CORPORATE HEADQUARTERS
200 COOPER AVE N, ST. CLOUD, MN 56303
320.253.1640 | MICROBIOLOGICS.COM

FSN Ref: 2021003

FSCA Ref: N/A

Date: 24:08:2021

Urgent Field Safety Notice

Helix Elite™ Synthetic Standard SARS-CoV-2 Process Control (Pellet)

For Attention of*: Clinical Laboratory Managers and Lab Technicians

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

This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

CORPORATE HEADQUARTERS
200 COOPER AVE N, ST. CLOUD, MN 56303
320.253.1640 | MICROBIOLOGICS.COM

FSN Ref: 2021003 FSCA Ref: N/A

Urgent Field Safety Notice (FSN)

HE0062S Helix Elite™ Synthetic Standard SARS-CoV-2 Process Control (Pellet)

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	RNA transcripts containing consensus sequences or diagnostically relevant targets encapsulated in a phage protein envelope.
1.	2. Commercial name(s)
	Helix Elite™ Synthetic Standard SARS-CoV-2 Process Control (Pellet)
1.	3. Unique Device Identifier(s) (UDI-DI)
	10845357043488
1.	4. Primary clinical purpose of device(s)*
	SARS-CoV-2 Process Control (Pellet) is intended for use as an external, non-viable control material to evaluate the performance of nucleic acid tests that detect SARS-CoV-2 virus. This product has no qualitative or quantitative assigned value. This control material is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This control is not intended for any specific patient population or specimen
1.	5. Device Model/Catalogue/part number(s)*
	HE0062S
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	HE0062-01-1, HE0062-01-2, HE0062-03-1, HE0062-04-1, HE0062-04-2, HE0062-05-1, HE0062-05-2, HE0062-06-1
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The product indicated is contaminated with a plasmid DNA that contains the target SARS-CoV-2 sequences. What this means is the product is not adequate for a full process control. The DNA compromises the function of the product by allowing amplification of the target sequence even if reverse transcriptase is not present in the PCR reaction. It is therefore not a full process control for RNA assays, as it will not clearly indicate whether extraction or the reverse transcriptase reagent is performing properly. The product does perform as an adequate control for PCR amplification and detection.
2.	2. Hazard giving rise to the FSCA*

FSN Ref: 2021003 FSCA Ref: N/A

	The product is a control for IVD tests. It does not have a direct impact on patients. As a control, it may impact individuals receiving certain PCR tests. However, because the control is adequate for PCR amplification, it is likely that test results from the assay would not be delayed. The sequence of events for this biocontamination hazard in this hazardous situation are: 1. Product is contaminated with DNA during production. 2. Users use material as a control for extraction, reverse transcriptase and PCR amplification. 3. The product gives expected results, positive call for SARS-CoV-2. 4. The user is unaware that the control did not test extraction and reverse transcriptase. 5. Patient test results are released. 6. No harm to patient. In this scenario there would be no reason to believe that the test results would not be correct. The extraction and reverse transcription methods used for SARS-CoV-2 are well documented and provided by the CDC and WHO. Microbiologics has received no complaints regarding this issue.
2.	3. Probability of problem arising
	The likelihood of occurrence of the hazard is high, nearly 100%. The likelihood of occurrence that the hazardous situation results in harm is nearly 0%.
2.	4. Predicted risk to patient/users
	The product is a control for IVD tests. It does not have a direct impact on patients. As a control, it may impact individuals receiving certain PCR tests. However, because the control is adequate for PCR amplification, it is likely that test results from the assay would not be delayed.
2.	5. Further information to help characterize the problem
	The control will still amplify and detect for many of the relevant genetics targets for SARS-CoV-2 since DNA exists. Most users will not experience any issues as results are still detectable
2.	6. Background on Issue
	This was discovered when preparing sample material for an IVD manufacturer on 8/9/21. They had requested a low concentration liquid stock for use in their internal QC. When we prepared the dilutions, we tested the material using both RT-ddPCR (which would amplify both RNA and DNA if present) and ddPCR (which would amplify only DNA) and found that we had amplification in the ddPCR reaction. We began a series of experiments to confirm whether these results were accurate or whether there were testing issues (such as cross-contamination), and by 8/20/21 had ruled out testing issues and replicated the results. The process used for the IVD Manufacturer material was the same manufacturing process for HE0062S has the same issue.
2.	7. Other information relevant to FSCA
	N/A

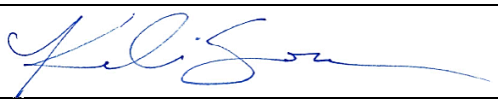
CORPORATE HEADQUARTERS
200 COOPER AVE N, ST. CLOUD, MN 56303
320.253.1640 | MICROBIOLOGICS.COM

FSN Ref: 2021003 FSCA Ref: N/A

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) Other ☐ None Use or discard the affected products depending on your lab procedures and how this information affects your usage of the product.
3.	2. By when should the action be completed? — Upon receipt of this notice
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Quarantine all current stock and initiate FSCA
3	6. By when should the action be completed? — Completed
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

CORPORATE HEADQUARTERS
200 COOPER AVE N, ST. CLOUD, MN 56303
320.253.1640 | MICROBIOLOGICS.COM

FSN Ref: 2021003 FSCA Ref: 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? *	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 Ave 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	Kali Sorum, Technical Support Manager 

	Transmission of this Field Safety Notice
	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) Please transfer this notice to other organizations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.*

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