

Urgent Field Safety Notice

IMI-15-01.A.OUS

June 2015

IMMULITE®
IMMULITE® 1000
IMMULITE® 2000
IMMULITE® 2000 XPi

Sample Cup Holders and Microsample Inserts Issue

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

Table 1. IMMULITE Systems Affected Product(s)

Product	Siemens Material Number (SMN)	Lot Number
Sample Cup Holder used on IMMULITE® / IMMULITE® 1000 Systems	10385360 - SAMPLE CUP HOLDER SET (Set of 1 - 50) 10385319 -SAMPLE CUP HOLDER SET (Set of 51 - 100)	15, 16
Microsample Insert used on IMMULITE 2000 / IMMULITE 2000 Xpi Systems	10385209 - MICROSAMPLING INSERT (Set of 15)	18, 19, 20

Reason for Correction

Siemens Healthcare Diagnostics has identified through internal investigation an issue with the IMMULITE®/IMMULITE® 1000 sample cup holders and the IMMULITE® 2000/IMMULITE® 2000 XPi microsample inserts, lots listed in Table 1.

- The conductive material of the IMMULITE/IMMULITE 1000 sample cup holders, which are used to process samples, does not meet specification for facilitating sample level sensing. Due to the problematic conductive material of the sample cup holders, sample level sensing errors can occur even if the required minimum sample volume is present in the sample cup.
- The conductive material of the IMMULITE 2000/IMMULITE 2000 XPi microsample inserts, which are used to process low volume samples, does not meet specification for facilitating sample level sensing. Due to the problematic conductive material of the microsample inserts, level sense errors can occur even if the required minimum sample volume is in the sample tube
- When sample level sensing is compromised, sample will not be pipetted and the test or tests ordered for the sample will not be run.

Error messages in Table 2 may also occur if there is insufficient sample in the microsample tube or the sample cup holder. Please consult the appropriate Operator's Guide for further information about the required sample volume.

Table 2. Potential Error Messages

Platform	Error Message
IMMULITE 2000/IMMULITE 2000 XPi	<i>[594] Marking sample tube as bad. [237] Assay Accession # XXXX Sample pipettor did not level sense.</i>
IMMULITE/IMMULITE 1000	<i>INSUFFICIENT SAMPLE-CURRENT TUBE INVALID</i>
IMMULITE 1000	<i>[31205] No Sample Pipetted Sample #XXX Test unit will appear as a white dot on display</i>
IMMULITE	<i>No Sample Pipetted Sample #XXX [Assay] Error Test unit will appear as a white dot on display</i>

The issue has been resolved with future lots of the IMMULITE/IMMULITE 1000 sample cup holders and IMMULITE 2000/IMMULITE 2000 XPi microsample inserts.

Risk to Health

There is no impact to health as results are not generated if a level sense error occurs.

Actions to be Taken by the Customer

For the IMMULITE/IMMULITE 1000:

- If the errors in table 2 are seen on IMMULITE/IMMULITE 1000, the issue can be resolved by adding additional sample to the sample cup.
- Inspect current inventory and if the affected lot as listed in Table 1 is identified on the sample cup holder label or package, the problematic sample cup holders will need to be replaced. Please order replacement holders. Upon receiving the new replacement holders, please discontinue use of and discard the sample cup holders from the problematic lots.

For the IMMULITE 2000/IMMULITE 2000 XPi:

- If the errors in table 2 are seen on IMMULITE 2000/IMMULITE 2000 XPi, the issue can be resolved by adding additional sample to the microsample tube.
- Due to shipping methodology of microsample inserts, lot numbers can only be tracked on the package and not on the microsample inserts. Inspect any unopened packaging versus the lots listed in Table 1. The problematic microsample inserts will need to be replaced. Please order, replacement microsample inserts. Upon receiving the new

Sample Cup Holders and Microsample Inserts Issue

replacement microsample inserts, please discontinue use of and discard the inserts from the problematic lots.

If you observe an increase of errors identified in table 2, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Complete and return the Field Correction Effectiveness Check 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.

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

IMMULITE is a trademark of Siemens Healthcare Diagnostics.