

November 11, 2024

URGENT FIELD SAFETY NOTICEXpert® 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:	<p>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.</p> <p>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.</p>
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 \(Nov 12, 2024 17:59 PST\)](#)

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, certify that I have Xpert® Xpress CoV-2 *plus*, catalog XP3SARS-COV2-10 batch 1001422724 (lot 15403), batch 1001423033 (lot 15405), batch 1001427489 (lot 15410), batch 1001436341 (lot 15413), batch 1001432116 (lot 15601), batch 1001427487 (lot 15701), batch 1001428322 (lot 15701), batch 1001428868 (lot 15801) or batch 1001432122 (lot 15901). I am requesting replacement product.

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001422724 (lot 15403)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001423033 (lot 15405)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001427489 (lot 15410)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001436341 (lot 15413)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001432116 (lot 15601)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001427487 (lot 15701)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001428322 (lot 15701)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001428868 (lot 15801)

Quantity Cartridges On-hand: _____ XP3SARS-COV2-10 batch 1001432122 (lot 15901)





☐ I acknowledge receipt of this letter, certify that I have Xpert® Xpress CoV-2/Flu/RSV *plus*, catalog XP3COV2/FLU/RSV-10 batch 1001421768 (lot 19202), batch 1001423029 (lot 19217), batch 1001429918 (lot 19227), batch 1001436704 (lot 19229), batch 1001424100 (lot 19301), batch 1001432902 (lot 19321), batch 1001428865 (lot 19401), batch 1001433942 (lot 19410), or batch 1001435579 (lot 19423). I am requesting replacement product.

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001421768 (lot 19202)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001423029 (lot 19217)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001429918 (lot 19227)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001436704 (lot 19229)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001424100 (lot 19301)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001432902 (lot 19321)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001428865 (lot 19401)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001433942 (lot 19410)

Quantity Cartridges On-hand: _____ XP3COV2/FLU/RSV-10 batch 1001435579 (lot 19423)

Product Disposal Attestation: I attest that I will dispose of any remaining Xpert Xpress CoV-2 *plus*, catalog XP3SARS-COV2-10 batch 1001422724 (lot 15403), batch 1001423033 (lot 15405), batch 1001427489 (lot 15410), batch 1001436341 (lot 15413), batch 1001432116 (lot 15601), batch 1001427487 (lot 15701), batch 1001428322 (lot 15701), batch 1001428868 (lot 15801) or batch 1001432122 (lot 15901). I will dispose of any remaining Xpert Xpress CoV-2/Flu/RSV *plus*, catalog XP3COV2/FLU/RSV-10 batch 1001421768 (lot 19202), batch 1001423029 (lot 19217), batch 1001429918 (lot 19227), batch 1001436704 (lot 19229), batch 1001424100 (lot 19301), batch 1001432902 (lot 19321), batch 1001428865 (lot 19401), batch 1001433942 (lot 19410), or batch 1001435579 (lot 19423).

Print Name: _____

Print Title: _____

Signature: _____

Date: _____



Product List

Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Expiration Date
07332940007928	XP3SARS-COV2-10	1001422724	15403	23-Mar-2025
07332940007928	XP3SARS-COV2-10	1001423033	15405	06-Apr-2025
07332940007928	XP3SARS-COV2-10	1001427489	15410	27-Apr-2025
07332940007928	XP3SARS-COV2-10	1001436341	15413	22-Jun-2025
07332940007928	XP3SARS-COV2-10	1001432116	15601	25-May-2025
07332940007928	XP3SARS-COV2-10	1001427487	15701	27-Apr-2025
07332940007928	XP3SARS-COV2-10	1001428322	15701	27-Apr-2025
07332940007928	XP3SARS-COV2-10	1001428868	15801	04-May-2025
07332940007928	XP3SARS-COV2-10	1001432122	15901	25-May-2025
07332940008000	XP3COV2/FLU/RSV-10	1001421768	19202	23-Mar-2025
07332940008000	XP3COV2/FLU/RSV-10	1001423029	19217	23-Mar-2025
07332940008000	XP3COV2/FLU/RSV-10	1001429918	19227	11-May-2025
07332940008000	XP3COV2/FLU/RSV-10	1001436704	19229	22-Jun-2025
07332940008000	XP3COV2/FLU/RSV-10	1001424100	19301	06-Apr-2025
07332940008000	XP3COV2/FLU/RSV-10	1001432902	19321	01-Jun-2025
07332940008000	XP3COV2/FLU/RSV-10	1001428865	19401	04-May-2025
07332940008000	XP3COV2/FLU/RSV-10	1001433942	19410	08-Jun-2025
07332940008000	XP3COV2/FLU/RSV-10	1001435579	19423	16-Jun-2025

