



August 30, 2023

**IMPORTANT PRODUCT NOTICE**  
AU/DxC AU Chemistry Transferrin REF OSR6152

REF	LOT	⌚
OSR6152	2573	01 August 2024

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding Transferrin OSR6152 Lot 2573.

<b>ISSUE:</b>	It has been determined that Transferrin REF OSR6152 Lot 2573 is not meeting the reagent on-board stability claim stated in the Instructions for Use (IFU).
<b>IMPACT:</b>	Customers using Transferrin REF OSR6152 Lot 2573 may experience reagent blank shifts, calibration failures, and/or QC failures.
<b>ACTION:</b>	<ul style="list-style-type: none"><li>• Discontinue the use of Transferrin OSR6152, Lot 2573.</li><li>• Check your inventory and dispose of any Transferrin OSR6152, Lot 2573 kits.</li><li>• Contact your local Beckman Coulter representative for replacement lots.</li><li>• No retrospective review of past patient results is required but this may be carried out at the discretion of the Laboratory Director.</li></ul>
<b>RESOLUTION:</b>	Beckman Coulter is working with the raw material supplier to determine the root cause of this issue.

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 listed above to another laboratory, please provide them 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 contact our Customer Support Center;

- From our website: <http://www.beckmancoulter.com>
- You may request replacement product by contacting your local Beckman Coulter Representative for replacement.



We apologize for any inconvenience that this caused your laboratory.

Sincerely,

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Cartha Donovan  
Director Quality & Regulatory Affairs

Enclosure: Response Form  
Replacement Order form

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