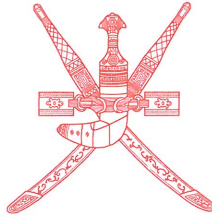


# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للأدوية  
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.....<sup>73</sup>..... dated <sup>24/3/2020</sup>..... Regarding recall of Atellica CH Reaction  
Cuvette Segment from Siemens Healthcare

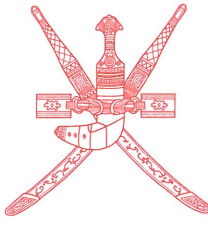
Copy to:

- 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

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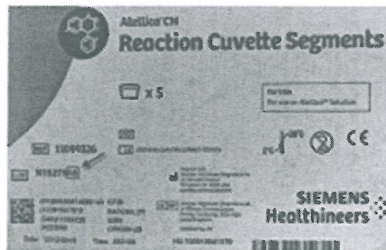
Circular No. 73 / 2020

01 -02-1441 H

26 -03-2020

Ref: 51/2020

## Recall of Atellica CH Reaction Cuvette Segment from Siemens Healthcare

Source of Recall	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=15118">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=15118</a>
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 Recall	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 (CO <sub>2</sub> _c) assay in 300 replicates to determine if any of the cuvette positions are impacted. - If you DO have CO <sub>2</sub> _c in your inventory, proceed to Appendix 1 - If you DO NOT have CO <sub>2</sub> _c in your inventory, proceed to Appendix 2. •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, 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 Director of Medical Device Control contact E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Directorate General of Pharmaceutical Affairs & Drug Control  
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

