URGENT FIELD SAFETY NOTICE – FSN - 23026

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

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

Dear 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:	• Beckman Coulter has determined that the DxI 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:	• You may observe reagent pipettor obstruction (RPO) flags if the DxI 9000 reagent pipettor does not completely puncture through the elastomeric coating of an Access Folate reagent pack. The following may occur:
	  o Failed calibration and QC results.
	  o Suppressed patient results that must be repeated.
	• An obstruction that is not detected by the instrument may occur if the DxI 9000 reagent pipettor does not completely puncture through the elastomeric coating of an Access TSH reagent pack. The following may occur:
	  o The system may dispense an incorrect volume of reagent as a result.
	  o A falsely decreased patient result may be generated.

ACTION:	• Discontinue use of the listed Access Folate and Access TSH reagent lots with the DxI 9000 Access Immunoassay Analyzer.
	• 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:	• 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 that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

Contact your local Beckman Coulter Representative to arrange for a replacement lot on 0870 243 6001 – Option 1 or bcieorders@beckman.com.

We apologise for the inconvenience that this caused your laboratory.

Yours sincerely,

Andy Brown
Quality & Regulatory Affairs Manager, Northern Region Europe
Tel +44 (0) 1494 429184/+44 (0)1494 429219

Enclosed: Vigilance Response Form