October 17, 2023

URGENT FIELD SAFETY NOTICE

Xpert® Xpress CoV-2/Flu/RSV *plus*

Legal Manufacturer	Single Registration Number (SRN)	Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Exp. Date
Cepheid	US-MF-000010979	07332940008000	XP3COV2/FLU/RSV-10	All	All	N/A

Attention Cepheid Customer,

Cepheid is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Certain laboratories using the Xpert® Xpress CoV-2/Flu/RSV *plus* test and its intended use specimen types have reported higher-than-expected 'INVALID' test results with error code 5015. An 'INVALID' result (due to error code 5015) may occur during early, otherwise normal-appearing PCR amplification cycles of specimens with particularly high concentrations of SARS-CoV-2 in the specimen. The Xpert® Xpress CoV-2/Flu/RSV plus test was developed and clinically validated to provide optimal value for patient care, including design controls to reduce the frequency of erroneous results. This particular error code, which may occur with certain high concentration (titer) specimens, is due to an intentional design to reduce the risk of false positive results caused by non-specific or irregular fluorescence detection occurring early during PCR. While an observable cycle threshold (Ct) value and amplification curve may be visible, it does not meet our acceptance criteria and an INVALID result (error code 5015) is returned. However, the test continues to meet design criteria and performance specifications. Additional reasons for 'INVALID' test results include: the specimen was not properly processed, PCR is inhibited, or the specimen was not properly collected.
IMPACT:	Delays in initiating specific antiviral treatment or in implementing appropriate respiratory isolation measures may occur.
ACTION:	Cepheid is bringing this issue to the attention of our customers. Laboratories may consider implementing additional internal protocols and/or quality assurance measures to mitigate the risk of delayed results and patient management measures.
RESOLUTION:	Cepheid will be implementing additional updates to the Instructions For Use (IFU) to include more information regarding 'INVALID' results due to the 5015 error and remains committed to providing you with the highest quality products.

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 above to another laboratory, please provide them with a copy of this letter.

Please provide information on the Customer Response Form (Page 3) acknowledging receipt of this letter by email to CFQ@cepheid.com or by fax to (408) 716-3143. 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 for applicable contact information.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Somesh Lalithraj
Somesh Lalithraj (Oct 19, 2023 17:33 PDT)

Somesh Lalithraj
Vice President, Global Quality

Oct 19, 2023
Date

Region	Telephone	Technical Support Email
US	+ 1 888 838 3222 Press 2	techsupport@cepheid.com
Austria	+43 720 380 091	support@cepheideurope.com
Australia and New Zealand	+ 1800 107 884 (AU) + 0800 001 028 (NZ)	techsupportANZ@cepheid.com
Belgium and Netherlands	+33 563 825 3319	support@cepheideurope.com
Brazil and Latin America	+ 55 11 3524 8373	latamsupport@cepheid.com
Canada	+1-855-202-6160	supportcanada@cepheid.com
China	+ 86 021 5406 5387	techsupportchina@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com
Denmark	+45-80-40-02-62	support@cepheideurope.com
Germany	+49 2151 3280 100	support@cepheideurope.com
India, Bangladesh, Bhutan, Nepal, and Sri Lanka	+ 91 11 48353010	techsupportindia@cepheid.com
Italy	+ 39 800 902 567	support@cepheideurope.com
Japan	+ 0120 95 4886	support@japan.cepheid.com
Middle East	+971-4-550-8617	support@cepheideurope.com
Norway	+47-800-62-561	support@cepheideurope.com
Poland	+48 22 504 85 23	support@cepheideurope.com
Portugal	+351-800-913-174	support@cepheideurope.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com
Spain	+34-919-906-762	support@cepheideurope.com
Sweden	+46-10-555-90-50	support@cepheideurope.com
Switzerland	+ 41 44 722 50 15	support@cepheideurope.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com
Other European and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com

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

CUSTOMER RESPONSE FORM

Xpert® Xpress CoV-2/Flu/RSV *plus*

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

Please select check box, print and sign name, and date below prior to returning:

☐ I acknowledge receipt of this letter, certify that I have Xpert® Xpress CoV-2/Flu/RSV plus and understood the described issue and recommended action.

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

Signature:_____ **Date:** _____