Thermo Fisher Scientific
Microbiology
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800.255.6730
877.428.1924 fax
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URGENT MEDICAL DEVICE FIELD ACTION RECALL
ATTN LABORATORY: RECALL INFORMATION – ACTION REQUIRED

08/13/2018

«Ship_To_Customer_Address_1»
«Ship_To_Customer_Address_2»
«Ship_To_Customer_Address_3»
«Ship_To_Customer_Address_4»

URGENT: DELIVER TO MICRO LAB

Product Number	Product Name	Lot Number	
R05152	Thio med w/ dex, hem, vit k (7ml)100/pk	258192	
R064700	Thio med w/o ind w/dex (9ml) 100/pk	254751	
		259508	
		272498	
R064702	Thio med w/o ind, w/ dex (9ml) 20/pk	274247	
R064720	Thio med w/ dex, hem, vit k (9ml)100/pk	254749	272497
		251145	272015
		258183	258626
		271479	258625
R064730	Thio med w/ dex, hem, vit k (5ml) 100/pk	254755	272020
		260509	258181
		273564	258627
		271476	258629
		271665	259507
		251146	272499
R064732	Thio med w/ dex, hemin, vit k (5ml)20/pk	271667	
		258182	
R07176	Thio med w/o ind w/dex (10ml) 100/pk	259521	
R07180	Thio med w/ dex, hem, vit k(10ml) 100/pk	259526	258906
		258903	
		258904	
		258905	
R07182	Thio med w/ dex, hem, vit k (10mL) 20/pk	258907	260413
		258908	260519

REASON FOR FIELD ACTION:
Customers are to be advised of the following:

An internal technical investigation has confirmed that **the products and lot numbers list above**, have intermittently failed performance testing during stability studies with various anaerobic microorganisms.

RISK TO HEALTH:

Thio media is recommended for use in qualitative procedures as a general purpose media for the cultivation of aerobes and anaerobes.

We believe the risk is low based on the following rationale:

The immediate health consequence may be a delay in the recovery of anaerobic bacteria associated with an infectious process. The risk is mitigated by the empiric treatment for anaerobic infections prior to bacteria isolation in patients already suspected of having an anaerobic infection. This is mainly due to the longer incubation time for anaerobes, which can be up to several days. This empiric treatment reduces the probability that patients with suspected anaerobic infections are at greater risk of impaired clinical response.

Furthermore, no complaints nor reports of illnesses or injuries have been received.

ACTIONS TO BE TAKEN BY THE CUSTOMER:
Our records indicate that you have received the above products.

Please notify any personnel who need to be aware of the potential for failure of performance for this product. Accordingly, in keeping with our Quality Policy, we request that you inspect your stock and destroy any remaining inventory of the lots listed above and contact Customer Services or your local distributor regarding replacement. You should review results and laboratory reporting associated with use of the listed lots and consider retesting and/or seek appropriate expert advice for further action.

The US Food and Drug Administration (FDA) has been informed of this Field Action Recall.

Please return the attached Medical Device Recall Return Response form acknowledging receipt of the notice and disposal of the affected product to help with our FDA reporting obligation.

This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected products have been transferred. If you have any questions, please contact our Technical Services Department at 800-255-6730 (US) or 913-888-0939 (International).

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PRODUCT AND DISTRIBUTION INFORMATION:

Product Name	Product Number	Lot Number	Distribution Date (MMDDYYYY)	Expiration Date (MMDDYYYY)	Distributed Total Quantity
Thio med w/ dex, hem, vit k (7ml) 100/pk	R05152	258192	12/26/2017 to 02/14/2018	06/28/2018	48
Thio med w/o ind w/dex (9ml) 100/pk	R064700	254751	12/18/2017 to 02/06/2018	08/27/2018	104
		259508	01/02/2018 to 02/19/2018	09/04/2018	102
		272498	01/30/2018 to 03/06/2018	10/04/2018	19
Thio med w/o ind, w/ dex (9ml) 20/pk	R064702	274247	02/20/2018 to 06/07/2018	10/09/2018	150
Thio med w/ dex, hem, vit k (9ml) 100/pk	R064720	254749	12/04/2017 to 12/13/2017	08/17/2018	94
		251145	11/28/2017 to 12/04/2017	08/27/2018	77
		258183	12/11/2017 to 01/15/2018	08/30/2018	98
		271479	01/22/2018 to 02/13/2018	08/31/2018	53
		272497	01/30/2018 to 02/19/2018	08/31/2018	39
		272015	01/24/2018 to 02/19/2018	10/02/2018	42
		258626	12/07/2017	10/03/2018	53
		258625	12/11/2017 to 01/15/2018	10/04/2018	38
Thio med w/ dex, hem, vit k (5ml) 100/pk	R064730	254755	12/14/2017 to 01/04/2018	08/17/2018	67
		260509	12/12/2017 to 01/04/2018	08/27/2018	110
		273564	01/24/2018 to 02/26/2018	08/30/2018	111
		271476	01/10/2018 to 02/05/2018	08/31/2018	86
		271665	01/18/2018 to 02/06/2018	08/31/2018	68
		251146	11/27/2017 to 12/11/2017	08/31/2018	58
		272020	01/09/2018 to 01/17/2018	08/31/2018	151
		258181	12/11/2017 to 12/21/2017	09/04/2018	59
		258627	12/11/2017 to 02/05/2018	09/04/2018	59
		258629	12/07/2017 to 12/26/2017	09/06/2018	82
		259507	12/12/2017	10/02/2018	75
		272499	01/29/2018 to 02/19/2018	10/08/2018	85
Thio med w/ dex, hemin, vit k (5ml) 20/pk	R064732	271667	01/12/2018 to 03/19/2018	08/30/2018	343
		258182	12/11/2017 to 01/15/2018	10/02/2018	343
Thio med w/o ind w/dex (10ml) 100/pk	R07176	259521	01/17/2018 to 02/21/2018	09/04/2018	9
Thio med w/ dex, hem, vit k (10ml) 100/pk	R07180	259526	12/27/2017 to 02/20/2018	09/03/2018	146
		258903	12/18/2017 to 01/29/2018	09/03/2018	22
		258904	12/18/2017 to 01/17/2018	09/03/2018	23
		258905	12/11/2017 to 01/03/2018	09/03/2018	21
		258906	12/12/2017 to 01/10/2018	09/04/2018	22
Thio med w/ dex, hem, vit k (10mL) 20/pk	R07182	258907	12/12/2017 to 03/12/2018	09/03/2018	106
		258908	12/11/2017 to 04/03/2018	09/03/2018	122
		260413	01/29/2018 to 04/03/2018	09/05/2018	43
		260519	02/05/2018 to 02/27/2018	09/06/2018	34

TYPE OF ACTION TO BE TAKEN BY THE MANUFACTURER:
Investigation into the root cause is currently on-going. Corrective actions will be implemented upon completion of the investigation.

We appreciate your immediate attention to this field correction. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

If you have any questions, please contact our Technical Services Department at 800.255.6730 (US) or 913.888.0939 (International).

Sincerely,

[redacted]

Gary Klaassen
Director Quality Assurance & Regulatory Affairs

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MEDICAL DEVICE RECALL/FIELD SAFETY NOTICE RETURN RESPONSE
Acknowledgment Form
***Response Required**

CUSTOMER INFORMATION:
Account Number: «Ship_To_Account»
«Ship_To_Customer_Address_1»
«Ship_To_Customer_Address_2»
«Ship_To_Customer_Address_3»
«Ship_To_Customer_Address_4»

I have read and understand the attached customer letter and field action instructions: _____ (initials)

I understand that this applies to all inventory of the affected product that I have received: _____ (initials)

Has the recalled product caused and/or contributed to any deaths or serious injuries? _____ Yes _____ No
If yes, please explain:
_____

_____

AFFECTED PRODUCT REFERENCE NUMBER:
See below for products listed below that were impacted by this notice:

Product Number	Lot Number	Units Received	Units Discarded
R05152	258192		
R064700	254751		
	259508		
	272498		
R064702	274247		
R064720	254749		
	251145		
	258183		
	271479		
	272497		
	272015		
	258626		
	258625		
R064730	254755		
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R07176	259521		
R07180	259526		
	258903		
	258904		
	258905		
	258906		
R07182	258907		
	258908		
	260413		
	260519		

RESPONSE BELOW.
Use additional sheet(s) if necessary.

CUSTOMER INFORMATION:
Account Number: «Ship_To_Account»
«Ship_To_Customer_Address_1»

RESPONSE (please provide additional information, if applicable):

PLEASE RETURN COMPLETED RESPONSE FORM TO THE FOLLOWING FAX NUMBER: 1.877.428.1924, ATTN: Technical Service & Regulatory Affairs. Replacement product will be issued upon completion and return of this form.

*The FDA evaluates recall effectiveness and may contact customers that do not respond to recall notices.

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Email Address:	