

May 8, 2019

## FIELD SAFETY CORRECTIVE ACTION NOTIFICATION

### iQ Control/Focus Set

REF	LOT	
800-3104	344-18	2019-07-31

Dear Beckman Coulter Customer,

Copy: Chairman Medical Board/Head of Departments of Affected consignees

\*Applicable to affected consignees in Singapore only

Beckman Coulter is sending this letter regarding mislabeled iQ Positive Control barcode labels in the iQ Control/Focus Set listed above. Test results are not affected.

<b>ISSUE:</b>	<p>Beckman Coulter has become aware of an issue affecting the positive control barcode labels for the iQ Control/Focus Set, lot number 344-18. There is the potential for the iQ Positive Control barcode labels, within the iQ Control/Focus Set, to contain an incorrect lot number 348-18, instead of the correct lot number 344-18.</p> <p>All other information contained in the barcode labels, the control's package labeling and the control bottles are correct. The iQ Positive Control bottle is correctly labeled as lot number 344-18 and will contain correct mean values. Distribution of lot number 344-18 began in December 2018. See Attachment 1 for example labeling.</p>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>• Patient results are not affected by this issue.</li> <li>• There is a potential for the following outcomes: <ul style="list-style-type: none"> <li>○ When affected iQ Positive Control labels are used: <ul style="list-style-type: none"> <li>▪ The positive control target values, lower and upper limits and all encoded QC statistics will be correct, but will be associated with the incorrect lot number 348-18.</li> <li>▪ The incorrect lot number will be read by the instrument and entered into the QC files, QC statistics, Quality Review log and Traceability files in the iQ 200 interface.</li> <li>▪ Your lab will have lost the traceability of the correct lot number for the positive control used in daily control runs on the iQ200, during the time the control was used.</li> </ul> </li> </ul> </li> </ul>
<b>ACTION:</b>	<ol style="list-style-type: none"> <li>1. Examine your current inventory to determine if you have the iQ Control/Focus Set, lot number 344-18 by reading the box label. <ul style="list-style-type: none"> <li>○ If lot number 344-18 is found: <ul style="list-style-type: none"> <li>▪ Open all boxes to determine if any of the kits contain affected positive control barcode labels with lot number 348-18.</li> </ul> </li> </ul> </li> </ol>

	<ul style="list-style-type: none"> <li>▪ Examine only one positive control barcode label per kit. Note: All positive control barcode labels will be labeled with the same lot number within one kit box. See Attachment 1.</li> <li>○ If positive control barcodes labeled as lot number 348-18 are found: <ul style="list-style-type: none"> <li>▪ Discontinue use of the kits with affected positive control barcode lot numbers.</li> <li>▪ Discard kits containing affected positive control barcodes according to your laboratory protocol.</li> <li>▪ Contact your local support representative for product replacement: <ul style="list-style-type: none"> <li>• For customer in U.S.: Complete the attached Replacement Order Form and email to <a href="mailto:askbeckman@beckman.com">askbeckman@beckman.com</a> or fax to (866) 294-7850 OR call Client Services at (800) 526-3821.</li> <li>• For customers in Canada: Complete the attached Replacement Order Form and email to <a href="mailto:Beckmancoultercanada@beckman.com">Beckmancoultercanada@beckman.com</a> or fax to (866) 294-7850 OR call Client Services at (800) 463-7828.</li> <li>• Outside of the U.S. and Canada, contact your local Beckman Coulter representative.</li> </ul> </li> </ul> </li> <li>○ <b>If no incorrectly labeled positive control barcode labels are found, continue to use lot number 344-18 as routine.</b></li> </ul> <p>2. Determine if a control file for lot number 348-18 was previously established. Refer to the iQ200 Series Instructions For Use; Chapter 4, Quality Control Review:</p> <ul style="list-style-type: none"> <li>○ Access the Quality Review screen.</li> <li>○ Sort by Lot number using the Lot ID Header. <ul style="list-style-type: none"> <li>▪ Review the screen to determine if there is an entry for positive control lot number 348-18.</li> </ul> </li> <li>○ If a positive control file for lot number 348-18 is found, displayed as 348-2018-PC on this screen, refer to Saving QC options in the iQ200 Series Instructions for Use; Chapter 4. Follow the steps below: <ul style="list-style-type: none"> <li>▪ If your instrument is configured with a printer: Select Search, highlight the specific control file entry, displayed as 348-2018-PC; select OK. Select Print list for the selected files. Make a notation on the printout that these positive control values belong to kit lot number 344-18.</li> <li>▪ For instruments without a printer: Select Search, highlight the specific control file entry, displayed as 348-2018-PC; select OK. Select Save to save the selected file list electronically. Make a notation that these positive control values belong to kit lot number 344-18.</li> </ul> </li> <li>○ Alternatively, access the QC Statistics screen to print or save the selected QC Statistics file.</li> <li>○ Retain these files for your records.</li> </ul>
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**RESOLUTION:**

- Beckman Coulter is working on a resolution to prevent the recurrence of this issue.
- This letter serves as the correction of the described issue.
- This letter provides information to appropriately track the correct lot number, 344-18 of the iQ Control/Focus Set, in cases where the incorrect lot number 348-18 for the positive control barcode label may have been provided.

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 with a copy of this letter.

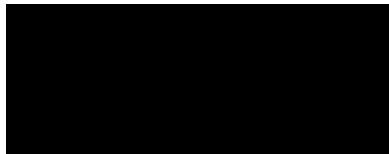
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone, call 800-854-3633 in the United States and Canada
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,



Roger A. Janczak  
Vice President, Quality Assurance and Regulatory Affairs

Enclosure: Response Form

Beckman Coulter, the stylized logo and the Beckman Coulter product and service names mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

## Attachment 1

[Example of correct lot number locations]



Lot 344-18 is expressed as follows:

- iQ Positive Control bottle: 344-18
  - iQ Control/Focus Set box: 344-18
  - Positive Control Barcode labels: PC18344G1032000000
- 11800 S.W. 147<sup>th</sup> Avenue  
Miami, FL 33196-9015
- Beckman Coulter Inc.  
11800 SW 147<sup>th</sup> Ave  
Miami, FL 33196-9015

Customer Service: 800-526-3821  
Internet: [www.beckmancoulter.com](http://www.beckmancoulter.com)