


February 13, 2025

## URGENT FIELD SAFETY NOTICE

### IRMA IGF-I

REF	UDI	LOT	
A15729	150995905A15729SH (SRN CZ-MF-000001761)	250106A	2025-02-24
		250106C	2025-02-24
		250106D	2025-02-24
		250203A	2025-03-24
		250203C	2025-03-24
		250203D	2025-03-24

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.

<b>ISSUE:</b>	Beckman Coulter has determined that the IRMA IGF-I kit lots above may be affected by an increased probability of falsely elevated results.
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>Assay results may be falsely increased.</li> <li>This increase is not detectable by kit control.</li> <li>Based on our investigational data, the average increase was +23% (c.v. 14%) with the tracer lot 1161 and +16% (c.v. 9.91%) with the tracer lot 1162.</li> <li>Patient may have a delay in diagnosis and treatment or subjected to additional testing.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous patient test results.</li> <li>Discard all affected kits.</li> <li>Please contact your Beckman Coulter representative for replacement of kits, as needed.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Raw material responsible for deterioration of tracer has been identified and Beckman Coulter is no longer shipping the affected IRMA IGF-I kit lots listed above.</li> </ul>

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.beckmancoulter.com>
- By email: [imunochem@beckman.com](mailto:imunochem@beckman.com)
- Or contact your local Beckman Coulter Representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Vit Oburka  
Manager, Quality and Regulatory Affairs  
Immunotech s.r.o.  
Radiova 1122/1  
Prague 10  
102 00  
Telephone: +420 272 017 368  
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*Enclosure: Response Form*

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