



Customer Notification

AIMC 24-05.A.OUS

January 2024

Atellica® Solution

Atellica IM Total Thyroxine (T4) Assay Master Curve Card Scanning Error

Reason for Customer Notification

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 below and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed an inability to successfully scan the master curve card (MCC) packaged with Total Thyroxine (T4) Assay Kit Lots 07485274 or 07444274 on the Atellica IM analyzer with Software Version 1.26 and below. An analyzer error message is generated and prevents customers from testing with these assay kit lots.

Note: The MCC packaged with Atellica IM T4 Assay Kit Lots 07485274 and 07444274 will scan successfully to the Atellica IM analyzer with Software Version 1.27 and above.

ADVIA Centaur XP, ADVIA Centaur XPT, ADVIA Centaur CP are not impacted by this issue.

Siemens is currently investigating root cause.

Table 1. Atellica IM Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot	Date of Manufacture (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
Atellica IM Total Thyroxine (T4) Assay (150 Test)	10995684	(01)00630414599977(10)07485274(17)20240808	07485274	2023-11-08	2024-08-08
Atellica IM Total Thyroxine (T4) Assay (750 Test)	10995685	(01)00630414599984(10)07444274(17)20240808	07444274		

Actions to be Taken by the Customer

- For the products listed in Table 1, when utilized on an Atellica IM analyzer with Software Version **1.27** and above, the product scans as designed, and no action is needed.
- For the products listed in Table 1, when utilized on an Atellica IM analyzer with Software Version **1.26** and below:

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- Scan the updated MCC from Figure 1 for Atellica IM Total Thyroxine (T4) Assay Kit Lots 07485274 or 07444274 per the Atellica Solution Operator's Guide instructions.

The assay lot specific data will be stored to the analyzer and allow for successful product utilization to be achieved. See Figure 1 in Additional Information below for the updated MCC.

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 Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.

Additional Information

Figure 1. Atellica IM Total Thyroxine (T4) Assay Kit Lots 07485274 or 07444274 MCC (updated)



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