



Cressier, April 12, 2022

Field Safety Corrective Action / FSCA 004-20 Follow-up

Affected products displaying the issue:

Product Name	Catalog No	Lot No	Expiry Date
ID-Dia (Diego) Positive	004134 / 004134VJ	All lot numbers until the lots indicated in Annexes	
ID-DiaCell SF	003640		
ID-DiaCell Pool	003630 / 003631		
ID-DiaCell ABO/I-II	003610		
ID-DiaCell ABO/I-II-III	003618		
ID-DiaScreen I-II-III-IV-VP-VIP	004316		
ID-DiaCell I-II	003613 / 003613VJ		
ID-DiaPanel	004114 / 004114VJ		
ID-DiaCell I-II-III	004310 / 004310VJ		
ID-DiaScreen I-II-III-IV	004311		
ID-DiaCell I-II-III Asia	003614		
ID-DiaScreen Prophylax	004330		
ID-DiaPanel Plus 6	004414		
ID-DiaCell ABO	003619 / 003617 / 003615 / 003624 / 003620 / 003621 / 003622 / 003623 / 003621VJ / 003623VJ / 003624VJ /		
ID-DiaCell IP-IIP-IIIP	005310 / 005310VJ		
ID-DiaScreen VP-VIP	005311 / 005311VJ		
ID-DiaPanel-P	004214 / 004214VJ		

Dear Customer,

This letter gives you further information related to the FSCA 004-20 on above-mentioned red blood cells reagents.

In December 2020, Bio-Rad released this field action following the identification of 2 phenomena observed with our red blood cells reagents;

1) Nonspecific reactions on QC samples, patient samples and eluates which may lead to a “?”, “wR”, “wF”, or “DP” or any option up to ++ with instrument reading

2) Insufficient homogenization of the red blood cells within the vials when stored on-board either on the IH-500 or on the IH-1000 and when the remaining volume reaches 2ml or lower

which can lead to a dispense of low-concentrated red blood cell reagent into the wells of the ID-cards.

As indicated in the initial letter, the root cause was highly suspected to be related to the type of glass vials used in the manufacturing. Today, we are pleased to announce that the root cause of the issue has been confirmed and that the corrective action has been implemented in manufacturing.

Glass vials from different suppliers were tested and permit to select a suitable candidate which confirm the correction of both phenomena described in this letter. The implementation in our manufacturing process has been done.

For the availability of corrected products of each reference, please refer to the attached Annexes which details the date of delivery according to the normal execution of your standing order as well as the first IHD batch manufactured with those new vials.

We demand you to transfer this information to all persons impacted in your institution and/or forward it to establishments where products may have been transferred.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

In case of any questions, in the first instance, please contact your customer technical support representatives:

[add here the local contact]

Our representatives are briefed to help you manage this situation.

We apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Representative

Marketing Manager Reagents

Diane Galéa

Inger-Anne Torsheim

Annex I

List of first lot manufactured with the new vials for each reference, delivery week 18 (Group B) according to standing orders

Product Name	Catalog No	IHD batch number	Expiration date
ID-Dia (Diego) Positive	004134	05980.55.1	June 27, 2022
ID-Dia (Diego) Positive	004134VJ	0598.55.11	June 27, 2022
ID-DiaCell ABO/I-II	003610	45002.19.1	June 27, 2022
ID-DiaCell ABO/I-II-III	003618	45012.19.1	June 27, 2022
ID-DiaCell I-II	003613	45151.14.1	June 27, 2022
ID-DiaCell I-II	003613VJ	4515.14.01	June 27, 2022
ID-DiaPanel	004114	45161.41.1	June 27, 2022
ID-DiaPanel	004114VJ	4516.41.01	June 27, 2022
ID-DiaCell I-II-III	004310	45184.83.1 45184.84.1 45184.85.1 45184.86.1 45184.87.1 45184.88.1 45184.89.1 45184.90.1 45184.91.1	June 27, 2022
ID-DiaCell I-II-III	004310VJ	4518.85.01	June 27, 2022
ID-DiaCell I-II-III Asia	003614	45330.07.1	June 27, 2022
ID-DiaScreen Prophylax	004330	45660.46.1	June 27, 2022
ID-DiaCell IP-IIP-IIIP	005310	45194.83.1 45194.84.1 45194.85.1	June 27, 2022
ID-DiaCell IP-IIP-IIIP	005310VJ	4519.85.01	June 27, 2022
ID-DiaPanel-P	004214	45171.41.1	June 27, 2022
ID-DiaPanel-P	004214VJ	4517.41.01	June 27, 2022
ID-DiaCell ABO A1, A2, B, O	003619	45022.19.1	June 27, 2022
ID-DiaCell ABO A1, A2, B	003617	45082.19.1	June 27, 2022
ID-DiaCell ABO A1, B, O	003615	45352.19.1	June 27, 2022
ID-DiaCell ABO A1, B	003624	45092.19.1	June 27, 2022
ID-DiaCell ABO A1	003620	06012.19.1	June 27, 2022
ID-DiaCell ABO A2	003621	06022.19.1	June 27, 2022
ID-DiaCell ABO B	003622	06032.19.1	June 27, 2022
ID-DiaCell ABO O	003623	06042.19.1	June 27, 2022
ID-DiaCell ABO A2	003621VJ	0602.19.11	June 27, 2022
ID-DiaCell ABO O	003623VJ	0604.19.11	June 27, 2022
ID-DiaCell ABO A1, B	003624VJ	4509.19.01	June 27, 2022
ID-DiaCell Pool	003630	<i>For these products, the first delivery with the new vials will be done week 22</i>	
ID-DiaCell Pool	003631		
ID-DiaScreen I-II-III-IV-VP-VIP	004316		
ID-DiaScreen I-II-III-IV	004311		
ID-DiaPanel Plus 6	004414		
ID-DiaScreen VP-VIP	005311		
ID-DiaScreen VP-VIP	005311VJ		

Annex II

List of first lot manufactured with the new vials for each reference, delivery week 20 (Group A) according to standing orders

Product Name	Catalog No	IHD batch number	Expiration date
ID-Dia (Diego) Positive	004134	05980.55.2	July 11, 2022
ID-DiaCell SF	003640	06060.23.1	July 11, 2022
ID-DiaCell Pool	003630	06070.80.1	July 11, 2022
ID-DiaCell Pool	003631	06070.80.1	July 11, 2022
ID-DiaCell ABO/I-II	003610	45002.20.1	July 11, 2022
ID-DiaCell ABO/I-II-III	003618	45012*	July 11, 2022
ID-DiaScreen I-II-III-IV-VP-VIP	004316	45070.20.1	July 11, 2022
ID-DiaCell I-II	003613	45151.15.1	July 11, 2022
ID-DiaPanel	004114	45161.42.1	July 11, 2022
ID-DiaCell I-II-III	004310	45184.92.1 45184.93.1 45184.94.1 45184.95.1 45184.96.1 45184.97.1 45184.98.1	July 11, 2022
ID-DiaScreen I-II-III-IV	004311	45200.20.1	July 11, 2022
ID-DiaCell I-II-III Asia	003614	45330.08.1	July 11, 2022
ID-DiaScreen Prophylax	004330	45660.46.2	July 11, 2022
ID-DiaCell IP-IIP-IIIP	005310	45194* 45194* 45194*	July 11, 2022
ID-DiaScreen VP-VIP	005311	45210.20.1	July 11, 2022
ID-DiaPanel-P	004214	45171.42.1	July 11, 2022
ID-DiaCell ABO A1, A2, B, O	003619	45022.20.1	July 11, 2022
ID-DiaCell ABO A1, A2, B	003617	45082.20.1	July 11, 2022
ID-DiaCell ABO A1, B, O	003615	45352.20.1	July 11, 2022
ID-DiaCell ABO A1, B	003624	45092.20.1	July 11, 2022
ID-DiaCell ABO A1	003620	06012.20.1	July 11, 2022
ID-DiaCell ABO A2	003621	06022.20.1	July 11, 2022
ID-DiaCell ABO B	003622	06032.20.1	July 11, 2022
ID-DiaCell ABO O	003623	06042.20.1	July 11, 2022
ID-DiaPanel Plus 6	004414	<i>For this product, the first delivery with the new vials will be done week 24</i>	

* These batches numbers will be confirmed April 13, 2022