WEB WWW.CEPHEID.COM
MAIN 1.888.336.2743
FAX 1.408.541.4192

June 18, 2024

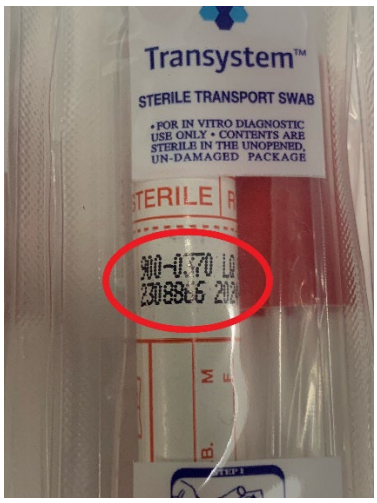
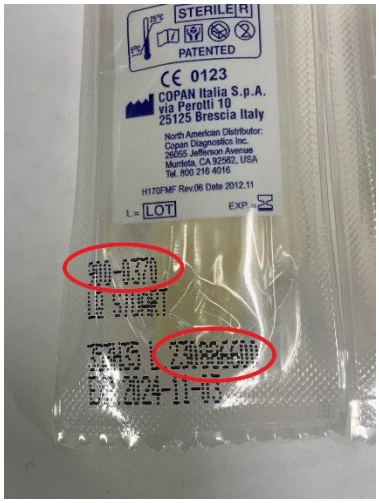
**Urgent Medical Device Recall**

Specimen Collection Device: Cepheid Catalog Number P/N 900-0370 (Transystem™)

| Legal Manufacturer | Unique Device Identifier (UDI) | Cepheid Part Number | COPAN Lot Number | Expiration Date |
|---|---|---|---|---|
| COPAN ITALIA Spa | 28053326001523 | 900-0370 | 230397900<br>230535300<br>230627500<br>231877400 | July 3, 2024<br>July 14, 2024<br>August 4, 2024<br>April 10, 2025 |

Attention Cepheid Customer,

Cepheid is initiating an Urgent Medical Device Recall for the product listed above. This letter contains important information that needs your immediate attention.

| | |
|---|---|
| ISSUE: | Cepheid has received customer complaints for Specimen Collection Device: Cepheid Catalog Number P/N 900-0370 (Collection Device) that have leaked after the patient sample swabs have been inserted into the test tubes. The supplier has confirmed the collection devices may be nonconforming. |
| IMPACT: | A collection device that leaks patient sample can result in biohazard exposure to the device operator, biohazard exposure to the environment and/or other devices, cross contamination causing false positive results for other specimens, and/or delay to test results. |
| ACTION: | Please dispose of Collection Device from Copan lots 230397900, 230535300, 230627500, and/or 231877400 you may currently have in use or in your inventory. Refer to the pictures below on how to identify the impacted lot numbers:<br>  <br>  |

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| | |
|---|---|
| ACTION (Continued): | Cepheid will provide replacement product. The replacement should ship within 5 business days following receipt of the completed online Customer Response Form.<br><br>Because the quality issue with the Collection Device is intermittent, Cepheid asks that if you receive a positive or negative test result, please follow the Instructions for Use (IFU) for your specific assay, and your facility's protocol related to management of test results.<br><br>Please continue to report complaints related to the Collection Device to Cepheid Technical Support for investigation.<br><br>Cepheid asks that you acknowledge receipt of this Urgent Medical Device Recall by completing the online Customer Response Form here: https://iqvia-response.my.site.com/mt/fca?cid=24far007<br><br>*Cepheid has partnered with IQVIA MedTech to assist in this recall. For any assistance regarding the online response processing for this recall, please contact IQVIA using the information in the table below.* |
| RESOLUTION: | Cepheid is investigating the root cause of the reported leaking issue and working with the supplier to avoid recurrence in the future. |

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.

Please complete the online Customer 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 next page for applicable contact information. We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Somesh Lalithraj
Somesh Lalithraj (Jun 19, 2024 10:17 GMT+2)

Somesh Lalithraj
Vice President, Global Quality

904 Caribbean Drive Sunnyvale, CA 94089 USA WWW.CEPHEID.COM

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Recall Response Support:

| Region/Country | Telephone | Technical Support Email |
|---|---|---|
| U.S. | +1 844 920 1427 | cepheidrecall-24far007@iqvia.com |
| Latin America | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| France | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| Germany | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| Portugal | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| Spain | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| Other European Countries | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| Hong Kong | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| Middle East and African Countries | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |
| Other Countries Not Listed | +44 808 178 5381 | cepheidrecall-24far007@iqvia.com |

Cepheid Technical Support:

| Region/Country | Telephone | Technical Support Email |
|---|---|---|
| U.S. | +1 888 838 3222, option 2 | techsupport@cepheid.com |
| Latin America | N/A | latamsupport@cepheid.com |
| France | + 33 563 825 319 | support@cepheideurope.com |
| Germany | + 49 21 514 474 524 | support@cepheideurope.com |
| Portugal | + 351 800 913 174 | support@cepheideurope.com |
| Spain | + 34 919 906 762 | support@cepheideurope.com |
| Other European Countries | + 33 563 825 319 | support@cepheideurope.com |
| Hong Kong | N/A | techsupportapac@cepheid.com |
| Middle East and African Countries | + 971 4 550 8617 | support@cepheideurope.com |
| Other Countries Not Listed | + 1 408 400 8495 | techsupport@cepheid.com |

904 Caribbean Drive Sunnyvale, CA 94089 USA WWW.CEPHEID.COM

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CUSTOMER RESPONSE FORM
Specimen Collection Device: Cepheid Catalog Number P/N 900-0370 (Transystem™)

| Legal Manufacturer | Unique Device Identifier (UDI) | Cepheid Part Number | COPAN Lot Number | Expiration Date |
|---|---|---|---|---|
| COPAN ITALIA Spa | 28053326001523 | 900-0370 | 230397900<br>230535300<br>230627500<br>231877400 | July 3, 2024<br>July 14, 2024<br>August 4, 2024<br>April 10, 2025 |

| | |
|---|---|
| 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 Specimen Collection Device: Cepheid Catalog Number P/N 900-0370 from lots 230397900, 230535300, 230627500, and/or 231877400. I am requesting replacement product.

**Quantity of Collection Devices On-hand:** _____

**Product Disposal Attestation:** I attest that I will dispose of any remaining Specimen Collection Device: Cepheid Catalog Number P/N 900-0370 from lots 230397900, 230535300, 230627500, and/or 231877400.

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

**Signature:**_____ **Date:** _____

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**Urgent Medical Device Recall**
**Specimen Collection Device: Cepheid Catalog Number P/N 900-0370 (Transystem™)**

## Online Acknowledgement Form Instructions

*Please complete the Field Correction Acknowledgement Form Online within **ten (10) business days** upon receipt of this notification.*

| | |
|---|---|
| | **STEP 1:** Scan the QR Code or visit the link below to access the response form<br><br>https://iqvia-response.my.site.com/mt/fca?cid=24far007 |
| | **STEP 2:** Enter your unique identifier<br><br>**Your Consignee ID** – [VARIABLE TO BE INSERTED] |
| | **STEP 3:** Acknowledge the receipt of this notice & complete the form online.<br><br>*Call IQVIA MedTech for any questions/concerns with response form*<br><br>**P: USA only: +1 844 920 1427**<br>**P: Outside of USA: +44 808 178 5381**<br>**E: cepheidrecall-24far007@iqvia.com** |

*Cepheid has partnered with IQVIA MedTech company, to assist in this field action. IQVIA MedTech specializes in providing outsourced commercial service teams and technologies for the medical device industry.*

*For any assistance regarding online response processing please contact IQVIA MedTech using the information above.*

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