TYPE OF ACTION BY THE MANUFACTURER:
We have identified and corrected the infrastructure fault and have taken measures to eliminate any residual contaminants. We have also implemented additional quality control steps to immediately detect manufacturing environmental changes.

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 devices have been transferred. We strive to ensure our customer's experience is the best it can be; however, if you have any concerns regarding media contamination, we encourage you to contact our Technical Services department at 800.255.6730 or email microbiology.ts.us@thermofisher.com to notify our Technical Quality team.

We appreciate your immediate attention to this matter and apologize for any inconvenience this may have caused.

Sincerely,

Gary Klaassen

Gary Klaassen
Director, Quality and Regulatory Affairs

ThermoFisher SCIENTIFIC
The world leader in serving science

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Microbiology
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MEDICAL DEVICE FIELD ACTION NOTICE
Remel, Inc. Non-irradiated Prepared Media Plates

CASE WESTERN RESERVE UNIV
2109 ADELBERT RD
CLEVELAND, OH, 44106
URGENT: DELIVER TO MICRO LAB

July 7, 2017

REASON FOR FIELD ACTION:
Recently, customers have reported an increase in fungal contamination in our Remel, Inc. unsterilized prepared media plates. Our root cause investigation identified a fault in recent infrastructure improvements which was allowing potential contaminants into our manufacturing environment.

RISK TO HEALTH:
Presence of contamination should be visually obvious upon removal from the packaging and prior to inoculation of the plates. We have not had any reports of contamination being detected post incubation. Discarding all plates within a package that appear to have contamination on one or more plates is recommended. As such, Remel, Inc. believes the risk to health is low.

PRODUCT INFORMATION:
Plates with expiration dates from 29 May 2017 to 17 August 2017 for the following reference numbers;

R01036	**R01140**	**R01228**	**R01302**	**R01508**	**R01750**	**R01832**	**R01886**	**R04052**
R01040	**R01144**	**R01231**	**R01318**	**R01552**	**R01753**	**R01855**	**R01917**	**R04055**
R01042	**R01148**	**R01245**	**R01320**	**R01565**	**R01760**	**R01856**	**R01919**	**R04057**
R01044	**R01176**	**R01246**	**R01322**	**R01580**	**R01763**	**R01857**	**R01920**	**R04080**
R01045	**R01180**	**R01252**	**R01338**	**R01587**	**R01766**	**R01858**	**R02006**	**R110107**
R01048	**R01190**	**R01254**	**R01341**	**R01605**	**R01768**	**R01859**	**R02041**	**R110204**
R01049	**R01198**	**R01255**	**R01342**	**R01620**	**R01770**	**R01862**	**R02049**	**R110238**
R01060	**R01200**	**R01280**	**R01400**	**R01630**	**R01772**	**R01864**	**R02053**	**R110412**
R01068	**R01201**	**R01292**	**R01402**	**R01685**	**R01776**	**R01865**	**R02066**	**R110590**
R01132	**R01202**	**R01293**	**R01480**	**R01702**	**R01800**	**R01874**	**R02112**	**R111028**
R01136	**R01217**	**R01300**	**R01505**	**R01722**	**R01821**	**R01875**	**R04033**	
R01139	**R01218**	**R01301**	**R01506**	**R01749**	**R01822**	**R01884**	**R04050**	

Plates with expiration dates from 3 August 2017 to 7 February 2018 for the following reference numbers;

R10252	**R10259**	**R111101**	**R20532**	**R20533**	

ACTIONS TO BE TAKEN BY THE CUSTOMER:
Our records indicate that you may have received one or more of the affected products.

We are confident that we have identified the contamination source and that the corrective actions taken have significantly decreased the potential for future contamination. Out of an abundance of caution, we are advising all customers to be vigilant when inspecting plates prior to use due to the increased potential for contamination. Good laboratory practices include pre-inspection of plates. This notification reinforces pre-inspection of the listed products.

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FIELD ACTION RESPONSE
Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:

Account Number: 412664
CASE WESTERN RESERVE UNIV
2109 ADELBERT RD
CLEVELAND, OH 44106

I have read and understand the attached Field Action Notice: _____ (initials)

Any adverse events associated with the affected product? _____ Yes _____ No

If yes, please explain:

_____

_____

AFFECTED PRODUCT REFERENCE NUMBERS:

R01036	R01140	R01228	R01302	R01508	R01750	R01832	R01886	R04052	R111101
R01040	R01144	R01231	R01318	R01552	R01753	R01855	R01917	R04055	R20532
R01042	R01148	R01245	R01320	R01565	R01760	R01856	R01919	R04057	R20533
R01044	R01176	R01246	R01322	R01580	R01763	R01857	R01920	R04080	
R01045	R01180	R01252	R01338	R01587	R01766	R01858	R02006	R10252	
R01048	R01190	R01254	R01341	R01605	R01768	R01859	R02041	R10259	
R01049	R01198	R01255	R01342	R01620	R01770	R01862	R02049	R110107	
R01060	R01200	R01280	R01400	R01630	R01772	R01864	R02053	R110204	
R01068	R01201	R01292	R01402	R01685	R01776	R01865	R02066	R110238	
R01132	R01202	R01293	R01480	R01702	R01800	R01874	R02112	R110412	
R01136	R01217	R01300	R01505	R01722	R01821	R01875	R04033	R110590	
R01139	R01218	R01301	R01506	R01749	R01822	R01884	R04050	R111028	

Use additional sheet(s) if necessary.
RESPONSE (please provide additional information, if applicable):

PLEASE RETURN THIS 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.
Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Email Address:	