FSN Ref: FSN_17.09.21_EN FSCA Ref: FSCA_17.09.21

Date: 17/09/2021

Urgent Field Safety Notice

TETANUS VIRCLIA® IgG MONOTEST

For attention of: Distributor/Final user

Manufacturer Contact details:
Vircell, S.L. Parque Tecnológico de la Salud, Avicena 8, 18016, Granada, Spain
Local contact details:
Local distributor

Urgent Field Safety Notice (FSN)

TETANUS VIRCLIA® IgG MONOTEST

Risk adressed by FSN

1.-Information on Affected Devices	
1	1.-Device Type
	Indirect chemiluminescent immunoassay (CLIA) to test quantitatively IgG antibodies against *Clostridium tetani* toxin in human serum/plasma.
1	2.-Commercial name
	TETANUS VIRCLIA® IgG MONOTEST
1	3.-Unique Device Identifier (UDI-DI)
	8436040326640
1	4.-Primary clinical purpose of device
	For in vitro diagnosis.
1	5.-Device reference
	VCM004
1	6.-Affected serial or lot number range
	21C004002
1	7.-Associated devices
	This device is used in combination with an automated processor: VIRCLIA® LOTUS and VIRCLIA® (TB).

2.-Reason for Field Safety Corrective Action (FSCA)	
2	1.-Description of the product problem
	A labelling error has been detected in lot 21C004002 of the reference TETANUS VIRCLIA® IgG MONOTEST (VCM004). This error was detected due to a claim from the Spanish distributor. The product labelling includes a bar code with the data for the master curve required for the use of the kit in combination with the automated processors (VIRCLIA® LOTUS and VIRCLIA® (TB)). The labelling error consists of barr codes included in the label, in order to allow the use of the kits in combination with automated processors, being wrong. Results from the final quality control of the device show that the product is correct and fulfils specifications. This error solely affects labelling.
2	2.-Hazard giving rise to the FSCA
	This error might generate false negatives when the kit is used for quantitative determination in the VIRCLIA® (TB) automated processor. Determinations performed using VIRCLIA® LOTUS are not affected.
2	3.-Probability of problem arising
	Probability of problem arising is low because this error only arises when determinations are performed in the VIRCLIA® (TB) automated processor. Additionally, this error is easy to detect, as general population is vaccinated against tetanus and

	getting a negative result is highly unlikely. In the case that the error is not detected false negative results might be obtained when using the VIRCLIA® (TB) automated processor.
2	4.-Predicted risk to patient/users
	Risk is low because the probability of detecting the error is very high and, in that case, the result is not delivered. On the other hand, even in the case that the error is not detected and a false negative was obtained, method limitations in the instructions for use indicate that "the results of samples should be used in conjunction with clinical evaluation and other diagnostic procedures. A definitive diagnosis should be made by direct diagnostic techniques". Additionally, the insert indicates that "this test has been only validated as a screening assay; follow local guidelines for the management of tetanus-prone wounds regarding the convenience of booster vaccination and tetanus immunoglobulin administration". Finally, it should be taken into account that patient health will not be affected if vaccinated after getting a false negative.

3.-Type of Action to mitígate the risk		
3	1.-Action to be taken by the user ☐Identify device ☐Quarantine device x 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.-Is customer reply required?	Kits return
3	3.-Action being taken by the manufacturer X Product removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	

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	
	a. Company name	Vircell,s.l.
	b. Address	Parque Tecnológico de la Salud, Avicena 8, 18016, Granada, Spain
	c. Website address	www.vircell.com
4	4.-The Competent (Regulatory) Authority of your country has been informed about this communication to customers	Yes
4	5.-List of Attachment/appendices	Distributor Verification form
4	6.-Name/Signature	Arantxa Cortés Ruiz Firmado digitalmente por Arantxa Cortés Nombre de reconocimiento (DN): cn=Arantxa Cortés, o=VIRCELL, ou, email=project@vircell.com, c=ES Fecha: 2021.09.24 13:21:14 +02'00'

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. Please transfer this notice to other organisations on which this action has an impact. 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.