

**IMMULITE® 2000 Immunoassay System
IMMULITE® 2000 XPi Immunoassay System****Waste Bottle Flexible Tube Replacement**

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

Table 1. IMMULITE® 2000 / XPi Immunoassay System Affected Product(s)

Product	Siemens Material Number (SMN)
IMMULITE 2000 Immunoassay System	SMN #10380062
IMMULITE 2000 XPi Immunoassay System	SMN #10373214

Reason for Correction

The purpose of this communication is to inform you of an issue with the IMMULITE 2000 and IMMULITE 2000 XPi Immunoassay systems indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has received customer complaints that the flexible tubing connected to the liquid waste bottle can crack during routine customer maintenance.

An on-site visit will be scheduled for Siemens Customer Service Engineers to replace the liquid waste bottle tubing at all customer locations.

Siemens has collaborated with suppliers to ensure that replacement part standards are met.

Risk to Health

The potential exists that liquid waste can leak onto the floor, creating a slip and fall hazard.

Siemens is not recommending a review of previously generated results as results are not affected by this issue.

Actions to be Taken by the Customer

- Please be aware of the potential hazard.
- There are no actions for Siemens customers to take. A Siemens Customer Service Engineer will replace the defective tubing.
- Customers are reminded to wear personal protective equipment and continue to follow waste bottle maintenance and instructions provided in the instrument Operator's Guide.

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.

Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.

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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics Inc.

FIELD CORRECTION EFFECTIVENESS CHECK

Waste Bottle
Flexible Tube Replacement

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UFSN IMI20-01.A.OUS dated May 2020 regarding Waste Bottle Flexible Tube Replacement. 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 UFSN instructions provided in this letter.

Yes ☐

No ☐

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Country:

Please send a scanned copy of the completed form via email to CruinnFSNGroup@cruinn.ie

Or to fax this completed form to the Customer Care Center at 01-6297401.

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