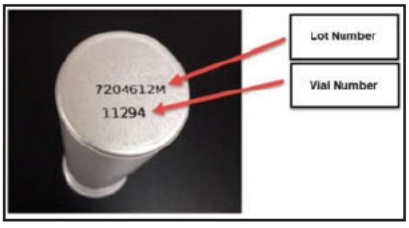
July 28, 2022

URGENT FIELD SAFETY NOTICE
iChemVELOCITY Strips
Product Recall

REF	LOT	
800-7204	7204612M	05-April-2023

Attention Beckman Coulter Customer,

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

ISSUE:	Beckman Coulter has become aware of a manufacturing error where the LEU (Leukocyte) and NIT (Nitrite) analyte pad locations were inadvertently switched on the iChemVELOCITY Strips (PN 800-7204). The defect exists on a subset of vials of the affected lot: • For lot # 7204612M, vials identified are from vial number 11200 to 12500 • Manufacture date: May 5, 2022
IMPACT:	The following outcomes may occur if these affected strips are used: • Quality control failures for Leukocyte Esterase (IRISpec CB False Negative) • Quality control failures for Nitrite (IRISpec CA or IRISpec CC False Positive) • False Positive or False Negative Nitrite and Leukocyte Esterase results when patient samples are run
ACTION:	• Inspect any remaining inventory to determine if you have the impacted vials (11200-12500) as shown in Figure 1 below. The vial number is located on the bottom of the vial beneath the lot number  ○ If any of the affected vial numbers are found, discard them according to your laboratory protocol. ▪ Contact your local support representative for product replacement if you have any of the affected vials of lot 7204612M. ○ If no affected vial numbers are found continue to use the strips from lot 7204612M as routine

	• Continue to use strips from any other lot numbers as routine. • Consult with your Laboratory Director to determine if a retrospective review of results is clinically warranted.
RESOLUTION	• Affected product will be replaced. • Beckman Coulter is working to prevent re-occurrence of this issue.

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 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:

- Contact your Local Beckman Coulter Representative
- From our website: http://www.beckmancoulter.com

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[redacted]

Enclosure: Response Form