Advisory Notice- NC

For Attention of : *DISTRIBUTORS and customers*
Date: 21-06-2024

Object: Problem/default Notification

Dear Customer,

Please be advised that a problem/default has been detected on the following products:

Affected Products :

Device type - Line	BlueDiver Dot – Dot for BDI

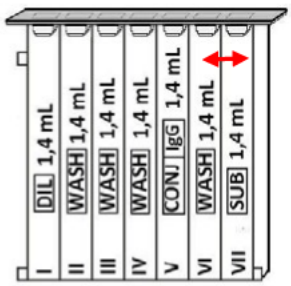
Product device Name	AD reference	Lot Number	Quantity received	Date of shipment – delivery note
NDH Chromatin + DFS70 Dot for BDI	AD NDHDFSDBD	FA240518		

Device deficiency:

Description of the problem

☐ Inadequacy of information: Error in labelling - Error in instructions given
☐ Error in assembling/packaging
☐ Malfunction
☒ Problem in the performance of the product
☐ Use error

Brief description
We have identified a defect of the reagent cartridges in several kits of the BlueDiver Dot and Quantrix range. In fact, the last two reagents were inverted in the latest wells.



Substrate was in **position VI instead of position VII**, **WASH** was in position **VII instead of position VI.**
This defect is not easy to identify because wash and substrate solutions have almost the same color.

Severity

☒Identification of minor non-conformity of the product, no impact on product safety was observed on the distributor, operator, healthcare professional or patient.

The products with defective cartridges cannot be used and could lead to inconsistent results: reactivity of parameters could be lower than expected. This could lead to false negative results.
The test shall be repeated if the clinician had obtained discrepancy of results compared to the reference method.

Field Safety Notice (FSN)

ALPHADIA Contact name : Bernard Noirhomme (noirhomme.b@alphadia.be), Benoit Autem (bautem@d-tek.be)

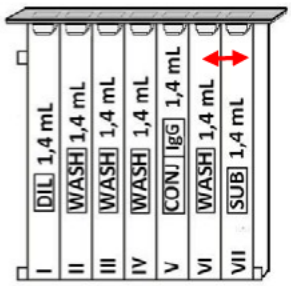
1. Other information on affected device

Inconsistent results with following products due to cartridge reagent defect:

Product device Name	AD reference	Lot Number	Quantity received	Date of shipment – delivery note
NDH Chromatin + DFS70 Dot for BDI	AD NDHDFSDBD	FA240518		

2. Reason for Field Safety Corrective Action

Risk of inconsistent results with the products:
We have identified a defect of the reagent cartridges in several kits of the BlueDiver Dot and Quantrix range. In fact, the last two reagents were inverted in the latest wells.



Substrate was in **position VI instead of position VII**, **WASH** was in **position VII instead of position VI**.
This defect is not easy to identify because wash and substrate solutions have almost the same color.
The products with defective cartridges cannot be used and could lead to inconsistent results: reactivity of parameters could be lower than expected. This could lead to false negative results.

3. Type of Action to mitigate the risk

Action(s) to be taken by the manufacturer

- Identify non-conforming products already distributed :
- Identify non-conforming product remaining in stock:
- Destroy non-conforming product remaining in stock:

When the action have to be done : 21-06-2024

This FSN requires to be communicated to the distributors/importers and customers concerned and will be supplied with Field Safety Notice – Distributor Importer Reply Form
(Appendix 1)

Action(s) to be taken by distributors and sub-distributors

- Identify non-conforming products already distributed
- Identify non-conforming product remaining in stock
- Destroy non-conforming product remaining in stock
- Advice sub-distributors and end-user with FSN

If applicable, this FSN requires to be communicated to the customers and end-user concerned and will be supplied with Field Safety Notice – Customer-End-user Reply Form
(based on Appendix 2)

When the action have to be done : 21-06-2024

Action(s) to be taken by customers-end-users

- Identify non-conforming products already used
- Identify non-conforming product remaining in stock
- Destroy non-conforming product remaining in stock

When the action have to be done : 21-06-2024

4. Other information

*The Competent (Regulatory) Authority of your country has been informed about this communication to customers. **

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Appendix 1: Template for a Field Safety Notice Distributor/Importer Reply Form

Appendix 2: Template for a Field Safety Notice Customer Reply Form Customer/End-User Reply Form

Note: Please refer to the document **md_sector_lang-req-table-ivdr** sent with this advisory notice for the translation requirements of the FSN template in European countries, please refer to your importers or authorized representative persons for the requirements in other countries.

We apologize for any inconvenience caused and remain at your disposal for any further information. Please contact our RA Manager, if needed.

François Christine RA Manager	[redacted]

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

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Appendix 1 - Template for a Field Safety Notice
Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	SQP 20240621-1
FSN Date	21-06-2024

Product device Name	AD reference	Lot Number	Quantity received	Date of shipment – delivery note
NDH Chromatin + DFS70 Dot for BDI	ADNDHDFSDBD	FA240518		

2. Distributor/Importer Details	
Company Name	D-Tek / Alphadia
Address	Rue du Bosquet 15A, 1435 Mont-Saint-Guibert
Contact Name	Benoit Autem
Telephone number	+32 65 841 888
Email	bautem@d-tek.be

3. Return acknowledgement to Sender	
Email	cfrancois@d-tek.be,glapage@d-tek.be , scaturano@d-tek.be
Distributor/Importer Helpline	+32 65 841 888
Postal Address	19, rue René Descartes B-7000 Mons BELGIUM
Web Portal	https://d-tek.be/fr
Deadline for returning the Distributor/Importer reply form	19-07-2024

4. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined inventory	
☐	I have identified customers that received or may have received this device	
☐	I have informed the identified customers of this FSN	
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected devices – enter number destroyed and date complete.	
Print Name		
Signature/ Stamp		
Date		

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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Appendix 2 - Template for a Field Safety Notice
Customer/End-User Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	SQP 20240621-1
FSN Date	21-06-2024

Product device Name	AD reference	Lot Number	Quantity received	Date of shipment – delivery note
NDH Chromatin + DFS70 Dot for BDI	ADNDHDFSDBD	FA240518		

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Shipping address if different to above	
Contact Name	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content		
☐	I performed all actions requested by the FSN		
☐	The information and required actions have been brought to the attention of all relevant users and executed		
☐	I have destroyed affected devices – enter number destroyed and date complete		
☐	No affected devices are available for destruction		
Print Name			
Signature			
Date			

4. Return acknowledgement to sender	
Email	
Postal Address	
Web Portal	
Deadline for returning the customer reply form	19-07-2024

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.