

Rev 1: September 2018  
FSN Ref: FSN-2023-003

FSCA Ref: FSN-2023-003

Date: 2 June 2023

**Urgent Field Safety Notice**  
**Thermo Scientific™ RapID™ STR System**

For Attention of\*: Lab Managers

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

E.mail : [mbd.vigilance@thermofisher.com](mailto:mbd.vigilance@thermofisher.com)

Telephone: +44(0) 1256 841144

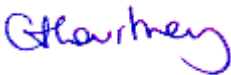
Fax: +44(0) 1256 479525

**Urgent Field Safety Notice (FSN)**  
**Thermo Scientific™ RapID™ STR System**

1. Information on Affected Devices*	
1.	1. Device Type(s)* IVD
1.	2. Commercial name(s) RapID™ STR System
1.	3. Unique Device Identifier(s) (UDI-DI) 00848838058073
1.	4. Primary clinical purpose of device(s)* Thermo Scientific™ RapID™ STR System is a qualitative micromethod employing conventional and chromogenic substrates for the identification of medically important streptococci and related organisms which have been isolated from human clinical specimens. The RapID STR System is intended to aid in the identification of Lancefield groups A, B, C, D, and G streptococci, viridans streptococci, and <i>Streptococcus pneumoniae</i> , <i>Enterococcus</i> spp., <i>Aerococcus</i> spp., <i>Gemella</i> spp., <i>Leuconostoc</i> spp., <i>Pediococcus</i> spp., <i>Weisella confusa</i> , and <i>Listeria monocytogenes</i> . 1-10 A complete listing of the organisms addressed by the RapID™ STR System is provided in the RapID STR Differential Chart.
1.	5. Device Model/Catalogue/part number(s)* R8311003
1.	6. Software version N/A
1.	7. Affected serial or lot number range 3599550, 3599549, 3608574 and 3616894
1.	8. Associated devices N/A

<b>2. Reason for Field Safety Corrective Action (FSCA)*</b>																											
2.	1. Description of the product problem*																										
	A technical investigation has determined <i>S. pyogenes</i> ATCC® 19615™ and <i>E. faecalis</i> ATCC® 29212™ gave a positive reaction to INU well where it should have given a negative reaction. The culture testing was completed with McFarland #1 standard turbidity.																										
2.	2. Hazard giving rise to the FSCA*																										
	The INU well is giving the incorrect reaction with certain strains.																										
2.	3. Probability of problem arising																										
	High																										
2.	4. Predicted risk to patient/users																										
	<p>There should be no immediate or long-term health consequences from using this product. The reagent Inulin (INU) contained in the RapID™ STR biochemical panel is primarily used to differentiate <i>S. pneumoniae</i> (positive) from other streptococci isolated from clinical specimens. The inconsistent positive INU results for the QC strains <i>S. pyogenes</i> and <i>E. faecalis</i> in these lots should be negative.</p> <p>However, other reactions on initial culture plates, including Gram smear (Gram positive lancet-shaped diplococci), haemolysis, bile solubility, and optochin susceptibility are the most definitive rapid and confirmatory tests for diagnostic identification of <i>S. pneumoniae</i>.</p> <p>Further, the entire range of biochemical tests and other tests should be considered in the identification of any streptococci isolated from clinical specimens. For <i>S. pyogenes</i> and <i>E. faecalis</i>, haemolysis, serotyping esculin results, etc. are clearly more definitive than inulin. In this context of a single false positive test as indicated above, the clinical risk should be considered negligible.</p>																										
2.	5. Further information to help characterise the problem																										
	N/A																										
2.	6. Background on Issue																										
	Customer complaint received for R8311003 RapID™ STR lot 3599550 stating QC failure for <i>S. pyogenes</i> ATCC® 19615™ with positive reaction (orange) in INU well, should be negative (red). When the QA retained kit was tested the same observation was seen.																										
2.	7. Other information relevant to FSCA																										
	<table border="1"> <thead> <tr> <th>Product Code</th> <th>Kit Lot Number</th> <th>Panel Lot Number</th> <th>Expiry</th> <th>Manufactured Date</th> </tr> </thead> <tbody> <tr> <td rowspan="4">R8311003</td> <td>3599550</td> <td>3599548</td> <td>2023-08-27</td> <td>2023-03-21</td> </tr> <tr> <td>3599549</td> <td>3599547</td> <td>2023-06-05</td> <td>2023-02-07</td> </tr> <tr> <td>3608574</td> <td>3608572</td> <td>2023-08-13</td> <td>2023-03-13</td> </tr> <tr> <td>3616894</td> <td>3599548</td> <td>2023-09-08</td> <td>2023-03-31</td> </tr> </tbody> </table>					Product Code	Kit Lot Number	Panel Lot Number	Expiry	Manufactured Date	R8311003	3599550	3599548	2023-08-27	2023-03-21	3599549	3599547	2023-06-05	2023-02-07	3608574	3608572	2023-08-13	2023-03-13	3616894	3599548	2023-09-08	2023-03-31
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<b>4. General Information*</b>		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	N/A
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	N/A
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Thermo Fisher Scientific
	b. Address	Clipper Boulevard West, Cross ways industrial estate, Dartford, Kent. DA2 6PT
	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	<b>Carissa Courtney</b> <b>Director, Quality EMEA</b>
	Signature	

<b>Transmission of this Field Safety Notice</b>	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

**Customer Reply Form**

<b>1. Field Safety Notice (FSN) information</b>			
FSN Reference number*	2023-003		
FSN Date*	2 June 2023		
Product/ Device name*	Thermo Scientific™ RapID™ STR System		
Product Code(s)	R8311003		
Batch/Serial Number (s)	3599550, 3599549, 3608574 and 3616894		
<b>2. Customer Details</b>			
Account Number			
Organisation Name*			
Organisation Address*			
Department/Unit			
Shipping address if different to above			
Contact Name*			
Title or Function			
Telephone number*			
Email*			
<b>3. Customer action undertaken on behalf of Healthcare Organisation</b>			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.		
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete or <b>N/A</b>	Qty:	Lot/Serial Number:
		Date Returned (DD/MM/YY)	
		Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Date Completed (DD/MM/YY)	
		Qty	Credit <input type="checkbox"/>
		Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction		
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).		
Print Name*			
Signature*			
Date*			
<b>4. Return acknowledgement to sender</b>			
Email	<a href="mailto:MBD.vigilance@thermofisher.com">MBD.vigilance@thermofisher.com</a>		
Telephone Number & Fax	Tel : +44(0) 1256 841144 & Fax :+44(0) 1256 479525		
Postal Address			
<b>Deadline for returning the reply form*</b>	<b>3 July 2023</b>		

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.**