

Date: 14 June 2022

Urgent Field Safety Notice

Thermo Scientific™ IDEIA™ Lyme Neuroborreliosis (K602811-2)

For Attention of*: Lab Managers

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

E.mail: mbd.vigilance@thermofisher.com
Telephone: +44(0) 1256 841144

Fax: +44(0) 1256 479525



Urgent Field Safety Notice (FSN)

Thermo Scientific™ IDEIA™ Lyme Neuroborreliosis

	1. Information on Affected Devices*					
1.	1. Device Type(s)*					
	IVD					
1.	2. Commercial name(s)					
Thermo Scientific IDEIA Lyme Neuroborreliosis (K602811-2)						
1.	Unique Device Identifier(s) (UDI-DI)					
	05032384501854					
1.	4. Primary clinical purpose of device(s)*					
	Thermo Scientific [™] IDEIA [™] Lyme Neuroborreliosis test is an enzyme immunoassay for the detection of intrathecally produced human IgG and IgM antibodies to <i>Borrelia burgdorferi</i> sensu lato. The kit is intended as an aid in the diagnosis of Lyme Neuroborreliosis.	;				
1.	Device Model/Catalogue/part number(s)*					
	K602811-2					
1.	6. Software version					
	N/A					
1.	7. Affected serial or lot number range					
	3346025, 3382296, 3399374					
1.	8. Associated devices					
	N/A					

		2. Reason for Field Safety Corrective Action (FSCA)*		
2.	Description of the product problem*			
		An internal technical investigation has determined that when testing at 20°C, K602811-2 IDEIA Lyme Neuroborreliosis Lots. 3346025, 3382296 and 3399374, results in the IgM positive control fall below the IFU criteria (>0.5) therefore causing an invalid test result.		
2.	2. Hazard giving rise to the FSCA*			
		Delay to patient treatment		
2.	3.	Probability of problem arising		
		High		
2.	4.	Predicted risk to patient/users		
	1.	There should be no immediate or long-term health consequences from use of K602811-2 IDEIA Lyme Neuroborreliosis Lots. 3346025, 3382296 and 3399374. The clinical risk should therefore be considered as minor as low positive control invalidates the assay.		
2.	5.	Further information to help characterise the problem		
		N/A		
2.	6.	Background on Issue		
		Fifteen complaints have been received from 11 customers stating that IgM control is 'too low'. All three lots use the same IgM control.		



2.	7. Other information relevant to FSCA			
	Lot	DOM (YYYY-MM-DD)	Exp. Date (YYYY-MM-DD)	
	3346025	2021-12-08	2023-03-31	
	3382296	2021-12-14	2023-04-30	
	3399374	2022-02-25	2023-04-30	

3. Type of Action to mitigate the Risk*					
3.	1.	. Action To Be Taken by the User*			
		\square Identify Device \square Quarantine Device \square Return Device \boxtimes Destroy Device			
		☐ On-site device modification/inspection			
		☐ Follow patient management recommendations			
		☐ Take note of amendment/reinforcement of Instructions For Use (IFU)			
		□ Other □ None			
3.	2.	By when should the action be completed?	Immediately		
3.	3.	Particular considerations for: IVD			
		Is follow-up of patients or review of patients' previous results recommended?			
		We request that the requirement for review of reported test results should be determined by the appropriate technical expert.			
3.		Is customer Reply Required? * Yes			
3.		f yes, form attached specifying deadline for return)			
J.	٥.	5. Action Being Taken by the Manufacturer			
		. 5	IFU or labelling change		
		□ Other □	None		
3	6.	By when should the action be completed?	As soon as possible		
3.	7.	Is the FSN required to be communicated to the patient No /lay user?			
3	8.		ovided additional information s lay or non-professional user i		
		Choose an item Choose an item			



	4. General Information*			
4.	1. FSN Type*	New		
4.	For updated FSN, reference N/A number and date of previous FSN			
4.	3. For Updated FSN, key new information as follows:			
	N/A			
4.	Further advice or information already expected in follow-up FSN? *	Not planned yet		
	5. If follow-up FSN expected, what is th	e further advice expected to relate to:		
4	N/A			
4	6. Anticipated timescale for follow-up N/A FSN			
4.	7. Manufacturer information			
	(For contact details of local representative re			
	a. Company Name	Thermo Fisher Scientific		
	b. Address	Remel Europe Ltd,		
		Clipper Boulevard West		
		Dartford		
		Kent		
		DA26PT		
	c. Website address	www.thermofisher.com		
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *			
4.	9. List of attachments/appendices:	Customer response form		
4.	10. Name	Carissa Courtney Director, Quality EMEA		
	Signature	Glarhey		

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.*



Customer Reply Form

1. Field Safety Notice (FSN) information						
FSN Reference number*			2-006			
FSN Date*		14 J	14 June 2022			
Product/ Device name*		Ther	Thermo Scientific™ IDEIA™ Lyme Neuroborreliosis			
Product Code(s)		K602	2811-2	-		
Batch/	Serial Number (s)	3346	6025, 338	32296, 3399374		
2. Cı	ustomer Details					
Accou	nt Number					
Organ	isation Name*					
Organ	isation Address*					
Depar	tment/Unit					
	ng address if different to above					
Conta	ct Name*					
Title o	r Function					
	none number*					
Email*	•					
3. Cı	ustomer action undertaken on be	half c	of Health	care Organisation		
	I confirm receipt of the Field Safety	у				
Ш	Notice and that I read and					
	understood its content.					
	I performed all actions requested					
ш	by the FSN.					
	The information and required					
actions have been brought to the						
attention of all relevant users and executed.						
I have returned affected devices -			Qty:	Lot/Serial Number:	Date Returned	
Ш	enter number of devices returned	9	χιy.	Lot/Senai Number.	(DD/MM/YY)	
	and date complete or N/A					
	and date complete of WA		Comments:			
	I have destroyed affected devices	0	Qty:	Lot/Serial Number:	Date Returned	
	 enter number destroyed and dat 		,.		(DD/MM/YY)	
	complete.		Qty	Credit □ Replacer	nent □	
- Sampleton		С	Comments:			
	No affected devices are available					
Ш	for return/ destruction					
	Other Action (Define):					
Ш	,					
	I do not have any affected devices	3.				
Ш	•					
I have a query please contact me						
	(e.g. need for replacement of the					
	product).					
Print Name*						
Signat	ure*					
Date*		1				



4. Return acknowledgement to sender		
Email	MBD.vigilance@thermofisher.com	
Telephone Number & Fax	Tel: +44(0) 1256 841144	
·	Fax :+44(0) 1256 479525	
Postal Address		
Deadline for returning the reply form*	12 July 2022	

Mandatory fields are marked with *

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.