BIOERSY 深圳市易瑞生物技术股份有限公司

Shenzhen Bioe:isv B1otechn" ogy Co. Ltd.

Rev 1: September 2018

FSN Ref: FSN20200609001 FSCA Ref: FSCA20200326001

Date: 08 June 2020

Urgent Field Safety Notice

BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test

For Attention of*: Interpharma

Contact details of local representative (name, e-mail, telephone, address etc.)*		
Name	Role	Information
Interpharma	Distributor	Address:C/ Castelló, 84 28006 Madrid, Spain Telephone:+34673222283 E-mail: jsn@interpharma.es

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Urgent Field Safety Notice (FSN)

BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test

Risk addressed by FSN

	1. Information on Affected Devices*
1	1. Device Type(s)
	The 2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test is an in vitro diagnostic device. It is a colloidal gold enhanced double antibody sandwich immunoassay for the qualitative determination of 2019-nCoV antigen in human nas9 pha ryngeal swab and oropharyngeal swab.
1	2. Commercial name(s)
	BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test
1	3. Unique Device Identifier(s) (UDI-DI)
	Not applicable
1	4. Primary clinical purpose of device(s)
	BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test is a colloidal gold enhanced, rapid immunoassay for the qualitative detection of 2019-nCoV antigen in nasopharyngeal swab and oropharyngeal swab samples from patients with suspected 2019-nCoV infection, patients with suspected clustering cases, and ethers who need to diagnose or differentially diagnose 2019-NovelCoronavirus (2019-nCoV).This product is for in vitro emergency use only during the pneumonia epidemie of the2019-nCoV infection since December 2019.
1	5. Device Model/Catalogue/part number(s)
	BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ag GIC. A Rapid Test - Catalogue Numbers: YRLG22201025 - YRLG22201050 - YRLG222011ào
1	6. Affected serial or lot number range
	Lot: 2003N206 ,2003N205

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2 Reason for Field Safety Corrective Action (FSCA)*

2	1. Description of the product problem*
	Low sensitivity was observed when comparing the device to PCR.
2	2. Hazard giving rise to the FSCA*
	Low sensitivity will result in false negative results for patients and they will thus not be considered for further treatment.
2	3. Probability of problem arising
	The probability of this issue arising is variable because many factors could potentially negatively affect the sensitivity of an antigen. These factors include the stage of infection, virus loading differences, whether the samples were inactive, sampling deviations, differences in the interpretation of visual results, product transportation, handling differences, the patienf s situation, etc
2	4. Predicted risk to patient/users
	A false negative result could potentially lead to the patient not being treated for SARS-CoV-2 and for the patient to have a false feeling of security and thus potentially infecting other individuals. However, this product is used for testing in medica! and health institutions for the auxiliary diagnosis of Sars-CoV-2. Negative results from the antigen test do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
2	5. Further information to help characterise the problem
	Bioeasy developed detailed instructions and a video training for fr·e cc·r 3ç · us J; '.',::: ;._.;- in order to minimise the probability of user related errors.
2	6. Background on Issue
	Upon testing the device prior to clinical use, the customer observed a lower than expected sensitivity versus PCR. After informing Bioeasy of this finding, the affected client was immediately requested to identify and quarantine the entire lot of test kits as well as return the affected product to Bioeasy. Bioeasy stopped the production of the test kit at the end of March. In addition, Bioeasy performed market analysis and further risk assessment, which led to the decision on May 27 2020 to cancel marketing of the product in the European Union market, to submit a declaration to de-notify the :devices and to remove the CE marking trom the devices on May 27,2020.

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	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***

= Identify Device i:gJ Quarantine Device 0 Return Device D Destroy Device

D On-site device modification/inspection

D Follow patient management recommendations

D Take note of amendmenUreinforcement of Instructions For IJse (IFU)

D Other D None

Provide further details of the action(s) identified.

3.	2. By when should the action be completed?	2020 /03/26
3.	3. Particular considerations for: IVO Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justific2tio- '": y -ors '" required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No

3. 5. Action Being Taken by the Manufacturer

i:gJ Produ c t Removal D On-site device modification/inspection
D Software upgrade D IFU or labelling change

D Other D None

Bioeasy decided to cancel marketing of the product in the ElTCoea, Ij-i'J:i 2-k"" ?n,.,

	submitted a declaration to cancel the CE listing of the product ori 1Vav 77.2:∶o	
3	6. By when should the action be completed?	2020/05/27
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?	
	No Not appended to this FSN	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	No
4.	3. For Updated FSN, key new information as fellows:	
	Summarise any key difference in devices affected and/or actic n to b ti:'k sr .	
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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of upd2,ted :::ic!·: i· e.
4.	7. Manufacturer information {For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Shenzhen Bioeasy Biotechnology Co.,Ltd.**
	b. Address	No. 2-1, Liuxian 1st Road, Xin'an Sub-District, Baoan District, Shenzhen,Guangdong Province, China 518101
	c. Website address	**www.bioeasy.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. Name/Signature	**Name: ……..** **Title: ……**
4.		

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	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.