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Cressier, 22nd December 2020

Field Safety Corrective Action / *FSCA 004-20*

Affected products displaying the issue:

Product Name	Catalog No	Lot No	Expiry Date
ID-Dia (Diego) Positive	004134 / 004134VJ	All lots currently in date	
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 /		

* For these products, only insufficient homogenization has been observed on the field but no nonspecific reactions.

Other reagents from the same product range not displaying the issue but requiring your attention:

Product Name	Catalog No	Lot No	Expiry Date
ID-DiaCell IP-IIP-IIIP **	005310 / 005310VJ	All lots currently in date	
ID-DiaScreen VP-VIP **	005311 / 005311VJ		
ID-DiaPanel-P **	004214 / 004214VJ		

** The 2 phenomena described in this letter have not been observed on the field or during investigations for these products. However, we require your attention on these products also and ask you to report us any issue you may be facing related to those phenomena.

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Dear Customer,

This letter contains important information that requires your immediate and urgent attention. Bio-Rad is voluntarily conducting a Field Safety Corrective Action for the products identified above.

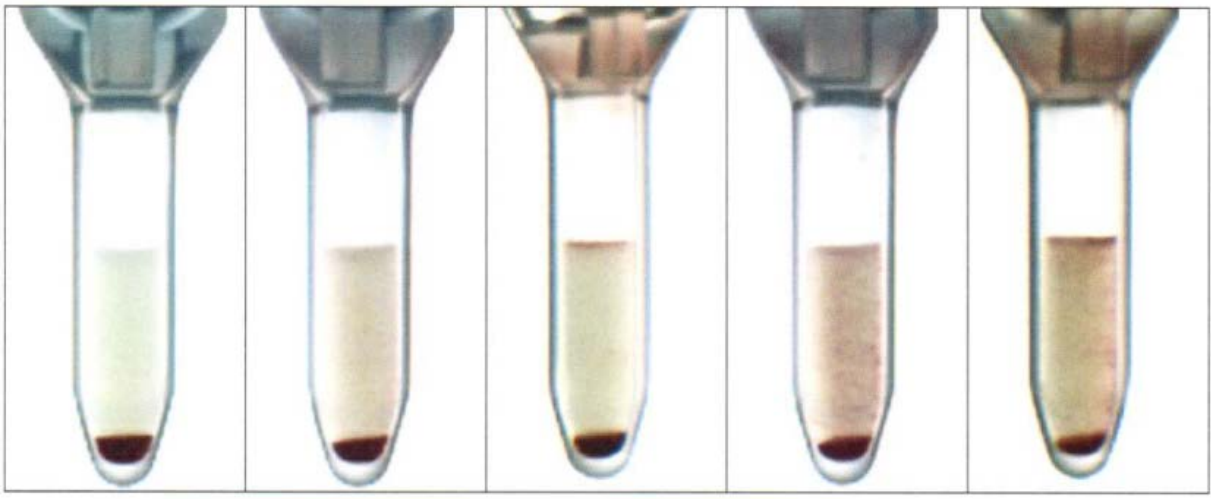
Description of the problem:

We would like to share with you, and your team, information about two phenomena which could be observed when using the products listed above.

The root cause for both these phenomena is highly suspected to be related to the type of glass vials used in the manufacturing of reagent red blood cells.

The first phenomenon concerns nonspecific reactions primarily observed on QC samples but also with patient samples and eluates. Doubtful reactions or in some cases false positive reactions may occur randomly between batches and within a same batch. This phenomenon can appear with both manual and all automated methods.

The following are examples of the type of image that can be seen when the phenomenon occurs (image 1 in Figure 1 shows a normal negative reaction for comparison). These nonspecific reactions vary from doubtful (images 2 and 3) to positive (images 4 and 5) as shown in the figure 1 below.



1	2	3	4	5
Negative	Doubtful	Doubtful	False positive	False positive

Figure 1_Example of nonspecific reactions observed in IAT

The analyzer (Banjo ID-Reader, Saxo ID-Reader II, IH-1000, IH-500 or Classic ID-GelStation) may interpret a “?”, “wR”, “wF”, or “DP” (image 2 and 3 in Figure 1) or any option up to ++ (images 4 and 5 in Figure 1), depending on the intensity of the reaction.

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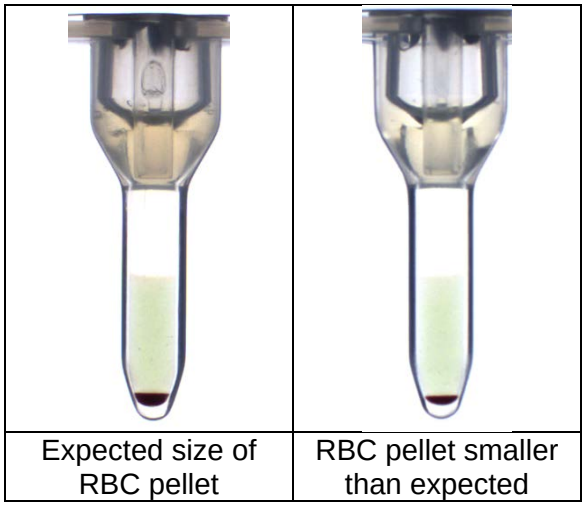
The second phenomenon concerns insufficient homogenization of the red blood cells within the vials when stored on-board either on the **IH-500 or on the IH-1000** and when the remaining volume reaches 2ml or lower. This lack of homogenization can lead to a dispense of low-concentrated red blood cell reagent into the wells of the ID-cards.

Refer to chapter 6.4.2.2 of IH-1000 user manual and chapter 7.2.1.2 of IH-500 user manual for a reminder how to display the remaining volume of reagent.

The following are examples of the type of images (Figure 2) that can be seen with small pellet compared to a well with expected red blood cell amount.



Expected size of RBC pellet	RBC pellet smaller than expected

Figure 2_Example of small pellet observed with insufficient red blood cell homogenization

Impact on the patient:

A risk assessment has been conducted and hereunder are the outcomes per application:

		Phenomenon of Nonspecific reaction	**Phenomenon of Insufficient homogenization**
	Impact of the reaction	False positive reaction	Weaker reaction or in worst case scenario a false negative reaction
Impact on the result	**Antibody screening**	Should lead to further investigations which may delay the reporting of the final result	A weaker reaction has no impact, but a false negative reaction might lead to a negative result that could impact the patient treatment in an antenatal or transfusion context. We advise you to assess this situation with your biologist to determine if a retest is deemed necessary.

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	Antibody identification	Should lead to further investigations which may delay the reporting of the final result	A weaker reaction has no impact, but a false negative reaction will lead to further investigations which may delay the reporting of the final result
	ABO reverse group	*Phenomenon not observed*	A weaker reaction has no impact, but a false negative reaction will lead to further investigations which may delay the reporting of the final result

Immediate protective measure for the user:

In case you are facing the **nonspecific reaction** during the result validation (referring to figure 1), we recommend to:

1. Invalidate the result,
2. Repeat the test using non-open vials of the same lot,

If the issue persists,

3. Repeat the test with using a kit of a new lot,

If the issue is also observed using a new lot,

4. Use an alternative method.

The issue might occur on any lot currently in date. Therefore, you might switch to the most recent lot received only if the problem persists on the lot in use.

If you work with the automatic validation activated, we recommend the visual confirmation of all positive results of indirect antiglobulin tests.

The **insufficient homogenization** leading to smaller pellets in the microtube occurs when the remaining volume of the reagent in the vial decreases.

If you detect smaller pellet than expected during the result validation (referring to figure 2 or comparing with other available result), we recommend to:

1. Invalidate the result,
2. Unload the reagent, swirl it gently to homogenize the reagent and load it back in the instrument,
3. Repeat the test,

If the issue persists,

4. Retest with a non-open vial

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To prevent this phenomenon, particularly if you are operating under the automatic validation of the results, we recommend resuspending manually the red blood cells at least every hour by gently swirling the vials, when the remaining volume has reached 2 mL or lower.

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 our Customer Service Laboratory:

product_support_cressier@bio-rad.com

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 Director Immunohematology
Diane Galéa	Marc Meyer