



September 10, 2024

URGENT FIELD SAFETY NOTICE

Xpert® Xpress CoV-2/Flu/RSV *plus* and 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	Refer to the product list at the end of the letter
		07332940008000	XP3COV2/FLU/RSV-10	Refer to the product list at the end of the letter

Attention Cepheid Customer,

Cepheid is initiating a field action for select lots of Xpert Xpress CoV-2/Flu/RSV *plus* and 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 identified on the product list 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 from the product list, 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 listed on the product list. 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) listed below 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.

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

Sincerely,

Somesh Lalithraj
Somesh Lalithraj (Sep 11, 2024 12:49 PDT)

Somesh Lalithraj
Vice President, Global Quality

Region	Telephone	Technical Support Email
US	+1 888 838 3222 Press 2	techsupport@cepheid.com
Australia and New Zealand	+1800 107 884 (AU) +0800 001 028 (NZ)	techsupportANZ@cepheid.com
Brazil and Latin America	+55 800-941-4610 option 1.	latamsupport@cepheid.com
China	+86 400 821 0728	tscn@cepheid.com
France	+33 563 825 319	support@cepheideurope.com
Germany	+49 21514474524	support@cepheideurope.com
India, Bangladesh, Bhutan, Nepal, and Sri Lanka	+91 124 6689450	techsupportindia@cepheid.com
Italy	+39 029 129 4615	support@cepheideurope.com
Japan	0120-228-899	techsupportapac@cepheid.com
South Africa	+27 87 006 1550	support@cepheideurope.com
United Kingdom	+44 3303 332 533	support@cepheideurope.com
Belgium	+32 93967953	support@cepheideurope.com
Netherlands	+31 180799637	support@cepheideurope.com
Other European, and African Countries	+33 563 825 326 +33 563 825 319	support@cepheideurope.com
United Arab Emirates, Other Middle East Countries	+971 4 550 8617	support@cepheideurope.com





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

CUSTOMER RESPONSE FORM

Xpert® Xpress CoV-2/Flu/RSV *plus* and Xpert® Xpress CoV-2 *plus* (please see the product list at the end)

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 1001425219 (lot 15406) or batch 1001425217 (lot 15407). I am requesting replacement product.

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001425219 (lot 15406)

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

I acknowledge receipt of this letter and certify that I have Xpert Xpress CoV-2/Flu/RSV *plus*, catalog XP3COV2/FLU/RSV-10 batch 1001420157 (lot 19108), batch 1001421769 (lot 19208), batch 1001423027 (lot 19123), batch 1001423028 (lot 19214), batch 1001423031 (19219), batch 1001426347 (lot 19304), batch 1001426590 (lot 19305), batch 1001427284 (lot 19124), or batch 1001427285 (lot 19306). I am requesting replacement product.

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001420157 (lot 19108)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001421769 (lot 19208)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001423027 (lot 19123)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001423028 (lot 19214)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001423031 (lot 19219)





Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001426347 (lot 19304)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001426590 (lot 19305)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001427284 (lot 19124)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001427285 (lot 19306)

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert Xpress CoV-2 *plus*, catalog XP3SARS-COV2-10 batch 1001425219 (lot 15406) or batch 1001425217 (lot 15407). I will dispose of any remaining Xpert Xpress CoV-2/Flu/RSV *plus*, catalog XP3COV2/FLU/RSV-10 batch 1001420157 (lot 19108), batch 1001421769 (lot 19208), batch 1001423027 (lot 19123), batch 1001423028 (lot 19214), batch 1001423031 (19219), batch 1001426347 (lot 19304), batch 1001426590 (lot 19305), batch 1001427284 (lot 19124), or batch 1001427285 (lot 19306).

Print Name: _____

Print Title: _____

Signature: _____

Date: _____





Product List

Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Expiration Date
07332940007928	XP3SARS-COV2-10	1001425219	15406	2025-Apr-13
07332940007928	XP3SARS-COV2-10	1001425217	15407	2025-Apr-13
07332940008000	XP3COV2/FLU/RSV-10	1001420157	19108	2025-Mar-09
07332940008000	XP3COV2/FLU/RSV-10	1001421769	19208	2025-Mar-23
07332940008000	XP3COV2/FLU/RSV-10	1001423027	19123	2025-Mar-30
07332940008000	XP3COV2/FLU/RSV-10	1001423028	19214	2025-Mar-30
07332940008000	XP3COV2/FLU/RSV-10	1001423031	19219	2025-Mar-30
07332940008000	XP3COV2/FLU/RSV-10	1001426347	19304	2025-Apr-13
07332940008000	XP3COV2/FLU/RSV-10	1001426590	19305	2025-Apr-20
07332940008000	XP3COV2/FLU/RSV-10	1001427284	19124	2025-Apr-20
07332940008000	XP3COV2/FLU/RSV-10	1001427285	19306	2025-Apr-20

