SIEMENS Healthineers
Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

ASI21-02.A.OUS

May 2021

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer
Atellica® CH 930 Analyzer

A manufacturing defect in some valves may cause them to leak

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

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

Product	Siemens Material Number (SMN)
Atellica CH 930 Analyzer	11067000
Atellica IM 1300 Analyzer	11066001
Atellica IM 1600 Analyzer	11066000

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified an issue with the Atellica Solution products listed in Table 1 and is providing instructions on actions your laboratory must take.

Siemens has identified a set of valves that are used on the Atellica CH 930, Atellica IM 1300 and Atellica IM 1600 analyzers that may develop a malfunction due to a manufacturing defect and may result in the valve wearing and leaking over time. The leaking is a risk in valves subject to high pressure or high wear and may impact the result accuracy of any assay.

Siemens service personnel will schedule a visit to your laboratory to replace these parts when the replacement parts are available.

Description of Observed Behaviors

Product	Observed Behavior	Description of Observed Behavior
Atellica IM 1300 Atellica IM 1600	Gradual valve leakage	The worst-case valve leaks identified may cause one of the following: • water to be aspirated along with reagent causing dilution of the reagent while samples are being processed.

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		• development of a leak over a period of multiple days, causing 'IM Wash' solution to contaminate the water line to the rinse probes. The failure does not occur until the valve has been in use for over 1 million cycles (1-2 years depending on the sample volume run on the instrument). A leak in these valves can be observed as a gradual bias in results due to a slow degradation of the valve seal causing a gradual change in control recovery and patient sample results.
Atellica CH 930	Valve leakage	The worst-case valve leak identified may cause a droplet of 'CH wash or CH-conditioner solution' to drip into the Atellica CH 930 cuvette while samples are being processed. The failure does not occur until the valve has been in use for over 1 million cycles (1-2 years depending on the sample volume run on the instrument). A potentially discrepant result may be reported from the analyzer if fluids drip into the cuvette during processing due to a malfunction of the valve.

Risk to Health

Product	Risk to Health
Atellica IM 1300 Atellica IM 1600	This issue leads to a gradual bias in results. Mitigations include the detection of a trend in quality control results leading to follow-up investigations with no impact to patient results. Siemens is not recommending a lookback of previously generated results due to this issue.
Atellica CH 930	When this issue occurs, the potential exists for the instrument to generate erroneously elevated or depressed patient results. Mitigations would include correlation to clinical information such as clinical presentation, other laboratory and diagnostic results and patient history. Siemens is not recommending a review of previously generated results due to the remote probability of a clinically significant impact on patient results.

Actions to be Taken by the Customer

The following actions must be taken until your system has been serviced to replace any leaking components.

1. When reporting results, ensure that all QC results are within the laboratory acceptable range before releasing results.

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2. On the Atellica CH930 Analyzer:
   If any water droplets are observed on the tips of any Reaction Wash Station or Dilution Wash Station probes, contact Siemens service so that the instrument can be checked for valves that may be failing.

3. On the Atellica IM 1300 or Atellica IM 1600 Analyzers:
   If any water droplets are observed forming at the tips of any Reagent probes, contact Siemens service so that the instrument can be checked for valves that may be failing.

- 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 Technical Support representative.
- Siemens Service representative will be contacting your laboratory to check and replace the identified valves.

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 Healthineers.

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FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASI21-02.A.OUS dated May, 2021 titled “A manufacturing defect in some valves may cause them to leak”. Please read the question below and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

Question 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 Healthineers technical support representative.

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