Urgent Field Safety Notice

NATtrol™ *Stapylococcus aureus* (SA) Positive Control

For Attention of: Mr Michael Moore
Sales and Marketing
Helvetica Health Care Sarl
PO Box 1158
CH-1211 Geneva 5AP
Switzerland

Contact details of local representative (name, e-mail, telephone, address etc.)*
ZeptoMetrix Corporation
25 Kenwood Circle
Franklin, MA 02038 USA

Urgent Field Safety Notice (FSN)

NATtrol™ *Stapylococcus aureus* (SA) Positive Control

1. Information on Affected Devices*	
1.	1. Device Type
	NATtrol™ Staphylococcus aureus (SA) Positive Control (MDZ061) is an in vitro diagnostic external run control intended for use in evaluating and monitoring of qualitative molecular diagnostic assays for the detection of SA nucleic acid. This product is classified as general per the IVD Directive 98/79/EC.
1.	2. Commercial name(s)
	NATtrol™ SA Positive Control
1.	3. Primary clinical purpose of device(s)*
	The use of external run controls enables laboratories to monitor daily test variation, lot-to-lot test kit performance, individual operator variation, and can provide assistance in identifying increases in random or systemic error.
1.	4. Device Model/Catalogue/part number(s)*
	MDZ061
1.	5. Affected serial or lot number range
	MD19-00064
1.	6. Associated devices
	None.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	NATtrol™ SA Positive Control giving not detected or negative results rather than the expected positive result.
2.	2. Hazard giving rise to the FSCA*
	The SA positive control has presumably degraded such that the control is giving false negative results.
2.	3. Probability of problem arising
	ZMC performed a risk evaluation for the product following established risk management procedures and the probability of viability loss was addressed and was deemed to be low.
2.	4. Predicted risk to patient/users
	As an in vitro diagnostic product, the possible harm to the patient is an indirect harm and as a quality control material the worst-case scenario could lead to delay of specimen testing which may lead to delay of patient treatment or management. ZeptoMetrix Corporation (ZMC) has determined that the probability of occurrence of harm is remote.
2.	5. Background on Issue
	ZMC received two complaints reporting that the SA Positive Control Lot (MD19-00064 was giving not detected or negative results. During our internal investigation, we ran a series of tests and confirmed the SA Positive Control Lot was showing not detected or negative results. We have quarantined all remaining product of MD19-00064 lot and end-users have been contacted. It has been determined that only one control pack of product was sent to each of two EU distributors.

2.	6. Other information relevant to FSCA
	None.

	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	
3.	2. By when should the action be completed?	Immediately.
3.	3. Particular considerations for: IVD Distributors should contact customer who purchased the product to notify them and have them destroy the material and send back the reply form.	
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	
3.	6. By when should the action be completed?	Immediately.
3.	7. Is the FSN required to be communicated to the customer/lay user?	Yes
3	8. If yes, has manufacturer provided additional information suitable for the customer/lay user in a customer/lay or non-professional user information letter/sheet? No	
	4. General Information*	
4.	1. FSN Type*	New

4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**ZeptoMetrix Corporation**
	b. Address	**25 Kenwood Circle, Franklin, MA 02038**
	c. Website address	**www.zeptometrix.com**
4.	4. The Competent (Regulatory) Authority of your country will be informed about this communication to customers.	
4.	5. List of attachments/appendices:	**(1) FSN Customer Reply Form** **(2) FSN Distributor Reply Form**
4.	6. Name/Signature	**Lynda S. Mungo** Lynda S. Mungo

	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) Please transfer this notice to other organisations 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.