



URGENT FIELD SAFETY NOTICE
iChemVELOCITY Strips

REF	LOT	
800-7204	7204285M 7204286A	11-11-2020 11-04-2020

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:	<p>Beckman Coulter has become aware of a manufacturing error where the Glucose and Protein pad locations were inadvertently switched on the iChemVELOCITY Strips.</p> <p>The defect exists on a subset of vials of the affected lots, as follows:</p> <ul style="list-style-type: none"> For lot# <u>7204285M</u>, vials numbered from <u>2997</u> through <u>3999</u> are impacted. For lot# <u>7204286A</u>, vials numbered from <u>3048</u> through <u>3581</u> are impacted.
IMPACT:	<p>The use of affected strips may result in the following:</p> <ul style="list-style-type: none"> Quality Control failures for Glucose and Protein. Erroneous Glucose results that may result in delay in recognition of diabetes and glycosuria, or to additional non-invasive work up. Erroneous Protein results that may result in delay in recognition and management of conditions and diseases associated with proteinuria, or to additional non-invasive work up.
ACTION:	<ul style="list-style-type: none"> Inspect your current iChemVELOCITY Strips inventory to determine if you have any remaining inventory from the affected lots 7204285M and 7204286A. If remaining inventory from the affected lots is found: <ul style="list-style-type: none"> Inspect for the vial number. The vial number is located on the bottom of the vial beneath the lot number, as shown in the example below. <div data-bbox="673 1470 1315 1858" style="text-align: center;">  <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>Lot# 7204285M Affected vials are from <u>2997</u> through <u>3999</u></p> </div> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>Lot# 7204286A Affected vials are from <u>3048</u> through <u>3581</u></p> </div> </div> </div>

	<ul style="list-style-type: none">▪ If any of the affected vial numbers are found, discard them according to your laboratory protocol.<ul style="list-style-type: none">• Contact your local Beckman Coulter support representative for product replacement.▪ If no affected vial numbers are found continue to use the strips as routine.• Consult with your Medical Director to determine if a retrospective review of results is clinically warranted.
RESOLUTION:	<ul style="list-style-type: none">• Affected product will be replaced.• Beckman Coulter is working to prevent the recurrence 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(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 Beckman Coulter Customer Support Center:

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

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Roger Janczak
Vice President, Quality and Regulatory Affairs
Enclosure: Response Form

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