



February 19, 2025

URGENT FIELD SAFETY NOTICE

Access Vitamin B12 Reagent Kit

REF	UDI**	LOT	
33000	15099590224301	439850	30-June-2025

Single Registration Number (SRN):** US-MF-000010288

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 received complaints of erroneous Vitamin B12 results when using Access Vitamin B12 Reagent lot 439850. Beckman Coulter has determined that 14.5% of Access Vitamin B12 reagent packs from lot 439850 were non-conforming and were distributed in error.
IMPACT:	<ul style="list-style-type: none"> Patient, Quality Control (QC), and calibrator materials tested with Access Vitamin B12 reagent lot 439850 may demonstrate erroneously increased and/or decreased results. Erroneous results may lead to improper diagnosis and/or repeat testing. Falsely increased Vitamin B12 patient and/or QC results may occur if an operator calibrates the Access Vitamin B12 assay with a conforming Access Vitamin B12 reagent pack and then uses a non-conforming Access Vitamin B12 reagent pack to test patients and/or QC samples. <ul style="list-style-type: none"> Internal testing indicates that this scenario may falsely increase Vitamin B12 results by approximately 152%. Falsely decreased Vitamin B12 patient and/or QC results may occur if an operator calibrates the Access Vitamin B12 assay using a non-conforming Access Vitamin B12 reagent pack and then uses a conforming Access Vitamin B12 reagent pack to test patient and/or QC samples. <ul style="list-style-type: none"> Internal testing indicates that this scenario may falsely decrease Vitamin B12 results by approximately -69%.
ACTION:	<ul style="list-style-type: none"> Discontinue using Access Vitamin B12 reagent lot 439850. Discard all remaining reagent packs from this lot following your laboratory procedures.



	<ul style="list-style-type: none"> • Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous patient results • Contact your local Beckman Coulter representative for replacement product requests.
RESOLUTION:	<ul style="list-style-type: none"> • Beckman Coulter is investigating the root cause of this issue. • Beckman Coulter will no longer distribute Access Vitamin B12 reagent lot 439850.

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>
- You may request replacement product by contacting your local Beckman Coulter Representative for replacement. [Remove for instrument field actions]

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:

 Signer Name: Ian Pilcher
 Signing Reason: I approve this document
 Signing Time: 19-Feb-2025 | 7:22:11 PM PST
 73C58D9A69DC485EA887E365533D3D7D

Ian Pilcher
 Director, RA

Enclosure: Response Form
 Product Replacement Form

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