

IMPORTANT PRODUCT NOTICE

Xpert® Xpress Strep A

Attention Cepheid Customer,

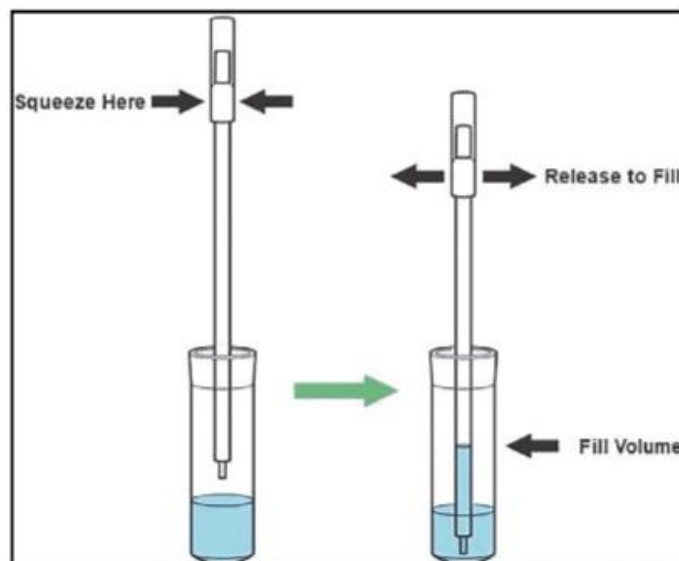
We are writing to inform you that Cepheid has initiated a field action for the product listed in the attachment. Specifically, Cepheid has become aware and has determined that pipettes packaged in our XPRSTREPA-10 or XPRSTREPA-CE-10 products may fail to dispense an adequate sample volume. In our internal testing, some pipettes have failed at a higher-than-expected rate, to aspirate the expected volume of ESwab transport medium containing the patient sample and have instead delivered a lower volume. We believe this lower volume of ESwab transport medium containing the patient sample has resulted in increased complaints from certain users mainly resulting in 'Invalid' or 'No Result' test results. Discrepant Results (False Negatives), though unlikely, can occur and we recommend continuing to follow the instructions in our Package Insert as stated below:

Per the Package Insert, a negative test result does not exclude the possibility of the presence of Streptococcus pyogenes because the test result may be affected by improper specimen collection, technical error, sample mix-up, or because the number of organisms in the sample is below the limit of detection of the test. As with many diagnostic tests, negative results from the Xpert Xpress Strep A test do not preclude a Strep A infection and should not be used as the sole basis for treatment or other patient management decisions. The results from the Xpert Xpress Strep A test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

Please note that we are working with our pipette supplier to correct this issue.

Because the pipette quality issue is intermittent, Cepheid is asking that you do the following:

When executing a test, please follow all instructions as normal per the Package Insert. Regarding using the pipette for transferring patient sample to a cartridge, please refer to the Package Insert detailing and providing a visualization of the proper squeezing of the pipette.





If, upon following this guideline for proper use of the pipette you determine that your pipette fails to aspirate an adequate volume of liquid, repeat the steps using a new pipette.

We ask that you acknowledge receipt of this Important Product Notice by responding via a web request from <https://www.cepheid.com/streppipette> (for US customer only) or by completing the enclosed Customer Response Form (email or Fax). In addition, replacement pipettes, if needed, can be requested via the above mentioned process. Please complete this activity within 10 days, so we are assured you have received this important communication. The Customer Response Form can be emailed to CFQ@cepheid.com or faxed to +1 (408) 716-3143. Your response will be received at the email address above and Cepheid does not send reply or confirmation emails related to your response.

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 a copy of this letter.

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 (Apr 24, 2023 22:12 PDT)

Apr 24, 2023

Somesh Lalithraj
Vice President, Global Quality



Region	Telephone	Technical Support Email
US	+ 1 888 838 3222, option 2	techsupport@cepheid.com
Australia and New Zealand	+ 61 1800 130 821 + 64 0800 001 028	techsupportANZ@cepheid.com
Brazil and Latin America	+ 0080 941 4610	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
Germany	+ 492151-3280-100	support@cepheideurope.com
Japan	+ 0120 95 4886	support@japan.cepheid.com
Middle East	+ 27 861 22 76 35	support@cepheideurope.com
Portugal	+ 800 913 174	support@cepheideurope.com
Spain	+ 34 919 90 6762	support@cepheideurope.com
Other European, Middles East, and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com
Other Countries not listed	+ 1 408 400 8495	techsupport@cepheid.com





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

CUSTOMER RESPONSE FORM

Xpert® Xpress Strep A (please see the product list at the end)

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

Please select one choice:

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 Strep A. I am requesting replacement pipettes.

Quantity On-hand: _____ bags of pipettes (bag of 12 pipettes)

Product Disposal Attestation: I attest that I will dispose of any remaining pipettes.

Print Name: _____

Print Title: _____

Signature: _____

Date: _____





Xpert® Xpress Strep A

Legal Manufacturer is Sunnyvale with Single Registration Number (SRN) US-MF-000010979.

Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Expiration Date
07332940006297	XPRSTREPA-CE-10	1000613359	23815	26-Nov-23
07332940006372	XPRSTREPA-10	1000413767	10309	21-May-23
07332940006372	XPRSTREPA-10	1000470375	23201	23-Jul-23
07332940006372	XPRSTREPA-10	1000478705	23305	30-Jul-23
07332940006372	XPRSTREPA-10	1000482576	23308	06-Aug-23
07332940006372	XPRSTREPA-10	1000489420	23312	13-Aug-23
07332940006372	XPRSTREPA-10	1000492158	23314	20-Aug-23
07332940006372	XPRSTREPA-10	1000494468	23315	20-Aug-23
07332940006372	XPRSTREPA-10	1000494469	23401	20-Aug-23
07332940006372	XPRSTREPA-10	1000494470	23402	20-Aug-23
07332940006372	XPRSTREPA-10	1000494471	23403	20-Aug-23
07332940006372	XPRSTREPA-10	1000495394	23404	20-Aug-23
07332940006372	XPRSTREPA-10	1000495396	23405	20-Aug-23
07332940006372	XPRSTREPA-10	1000496223	23406	20-Aug-23
07332940006372	XPRSTREPA-10	1000496224	23407	20-Aug-23
07332940006372	XPRSTREPA-10	1000501407	23501	27-Aug-23
07332940006372	XPRSTREPA-10	1000501663	23504	27-Aug-23
07332940006372	XPRSTREPA-10	1000502282	23505	27-Aug-23
07332940006372	XPRSTREPA-10	1000502290	23506	27-Aug-23
07332940006372	XPRSTREPA-10	1000506351	23408	03-Sep-23
07332940006372	XPRSTREPA-10	1000507305	23410	03-Sep-23
07332940006372	XPRSTREPA-10	1000508428	23510	03-Sep-23
07332940006372	XPRSTREPA-10	1000510024	23411	10-Sep-23
07332940006372	XPRSTREPA-10	1000514762	23604	17-Sep-23
07332940006372	XPRSTREPA-10	1000514765	23605	17-Sep-23
07332940006372	XPRSTREPA-10	1000514772	23607	17-Sep-23
07332940006372	XPRSTREPA-10	1000516576	23608	17-Sep-23
07332940006372	XPRSTREPA-10	1000518826	23609	17-Sep-23
07332940006372	XPRSTREPA-10	1000519450	23610	17-Sep-23
07332940006372	XPRSTREPA-10	1000520779	23611	17-Sep-23
07332940006372	XPRSTREPA-10	1000520869	23612	17-Sep-23
07332940006372	XPRSTREPA-10	1000522864	23701	24-Sep-23
07332940006372	XPRSTREPA-10	1000522877	23702	24-Sep-23
07332940006372	XPRSTREPA-10	1000527214	23703	24-Sep-23
07332940006372	XPRSTREPA-10	1000527215	23705	24-Sep-23
07332940006372	XPRSTREPA-10	1000527216	23706	24-Sep-23
07332940006372	XPRSTREPA-10	1000535892	23707	08-Oct-23
07332940006372	XPRSTREPA-10	1000535895	23708	08-Oct-23
07332940006372	XPRSTREPA-10	1000535906	23709	08-Oct-23



Unique Device Identifier (UDI)	Part Number	Batch Number	Lot Number	Expiration Date
07332940006372	XPRSTREPA-10	1000535907	23710	08-Oct-23
07332940006372	XPRSTREPA-10	1000535908	23711	08-Oct-23
07332940006372	XPRSTREPA-10	1000542612	23712	08-Oct-23
07332940006372	XPRSTREPA-10	1000543679	23714	08-Oct-23
07332940006372	XPRSTREPA-10	1000544555	23716	15-Oct-23
07332940006372	XPRSTREPA-10	1000544577	23717	15-Oct-23
07332940006372	XPRSTREPA-10	1000552140	23718	22-Oct-23
07332940006372	XPRSTREPA-10	1000552141	23719	22-Oct-23
07332940006372	XPRSTREPA-10	1000552142	23720	22-Oct-23
07332940006372	XPRSTREPA-10	1000560158	23113	29-Oct-23
07332940006372	XPRSTREPA-10	1000566813	23316	29-Oct-23
07332940006372	XPRSTREPA-10	1000605218	23912	26-Nov-23
07332940006372	XPRSTREPA-10	1000693093	24112	14-Jan-24
07332940006372	XPRSTREPA-10	1000753684	23820	11-Feb-24
07332940006372	XPRSTREPA-10	1000757279	24704	18-Feb-24
07332940006372	XPRSTREPA-10	1000763861	24302	18-Feb-24
07332940006372	XPRSTREPA-10	1000778789	24307	25-Feb-24
07332940006372	XPRSTREPA-10	1000784990	24507	03-Mar-24
07332940006372	XPRSTREPA-10	1000785035	24508	03-Mar-24
07332940006372	XPRSTREPA-10	1000785324	24511	03-Mar-24
07332940006372	XPRSTREPA-10	1000799629	23822	10-Mar-24
07332940006372	XPRSTREPA-10	1000801610	23823	10-Mar-24
07332940006372	XPRSTREPA-10	1000801727	23824	10-Mar-24
07332940006372	XPRSTREPA-10	1000808180	24512	10-Mar-24
07332940006372	XPRSTREPA-10	1000808181	24513	10-Mar-24
07332940006372	XPRSTREPA-10	1000808182	24514	10-Mar-24
07332940006372	XPRSTREPA-10	1000808183	23825	10-Mar-24
07332940006372	XPRSTREPA-10	1000810140	24313	10-Mar-24
07332940006372	XPRSTREPA-10	1000810141	24515	10-Mar-24
07332940006372	XPRSTREPA-10	1000810317	24516	10-Mar-24
07332940006372	XPRSTREPA-10	1000810318	24517	10-Mar-24
07332940006372	XPRSTREPA-10	1000823007	24805	17-Mar-24

