Medion Diagnostics

Düdingen, November 11th, 2013

# Field Safety Corrective Action 03-13

## Data-Cyte Plus 0.8% REF 213587 Lot: 610013011 Exp: 2013-12-07

Ladies and Gentlemen,

Please find attached guidance and documents regarding a Field Safety Corrective Action on the above mentioned product.

**Problem description:**
Through one of our customers we have identified that the cell # 6 of the above mentioned panel may react weakly false positive with serum/plasma which does not contain unexpected antibodies. The results of our internal investigation have shown that the false positive results are due to the very weak positive reaction with cell # 6 in the Direct Antiglobulin Test (DAT).

Cell # 6 being the only cell of the panel to have the V antigen, we draw your attention to the fact that it will therefore not be possible anymore to identify the presence of an anti-V antibody and consider this possibility in the identification of antibodies.

We would like to emphasize that our risk analysis has shown that there is no danger for the patient and that the remaining risk is exclusively reduced to a delay in transfusion but in no case a wrong transfusion may result due the test interpretation.

As a reminder and in view of the wide variety of possible antibodies, no cell panel on the market can claim to detect all antibodies present in serum/plasma of patient and this must always be taken into account when interpreting the results.

In conclusion, since the product's intended use is to identify irregular antibodies, we ask the customers **working manually to discontinue the use of cell No. 6 of the lot above and to discard any remaining vials immediately** or **for the customers working with automatic systems (Wadiana or Erytra) to invalidate any results obtained with the cell No. 6.** We also would like to underline that the other cells of the panel can be used until their expiry date. We are working to anticipate the delivery of new cell panels.

**Therefore, we kindly request you to inform your customers.**

**Course of Action:**

- Please notify your customers that have received products of this lot by supplying them with a customer letter. Make sure the letter or a translation thereof has the same content and meaning as the present letter.
- Each customer should **confirm receipt** of this important information by returning the confirmation form to your attention. Please send copies of the returned forms to our attention later on.

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- As soon as all customers are informed, the attached response form (FOR0660/06) must be filled in completely and returned to Medion Grifols Diagnostics AG, Switzerland.
- Due date for completion: **November 25th, 2013.**

We apologize for any inconvenience this action might cause and thank you very much for your cooperation.

Yours sincerely,

[redacted]
QA/RA Manager

Medion Diagnostics

Düdingen, November 11th, 2013

# Field Safety Corrective Action 03-13

## Data-Cyte Plus Di[a] 0.8% REF 213627 Lot: 611313011 Exp: 2013-12-07

Ladies and Gentlemen,

Please find attached guidance and documents regarding a Field Safety Corrective Action on the above mentioned product.

**Problem description:**
Through one of our customers we have identified that the cell # 6 of the above mentioned panel may react weakly false positive with serum/plasma which does not contain unexpected antibodies. The results of our internal investigation have shown that the false positive results are due to the very weak positive reaction with cell # 6 in the Direct Antiglobulin Test (DAT).

Cell # 6 being the only cell of the panel to have the V antigen, we draw your attention to the fact that it will therefore not be possible anymore to identify the presence of an anti-V antibody and consider this possibility in the identification of antibodies.

We would like to emphasize that our risk analysis has shown that there is no danger for the patient and that the remaining risk is exclusively reduced to a delay in transfusion but in no case a wrong transfusion may result due the test interpretation.

As a reminder and in view of the wide variety of possible antibodies, no cell panel on the market can claim to detect all antibodies present in serum/plasma of patient and this must always be taken into account when interpreting the results.

In conclusion, since the product's intended use is to identify irregular antibodies, we ask the customers **working manually to discontinue the use of cell No. 6 of the lot above and to discard any remaining vials immediately** or **for the customers working with automatic systems (Wadiana or Erytra) to invalidate any results obtained with the cell No. 6.** We also would like to underline that the other cells of the panel can be used until their expiry date. We are working to anticipate the delivery of new cell panels.

**Therefore, we kindly request you to inform your customers.**

**Course of Action:**

- Please notify your customers that have received products of this lot by supplying them with a customer letter. Make sure the letter or a translation thereof has the same content and meaning as the present letter.
- Each customer should **confirm receipt** of this important information by returning the confirmation form to your attention. Please send copies of the returned forms to our attention later on.
- As soon as all customers are informed, the attached response form (FOR0660/06) must be filled in completely and returned to Medion Grifols Diagnostics AG, Switzerland.
- Due date for completion: **November 25th, 2013.**

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Yours sincerely,

[redacted]

QA/RA Manager