



December 16, 2015

### IMPORTANT PRODUCT NOTICE

REF	KIT/VIAL LOT NUMBERS
COULTER® S-CAL® Calibrator Kits 624519, 179310 and 628026	See attached table for kit and vial lot numbers

Attention Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding Coulter S-CAL Calibrator Kits as noted above. Patient test results are not affected.

<b>ISSUE:</b>	<p>Beckman Coulter has received an increased number of customer complaints observed after S-CAL calibration on the Unicel® DxH™ 800 and DxH™ 600 Coulter® Cellular Analysis Systems, and the Coulter® LH 750 and LH 780 Hematology Systems. Customers have reported a variety of issues during calibration including:</p> <ul style="list-style-type: none"> <li>• An increase in H&amp;H Check messages</li> <li>• Low MCH recovery in XB</li> <li>• Low MCHC recovery in XB</li> </ul> <p>These issues are not observed with all analyzers.</p>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>• Patient test results are not affected.</li> <li>• Calibration adjustments made using the identified S-CAL kits/lots may have resulted in shifted MCV recovered values.</li> <li>• Shifted MCV values may in turn affect calculated HCT values, resulting in increases in the reported issues.</li> <li>• If you monitor XB trends, the calibration adjustment may indicate that you need to perform maintenance that is not necessary.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>• Continue to monitor other quality control performance and adhere to your established maintenance schedule.</li> <li>• For laboratories who reported issues after calibration with the affected lots, recalibration with S-CAL vial lots beginning with 4782 or 113160400 or beyond is suggested.</li> <li>• For product replacement, please fill out and return the Replacement Order form included with this notice or contact your local Customer Service Support.</li> </ul>
<b>RESOLUTION:</b>	<p>Adjustments have been made to SCAL values to provide closer agreement between instrument and reference for whole blood. These adjustments will begin with SCAL vial lots 4782 and 113160400.</p>

Share this information with your laboratory staff and retain this notice 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.

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

**IPN-26657**



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 800-526-7694 in the United States and Canada
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for the inconvenience to your laboratory.

Sincerely,

Marwan Fathallah  
Vice President, Quality Assurance and Regulatory Affairs

Enclosure:      Response Form  
                         Table of Affected S-CAL Calibrator Lots

**Table of affected S-CAL Calibrator Kits and vial lot numbers**

Vial Lot	Kit PN	Kit Lot #	Exp Date	Vial Lot	Kit PN	Kit Lot #	Exp Date
4770	624519	1158328F	8-Aug-15	4776	624519	1158334F	31-Oct-15
4770	179310	1169284F	8-Aug-15	4777	624519	1158336F	21-Nov-15
4770	624519	1158327F	8-Aug-15	4777	179310	1169291F	21-Nov-15
4771	624519	1158329F	22-Aug-15	4777	624519	1158335F	21-Nov-15
4771	179310	1169285F	22-Aug-15	4778	624519	1158337F	5-Dec-15
4772	624519	1158330F	5-Sep-15	4778	179310	1169292F	5-Dec-15
4772	179310	1169286F	5-Sep-15	4779	179310	1169293F	19-Dec-15
4773	179310	1169287F	19-Sep-15	4779	624519	1158338F	19-Dec-15
4773	624519	1158331F	19-Sep-15	4779	624519	1158339F	19-Dec-15
4774	179310	1169288F	3-Oct-15	4780	179310	1169294F	2-Jan-16
4774	624519	1158332F	3-Oct-15	4780	624519	1158340F	2-Jan-16
4775	179310	1169289F	17-Oct-15	4780	624519	1158341F	2-Jan-16
4775	624519	1158333F	17-Oct-15	4781	179310	1169295F	16-Jan-16
4776	179310	1169290F	31-Oct-15	4781	624519	1158342F	16-Jan-16

Vial Lot	Kit PN	Kit Lot #	Exp Date	Vial Lot	Kit PN	Kit Lot #	Exp Date
113160280	628026	4110360F	8-Aug-15	113160350	628026	4110430F	21-Nov-15
113160290	628026	4110370F	22-Aug-15	113160360	628026	4110440F	5-Dec-15
113160300	628026	4110380F	5-Sep-15	113160370	628026	4110450F	19-Dec-15
113160310	628026	4110390F	19-Sep-15	113160370	628026	4110460F	19-Dec-15
113160320	628026	4110400F	3-Oct-15	113160380	628026	4110470F	2-Jan-16
113160330	628026	4110410F	17-Oct-15	113160380	628026	4110480F	2-Jan-16
113160340	628026	4110420F	31-Oct-15	113160390	628026	4110490F	16-Jan-16