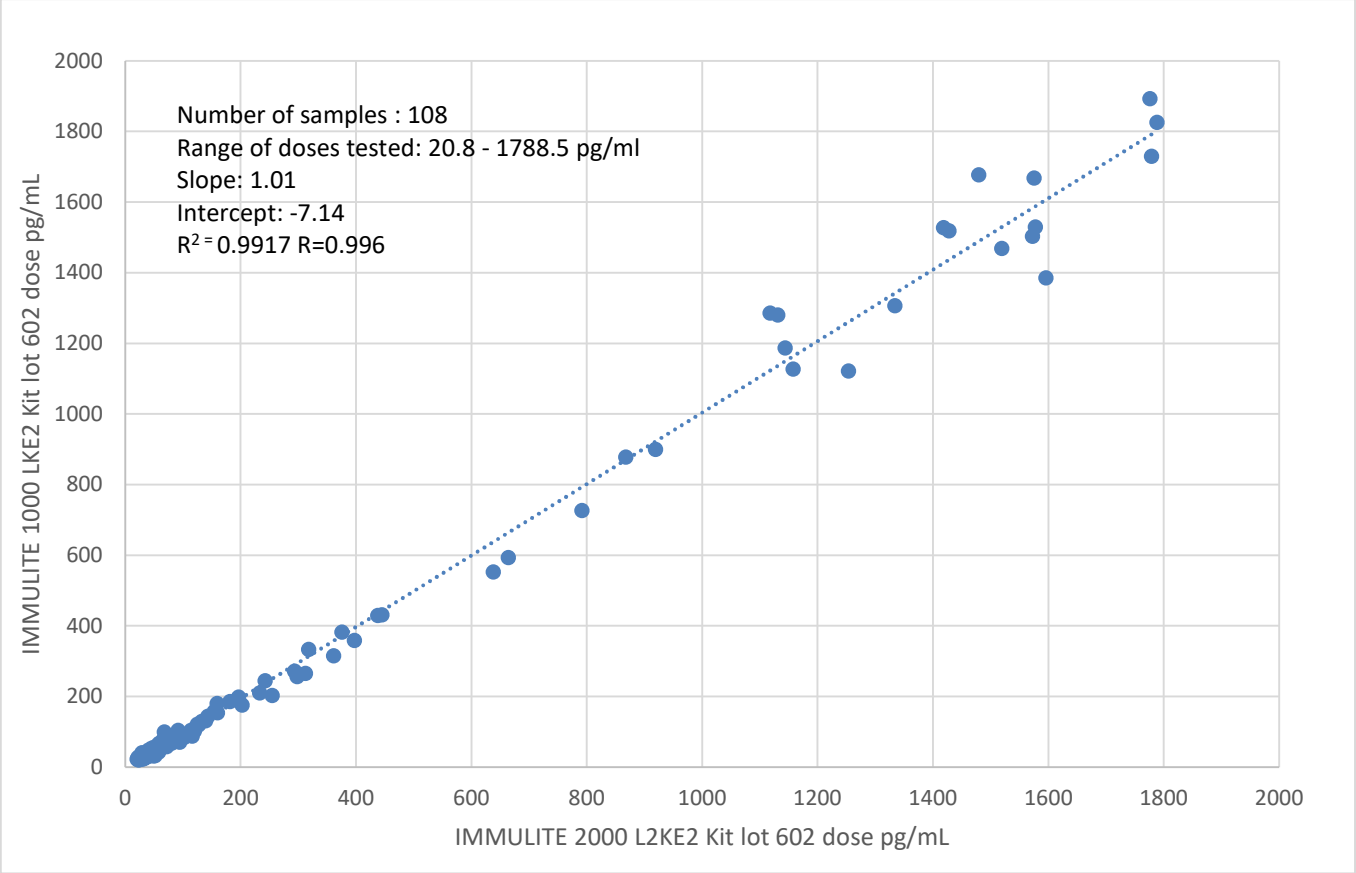
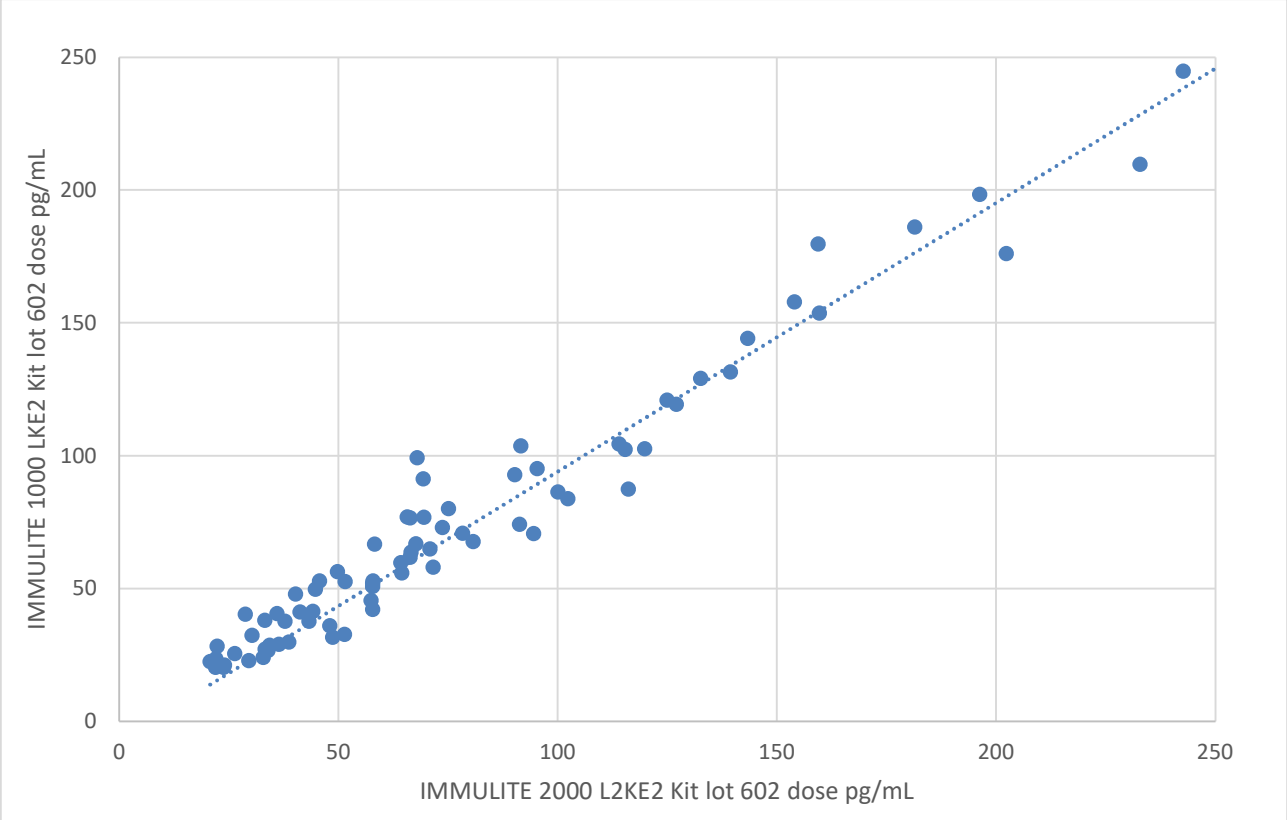


Figure 2: IMMULITE/IMMULITE 1000 Estradiol Reagent Lot 602 (reformulated, new) vs. IMMULITE 2000/IMMULITE 2000 XPi Estradiol Reagent Lot 602 (reformulated, new) – Patient samples < 250 pg/mL from Figure 1



Frequently Asked Questions

Question: Are there new SMNs for the IMMULITE and IMMULITE 1000 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 501-553 contributed 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: Laboratories will be expected to re-establish quality control ranges.

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