

Cc to Chairman Medical Board and
relevant Head of Departments

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer

SW V 1.19.0 and 1.19.2 - Issues Scanning New Reagent Lot Test Definition

Our records indicate that your facility has received one or more of the following products:

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

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

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of two issues that occur when scanning a new reagent lot Master Curve/ Test Definition (TDef) on the Atellica IM Analyzers, listed in Table 1, with Atellica Solution software (SW) version V1.19.0 and V1.19.2.

When scanning a new reagent lot Master Curve/ TDef:

1. If there are active workorders for the assay being scanned in the Worklist, the following error may occur: "Unable to save test because current orders are using the assay. Failed to save assay."
2. When the new reagent lot Master Curve/ TDef has successfully been scanned and saved, the system will use the default settings, instead of the customized entries, for the settings listed below, in Table 2.

TDefs that have not been customized by the user are not impacted by this behavior.

Table 2. Affected TDef Settings:

Issue Number	Definition Tab	Description of Observed Behavior
1	Display Name	Order entry screens will display the default test name instead of the customized name.
2	Print Name	Test names in printed reports will display the default test name instead of the customized name.
3	LIS Code	A mismatch in the LIS code (Test name) between Atellica Solution and LIS systems/automation will lead to orders for the test not being processed.
4	Centrifuge before Repeating	Sample will be flagged and held for centrifugation for the cHIV and eHIV assays.
5	Apply Final Result Rule (Only displayed if test type is ID Auto FRR)	The Final Result Rule (FRR) will be applied to all Auto FRR tests (e.g. Infectious disease tests).
	Result Calculation Tab	
6	Hemolysis, Icteric and Lipemic (HIL) Threshold	Flagging thresholds will revert back to default settings, customized thresholds will not be applied.
7	Units	Results (numeric value) are computed using the customized conversion factor but labeled with the default units. Reference ranges are not affected. <u>Note:</u> Middleware such as Atellica Data Manager may reject results due to a mismatch in labeled units. Some 3rd party LIS systems may accept and report the results.

The custom values are still displayed in the TDef screen but other system screens (Range setting or Worklist screen) will show the default values.

This behavior is corrected in software version v1.20.0 or higher, which will be available soon.

Risk to Health

Issue Number	Risk to Health
1 - 5	This issue only affects user-customized TDef settings. These behaviors may cause an apparent delay with negligible risk to health. Siemens is not recommending a lookback of previously generated results due to this issue.
6	This issue only affects user-customized TDef settings. Reset of the HIL flagging thresholds to the default settings has negligible risk to health, as HIL flagging will still be present at manufacturer validated thresholds. Siemens is not recommending a lookback of previously generated results due to this issue.
7	This issue only affects user-customized TDef settings. Worst case, this issue may cause incorrect unit labels in the result calculation tab on the instrument. However, the correct numerical result with the customized conversion factor is reported and associated with the correct reference range for that analyte, on the instrument and in an electronic medical record. Therefore, the risk to health is negligible. Siemens is not recommending a lookback of previously generated results due to this issue.

Actions to be Taken by the Customer

The following actions must be taken when scanning a new reagent lot Master Curve/ TDef until your system has been updated to software version v1.20.0 or higher.

1. Prior to scanning a new reagent lot Master Curve/ TDef, all orders for the assay must be moved to Historical by performing the following steps:

Note: Once results are moved to Historical they cannot be transmitted to the LIS. If samples that are moved to Historical need to be run, the test order will need to be recreated after saving the TDEF.

- Ensure that results for all samples have been transmitted to the LIS.
- Navigate to the Worklist=>Worklist Overview. Remove all Worklist filters so all Orders are visible, sort the results by Test, select all orders for the test on the Worklist screen and click the button "Move to Historical".
- Confirm there are no active orders remaining on the Worklist for the assay being scanned.

2. After scanning a new reagent lot Master Curve/ TDef perform the following steps.

Note: To ensure the Analyzer uses the desired settings, temporarily change the Display Name, save it, and then change it back to the customized Display Name. The steps below will restore all seven (7) settings.

- Navigate to IM Test Definition (Setup=>Test Definition=>IM Test Definition)
- Select the Test that was just scanned.
- Change the Display Name to a different name and select save.
 - Example: Change FT4 to FT4X.
- Verify the temporary Display Name is shown on the Patient Order screen by navigating to the Patient Order screen. (Patient Order=>Create Patient Orders).
 - Do not create orders at this time.
- Change the Display Name back to its originally customized name and select save.
 - Example: Change FT4X back to FT4.
- Verify the customized Display Name is shown by navigating to the Patient Order screen. (Patient Order=>Create Patient Orders).

3. Verify that QC results are not affected, and that results and all associated customized parameters (units, flags, etc.) are reported correctly.

- Please review this letter with your Medical Director.
- Complete and return the Field Correction 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 Customer Care Center or 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 Siemens Healthineers Customer Care Center or your local technical support provider.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

FIELD CORRECTION EFFECTIVENESS CHECK

Issues Scanning new Reagent Lot Test Definition Master Curve Cards in SW V1.19.0 and V1.19.2

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW19-05.B.OUS, dated August, 2019 titled "SW V 1.19.0 and 1.19.2 - Issues Scanning New Reagent Lot Test Definition". 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 UMDC instructions provided in this letter.

Yes ☐

No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number(s): _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

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