Rev 1: September 2018
FSN Ref: 273AV

Date: 01-03-2021

Urgent Field Safety Notice - NF-light® ELISA

For Attention of: End users of NF-light® ELISA, i.e. clinical laboratory personnel, researchers, doctors interpreting test results from the assay

Contact details of local representative (name, e-mail, telephone, address etc.)
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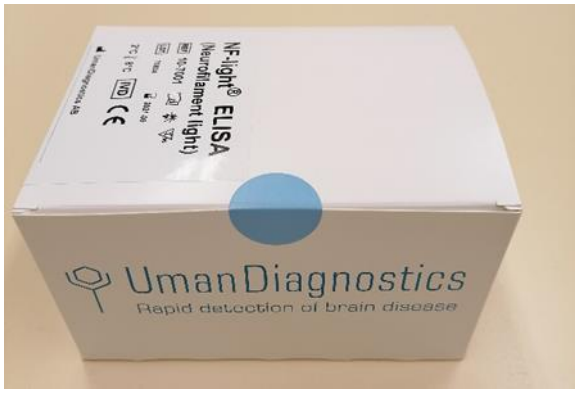
Risk addressed by FSN

	1. **Information on Affected Devices**
1.	1. Device Type(s)
	In-vitro diagnostic immunoassay device intended for quantitative determinations of human Neurofilament light (NF-L) protein in cerebrospinal fluid (CSF). 
1.	2. Commercial name(s)
	NF-light® ELISA
1.	3. Primary clinical purpose of device(s)
	NF-light® ELISA is an invitro diagnostic device intended for quantitative determinations of human Neurofilament light (NF-L) protein in cerebrospinal fluid (CSF). The result is used to aid the diagnosis of neurological diseases such as amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), dementias and Parkinson's disease (PD).
1.	4. Device Model/Catalogue/part number(s)
	10-7001
1.	5. Affected serial or lot number range
	Kit lot 70757 Expiry date 2021-07

2	**Reason for Field Safety Corrective Action (FSCA)**
2.	1. Description of the product problem
	Instability of specific kit lot detected.
2.	2. Hazard giving rise to the FSCA
	The decreased stability causes a general lowering of absorbance signals, and the risk for false high sample read-out increases. The false high result could be interpreted to be caused by degradation of nerve cells.
2.	3. Probability of problem arising
	Low if kit was used before 2021-01-31. Medium if kit has been used after this date.
2.	4. Predicted risk to patient/users
	There is a low risk to patient safety or health orientation, due to the role the generated results play in clinical decisions. The test result should always be used together with other clinical findings. The test result is not intended to be used as a sole basis for clinical decisions. There is no risk to users. No product complaint has been recorded for this lot yet.
2.	5. Background on Issue
	The stability of the kit lot has been studied in-house during the shelf-life of the product. After 12 months, an unexpected drop in absorbance has been observed.
2.	6. Other information relevant to FSCA
	There are no indications that other lots of this device are affected by this issue.

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None • Do not continue to use kit lot 70757 expiry date 2021-07. • Destroy any unused product. • Fill in the attached Customer Reply Form and return to UmanDiagnostics.	
3.	2. By when should the action be completed?	No further use of lot 70757 after receiving this information. Customer Reply Form should be returned by 2021-04-01

3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes For samples analysed after 2021-01-31, analysis results should be reviewed. If absorbances for the highest calibrator level (10 000 pg/ml) were below < 2.0 AU, results should be rejected.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes Deadline 2021-04-01
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None • All kits in stock have been rejected. • All customers who have received this lot will be informed about this quality defect. • If kits could not be used as intended, replacement kits of a different lot will be sent free of charge.	
3	6. By when should the action be completed?	Within two weeks after receival of the Customer Reply Form.

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**UmanDiagnostics**
	b. Address	**Tvistevägen 48A, 906 37 Umeå Sweden**
	c. Website address	**www.umandiagnostics.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature 	**Malin Stigbrand** **Head of Quality Assurance and Regulatory Affairs**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations 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..*

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	273AV
FSN Date*	2021-03-01
Product/ Device name*	NF-light® ELISA
Product Code(s)	10-7001
Batch/Serial Number (s)	Kit lot 70757 Expiry date 2021-07

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
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.	Customer to complete or enter N/A	
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to sender	
Email	info@umandiagnostics.se
Customer Helpline	+46 90 777880
Postal Address	Tvistevägen 48A, 907 36 Umeå, Sweden
Web Portal	www.umandiagnostics.com
Deadline for returning the customer reply form*	2021-04-01

* Mandatory field

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.