Urgent Field Safety Notice

AIMC 23-01.A.OUS

November 2022

Atellica® Solution

Atellica IM Free Prostate-Specific Antigen (fPSA) Negative Bias with Kit Lots Ending in 104

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

Table 1. Atellica IM Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Batch Number (Kit Lot #)	Exp. Date (YYYY-MM-DD)	Mfg. Date (YYYY-MM-DD)
Atellica IM Free Prostate-Specific Antigen (fPSA)	10995577	(01)00630414599014(10)83663104(17)20231111	83663104	2023-11-11	2021-11-21
		(01)00630414599014(10)89551104(17)20231111	89551104		
		(01)00630414599014(10)92649104(17)20231111	92649104		
		(01)00630414599014(10)00306104(17)20231111	00306104		
		(01)00630414599014(10)00307104(17)20231111	00307104		

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 a negative bias at the lower end of the analytical measuring range with Quality Controls (QC) and patient samples on Atellica IM fPSA kit lots ending in 104. QC may not detect the negative bias. Refer to Table 2 for summary of biases observed for all reagent and calibrator lot combinations during internal testing.

Table 2. Atellica IM fPSA Kit Lots Ending in 104 Results vs. Other In-Date Lots

fPSA Sample Range	Average Bias	Range of Bias
<0.3 ng/mL (µg/L)	-19%	-9% to -29%
0.3 to 2.0 ng/mL (µg/L)	-13%	-3% to -20%
>2.0 ng/mL (µg/L)	-1%	7% to - 9%

This issue is limited to Atellica IM fPSA kit lots ending in 104 only; alternate lots are available.

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

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East Walpole, Massachusetts 02032

Risk to Health

When this issue occurs, there is a potential for erroneously depressed free PSA patient results. This may confound the discrimination between prostate cancer and benign prostatic disease. Mitigations include correlation of test results with patient's clinical signs and symptoms, additional testing such as total PSA results, imaging studies, and Digital Rectal Examination. A review of previously generated results is not recommended as results would not be used in isolation.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of and discard the lots listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- 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.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

Legal Manufacturer SRN: US-MF-000016560

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