

**URGENT MEDICAL DEVICE FIELD ACTION RECALL  
RECALL INFORMATION – ACTION REQUIRED**

**April 17, 2019**

«Ship\_To\_Name»

«Ship\_To\_Address»

«Ship\_To\_City», «Ship\_To\_State», «Ship\_To\_Zip»

**URGENT: DELIVER TO MICRO LAB**

**R064730 Thio Med w/Dex,Hem,Vit K (5ml) 100/PK**

**R05153 Thio Med w/Dex,Hem,Vit K (7ml) 20/PK**

**R05152 Thio Med w/Dex,Hem,Vit, K (7ml) 100/PK**

**R064732 Thio Med w/Dex,Hemin,Vit K (5ml) 20/PK**

**REASON FOR FIELD ACTION:**

Customers are to be advised of the following:

An internal technical investigation has confirmed that the following **products and lot numbers** listed below may fail performance testing per the Instructions for Use (IFU) starting at 57 days after date of manufacture (**see list below**).

Therefore, product used within the first 56 days will perform as intended per the IFU. See list below, column “Updated Expiration Date (MMDDYYYY)”.

**RISK TO HEALTH:**

This product is recommended for use in qualitative procedures as a general purpose medium for the cultivation of aerobes and anaerobes.

The immediate health consequence may be a delay in the recovery of anaerobic bacteria associated with an infectious process. Clinical risks are mitigated as it is typical for other culture media to be inoculated (e.g. Blood agar or anaerobic plates) for isolation of these aerobic and anaerobic species from clinical specimens in conjunction with the fluid thioglycollate medium. Furthermore, 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.

Additionally, performance failures are detectable when used as recommended per the Instructions for Use. Therefore, it is unlikely there would be immediate or long term health consequences.

**PRODUCT AND DISTRIBUTION INFORMATION:**
**R064730: Thio Med w/Dex,Hem,Vit K (5ml) 100/PK**

<b>Lot Number</b>	<b>Updated Expiration Date (MMDDYYYY)</b>	<b>Distribution Date (MMDDYYYY)</b>	<b>Quantity</b>	<b>Labeled Expiration Date (MMDDYYYY)</b>
298222	04/19/2018	03/19/2018 to 04/09/2018	151	11/22/2018
298278	04/23/2018	03/21/2018 to 04/16/2018	154	11/26/2018
309142	05/09/2018	03/29/2018 to 04/10/2018	34	12/12/2018
314202	05/17/2018	04/02/2018 to 04/17/2018	151	12/20/2018
318109	05/24/2018	04/09/2018 to 04/30/2018	153	12/27/2018
321247	05/30/2018	04/16/2018 to 05/01/2018	120	01/02/2019
321615	05/31/2018	04/13/2018 to 05/07/2018	127	01/03/2019
322654	06/04/2018	04/16/2018 to 05/03/2018	134	01/07/2019
323445	06/05/2018	04/18/2018 to 06/06/2018	143	01/08/2019
323457	06/05/2018	04/17/2018 to 05/14/2018	102	01/08/2019
325888	06/07/2018	04/20/2018 to 05/15/2018	88	01/10/2019
325891	06/07/2018	04/24/2018 to 05/15/2018	161	01/10/2019
327637	06/12/2018	04/26/2018 to 05/18/2018	157	01/15/2019
328656	06/13/2018	05/01/2018 to 05/18/2018	22	01/16/2019
328730	06/13/2018	05/08/2018 to 06/04/2018	128	01/16/2019
331413	06/19/2018	05/09/2018 to 06/14/2018	146	01/22/2019
332316	06/20/2018	05/02/2018 to 06/01/2018	149	01/23/2019
333823	06/21/2018	05/25/2018	63	01/24/2019
334609	06/25/2018	05/08/2018 to 06/04/2018	56	01/28/2019
335243	06/26/2018	05/15/2018 to 06/04/2018	131	01/29/2019
336083	06/27/2018	05/16/2018 to 06/16/2018	83	01/30/2019

<b>Lot Number</b>	<b>Updated Expiration Date (MMDDYYYY)</b>	<b>Distribution Date (MMDDYYYY)</b>	<b>Quantity</b>	<b>Labeled Expiration Date (MMDDYYYY)</b>
337937	07/03/2018	05/29/2018 to 06/16/2018	40	02/05/2019
340117	07/05/2018	05/30/2018 to 06/08/2018	86	02/07/2019
340303	07/05/2018	05/30/2018 to 06/12/2018	50	02/07/2019
340777	07/09/2018	05/23/2018 to 06/16/2018	79	02/11/2019
341993	07/10/2018	05/30/2018 to 06/19/2018	143	02/12/2019
343924	07/12/2018	06/07/2018 to 06/18/2018	54	02/14/2019
344723	07/16/2018	06/11/2018 to 06/21/2018	148	02/18/2019
344727	07/16/2018	06/04/2018 to 07/02/2018	78	02/18/2019
345317	07/17/2018	06/05/2018 to 06/25/2018	159	02/19/2019
345632	07/18/2018	06/06/2018 to 06/29/2018	154	02/20/2019
345635	07/18/2018	06/13/2018 to 07/02/2018	116	02/20/2019
346533	07/19/2018	06/19/2018 to 07/10/2018	141	02/21/2019
346643	07/19/2018	06/08/2018 to 07/09/2018	130	02/21/2019
346668	07/24/2018	06/25/2018 to 07/16/2018	114	02/26/2019
346710	07/25/2018	06/26/2018 to 07/16/2018	112	02/27/2019
347381	07/26/2018	06/26/2018 to 07/17/2018	101	02/28/2019
356316	08/07/2018	07/10/2018 to 07/19/2018	82	03/12/2019
357251	08/08/2018	06/29/2018 to 07/30/2018	142	03/13/2019
357252	08/08/2018	07/05/2018 to 07/30/2018	158	03/13/2019
359078	08/13/2018	07/09/2018 to 08/06/2018	102	03/18/2019
359887	08/14/2018	07/16/2018 to 08/01/2018	151	03/19/2019
360823	08/15/2018	08/03/2018 to 08/09/2018	101	03/20/2019

<b>Lot Number</b>	<b>Updated Expiration Date (MMDDYYYY)</b>	<b>Distribution Date (MMDDYYYY)</b>	<b>Quantity</b>	<b>Labeled Expiration Date (MMDDYYYY)</b>
360813	08/15/2018	07/30/2018 to 08/03/2018	30	03/20/2019
362019	08/16/2018	07/17/2018 to 08/09/2018	145	03/21/2019
366795	08/27/2018	07/20/2018 to 08/13/2018	123	04/01/2019
366791	08/27/2018	07/27/2018 to 10/03/2018	87	04/01/2019
367418	08/28/2018	07/24/2018 to 08/20/2018	146	04/02/2019
370206	09/04/2018	07/30/2018 to 08/20/2018	85	04/09/2019
371226	09/05/2018	08/02/2018 to 08/23/2018	117	04/10/2019
372100	09/06/2018	08/13/2018 to 08/30/2018	152	04/11/2019
373087	09/10/2018	08/07/2018 to 08/31/2018	146	04/15/2019
373799	09/11/2018	08/08/2018 to 08/28/2018	138	04/16/2019
376324	09/13/2018	08/16/2018 to 08/28/2018	42	04/18/2019
377039	09/17/2018	08/11/2018 to 08/29/2018	35	04/22/2019
377642	09/18/2018	08/13/2018 to 09/12/2018	145	04/23/2019
378521	09/19/2018	08/16/2018 to 09/10/2018	129	04/24/2019
379725	09/20/2018	08/31/2018 to 09/21/2018	70	04/25/2019
380472	09/24/2018	08/27/2018 to 09/12/2018	121	04/29/2019
381210	09/25/2018	08/15/2018 to 09/24/2018	146	04/30/2019
381231	09/26/2018	09/10/2018 to 09/21/2018	148	05/01/2019
382455	09/27/2018	09/11/2018 to 09/27/2018	30	05/02/2019
384276	10/01/2018	09/18/2018 to 09/19/2018	22	05/06/2019
385228	10/02/2018	08/20/2018 to 09/25/2018	124	05/07/2019
386110	10/03/2018	09/18/2018 to 09/25/2018	147	05/08/2019

<b>Lot Number</b>	<b>Updated Expiration Date (MMDDYYYY)</b>	<b>Distribution Date (MMDDYYYY)</b>	<b>Quantity</b>	<b>Labeled Expiration Date (MMDDYYYY)</b>
388169	<b>10/08/2018</b>	09/06/2018 to 10/08/2018	103	05/13/2019
390399	<b>10/11/2018</b>	09/12/2018 to 10/02/2018	122	05/16/2019
393235	<b>10/17/2018</b>	09/24/2018 to 10/16/2018	152	05/22/2019
395637	<b>10/22/2018</b>	10/10/2018	5	05/27/2019
396586	<b>10/24/2018</b>	09/18/2018 to 10/09/2018	126	05/29/2019
396645	<b>10/25/2018</b>	09/10/2018 to 10/10/2018	131	05/30/2019
397090	<b>10/30/2018</b>	10/01/2018 to 10/09/2018	72	06/04/2019
397589	<b>10/31/2018</b>	09/26/2018 to 10/09/2018	55	06/05/2019
397583	<b>10/31/2018</b>	10/01/2018 to 10/08/2018	8	06/05/2019
398225	<b>11/01/2018</b>	10/01/2018 to 10/10/2018	25	06/06/2019
399822	<b>11/19/2018</b>	10/08/2018 to 10/22/2018	99	06/11/2019
409550	<b>11/21/2018</b>	10/12/2018 to 10/18/2018	96	06/26/2019
412073	<b>11/23/2018</b>	10/11/2018 to 10/18/2018	75	06/28/2019
413484	<b>11/29/2018</b>	10/11/2018 to 10/23/2018	98	07/04/2019
413493	<b>01/03/2019</b>	11/12/2018 to 11/13/2018	77	11/29/2018
470812	<b>03/19/2019</b>	01/29/2019 to 02/18/2019	149	05/07/2019

**R05153: Thio Med w/Dex,Hem,Vit K (7ml) 20/PK**

Lot Number	Updated Expiration Date (MMDDYYYY)	Distribution Date (MMDDYYYY)	Quantity	Labeled Expiration Date (MMDDYYYY)
303285	04/26/2018	03/09/2018 to 05/14/2018	23	09/27/2018
309151	05/09/2018	05/21/2018 to 07/17/2018	39	10/10/2018
353575	08/01/2018	07/19/2018 to 10/08/2018	51	01/02/2019

**R05152: Thio Med w/Dex,Hem,Vit, K (7ml) 100/PK**

Lot Number	Updated Expiration Date (MMDDYYYY)	Distribution Date (MMDDYYYY)	Quantity	Labeled Expiration Date (MMDDYYYY)
309152	05/09/2018	04/16/2018 to 06/25/2018	78	10/10/2018
337708	07/02/2018	06/11/2018 to 07/21/2018	39	12/03/2018
353574	08/01/2018	07/18/2018 to 09/14/2018	75	01/02/2019
378524	09/19/2018	09/10/2018 to 10/18/2018	50	02/20/2019

**R064732: Thio Med w/Dex,Hemin,Vit K (5ml) 20/PK**

Lot Number	Updated Expiration Date (MMDDYYYY)	Distribution Date (MMDDYYYY)	Quantity	Labeled Expiration Date (MMDDYYYY)
328725	06/13/2018	04/23/2018 to 07/16/2018	339	01/16/2019
345633	07/18/2018	06/11/2018 to 09/17/2018	231	02/20/2019
346706	07/25/2018	07/13/2018 to 10/05/2018	322	02/27/2019
385229	10/02/2018	08/28/2018 to 10/08/2018	116	05/07/2019
396646	10/25/2018	09/12/2018 to 10/09/2018	143	05/30/2019
399823	11/06/2018	09/28/2018 to 10/22/2018	54	06/11/2019

**ACTIONS TO BE TAKEN BY THE CUSTOMER:**

Our records indicate that you have received the above product.

Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lots listed above and contact Customer Services or your local distributor regarding any necessary replacements. Requirement for review of reported test results using product **beyond the updated expiry date** should be determined by the appropriate technical expert. Please keep this notification on file.

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 or concerns, please contact our Technical Services Department at 800-255-6730 (US) or 913-888-0939 (International).

You should complete the accompanying Acknowledgment Form.

**TYPE OF ACTION BY THE MANUFACTURER:**

Remel Inc., part of Thermo Fisher Scientific, is investigating the root cause and will implement corrective actions to prevent future recurrence.

We appreciate your immediate attention to this field action. 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) or email [microbiology.ts.us@thermofisher.com](mailto:microbiology.ts.us@thermofisher.com).

Sincerely,



Gary Klaassen  
Director, Quality and Regulatory Affairs

Enclosure - Acknowledgment & Receipt Form

**FIELD ACTION RESPONSE**  
**Acknowledgment & Receipt Form**  
**Response Required**

**CUSTOMER INFORMATION:**

Account Number: «Ship\_To\_Customer»

«Ship\_To\_Name»

«Ship\_To\_Address»

«Ship\_To\_City», «Ship\_To\_State» «Ship\_To\_Zip»

I have read and understand the attached customer letter and field action instructions: ☐

I understand that this applies to all inventory of the affected product that I have received: ☐

**AFFECTED PRODUCT REFERENCE NUMBERS:**

Product Number	Quantity Currently in Stock & To Be Destroyed
R064730	
R05153	
R05152	
R064732	

Use additional sheet(s) if necessary.

**RESPONSE (please provide additional information, if applicable):**

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**PLEASE RETURN THIS COMPLETED RESPONSE FORM TO THE FOLLOWING EMAIL**  
[microbiology.ts.us@thermofisher.com](mailto:microbiology.ts.us@thermofisher.com) or fax to 1.877.428.1924, ATTN: Technical Service & Regulatory Affairs.

**Replacement product will be issued upon completion and return of this form.**

**Signature of Receipt by Customer:** \_\_\_\_\_ **Date:** \_\_\_\_\_

<b>Name/Title:</b>	
<b>Telephone:</b>	
<b>Email Address:</b>	