



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 49 dated 16/3/2023 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



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

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



Circular No. 49/2023

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16 -03-2023

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2040
Oman Vision

Field Safety Corrective Action of Atellica CH 930 Analyzer from Siemens Healthcare Diagnostics Gm.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18463
Product	Atellica CH 930 Analyzer.
Description	Clinical chemistry-specific protein IVDs & Clinical chemistry substrate IVDs.
Manufacturer	Siemens Healthcare Diagnostics GmbH.
Local Agent	Bahwan Healthcare Center.
The affected products	Assay: Atellica CH LDL Cholesterol Direct, Atellica CH Total Protein II, Atellica CH Triglycerides (concentrated), Atellica CH Triglycerides_2. Refer to the attached FSN for more details.
Reason	A potential for reagent carryover impacting Magnesium (Mg) quality control (QC), patient samples, and calibrator results. Internal testing has shown that the impact on Mg test results can vary.
Action	1. Perform the instructions provided in the "Additional Information" section in the attached FSN. 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® CH 930 Analyzer

Reagent Carryover from LDL Cholesterol Direct (DLDL), Total Protein II (TP), Triglycerides (Trig), and Triglycerides_2 (Trig_2) Impacting Magnesium (Mg) Results

Our records indicate that your facility may have received 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 LDL Cholesterol Direct	DLDL	11097632	00630414596181	All lots
Atellica CH Total Protein II	TP	11097604	00630414596372	All lots
Atellica CH Triglycerides (concentrated)	Trig	11097591	00630414596495	All lots
Atellica CH Triglycerides_2	Trig_2	11537222	00630414610955	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 provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed through customer complaints the potential for reagent carryover impacting Magnesium (Mg) quality control (QC), patient samples, and calibrator results. Internal testing has shown that the impact on Mg test results can vary.

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.

Investigation into the carryover from the assays (DLDL, TP, Trig, Trig_2) in Table 1 indicates that the addition of Reagent Probe Cleaner 2 (RPC2) wash prevents this issue.

This issue is resolved by the addition of a Reagent Probe Cleaner 2 (RPC2) wash to the assays listed in Table 1 and will be implemented in Atellica Solution Software (SW) v1.27 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 SW v1.27 or higher.

Reagent Carryover from LDL Cholesterol Direct (DLDL), Total Protein II (TP), Triglycerides (Trig), and Triglycerides_2 (Trig_2) Impacting Magnesium (Mg) Results

Risk to Health

Worst case, there is a potential for erroneously increased magnesium patient results, which may lead to additional investigation for hypermagnesemia or delayed investigation for hypomagnesemia. Mitigations include signs and symptoms, additional laboratory findings, and repeat testing. A review of previously generated results is not recommended as patient results would not be used in isolation, rather results would be used in conjunction with overall clinical presentation.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- 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 DLDL, TP, Trig and Trig_2 on an analyzer separate from Mg.

If you choose not to separate the assays as indicated above, batch testing of Mg may be performed.

Note: When batch testing Mg, an RPC2 wash mitigation must be initiated after completion of DLDL, TP, Trig and Trig_2. 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.

Reagent Carryover from LDL Cholesterol Direct (DLDL), Total Protein II (TP), Triglycerides (Trig), and Triglycerides_2 (Trig_2) Impacting Magnesium (Mg) Results

The maximum observed biases from Siemens and customer data are shown in Tables 2 - 5.

Table 2. Impact of DLDL Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After DLDL mg/dL (mmol/L)	% Bias
Serum QC L1	0.91 (0.37)	1.67 (0.69)	84%
Serum Sample	2.31 (0.95)	2.90 (1.19)	26%

Table 3. Impact of TP Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After TP mg/dL (mmol/L)	% Bias
Serum QC L1	0.93 (0.38)	1.00 (0.41)	8%
Serum QC L2	2.46 (1.01)	2.53 (1.04)	3%
Serum QC L3	3.94 (1.62)	4.04 (1.66)	3%

Table 4. Impact of Trig Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After Trig mg/dL (mmol/L)	% Bias
Serum QC L1	0.91 (0.37)	1.48 (0.61)	63%
Serum Sample	2.31 (0.95)	2.68 (1.10)	16%
Serum QC L3	3.94 (1.62)	4.00 (1.64)	2%

Table 5. Impact of Trig_2 Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After Trig_2 mg/dL (mmol/L)	% Bias
Serum Sample	1.83 (0.75)	2.77 (1.14)	51%
Serum Sample	2.83 (1.16)	3.74 (1.54)	32%

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

Reagent Carryover from LDL Cholesterol Direct (DLDL), Total Protein II (TP), Triglycerides (Trig), and Triglycerides_2 (Trig_2) Impacting Magnesium (Mg) Results

FIELD CORRECTION EFFECTIVENESS CHECK

Reagent Carryover Impacting Magnesium Results

This response form is to confirm receipt of the enclosed Siemens Healthcare Urgent Field Safety Notice ACHC23-01.B.OUS dated January 2023 regarding Reagent Carryover from LDL Cholesterol Direct (DLDL), Total Protein II (TP), Triglycerides (Trig), and Triglycerides_2 (Trig_2) Impacting Magnesium (Mg) Results.

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. Is your laboratory currently running any of the assays in Table 1 on the Atellica CH 930? Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

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.