



Date: 17/12/2019

Urgent Field Safety Notice
**Microbiologics 8180 Gram-Positive Blood Culture
Control Panel (Inactivated Pellet)**

For Attention of*: Clinical laboratory managers and lab technicians.

Contact details of local representative (name, e-mail, telephone, address etc.)*





Urgent Field Safety Notice (FSN)
Microbiologics 8180 Gram-Positive Blood Culture Control Panel (Inactivated Pellet)

Risk addressed by FSN

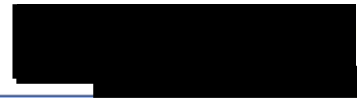
1. Information on Affected Devices*	
1.	<p>1. Device Type(s)*</p> <p>Unassayed quality control material for microbiology assays.</p>
1.	<p>2. Commercial name(s)</p> <p>8180 Gram-Positive Blood Culture Control Panel (Inactivated Pellet)</p>
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>70845357041424</p>
1.	<p>4. Primary clinical purpose of device(s)*</p> <p>Helix Elite™ Molecular Standards (Inactivated Pellet) and QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet) are intended for use as external controls for qualitative detection by molecular assays.</p> <p>8180 Gram-Positive Blood Culture Control Panel (Inactivated Pellet) includes 3 pools containing 3-4 inactivated microorganisms per pool. Kits contain 5 vials of each pool (15 total vials) and feature color coordinated labels for easy pool identification.</p> <p>Pool 1 S. epidermidis S. lugdunensis E. faecium L. monocytogenes</p> <p>Pool 2 S. pyogenes S. agalactiae S. anginosus</p> <p>Pool 3 S. aureus E. faecalis S. pneumoniae</p>
1.	<p>5. Device Model/Catalogue/part number(s)*</p> <p>8180</p>
1.	<p>6. Software version</p> <p>N/A</p>
1.	<p>7. Affected serial or lot number range</p> <p>8180-51 and 8180-52</p>
1.	<p>8. Associated devices :</p> <p>Verigene instrument and the Verigene Gram-Positive Blood Culture Nucleic Acid Test (BC-GP)</p>




2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* An interfering substance was identified when the 8180 is used with the Verigene instrument and the Verigene Gram-Positive Blood Culture Nucleic Acid Test (BC-GP). Saline and other salt solutions, when used as hydration fluid in this application may inhibit the PCR reaction. An inhibited PCR reaction may cause positive controls to not detect positive.
2.	2. Hazard giving rise to the FSCA* Saline and other salt solutions, when used as hydration fluid in this application may inhibit the PCR reaction. An inhibited PCR reaction may cause positive controls to not detect positive.
2.	3. Probability of problem arising The 8180 product is used as a control for molecular assays. Customers reporting this issue are specifically using the Verigene BC-GP assay. There are only 3 kits within their expiration date in the EU. If a saline solution is used to hydrate the pellets, the chance of the problem arising is estimated as possible (~ 1/100).
2.	4. Predicted risk to patient/users If the control is hydrated with saline solution or another salt solution, it may cause PCR inhibition resulting in a positive control not being detected by the assay. In this situation, a lab would not be able to officially report the assay test results to physicians until the issue is resolved. The lab may need to use other diagnosis protocols. They may need to send patient samples to another facility to obtain results. This may delay definitive diagnosis. However, it should not delay treatment as physicians may treat and diagnose based on patient symptoms and other tests. In fact, the Verigene BC-GP assay product insert states the assay is indicated for use in conjunction with other clinical and laboratory findings to aid in diagnosis.
2.	5. Further information to help characterize the problem N/A
2.	6. Background on Issue During a complaint investigation, an interfering substance was identified when the 8180 is used with the Verigene instrument and the Verigene Gram-Positive Blood Culture Nucleic Acid Test (BC-GP). Saline and other salt solutions, when used as hydration fluid in this application may inhibit the PCR reaction. An inhibited PCR reaction may cause positive controls to not detect positive. Microbiologics does not provide hydration fluid as users have many choices, however, we do have recommended hydration fluids documented in a technical information document on our website. This document, titled QC Sets and Panels – Technical Information, referenced saline as one of the hydration fluids for the 8180 product. This document has been updated replacing the saline reference with DI Water. This document has also been updated to include interfering factors. This document is referenced in the product insert. This correction is to inform users that salt solutions such as saline may be an interfering factor in some PCR applications.
2.	7. Other information relevant to FSCA Please reference TIB.2034 - QC Sets and Panels - Technical Information Revision G.



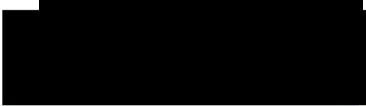
3. Type of Action to mitigate the risk*			
3.	<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Please reference TIB.2034 - QC Sets and Panels - Technical Information Revision G.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">2. By when should the action be completed?</td> <td>Upon receipt of this notice.</td> </tr> </table>	2. By when should the action be completed?	Upon receipt of this notice.
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3.	<p>3. Particular considerations for:</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 65%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="text-align: center;">Yes</td> </tr> </table>	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes		
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Update TIB.2034 - QC Sets and Panels - Technical Information to include information about interfering substances.</p>		
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">6. By when should the action be completed?</td> <td>Completed</td> </tr> </table>	6. By when should the action be completed?	Completed
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3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 65%;">7. Is the FSN required to be communicated to the patient /lay user?</td> <td style="text-align: center;">No</td> </tr> </table>	7. Is the FSN required to be communicated to the patient /lay user?	No
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3.	<p>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?</p> <p>N/A</p>		



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? * No
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 (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Microbiologics, Inc.
	b. Address 200 Cooper Avenue North, St. Cloud, MN 56303 USA
	c. Website address www.microbiologics.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 Reply Form
4.	10. Name/Signature 

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organizations 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>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.



Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2019003
FSN Date*	17/12/2019
Product/ Device name*	Microbiologics 8180 Gram-Positive Blood Culture Control Panel (Inactivated Pellet)
Product Code(s)	8180
Batch/Serial Number (s)	8180-47, 8180-51, 8180-52

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization 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.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<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):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/	Customer to complete or enter N/A		



	destruction	
<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
	Print Name*	Customer print name here
	Signature*	Customer sign here
	Date*	

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.