



URGENT: Field Safety Corrective Action- FSCA#07-12

Commercial name of affected products	Capture-P® Indicator Red Cells Lot 226183, Exp: 09NOV2012 Lot 226184, Exp: 23NOV2012 Lot 226185, Exp: 07DEC2012 Cat. No. 0066240
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November 19, 2012

Dear Valued Customer:

Detail of affected devices: Field Safety Corrective Action regarding Capture-P® Indicator Red Cells. Lots listed above.

Detail of the occurrence

Our records show that you received the Capture-P Indicator Red Cells lot(s) listed above. We have confirmed weaker than expected reactivity with the weak positive control when testing is performed using these lots of indicator cells. This has been demonstrated with testing performed with Capture-P and Capture-P Ready-Screen.

Advise on action to be taken by the user

We request that you stop using these lots of Capture-P Indicator Red Cells and discard any remaining inventory.

Previous testing results are not affected by this action provided quality control results as detailed in the Quality Control section of the package insert (Instructions for Use) were acceptable when testing was performed.

Additional lots of indicator red cells are currently being manufactured and are scheduled for release the week of 19NOV2012. If you need additional product, please contact the Customer Service Department at the phone number +49 (0) 6074 8420-20.

Any technical concerns should be addressed to Technical Support at tech.support.eu@immucor.com or at the phone number +49 (0) 6074 8420-50.



Please verify your receipt of this notification by completing the following Vigilance Response Form and returning it to us by facsimile +49 (0) 6074 8420-99, or by mail to

IMMUCOR Medizinische Diagnostik GmbH
Adam-Opel-Straße 26A
63322 Rödermark, Germany

We apologize for any inconvenience that this action causes you.

Sincerely,



Director International Quality and Regulatory Affairs

VIGILANCE RESPONSE FORM

I verify that our facility is aware of FSCA#07-12 regarding Capture-P® Indicator Red Cells, lots 226183, 226184, 226185.
Name:
Position:
Facility/Institution:
Account number:
City/State:
Telephone:
Fax number:

Signature.....