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Urgent Field Safety Notice:

Atellica® Solution

Free Beta Human Chorionic Gonadotropin (FBHCG) Not Meeting Detection Capability

To whom it may concern,

Our records indicate that your facility has received the following product:

Table 1. Atellica® IM Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing Date (YYYY-MM-DD)
Atellica IM FBHCG	10733009	00630414245805522110342023092 9	52211034	2023-09-29	2022-10-11
Atellica IM FBHCG	10733009	00630414245805542640372024041 9	54264037	2024-04-19	2023-05-10

Reason for Correction

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

Siemens Healthcare Diagnostics Inc. has confirmed through internal investigation that the Free Beta Human Chorionic Gonadotropin (FBHCG) assay does not meet the Limit of Quantitation (LOQ), Limit of Blank (LoB), and Limit of Detection (LoD) as stated in the Instructions for Use (IFU) for the Atellica IM Analyzers.

Siemens has defined an interim LOQ for the FBHCG assays for customers to utilize for the lots listed in Table 1 and future lots. Furthermore, future lots will be aligned to these interim values. Refer to Table 2 for the interim LOQ values.

Since the LoB and LoD fall below the assay measuring interval as defined by the LOQ, the establishment of an interim LoB and LoD was not conducted nor indicated.

Table 2: FBHCG Current IFU and Interim LOQ (IU/L (ng/mL))

Platform	Current IFU LOQ	Interim LOQ
Atellica IM	0.14	1.69

Siemens Healthcare Diagnostics is currently investigating the root cause of the issue.

Risk to Health

No risk to health is expected as a result of this issue. While the lowest measured value will be increased from the IFU, the revised interim lower limit of quantitation remains well below values observed in pregnant individuals.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Create a linearity range utilizing the interim LOQ values provided in Table 2 with instructions available in the Atellica Solution Operator's Guide and/or Online Help.
- All Atellica IM FBHCG assay kit lots can continue to be utilized with the interim LOQ until further notice. Results below the newly defined linearity range are flagged as 'Below Linearity' and may be reported as less than the interim LOQ.
- 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 Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl*
Reason: I am approving this document
Date: Sep 6, 2023 11:53 GMT+2

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA

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