Rev 1: September 2018
FSN Ref: FSN-2020-0006 FSCA Ref: FSN-2020-0006

Date: 22-JUL-2020

Urgent Field Safety Notice
Thermo Scientific™ Remel™ Bordetella pertussis Agglutinating Serum

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 334 994

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Urgent Field Safety Notice (FSN)
Thermo Scientific™ Remel™ Bordetella pertussis Agglutinating Serum
Risk addressed by FSN

	1. **Information on Affected Devices***	
1.	1. Device Type(s)*	
	IVD/ Antisera for agglutination	
1.	2. Commercial name(s)	
	Thermo Scientific™ Remel™ Bordetella pertussis Agglutinating Serum	
1.	3. Unique Device Identifier(s) (UDI-DI)	
	05056080501826	
1.	4. Primary clinical purpose of device(s)*	
	Bordetella pertussis antiserum is suitable for use in slide agglutination tests to serologically identify *Bordetella pertussis* for epidemiological and diagnostic purposes. The serum has been absorbed to render it specific within the genus described; full identification of an organism must only be made in conjunction with biochemical testing.	
1.	5. Device Model/Catalogue/part number(s)/product code*	
	R30165501/ZM10	
1.	6. Software version	
	N/A	
1.	7. Affected serial or lot number range	
	2407976, 2846557 and 2915974	
1.	8. Associated devices	
	N/A	

	2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*	
	An internal technical investigation has determined that Thermo Scientific™ Remel™ Bordetella pertussis Agglutinating Serum (R30165501) is not performing in accordance with the IFU (Instructions For Use).	
2.	2. Hazard giving rise to the FSCA*	
	May give false negative results to 1,3 serotype when used according to the IFU.	
2.	3. Probability of problem arising	
	High	
2.	4. Predicted risk to patient/users	
	The clinical risk for patients in this scenario should be considered minor. Any false negatives are unlikely to have epidemiological consequences or infection control consequences (since a biochemically confirmed Bordetella species will be started on respiratory precautions if in hospital).	
2.	5. Further information to help characterise the problem	
	None	
2.	6. Background on Issue	
	Internal investigation.	

2.	7. Other information relevant to FSCA
	2407976 DOM; 20-Dec-2018 Expiry; 31-Dec-2021 2846557 DOM; 25-Oct-2019 Expiry; 01-Jan-2022 2915974 DOM; 11-Feb-2020 Expiry; 02-Jan-2022

	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	
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? Yes We request that the requirement for review of reported test results should be determined by the appropriate technical expert	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	ASAP
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Choose an item.	

	4. General Information*	
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 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	xxx
	Signature	

	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.*

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-2020-0006
FSN Date*	22 July 2020
Product/ Device name*	Thermo Scientific™ Remel™ Bordetella pertussis Agglutinating Serum
Product Code(s)	R30165501 / ZM10
Batch/Serial Number (s)	2407976, 2846557 and 2915974

2. Customer Details	
Account Number	
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.			
☐	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 returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete. **(EDIT WHEN NECESSARY)**	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction			
☐	Other Action (Define):			
☐	I do not have any affected devices.			
☐	I have a query please contact me (e.g. need for replacement of the product).			

Print Name*	
Signature*	
Date*	
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*	**19 August 2020**

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.