Advisory Notice – Non-Conformity
Field Safety Notification

PART B. Field Safety Notice Form + Appendix 2

Field Safety Notice (FSN): RC 2501131
Device Commercial Name: IFPCADIV-24
Risk addressed by FSN: risk of false negative result with IF antigen

*Contact details of local representative (name, e-mail, telephone, address etc.)**

PRAXIS MEDICA SRL
Strada Rufeni 8, Iași 700304, Roumanie

This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

1. General information on affected device

Primary clinical purpose of the device

BlueDiver Dot Gastritis IgG is an Immunodot kit intended for the detection, in human sera only, of IgG autoantibodies against the following antigens: the Intrinsic Factor (IF) and the Parietal Cell Antigen (PCA).

This kit is intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kit is intended as an aid in the diagnosis of several autoimmune diseases (for more details, see 11.5 *Auto-antibodies diagnostic values in the IFU*).

The test is intended for a large, routine population. This kit is strictly reserved for professional use in clinical analysis laboratories. This kit is strictly foreseen as an automated test and can only be used in a BlueDiver Instrument Model I or II

UDI (optional)

Immediate stop to the use of the product here under!
According to the information given from distributor to manufacturer concerning **quantities** and **locations**, the stock is at end-users' level as follows:

Country: Romania **End-User: Name of end-user**

Product Device Name	Reference	Lot Number	Qty	Date of Shipment – Delivery Note
BlueDiver Dot Gastritis IgG	IFPCADIV-24	CU241138	1	XXXXX

2. Reason for Field Safety Corrective Action (FSCA)

After receiving a complaint from a customer and after investigations, we observed that the quality of IF antigen on the production batch CU241138 showed lower reactivity than expected and leading to false negative results for some samples. Although the positive samples used in our QC gave results conforming to specifications, we decided to stop the use of this product to avoid risk of false negative results.
As a corrective action, D-tek had already tested several antigens from different suppliers as back-up solution. After validation tests made with EQAS samples, we decided to use a recombinant form of the antigen which demonstrates higher performance than the previous one which was a native antigen.

3. Type of Action to mitigate the risk

Action(s) taken by the manufacturer

- Manufacturer has identified the device and the stock remaining at manufacturer's site and proceeded:
  - ☐ To put device in quarantine
  - ☒ To destroy device
  - ☐ To have an on-site device modification/ inspection of the device
  - ☐ To change the Instructions for Use (IFU) or labels
  - ☒ Other : inform the concerned distributors
  - ☐ None

Action(s) have been carried out by: 24-01-2025

Action(s) taken by distributors and sub-distributors

- Distributor has identified the device and the quantities remaining in stock at distributor's site and has followed the instructions given by manufacturer, i.e.:
  - ☐ Device has been put in quarantine
  - ☐ Device has been returned
  - ☒ Device has been destroyed
  - ☐ Device has been modified/inspected on site
  - ☐ Distributor has taken note of amendment / reinforcement of Instructions for Use (IFU) or labels
  - ☒ Other: inform the concerned end-users
  - ☐ None

Action(s) have been carried out by: dd-mm-yyyy

This FSN is required to be communicated to the patient/lay user and is supplied with the "Customer Reply Form template" in the local languages as given by distributor (Appendix 2)

Action(s) to be taken by Customers/End-Users

- Distributor has identified the device and the quantities remaining in stock at end-user's site and demands that end-user follows these instructions:
  - ☐ Put device in quarantine
  - ☐ Return device
  - ☒ Destroy device
  - ☐ On site device modification/ inspection of the device
  - ☐ Follow patient management recommendations
  - ☐ Take note of amendment / reinforcement of Instructions for Use (IFU) or labels
  - ☐ Other:
  - ☐ None

By when the actions must be carried out: 26-02-2025

4. Other information

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

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

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

Mrs Christine FRANCOIS
RA Manager

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 2 -
Field Safety Notice
Customer/End-User Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**RC 2501131**
FSN Date	DD-MM-YYYY

Immediate stop to the use of the product hereunder!
Follow the instructions given in FSN

- ☐ Put device in quarantine
- ☐ Return device
- ☒ Destroy device
- ☐ On site device modification/ inspection of the device
- ☐ Follow patient management recommendations
- ☐ Take note of amendment / reinforcement of Instructions for Use (IFU) or labels
- ☐ Other
- ☐ None

Country: Romania **End-User:** Name of end-user

Product Device Name	Reference	Lot Number	Qty	Date of Shipment – Delivery Note
BlueDiver Dot Gastritis IgG	IFPCADIV-24	CU241138	1	XXXXX

2. Customer Details	Customer-end-user to complete
Healthcare Organisation Name	XXX
Healthcare Organisation Address	XXX
Shipping address if different to above	XXX
Contact Name	XXX
Telephone number	XXX
Email	XXX

3. Customer action undertaken on behalf of Healthcare Organisation End-User: Tick or add N/A				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content			
☐	I have returned affected devices	If yes, add Quantity, Lot, Date		
		Qty	Lot	Date
☒	I have destroyed affected devices	If yes, add Quantity, Lot, Date		
		Qty	Lot	Date
☐	No affected devices are available for destruction anymore			
☐	Other action (Define):	(Text)		

Print Name	End-User print name here
Signature	End-User sign here
Date	Date

4. Return acknowledgement to sender	**Please send this document back to:**
Email	cfrancois@d-tek.be
Postal Address	**D-tek s.a.** Parc Initialis Rue René Descartes 19 BE-7000 Mons BELGIQUE
Web Portal	www.d-tek.be
Deadline for returning the customer reply form	Date 26-02-2025 *Date*

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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