Urgent Field Safety Notice

ASI22-01.A.OUS

April 2022

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer

Atellica IM T3 Assay – Lots incompatible with Test Definition (TDef) Version 1.4

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

Table 1. Atellica® Solution Affected Product(s):

Product	Siemens Material Number (SMN)
Atellica IM 1300 Analyzer	11066001
Atellica IM 1600 Analyzer	11066000

Reason for Correction

Siemens Healthcare Diagnostics Inc. has confirmed that Atellica IM analyzers listed in Table 1 may produce inconsistent results for Atellica IM T3 Assay (Triiodothyronine) reagent kit lots ending in numbers below 244 after scanning the Master Curve (MC) Card for reagent lots ending in 244 or above. If your facility is only using T3 kit lots ending in 244 or above, you are not impacted, and no further action is required.

The issue is caused by a modification to the Test Definition (TDef) that was introduced with Atellica IM T3 kit lots ending in 244. When multiple reagent lots are present on the system, after the 2D TDef barcode in the MC Card for a kit lot ending in 244 or above (TDef version 1.4) has been scanned, if the system uses a kit lot number lower than lots ending in 244 to process results, you may observe, imprecision in the range of -50% to +117% across the entire analytical measuring range, inconsistent QC results (out of range) or a calibration failure.

No other assay is impacted as the TDef update was specific for the T3 assay.

Siemens Healthcare Diagnostics has determined that reagent kit lots ending in lot numbers below 244 are not compatible with the design of the T3 TDef v1.4 that is used with reagent kit lots ending in 244 and above. All reagent kit lots ending in numbers below 244 must be used with the TDef that is on the MC Card for the corresponding lot (TDef v1.3 or below).

Siemens Healthcare Sdn Bhd [201501001338 (1126670-U)]
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Please refer to the instructions in the 'Actions to be Taken' section below on actions that your laboratory must take when running the T3 assay until all lots ending in numbers below 244 have been fully consumed or expired.

Risk to Health

This issue could potentially lead to the generation of erroneous total T3 results and additional investigation for hypo- or hyperthyroidism. Mitigations include correlation with historical results, clinical signs and symptoms for thyroid disorders, repeat testing, and other thyroid tests such as TSH, free T4 and free T3. A review of previously generated results is not recommended since total T3 results would be interpreted in conjunction with other laboratory and clinical information, as described.

Actions to be Taken by the Customer

If your facility has multiple lots of T3 available for use and some kit lots are below lots ending in 244, follow the steps below to ensure that T3 results will be correct for all available lots until all kit lots available for use are kit lots ending in 244 or above.

- Ensure that all IM modules connected to an Atellica Solution have only 1 lot of T3 reagent (all IM modules have the same lot of T3 reagent packs) loaded onto every IM.
- For reagent kit lots **below** lots ending in 244:

  Rescan the Master Curve Card (MCC) for the T3 reagent lot that is on the Atellica IM before processing with that reagent lot, following instructions in the Atellica Online Help (SMN 11313586, section "Scanning IM Master Curves and Assay Test Definitions 2D Barcodes").

  Note: If the IM is rebooted while using kit lots below lots ending in 244, the MCC will need to be re-scanned before samples are processed.

- For reagent lots ending in **244 and above**:

  Rescan the Master Curve Card (MCC) for the T3 reagent kit lot that is on the Atellica IM, following instructions in the Atellica Online Help (SMN 11313586, section "Scanning IM Master Curves and Assay Test Definitions 2D Barcodes".

  Reboot all IM modules connected to Atellica Solution following instructions in the Atellica Online Help (SMN 11313586, section titled 'Shutting Down and Powering Off Analyzers within the System") when changing from reagent kit lots below lots ending in 244 to a reagent pack associated with kit lots ending in 244 or above before processing with that reagent kit lot.

- Please review this letter with your Medical Director.
- Complete and return the Field Action Effectiveness Check Form attached to this letter within 30 days.

- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers technical support representative.

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 local Siemens Healthineers technical support representative.

Atellica is a trademark of Siemens Healthineers.

Legal Manufacturer SRN: US-MF-000016560

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FIELD ACTION EFFECTIVENESS CHECK

Atellica IM T3 Assay– Lot's incompatible with Test Definition (TDef) Version 1.4

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics, Urgent Field Safety Notice (UFSN) ASI22-01.A.OUS dated April 2022 regarding "Atellica IM T3 Assay – Lot's incompatible with Test Definition (TDef) Version 1.4". 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: xxxx@siemens-healthineers.com.

Or to fax this completed form to the Customer Care Center at: (xxx) xxxxxxxx.

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

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