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

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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.....97..... dated 20/05/12 Regarding FSN of Atellica CH Reaction Cuvette Segment from Siemens Healthcare

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**

ص . ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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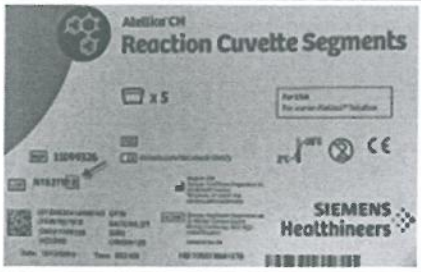
Circular No. 97 / 2020

26 -Ramadhan-1441 H

20 -May-2020

Field Safety Corrective Actions (FSCA) of Atellica CH Reaction Cuvette Segment from Siemens Healthcare

Source of FSN	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=15148
Product	Atellica CH Reaction Cuvette Segment-IVDs
Manufacturer	Siemens Healthcare Diagnostics Inc
The affected products	Material Number: 11099326 kit lots ending in "17" or "18" "19" and above are potentially impacted
Local Agent	New Source
Reason for FSN	Siemens Healthcare Diagnostics Inc. through the investigation of customer complaints has determined that a small percentage (<0.5) of Atellica CH Reaction Cuvette Segment may have cuvette defects allowing water from the water bath to contaminate the interior of the cuvette
Action	Customers should run Atellica CH Carbon Dioxide, concentrated (CO2_c) assay in 300 replicates to determine if any of the cuvette positions are impacted. - If you DO have CO2_c in your inventory, proceed to Appendix 1. (See attachment) - If you DO NOT have CO2_c in your inventory, proceed to Appendix 2. (See attachment) •This action should be repeated each time cuvette segments are replaced (4 months). •Please review this letter with your Medical Director. •If you have received any complaints of illness or adverse events associated with the products listed in Table 1. (See attachment) immediately contact your local Siemens Healthineers Customer Care Center representative and the E-mail mentioned below
Product image	
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Appendix 1: Required of all customers who have CO2_c (reagent SMN 11097521, calibrator SMN 11099401) in their inventory.

1. Ensure that your Atellica CH 930 analyzer is in standby or ready mode.
2. **(New Information)** If your Laboratory utilizes comma "," separators (rather than period ".") then it will be necessary to change the Display Language to English, by following the steps in the Atellica Solution Online Help, **"About Regional Settings in General Setup". Note:** The language change is only required to complete the instructions provided in this letter. Restart is required when changing languages. In addition, refer to New Information in Appendix 4 last bullet.
3. Run 300 replicates of CO2_c calibrator as indicated in Appendix 3. This may take approximately 15 minutes of processing time on the analyzer.
4. Determine the mean value of the 300 calibrator replicates. Details provided in Appendix 4.
5. If all individual calibrator results are ≤12% of the mean calibrator value, no further action is required, and you can continue to process patient samples.
6. If any individual calibrator result is >12% of the mean calibrator value, please contact Siemens Customer Care Center to determine additional action to be taken prior to processing patient samples.
7. Ensure that steps 1-6 are followed each time cuvette segments are replaced on the analyzer.

Appendix 2: Required of all customers who do not have CO2_c (reagent SMN 11097521, calibrator SMN 11099401) in their inventory.

1. Run all patient samples in duplicate for every assay except for Sodium, Potassium, and Chloride.
2. Follow your established internal procedures to determine if additional testing is needed to identify samples with suspected discordance and to determine if the patient sample result is accurate.
3. If discordance is identified, please contact your Siemens Customer Care Center to determine additional action to be taken prior to processing patient samples.

Note: Siemens Customer Service is working to proactively provide CO2_c reagent and calibrator to customers who do not routinely run CO2_c in their laboratory. If you have not received this shipment, please contact your customer service representative. Once CO2_c is received by your laboratory follow steps 1-5 in Appendix 1.

511 Benedict Avenue
Tarrytown, NY 10591

SIEMENS Healthineers

Updated Follow up Urgent Field Safety Notice
ACHC20-05.C.OUS
March 2020

Atellica® CH Analyzer

Atellica® CH 930 Analyzer – Potential for Inaccurate Test Results Associated with Reaction Cuvette Segments

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

Table 1. Atellica CH 930 Affected Product(s)

Product	Siemens Material Number (SMN)	Kit lots
Atellica CH Reaction Cuvette Segment	11099326	Kit lots ending in "19" and above

Reason for Correction

Siemens Healthcare Diagnostics Inc. issued a Follow up Urgent Field Safety Notice ACHC20-05.B.OUS in February 2020 to inform customers of a cuvette defect which impacts all cuvette segment kit lots ending in "19" and above.

In the UFSN, ACHC20-05.B.OUS, the operator was required to export carbon dioxide (CO2_c) data using the **Worklist>Worklist Overview>Statistics** button (Appendix 4 bullet 1). Laboratories utilizing comma "," separators (rather than period ".") with patient sample results have observed that the exported data file does not present the values required to assess whether any onboard cuvette segments must be replaced.

Siemens is providing additional instructions, if your laboratory utilizes comma "," separators (rather than period ".") in Appendix 1 Step 2 (New Information) to successfully evaluate the data and determine if cuvette segments are acceptable for patient sample testing.

Risk to Health

When an affected cuvette is used for testing, the potential exists to report erroneous patient results depending on the analyte. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing and/or serial testing. As the likelihood of an affected cuvette and a subsequent clinically significant effect is unlikely, Siemens Healthineers is not recommending a lookback.

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