SIEMENS Healthineers

Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

ASW20-02.A.OUS

January 2020

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer

Humidity Packs Incorrectly Identified as Expired (Lot 0010)

Our records indicate that your facility may have received one or more or a combination of the following products:

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

Product	Siemens Material Number (SMN)
Atellica IM Humidity Pack (Qty 5)	11313505
Atellica IM Humidity Pack (Qty 1)	11313496

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an ongoing investigation involving the products listed in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has received customer complaints stating that Atellica IM Humidity Packs Lot 0010 have expired, causing the analyzer to eject the Humidity Packs and stop processing samples.

Atellica IM Humidity Packs do not have a shelf life (lot) expiration, therefore, the system is identifying these packs as expired in error. Preliminary investigation indicates this error is attributed to the software.

It is important to note that Humidity Packs do have an onboard stability (OBS) of 180 days that is monitored by the system software. Once loaded onto an analyzer, the OBS of each pack is monitored.

Siemens is actively working to investigate the root cause and customers will be notified when additional information is available. This behavior will be corrected in a new version of software that will be available shortly.

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Risk to Health

The potential exists for an apparent delay in testing when this issue occurs. Siemens is not recommending a review of previously generated results as the accuracy of results is not affected by this issue.

Actions to be Taken by the Customer

The error can be resolved by manually entering the Humidity Pack barcode information with the following steps.

1. Cover the existing Humidity Pack 2D barcode with permanent marker so it cannot be read by the system. Do not remove the original barcode. (top view)

2. On the Command bar, select **Inventory**.

Note: Steps 2 through 8 correspond to the screen shot on page 3 below.

3. Select the **Reagent Loader** tab.
    a. Select the **IM module** where the packs are to be loaded.
4. Select **Manual Entry**.
5. Select pack type as **Ancillary**.
6. Enter the following barcode number.
    a. 78710600PPPPPP
    b. PPPPPP is a unique six-digit pack number. Use the unique identifier on the Humidity Pack being manually entered.
    c. The unique identifier on the Humidity Pack label is depicted below. In this example the unique identifier if 034831. (side view)

7. Select Verify.

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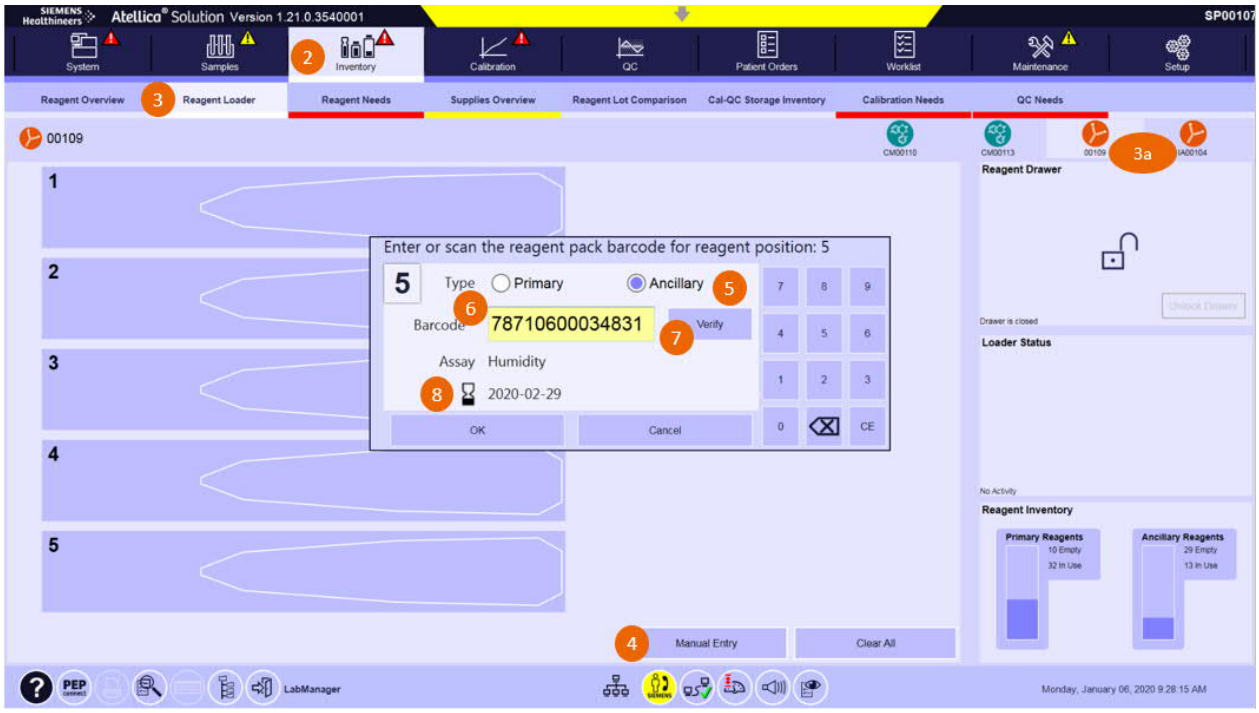
8. Confirm Assay equals Humidity and the date next to the hourglass symbol is 2020-02-29.
9. Select OK.
10. Load the Humidity Pack in position 5 of the reagent tray.
11. Repeat this procedure for all required Humidity Packs. Each analyzer will require, 7 to 10 packs based on analyzer environmental requirements. When the full set of required Humidity Packs are loaded, the analyzer will resume normal operation.



Note: Anytime the analyzer must repeat the “Startup” routine, the humidity packs with covered barcodes will be identified as “unknown.” This will require the above actions to be completed again. The analyzer will perform the “Startup” routine after a reboot, mechanics off/on and/or opening of the front or rear top covers.

- 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 Customer Care Center or your local Technical Support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local technical support provider.

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FIELD CORRECTION EFFECTIVENESS CHECK

Humidity Packs Incorrectly Identified as Expired

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW20-02.A.OUS, dated January 2020 titled “Humidity Packs Incorrectly Identified as Expired (Lot 0010)”. 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 the following e-mail address XXXX@XXXX.

Or fax this completed form to the Customer Care Center at (XXX) XXX-XXXX.

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

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