Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

تتقدم بثقة Moving Forward with Confidence | رؤية عُمان 2040

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 173 **dated** 21/8/23 **Regarding NCMDR FSCA of Atellica® CH 930 Analyzer 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**

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Circular No. 173 / 2023

05 -02-1445 H

21 -08-2023

Field Safety Corrective Action of Atellica® CH 930 Analyzer from Siemens Healthcare Diagnostics GmbH

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19641
Product	Atellica® CH 930 Analyzer.
Description	IVD.
Manufacturer	Siemens Healthcare Diagnostics GmbH.
Local Agent	Diamond Stone Investment.
The affected products	Refer to "Table 1" in the attachment
Reason	A potential for reagent carryover on the Atellica CH 930 resulting in a positive bias that could impact quality control (QC), patient samples, and calibrator results with specific assays as listed in Tables 2 – 5 in the attachment.
Action	1. Perform the instructions provided in the "Additional Information" section in the attachment. 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

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

PADC
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

SIEMENS Healthineers

Urgent Field Safety Notice

ACHC23-01.C.OUS

July 2023

Atellica® CH 930 Analyzer

Reagent Carryover from Atellica CH Total Bilirubin_2 (TBil_2), Atellica CH LDL Cholesterol (LDLC), Atellica CH Gamma-Glutamyl Transferase (GGT) and Atellica CH HDL Cholesterol (HDLC)

Our records indicate that your facility may have received any of the following products:

Table 1. Atellica CH Products Causing Carryover

Assay	Test Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Atellica CH Total Bilirubin_2	TBil_2	11097531	00630414595818	All lots
Atellica CH LDL Cholesterol	LDLC	11537214	00630414611037	All lots
Atellica CH Gamma-Glutamyl Transferase	GGT	11097597	00630414596440	All lots
Atellica CH HDL Cholesterol	HDLC	11537213	00630414610832	All lots

Reason for Correction

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

If you do not run any of the assays listed in Table 1, there are no actions for your laboratory to take at this time.

Through a proactive internal screening, Siemens Healthcare Diagnostics Inc. has identified the potential for reagent carryover on the Atellica CH 930 resulting in a positive bias that could impact quality control (QC), patient samples, and calibrator results with specific assays as listed below in Tables 2 - 5. The addition of Reagent Probe Cleaner 2 (RPC2) wash mitigates this issue.

The resolution for the reagent carryover issues is implemented in Atellica Solution Software (SW) v1.25.4 SP3 and v1.28 which will be released soon. In the interim, please follow the instructions in the "Actions to be Taken by the Customer" section until all Atellica CH 930 Analyzers in your laboratory are updated to either SW v1.25.4 SP3 or v1.28 and higher.

511 Benedict Avenue
Tarrytown, N.Y. 10591

Reagent Carryover from Atellica CH Total Bilirubin_2 (TBil_2), Atellica CH LDL Cholesterol (LDLC), Atellica CH Gamma-Glutamyl Transferase (GGT) and Atellica CH HDL Cholesterol (HDLC)

Risk to Health

For Glucose, Lipase, and Magnesium if this issue occurs there is a potential for erroneously increased patient results. Biases near medical decision levels would not be expected to lead to a clinically significant impact on patient management. Mitigations include patient history, signs and symptoms, and additional laboratory findings.

For Uric Acid, if this issue occurs there is a potential for erroneously increased patient results with biases that could lead to additional follow up testing for hyperuricemia. Mitigations include patient history, signs and symptoms, and additional laboratory findings including repeat testing.

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.
- Perform the instructions provided in the "Additional Information" section.
- 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.

Additional Information

If your laboratory has multiple Atellica CH 930 Analyzers, separate the assays as follows:

- Perform testing of TBil_2 on a separate analyzer from Glucose Oxidase (GluO)
- Perform testing of LDLC on a separate analyzer from Lipase (Lip)
- Perform testing of GGT on a separate analyzer from Magnesium (Mg)
- Perform testing of HDLC on a separate analyzer from Uric Acid (UA)

If you choose not to or are unable to separate the assays as indicated above, batch testing of GluO, Lip, Mg and UA may be performed.

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Reagent Carryover from Atellica CH Total Bilirubin_2 (TBil_2), Atellica CH LDL Cholesterol (LDLC), Atellica CH Gamma-Glutamyl Transferase (GGT) and Atellica CH HDL Cholesterol (HDLC)

Note: When batch testing impacted assays, GluO, Lip, Mg and UA, an RPC2 wash mitigation must be initiated after completion of tests with the assay causing carryover, TBil_2, LDLC, GGT and HDLC, respectively. Any of the following will initiate the RPC2 wash:

- After the Atellica CH 930 Analyzer has been in standby status for 12 minutes.
- Upon completion of any open channel assay.
- A restart of the Atellica CH 930 Analyzer.

Representative observed biases from Siemens internal testing are shown in Tables 2 - 5.

Table 2. Impact of TBil_2 Carryover on GluO Results

Sample	GluO mg/dL (mmol/L)	GluO After TBil_2 mg/dL (mmol/L)	Bias mg/dL (mmol/L)	% Bias
Serum QC L1	60 (3.3)	68 (3.8)	8 (0.4)	13%
Serum QC L2	112 (6.2)	121 (6.7)	9 (0.5)	8%
Serum QC L3	342 (19.0)	346 (19.2)	4 (0.2)	1%

Table 3. Impact of LDLC Carryover on Lip Results

Sample	Lip U/L	Lip After LDLC U/L	Bias U/L	% Bias
Serum QC L1	18	34	16	89%
Serum QC L2	51	64	13	25%
Serum QC L3	144	155	11	8%

Table 4. Impact of GGT Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After GGT mg/dL (mmol/L)	Bias mg/dL (mmol/L)	% Bias
Serum QC L1	1.08 (0.44)	1.34 (0.55)	0.26 (0.11)	24%
Serum QC L1 & L2 mixture	1.64 (0.67)	1.88 (0.77)	0.24 (0.10)	15%
Serum QC L2	2.61 (1.07)	2.83 (1.16)	0.22 (0.09)	8%
Serum QC L3	4.32 (1.78)	4.53 (1.86)	0.21 (0.09)	5%

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Table 5. Impact of HDLC Carryover on UA Results

Sample	UA mg/dL (µmol/L)	UA After HDLC mg/dL (µmol/L)	Bias mg/dL (µmol/L)	% Bias
Serum QC L1	3.3 (196)	5.1 (303)	1.8 (107)	55%
Serum QC L2	5.4 (321)	7.7 (458)	2.3 (137)	43%
Serum QC L3	8.8 (524)	11.2 (666)	2.4 (143)	27%

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

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