

Rev 1: September 2018  
FSN Ref: FSN-2026-002

Date: 19 March 2026

## **Urgent Field Safety Notice**

### **Oxoid™ Agglutinating Sera, Salmonella 9-0 (R30957301)**

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

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**Urgent Field Safety Notice (FSN)**

**Oxoid™ Agglutinating Sera, Salmonella 9-0 (R30957301)**

<b>1. Information on Affected Devices*</b>																						
1.	1. Device Type(s)* IVD																					
1.	2. Commercial name(s) OXOID™ Agglutinating Sera, Salmonella 9-0																					
1.	3. Unique Device Identifier(s) (UDI-DI) 50560805002708																					
1.	4. Primary clinical purpose of device(s)* Salmonella Agglutinating Sera are intended for use in slide agglutination screening procedures to serologically identify Salmonella cultures for epidemiological and diagnostic purposes. The monovalent Salmonella H Agglutinating sera may be used in phase change procedures <sup>1</sup> . For in vitro diagnostic use only. For professional use only.																					
1.	5. Device Model/Catalogue/part number(s)* R30957301																					
1.	6. Software version N/A																					
1.	7. Affected serial or lot number range <table border="1" data-bbox="303 1041 901 1780"> <thead> <tr> <th>Kit Lot Number</th> </tr> </thead> <tbody> <tr><td>6172600</td></tr> <tr><td>3797949</td></tr> <tr><td>3797948</td></tr> <tr><td>6172741</td></tr> <tr><td>6171393</td></tr> <tr><td>6150168</td></tr> <tr><td>6107767</td></tr> <tr><td>3766399</td></tr> <tr><td>3766400</td></tr> <tr><td>3780497</td></tr> <tr><td>3719592</td></tr> <tr><td>3709358</td></tr> <tr><td>6266130</td></tr> <tr><td>6253410</td></tr> <tr><td>6260215</td></tr> <tr><td>6222350</td></tr> <tr><td>6196409</td></tr> <tr><td>6233859</td></tr> <tr><td>6233858</td></tr> <tr><td>6206685</td></tr> </tbody> </table>	Kit Lot Number	6172600	3797949	3797948	6172741	6171393	6150168	6107767	3766399	3766400	3780497	3719592	3709358	6266130	6253410	6260215	6222350	6196409	6233859	6233858	6206685
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1.	8. Associated devices N/A																					

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<b>2. Reason for Field Safety Corrective Action (FSCA)*</b>			
2.	<p>1. Description of the product problem*</p> <p>An internal technical investigation has determined that the following lots of R30957301 OXOID™ Agglutinating Sera, Salmonella 9-0 are not performing to IFU criteria showing cross reactions with 2-0 within 60 seconds.</p>		
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>Cross reactions with Salmonella 2-0 leading to false positive results.</p>		
2.	<p>3. Probability of problem arising</p> <p>High</p>		
2.	<p>4. Predicted risk to patient/users</p> <p>There should be no immediate or long-term health consequences associated with the use of the affected lots of R30957301 Oxoid™ Agglutinating Sera, Salmonella 9-O. The clinical risk is therefore considered to be negligible. This kit is intended for use in the serological identification of Salmonella serogroups and is not used to determine the presence or absence of Salmonella infection. Clinical management of Salmonella infections is not typically dependent on serogroup identification. While cross-reactivity may result in the misidentification of a Salmonella 9-O serotype as a 2-O serotype, such misclassification does not impact patient diagnosis or treatment decisions. Accordingly, the risk to patients is considered negligible.</p>		
2.	<p>5. Further information to help characterise the problem</p> <p>N/A</p>		
2.	<p>6. Background on Issue</p> <p>Cross reaction has been identified</p>		
2.	<p>7. Other information relevant to FSCA</p> <p>N/A</p>		
<b>3. Type of Action to mitigate the Risk*</b>			
3.	<p>1. Action To Be Taken by the User*</p> <p><input checked="" type="checkbox"/> Identify Device    <input type="checkbox"/> Quarantine Device    <input type="checkbox"/> Return Device    <input checked="" type="checkbox"/> Destroy Device</p> <p><input type="checkbox"/> On-site device modification/inspection</p> <p><input checked="" type="checkbox"/> Follow patient management recommendations</p> <p><input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)</p> <p><input type="checkbox"/> Other            <input type="checkbox"/> None</p>		
3.	<table border="1"> <tr> <td>2. By when should the action be completed?</td> <td>Immediately</td> </tr> </table>	2. By when should the action be completed?	Immediately
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3.	<p>Particular considerations for:                    IVD</p> <p>Is follow-up of patients or review of patients' previous results recommended? Yes</p> <p>Review results</p>		

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3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer	
	<input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
3	6. By when should the action be completed?	Immediately
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?	
	N/A 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	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	[REDACTED]
	b. Address	[REDACTED]
	c. Website address	www.thermofisher.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. <b>Yes</b>	
4.	9. List of attachments/appendices:	Customer response form
4.	10. Name	[REDACTED]
	Signature	[REDACTED]

Transmission of this Field Safety Notice	
<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>	

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**Customer Reply Form**

1. Field Safety Notice (FSN) information			
FSN Reference number*	2026-002		
FSN Date*	19 March 2026		
Product/ Device name*	Oxoid™ Agglutinating Sera, Salmonella 9-0		
Product Code(s)	R30957301		
Batch/Serial Number (s)	20 Batches (Refer to Notification)		
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			
<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	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"/> Replacement <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*			
4. Return acknowledgement to sender			
Email	<a href="mailto:MBD.vigilance@thermofisher.com">MBD.vigilance@thermofisher.com</a>		
<b>Deadline for returning the reply form*</b>	<b>16 April 2026</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.**