



رؤية عمان 2040
Vision
نتقدم بثقة
Moving Forward
With Confidence

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 231 dated 18/12/2022 Regarding NCMDR recall of Siemens Healthcare Diagnostics GmbH from (mfr: Siemens Healthcare Diagnostics GmbH).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADDC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 231 / 2022

24 -05-1444 H

18 -12-2022

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رؤية عُمان
2040
Oman Vision

Recall of Atellica IM Free Prostate-Specific Antigen (fPSA) from Siemens Healthcare Diagnostics GmbH.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=18372
Product	Atellica IM Free Prostate-Specific Antigen (fPSA).
Description	In-vitro diagnostics - immunological products.
Manufacturer	Siemens Healthcare Diagnostics GmbH.
Local agent	Bahwan Healthcare Center.
The affected products	SMN: 10995577 Kit Lot # 83663104, 89551104, 92649104, 00306104, 00307104.
Reason	Negative Bias with Kit Lots Ending in 104.
Action	1. Discontinue use of and discard the lots listed in Table 1, found in the attached recall. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General



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.

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.
- 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.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

Legal Manufacturer SRN: US-MF-000016560

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

FIELD CORRECTION EFFECTIVENESS CHECK

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

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) AIMC 23-01.A.OUS dated November 2022 regarding Atellica IM Free Prostate-Specific Antigen (fPSA) Negative Bias with Kit Lots Ending in 104. 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 []
2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes [] No []

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Table with 2 columns: Product Description (Product Catalog #/ SMN/ Lot #) and Quantity of Affected Product in Inventory (Discarded/ Replacement Quantity Required). Row 1: Atellica IM Free Prostate-Specific Antigen (fPSA) SMN 10995577 / kit lots 83663104, 89551104, 92649104, 00306104, 00307104.

Name of Person Completing Questionnaire:
Title:
Institution: Instrument Serial Number:
Street:
City: State:
Phone: Country:
Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXX.

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