September 22, 2021

URGENT FIELD SAFETY NOTICE

Stem – Kit Reagents 50 tests

REF	LOT	
IM3630	200326	14-DEC-2021
	200327	14-DEC-2021
	200328	16-FEB-2022
	200329	16-FEB-2022
	200330	17-MAY-2022
	200332	17-MAY-2022

Attention Beckman Coulter Customer,

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

ISSUE:	Beckman Coulter has discovered that the recommended specimen storage temperature and prepared sample stability for some specimen types listed are erroneously indicated in the Stem-Kit Reagents Instructions for Use (PN B60229 Rev. AH) and stemCXP System Guide (PN 627260 Rev. BC), which may lead to erroneous results.
IMPACT:	In the worst-case scenario, inappropriate storage of samples may lead to degradation of CD34+ cells potentially leading to the following scenarios for the different sample types: **<u>Collected apheresis product and bone marrow aspirates:</u>** False low number of viable CD34+ cells in the collected product. The physician may be misled into thinking that the yield of viable CD34+ cells in the collected product is lower than it is. The physician may determine that the yield of viable CD34+ cells in apheresis product and bone marrow aspirate is lower than the required level, thereby the patient/donor may require an additional or unnecessary stem cell collection to achieve a final dose of 2-5 x 10^6/kg. **<u>Mobilized whole blood samples:</u>** In the worst-case scenario, due to the extended storage conditions, the viable CD34+ cells enumerated in the mobilized peripheral blood sample may underestimate the number of viable CD34+ cells present in fresh or properly stored specimen. The physician may be misled into thinking that the number of CD34+ cells/uL is lower than it actually is, thereby delaying or missing the narrow window of opportunity for peripheral blood stem cell

<table>
<tr><td></td><td>collection necessary to proceed to cancer chemotherapy that requires stem cell infusion and reconstitution of bone marrow. Another mobilized peripheral blood sample for CD34+ assessment may be required. For stem cell mobilization, placing patient (for autologous transplantation) and healthy matched donor (allogeneic transplantation) at unnecessary risks of repeat cytokine pulse, (which includes risk of splenic rupture), and all risks of high blood volume apheresis collection.

Note: No impact to cord blood samples as there was no change in claims. No clinical impact due to change in claims for normal whole blood samples as these samples are used for base line definition only.</td></tr>
<tr><td>ACTION:</td><td>• While using Stem-Kit Reagents, use the storage conditions listed in the table below in the “Revised Storage Conditions” column for each sample type.
<table>
<tr><th rowspan="2">Sample</th><th colspan="2">Current IFU Storage Conditions</th><th colspan="2">Revised Storage Conditions</th></tr>
<tr><th>Sample stability</th><th>Prepared sample stability</th><th>Sample stability</th><th>Prepared sample stability</th></tr>
<tr><td>Whole Blood</td><td rowspan="3">24 hours at room temperature (18-25°C)</td><td rowspan="3">1 hour, stored on ice</td><td><u>20 hours</u> at room temperature (18-25°C)</td><td><u>45 minutes,</u> stored on ice</td></tr>
<tr><td>Mobilized Whole Blood</td><td rowspan="2">24 hours at <u>2-8°C</u></td><td rowspan="2">1 hour, stored on ice
(No change)</td></tr>
<tr><td>Apheresis</td></tr>
<tr><td>Bone Marrow</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Cord Blood</td><td>24 hours at room temperature (18-25°C)</td><td>1 hour, stored on ice</td><td>24 hours at room temperature (18-25°C)
(No change)</td><td>1 hour, stored on ice
(No change)</td></tr>
</table>
• Consult your Laboratory Medical Director to determine if retrospective review of test results is needed.</td></tr>
<tr><td>RESOLUTION:</td><td>Beckman Coulter will update the Stem-Kit Reagents Instructions for Use (PN B60229) and stemCXP System Guide (PN 627260) to indicate the revised storage conditions.</td></tr>
</table>

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 our Customer Support Center

- From our website: http://www.beckman.com

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Nancy Nadler
Vice President, Quality and Regulatory Affairs

Enclosure: Response Form