Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 131 **dated** 25/9/2024 **Regarding SFDA Field Safety Corrective Action Xpert Xpress CoV-2 plus from (mfr: Cepheid).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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سلطنة عُمان
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Circular No. 131 **/ 2024**

21-03-1446 H
25-09-2024

Field Safety Corrective Action of Xpert Xpress CoV-2 plus from Cepheid.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/104
Product	Xpert Xpress CoV-2 plus.
Manufacturer	Cepheid.
Local agent	Advance Healthcare Solution.
The affected products	Attached.
Reason	Some of the above product customers have experienced a higher number of E5007 Probe Check Too Low errors than would typically be expected when using these tests and their intended use specimen types. E5007 yields a non-determinate result (Error).
Action	1. If you experience an E5007 error when using a cartridge, repeat testing on another cartridge. If another E5007 error occurs, or if you have been experiencing intermittent E5007 errors on tests from these lots, Cepheid will replace any remaining tests that you currently have in inventory from lots. If you are experiencing issues and you would like to request replacement product, please refer to the attachment for instructions, stop using, and then dispose of any remaining tests from the applicable lots that are in your inventory. 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: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Cepheid

September 10, 2024

URGENT FIELD SAFETY NOTICE
Xpert® Xpress CoV-2 *plus*

Legal Manufacturer	Single Registration Number (SRN)	Unique Device Identifier (UDI)	Catalogue Number	Batch Number	Lot Number	Expiration Date
Cepheid	US-MF-000010979	07332940007928	XP3SARS-COV2-10	1001425217	15407	2025-Apr-13

Attention Cepheid Customer,

Cepheid is initiating a field action for Xpert Xpress CoV-2 *plus*. This letter contains important information that requires your immediate attention for this intermittent and lot specific issue.

ISSUE:	Cepheid has received reports that some of our customers have experienced a higher number of E5007 Probe Check Too Low errors than would typically be expected when using these tests and their intended use specimen types. E5007 yields a non-determinate result (Error).
IMPACT:	As with all Xpert tests, no patient results are reported when the test yields a non-determinate result (Error) and the user is instructed to retest on a new cartridge. Customers who conduct a retest will experience a delay in final test results.
ACTION:	If you experience an E5007 error when using a cartridge, repeat testing on another cartridge. If another E5007 error occurs, or if you have been experiencing intermittent E5007 errors on tests from these lots, **Cepheid will replace any remaining tests that you currently have in inventory from lots. If you are experiencing issues and you would like to request replacement product, you should document (see Response Form), stop using, and then dispose of any remaining tests from the applicable lots that are in your inventory.** The Customer Response Form can be completed and emailed to CFQ@cepheid.com or faxed to +1 (408) 716-3143. Your response will be received at the email address above; however, Cepheid will not reply or send a confirmation email related to your response. The replacement product should ship to you within 5 business days following receipt of the Customer Response Form.
RESOLUTION:	The error was investigated, and the root cause was determined to be production lot specific. Cepheid is implementing changes to correct the issue and to prevent future occurrences.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) to another laboratory, please provide them with a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please refer to the table on the following page for applicable contact information.

Cepheid

We apologize for the inconvenience this may have caused your laboratory and appreciate your continued partnership.

Sincerely,

Angel Lopez
Angel Lopez (Sep 11, 2024 10:17 PDT)

Angel Lopez
Senior Director, Post-Market Quality

Region	Telephone	Technical Support Email
United Arab Emirates, Other Middle East Countries	+971 4 550 8617	support@cepheideurope.com

904 Caribbean Drive Sunnyvale, CA 94089 USA www.cepheid.com

Cepheid

Please return only completed Customer Response Forms to Cepheid by email CFQ@cepheid.com or FAX +1 (408) 716-3143

CUSTOMER RESPONSE FORM

Xpert® Xpress CoV-2 *plus*

Customer / Institute Name:	
Ship to Address:	
Phone Number:	
E-mail:	

Please select below:

☐ I acknowledge receipt of this letter and I am not requesting any replacement product.

OR

☐ I acknowledge receipt of this letter and certify that I have Xpert Xpress CoV-2 *plus*, catalog XP3SARS-COV2-10 batch 1001425217 (lot 15407). I am requesting replacement product.

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001425217 (lot 15407)

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert Xpress CoV-2 *plus*, catalog XP3SARS-COV2-10 batch 1001425217 (lot 15407).

Print Name:_____ **Print Title:**_____

Signature:_____ **Date:** _____

904 Caribbean Drive Sunnyvale, CA 94089 USA www.cepheid.com