Siemens Healthcare Diagnostics GmbH, SHS EMEA CEET QT, Siemensstrasse 90,
1210 Vienna

Name M.A. Roland Ertl
Department SHS EMEA CEET QT

Telephone +43 51707-38274
Mobile +43 (664) 8011738274
E-mail roland.re.ertl@siemens-healthineers.com

Date May 21, 2020

Document Ref# ASI20-02.A.OUS

Urgent Field Safety Notice:

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer

Insufficient Sample May Not Be Detected on Selected Sample Containers

Dear Sirs,

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

Table 1. Atellica® Solution Affected Product:

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

Reason for Correction

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

Siemens Healthcare Diagnostics Inc. through the investigation of customer complaints has determined that there is a potential to generate results on samples with insufficient volume when processed in the sample tubes listed in Table 2. Only sample containers listed in Table 2 are affected.

The Minimum Required Volume (MRV) defined in the Atellica Operator Guide SMN 11069101, Section 9 Sample Management must be used when sample containers are in use. However, if the volume of sample in the container does not meet the MRV, the shape of the tube bottom in conjunction with the sample probe movement may give a false total sample volume that fails to trigger an “Insufficient Sample” flag. This failure to trigger an “insufficient sample” flag does not occur for every true case of insufficient sample volume. Any sample type (quality control, calibrators and patient samples) may be affected and erroneously depressed results may be generated. The magnitude of the impact depends on the amount of sample that failed to aspirate, with an increased effect as the sample volume aspirated is reduced.

Table 2. Atellica Solution Sample Containers affected:

Sample Cup	Description	Volume
1	Atellica Tube Top Sample Cups - Siemens SMN 11069061	1mL
2	Atellica Tube Top Sample Cups - Siemens SMN 11069062	2mL
3	Sarstedt 62.612 - 15.3 x 92 False Bottom	4 mL

Siemens investigation has shown that if the minimum required volume of sample is present in any of the containers listed in Table 2, all results will be correctly processed and reported.

Siemens has not received any reports of illness or adverse events due to this issue.

Quality control samples may or may not detect this issue.

Siemens is actively working to investigate the root cause and customers will be notified when additional information is available.

Risk to Health

When this issue occurs, the potential exists to report erroneously depressed immunoassay results. The magnitude of difference in results is proportional with the amount of insufficient sample being pipetted. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing and/or serial testing. As the likelihood of an insufficient sample and a subsequent clinically significant effect is unlikely, Siemens Healthineers is not recommending a review of previously generated results.

Actions to be Taken by the Customer

1) If sample containers listed in Table 2 are not in use in your laboratory, no action is required beyond completion of the Field Correction Effectiveness Check Form attached to this letter.

2) The following actions must be taken when using any of the sample containers listed in Table 2.

   The IM Analyzer has a minimum required sample volume for any reportable result. The volume depends on the following factors:
   - Sample volume for the assay
   - Sample volume to prime the sample tip
   - Volume of unusable sample for the sample container

   Detailed information on how to calculate the minimum required sample volume is available in the Atellica Operator Guide SMN 11069101 Section 9 Sample Management.
   Siemens recommends following the operating instructions and ensuring that there is sufficient sample available in any sample container.

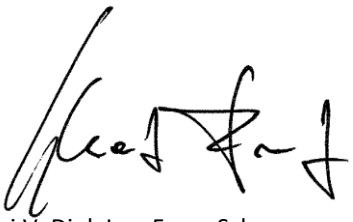
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your 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 Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE

i.A. Dr.in Brigitte Gassner
Product Manager Austria & SEE