



June 21, 2023

URGENT FIELD SAFETY NOTICE

Access Folate and Access TSH Reagent Packs when used on Dxl 9000 Access Immunoassay Analyzer

REF	Lot	
A98032	234262	August 31, 2023
	234402	October 31, 2023
B63284	233718	February 28, 2023
	234177	June 30, 2023
	234374	July 31, 2023
	234375	August 31, 2023
	234554	September 30, 2023
	234555	October 31, 2023
	234742	November 30, 2023
	338248	March 31, 2024
	338249	April 30, 2024

Attention Beckman Coulter Customer,

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

ISSUE:	<ul style="list-style-type: none"> Beckman Coulter has determined that the Dxl 9000 Access Immunoassay Analyzer reagent pipettors may not fully puncture through the elastomeric coating on the Access Folate and Access TSH reagent pack lots listed in the table above. This issue is caused by the elastomeric coating that was used to manufacture the reagent listed in the table above. No other versions of instruments are affected.
IMPACT:	<ul style="list-style-type: none"> You may observe reagent pipettor obstruction (RPO) flags if the Dxl 9000 reagent pipettor does not completely puncture through the elastomeric coating of an Access Folate reagent pack. The following may occur: <ul style="list-style-type: none"> Failed calibration and QC results. Suppressed patient results that must be repeated. An obstruction that is not detected by the instrument may occur if the Dxl 9000 reagent pipettor does not completely puncture through the elastomeric coating of an Access TSH reagent pack. The following may occur: <ul style="list-style-type: none"> The system may dispense an incorrect volume of reagent as a result. A falsely decreased patient result may be generated.
ACTION:	<ul style="list-style-type: none"> Discontinue use of the listed Access Folate and Access TSH reagent lots with the Dxl 9000 Access Immunoassay Analyzer.



	<ul style="list-style-type: none">• Share this letter with your laboratory and /or medical director and determine if a retrospective review of previous patient test results is necessary.• Contact your local Beckman Coulter representative for product replacement requests.
RESOLUTION:	<ul style="list-style-type: none">• Beckman Coulter is no longer distributing the listed Access Folate and Access TSH reagent pack lots to all DxI 9000 Access Immunoassay Analyzer customers.• Beckman Coulter has investigated and corrected the issue. Access TSH and Access Folate reagent packs will not be manufactured using the affected elastomeric coating.

The national competent authority has been informed of this field safety corrective action.

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 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>

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:
Rachel Davison
Signer Name: Rachel Davison
Signing Reason: I approve this document
Signing Time: 21-Jun-2023 | 3:34:43 PM PDT
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Enclosure: Response Form

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