Rev 1: September 2018
FSN Ref: FSN-2022-004 FSCA Ref: FSN-2022-004

Date: 16 March 2022

# Urgent Field Safety Notice (FSN)

## Thermo Scientific™ Remel™ Culti-Loops™ Candida albicans ATCC™ 10231™ PK/5

For Attention of*: Lab Managers

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
| --- |
| E.mail : mbd.vigilance@thermofisher.com<br>Telephone: +44(0) 1256 841144<br>Fax: +44(0) 1256 479525 |

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## Thermo Scientific™ Remel™ Culti-Loops™ Candida albicans ATCC™ 10231™ PK/5

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | IVD |
| 1. | 2. Commercial name(s) |
| | Remel™ Culti-Loops™ Candida albicans ATCC™ 10231™ PK/5 |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 00848838038075 |
| 1. | 4. Primary clinical purpose of device(s)* |
| | This product is a ready to use, disposable bacteriological loop containing stabilized viable microorganisms and is recommended for use in the performance testing of culture media, stains, diagnostic kits and reagents, for the maintenance of stock cultures and in the evaluation of bacteriological procedures. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | R4601503 |
| 1. | 6. Software version |
| | N/A |
| 1. | 7. Affected serial or lot number range |
| | 294388 |
| 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 confirmed that Remel™ Culti-Loops™ Candida albicans ATCC™ 10231™ PK/5 R4601503 Lot 294388 may exhibit lower than expected or no growth of *C. albicans* ATCC 10231. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | Lower than expected or no growth of *C. albicans*. |
| 2. | 3. Probability of problem arising |
| | Low to medium |
| 2. | 4. Predicted risk to patient/users |
| | There should be no immediate or long-term health consequences from use of this product. The *C. albicans* culture is a quality control strain. It should have little or no effect on the ability of clinical specimens to grow such a fungus on standard primary fungal isolation media. The clinical risk should be considered negligible. |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |
| | An internal investigation has found that R4601503 lot 294388 is not performing as expected. |
| 2. | 7. Other information relevant to FSCA |
| | Lot. 294388 with the expiry of 11-Nov-2022 |

| 3. Type of Action to mitigate the Risk* | | |
|---|---|---|
| 3. | 1. Action To Be Taken by the User*<br><br>☒ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device<br><br>☐ On-site device modification/inspection<br><br>☐ Follow patient management recommendations<br><br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br>☐ Other ☐ None | |
| 3. | 2. By when should the action be completed? | Immediately |
| 3. | 3. Particular considerations for: IVD<br>Is follow-up of patients or review of patients' previous results recommended?<br>No<br><br>Provide further details of patient-level follow-up if required or a justification why none is required | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |
| 3. | 5. Action Being Taken by the Manufacturer<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None | |
| 3 | 6. By when should the action be completed? | As soon as possible |
| 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 | |

| 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<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Remel Inc. |
| | b. Address | 12076 Santa Fe Trail Drive<br>Lenexa KS 66215 |
| | 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 | [redacted] |
| | Signature | [redacted] |

| | 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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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* | 2022-004 | | | |
| FSN Date* | 16 March 2022 | | | |
| Product/ Device name* | Thermo Scientific™ Remel™ Culti-Loops™ Candida albicans ATCC™ 10231™ PK/5 | | | |
| Product Code(s) | R4601503 | | | |
| Batch/Serial Number (s) | 294388 | | | |
| **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 or **N/A** | Qty: | Lot/Serial Number: | Date Returned (DD/MM/YY) |
| | | Comments: | | |
| ☐ | I have destroyed affected devices – enter number destroyed and date complete. | Qty: | Lot/Serial Number: | Date Returned (DD/MM/YY) |
| | | Qty | Credit ☐ Replacement ☐ | |
| | | 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<br>Fax :+44(0) 1256 479525 |
| Postal Address | |
| Deadline for returning the reply form* | **13 April 2022** |

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.