



12<sup>th</sup> December 2017

**IMPORTANT PRODUCT NOTICE**

**DuraClone B27 Reagent Kit**

REF	LOT	
B36862	031016	2 <sup>nd</sup> Oct 2017
	061016	5 <sup>th</sup> Oct 2017
	111016_09	10 <sup>th</sup> Oct 2017
	181016_12	17 <sup>th</sup> Oct 2017
	211016_01	20 <sup>th</sup> Oct 2017
	041116	1 <sup>st</sup> Nov 2017
	021116	3 <sup>rd</sup> Nov 2017
	300117	29 <sup>th</sup> Jan 2018
	130217_09	12 <sup>th</sup> Feb 2018
	200317_02	19 <sup>th</sup> Mar 2018
	070417_01	6 <sup>th</sup> Apr 2018
	070417_11	6 <sup>th</sup> Apr 2018
	170417_09	16 <sup>th</sup> Apr 2018
	170417_11	16 <sup>th</sup> Apr 2018
	090517	8 <sup>th</sup> May 2018
	070617_10	6 <sup>th</sup> Jun 2018
	120617_02	11 <sup>th</sup> Jun 2018
	190617	18 <sup>th</sup> Jun 2018
	240717	23 <sup>rd</sup> Jul 2018
	280817	27 <sup>th</sup> Aug 2018
050917	4 <sup>th</sup> Sep 2018	

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding false negative results using DuraClone B27 reagent.

<b>ISSUE:</b>	As a result of internal investigations, Beckman Coulter has determined that the DuraClone B27 reagent lot number listed above have a defect that may generate false negative results in some samples.
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>• DuraClone B27 Reagent is likely to incorrectly type certain samples expressing HLA B27 antigen as negative thereby resulting in false negative results.</li> <li>• This defect is most likely to affect samples with MFI values between 10 to 19 when tested on Navios/Cytomics FC 500 cytometers and channel values between 517 to 602 when tested on BD FACSCalibur/ BD FACScan cytometers.</li> </ul>

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	<ul style="list-style-type: none"> <li>• This does not affect samples that were determined to be positive (MFI &gt;19 in case on Navios/FC500 and Channel Value &gt;602 in case of BD FACSCalibur / BD FACScan) and samples determined to be negative (MFI &lt;10 in case on Navios/FC500 and channel values &lt;517 in case of BD FACSCalibur / BD FACScan).</li> <li>• A re-draw and re-testing of blood samples from some patients may be necessary.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>• You can continue to use remaining inventory of lot numbers 050917, 070417_11, 090517, 120617_02, 170417_09, 170417_11, 190617 and 240717 with the new determinant and indeterminant zone values provided along with this letter.</li> <li>• Discard any remaining inventory of any other lots not listed in the Action first bullet point. Follow your local regulatory requirements for proper disposal. Please contact your local Beckman Coulter representative for replacement product.</li> <li>• Consult your medical director of the laboratory to determine the need for retrospective review of test results and possible re-testing.</li> <li>• If you have already generated and reported results using lot numbers: 050917, 070417_11, 090517, 120617_02, 170417_09, 170417_11, 190617 or 240717, it is recommended that the sample typing be re-determined for all the samples that had MFI values between 10 to 19 when tested on Navios/Cytomics FC 500 cytometers and channel values between 517 to 602 when tested on BD FACSCalibur/ BD FACScan cytometers, using the new determinant values provided in the letter.</li> <li>• If you have already generated and reported results using lot numbers other than those mentioned in the Action first bullet, it is recommended to verify the HLA B27 results for all the samples that have MFI between 10 to 19 using Navios/Cytomics FC 500 and channel values between 517 to 602 using BD FACSCalibur/ BD FACScan using alternate methods such as PCR.</li> </ul>

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

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone, call 800-369-0033 in Canada

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- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

A handwritten signature in black ink that reads 'Nancy Nadler'.

Nancy Nadler  
Vice President, Quality and Regulatory Affairs

Enclosure:

- Response Form
- Annexure: Corrected Labeling Information

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**ANNEXURE**  
**CORRECTED LABELING INFORMATION**  
**DuraClone B27 Reagent Kit**

REF	LOT	Corrected Determinant and Indeterminant Zone Values		
B36862	050917 170417_09 190617	<b>Instrument</b>	<b>Determinant</b>	<b>Indeterminant Zone</b>
		Navios and Cytomics FC500 Flow Cytometers	14.7	11.4 to 18
		BD FACSCalibur and BD FACScan Flow Cytometers	555	526 to 579
	070417_11 090517 120617_02 170417_11 240717	<b>Instrument</b>	<b>Determinant</b>	<b>Indeterminant Zone</b>
		Navios and Cytomics FC500 Flow Cytometers	13.3	10 to 16.6
		BD FACSCalibur and BD FACScan Flow Cytometers	544	517 to 571