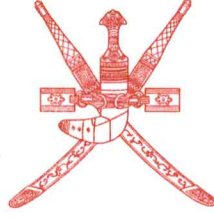


# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للصحة  
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. 209..... dated 8/11/2020 Regarding NCMDR Field Safety Corrective Action of Sofia SARS Antigen FIA Package Insert from (mfr: Quidel Corporation).

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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مسقط

Circular No. 209/2020

22 -03-1442 H

08 -11-2020

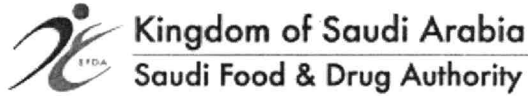
Field Safety Corrective Action of Sofia SARS Antigen FIA Package Insert from Quidel Corporation.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=15415">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=15415</a>
Product	Sofia SARS Antigen FIA Package Insert.
Description	Coronavirus antigen detection test system.
Manufacturer	Quidel Corporation.
Local agent	Health for All.
The affected products	1438900EN00 (03/20) and 1438901EN00 (05/20).
Reason	Use of the specific viral transport medium products may result in False-positive results. Directly testing from specimens (NS or NP swab) is recommended.
Action	<ol style="list-style-type: none"><li>1. Discontinue the use of affected package inserts.</li><li>2. Access the updated instructions for use labeling which can be located by going to <a href="http://quidel.com/docs">quidel.com/docs</a> and selecting the Sofia SARS Antigen FIA Package Insert document.</li><li>3. In the event that your facility has used Remel viral transport media products (e.g., M4, M4RT, M6), please contact Quidel Technical Support to discuss your results.</li><li>4. Contact local agent for remedial action.</li></ol>
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 through an E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General





## Medical Devices Sector

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# NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

## U.S FDA Recall

**Reference Number:** mdprc 036 10 20 000

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**Date submitted:** 10/29/2020

<b>Manufacturer:</b>	Quidel Corporation
<b>Device Type:</b>	Sofia SARS Antigen FIA Package Insert
<b>Description:</b>	Coronavirus antigen detection test system.
<b>Medical Device Identifier:</b>	1438900EN00 (03/20) and 1438901EN00 (05/20)
<b>Reason of Field Safety Corrective Action:</b>	Use of the specific viral transport medium products may result in False-positive results. Directly testing from specimens (NS or NP swab) is recommended.
<b>Remedy Action:</b>	Customers were asked to take the following actions: 1) Discontinue the use of affected package inserts. 2) Access the updated instructions for use labeling which can be located by going to <a href="https://quidel.com/docs">quidel.com/docs</a> and selecting the Sofia SARS Antigen FIA Package Insert document. 3) In the event that your facility has used Remel viral transport media products (e.g., M4, M4RT, M6), please contact Quidel Technical Support to discuss your results.
<b>Athorized Representative/Importer/Distributor:</b>	ABDULLA FOUAD HOLDING COMPANY
<b>Report Source:</b>	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=183267">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=183267</a>
<b>Source Ref. Number:</b>	Z-0124-2021
<b>SFDA Comments:</b>	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
<b>Attachments:</b>	No Attachments

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