IMMULITE® 2000 Immunoassay System
IMMULITE® 2000 XPi Immunoassay System

**Siemens Healthcare Diagnostics Inc.**

**Customer Bulletin**

October 2020

# Change in Reaction Tubes (LRXT) – FINAL UPDATE

11536664, Rev. C

## Introduction

Siemens Healthineers is providing additional information regarding an upcoming change to the Reaction Tubes (LRXT) used for all IMMULITE® immunoassays run on the IMMULITE 2000 and IMMULITE 2000 XPi Immunoassay Systems.

Table 1. **Product Ordering Information**

| Product Name | Product Description | Catalog Number | Siemens Material Number (SMN) |
|---|---|---|---|
| Reaction Tubes (disposable) | Bag of 1000 tubes | LRXT | 10385206 |

The purpose of this communication is to remind you of a planned update to the product listed in Table 1 and provide additional information and instructions on actions your laboratory must take.

Our supplier for the plastic resin used in the reaction tubes has modified its formulation. The current and new reaction tube formulations cannot be used together or interchangeably. Siemens Healthineers has validated the new reaction tube and verified performance is acceptable when the same formulation of reaction tube is used for both adjustment and testing of samples (Quality Control [QC] and patient samples).

For your convenience, the new reaction tubes will be supplied in a blue-fronted bag to be easily distinguished from the current reaction tubes that are supplied in a white-fronted bag. The new reaction tube bag will also contain an additional label referencing this customer bulletin. The product ordering information will remain the same.

In preparation for use of the new reaction tubes, we recommend inventory management of current reaction tubes and a planned transition to the new reaction tubes based on the important information below.

## Important Information

Once you receive the blue-fronted bags of new reaction tubes, you must do the following:

- Deplete your remaining stock of (current) white-fronted bags of reaction tubes as much as possible before using the (new) blue-fronted bags.
- Purge each IMMULITE 2000 and IMMULITE 2000 XPi instrument of all current reaction tubes before moving to the new version of reaction tube. Use the following steps to ensure all reaction tubes are emptied from the tube queue chute:

  - Use the IMMULITE 2000/2000 XPi Diagnostic Programs “Empty Incubator – 2000” followed by “Home All Motors” and lastly “Tube Purge – 2000.”
- Before running QC and patient samples, perform a readjustment for each IMMULITE 2000/2000 XPi assay and kit lot using the new reaction tubes.

**Note:** The new formulation of reaction tube is visually identical to the current reaction tube and you will not be able to distinguish between the current and new formulation of reaction tubes once they are removed from the plastic bag.

## Adjustment

- **When readjusting assays** with the new reaction tubes, you may observe a greater than 10% change in slope from the last adjustment generated with the previous formulation of reaction tube. Accept the adjustment by verifying valid QC performance.
- **When performing an initial adjustment on a new kit lot** with the new reaction tubes, you may observe a slope outside of the ±20% mean slope range for the system. Accept the adjustment by verifying valid QC performance.

Results from QC run immediately following an adjustment are the primary means for validating an acceptable adjustment and QC results should be within established ranges.

A copy of this communication can be kept as part of your documentation indicating the change in reaction tubes for the IMMULITE 2000 and IMMULITE 2000 XPi systems in your laboratory. Please refer to the IMMULITE 2000/2000 XPi Operator’s Guide for additional information and instruction.

## Performance

The change in reaction tube formulation required Siemens Healthineers to perform testing to verify acceptable performance of the new formulation. Verification testing was performed on all IMMULITE 2000/2000 XPi assays comparing QC, patient sample, and precision performance when using current or new formulation reaction tubes.

During the verification testing of the new plastic resin formulation, differences were observed in QC and patient results when a mixture of the current and new reaction tubes were used together. When the current reaction tubes were used to perform an adjustment, and the new reaction tubes were then used to test QC material and patient samples, shifts in sample results relative to expected values were observed. Similarly, shifts in performance were observed for the reverse situation, when the new reaction tubes were used for the adjustment and the current reaction tubes were used for the QC material and patient samples. These differences were not observed when the adjustment and sample runs were performed using the same plastic formulation of reaction tube.

**All Siemens Healthineers testing demonstrated that patient sample and QC results produced using the new reaction tube are equivalent to the results produced using the current reaction tube.**

These differences in results when using a mix of the two types of reaction tubes require customers to ensure that *only the current OR new reaction tube* is used for adjustment and QC and patient sample testing to avoid the risk of potential performance shifts.

The table below summarizes the potential outcomes customers may see when the current and new reaction tubes are mixed.

Table 2. **Potential Outcomes for Assay Runs Depending on Reaction Tube Type Used**

| | Adjustment | Sample | Outcome |
|---|---|---|---|
| **Reaction Tube Type** | Current | Current | ✓ |
| | New | New | ✓ |
| | Current | New | **X** |
| | New | Current | **X** |

## Availability

The transition timing has been revised. Siemens Healthineers will begin transition to the new reaction tubes immediately. During the transition period there is a slight chance you may receive shipments containing a mixture of current (white bag) and new (blue bag) reaction tubes. However, every effort is being made to minimize this possibility.

## Additional Information

To help identify the change in reaction tubes, we will be implementing the following actions:

1. There will be a change to the color of the reaction tube bag. Currently, the tubes come in a white-fronted bag that will change to a blue-fronted bag. See pictures below.

Figure 1. **Current Reaction Tubes Bag – White Color**

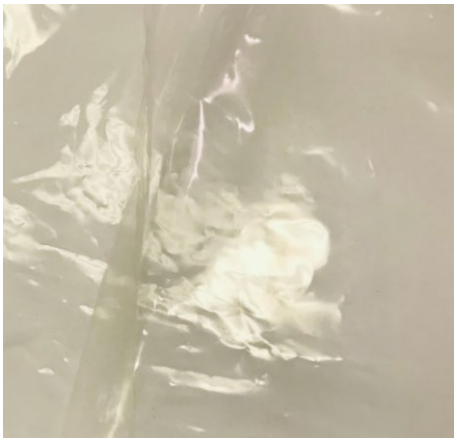

Figure 2. **New Reaction Tubes Bag – Blue Color**

2. An additional sticker label will be placed on the outside of the bag containing the new reaction tubes. This label will be printed with the SMN number of this customer bulletin (SMN 11536664).

## Frequently Asked Questions

Table 3. **Frequently Asked Questions**

| |
|---|
| **Question:** Why is Siemens Healthineers changing the reaction tubes? |
| Our supplier for the plastic resin used in the reaction tubes has changed formulations. |
| **Question:** Has the ordering information changed? |
| No. The catalog number and SMN number are the same. |

| **Question:** When will the new reaction tubes be implemented? |
| --- |
| The new reaction tubes introduction timing has been revised and will begin to ship immediately based on current demand. You may receive a mixture of white- and blue-fronted bags when ordering reaction tubes during this transition period until our inventory of the previous formulation has been depleted. However, every effort is being made to minimize this possibility. |
| **Question:** What should I do if I receive a blue-fronted bag of reaction tubes? |
| Refer to this customer bulletin for additional information and instructions. |
| **Question:** Will additional information be provided regarding the transition to the new reaction tubes? |
| Additional information will be provided as needed during the transition period. |

## Regulatory Information

Product and system availability are subject to local regulatory requirements and, therefore, vary by country. If you have any questions or need additional information, please contact your local technical support provider or distributor.

## Additional Assistance

Technical information is available at https://www.healthcare.siemens.com/doclib/. If you need additional assistance, please contact your Siemens Healthineers Remote Services Center.

Please retain this bulletin with your records for future reference.

## Trademark Information

IMMULITE is a trademark of Siemens Healthcare Diagnostics.

All other trademarks are the property of their respective owners.