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Date: 28.Oct.2020

Urgent Field Safety Notice
Nowcheck COVID-19 Ag Test

For Attention of*:

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Urgent Field Safety Notice (FSN)

Nowcheck COVID-19 Ag Test

Since the swab in issue has only incorrect labelling, and it is actually a sterile swab, the severity of the risk is very low.
It is highly likely to not cause performance, safety and health problems in the field.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	NowCheck COVID-19 Ag Test is a rapid chromatographic immunoassay. Materials provided in this kit is as below. 1) Test device (Plastic cassette), 2) Extraction buffer tube (To dilute collected sample), 3) Nozzle cap (that will be combined with extraction buffer tube for testing). 4) Swab (for collecting sample), 5) Paper stand (can be used to stand up extraction buffer tubes when multiple tests are required at same time), 6) Film (can be attached to device's window to protect the device from dry condition. 7), Instruction for use.
1.	2. Commercial name(s)
	NowCheck COVID-19 Ag Test
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	NowCheck COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific SARS-CoV-2 antigens present in human nasopharynx. This test is for administration by healthcare workers and labs only as an aid to early diagnosis of COVID-19 in patients that are suspected to have a SARS-CoV-2 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection. COVID-19 in patients that are suspected to have a SARS-CoV-2 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.
1.	5. Device Model/Catalogue/part number(s)*
	NowCheck COVID-19 Ag Test/RG1901DG
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	1901D001/1901D002/1901D003/1901D004/1901D005
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	There were no quality problems, but only The labelling of the components (swabs) did not meet EU regulations.
2	2. Hazard giving rise to the FSCA*

.	1. Huachenyang (Shenzhen) Technology Co., Ltd of the manufacturer of the swab guarantees that they actually have sterilized the all swabs distributed by EO treatment in accordance with EN ISO11135:2014. Therefore, the less likely the user are to have a quality problem such as infection of disease or improper diagnosis. 2. BIONOTE, Inc. reviewed the details submitted by the swab manufacturer and confirmed that there were no problems with the product sterilization process. Therefore, the severity of the risk is very low, as swabs with incorrectly labelling are unlikely to cause problems with performance and safety and health effects in Field.
2 .	3. Probability of problem arising
	There is no problem because the components are sterilized.
2 .	4. Predicted risk to patient/users
	1. Huachenyang (Shenzhen) Technology Co., Ltd of the manufacturer of the swab guarantees that they actually have sterilized the all swabs distributed by EO treatment in accordance with EN ISO11135:2014. Therefore, the less likely the users are to have a quality problem such as infection of disease or improper diagnosis. 2. BIONOTE, Inc. reviewed the details submitted by the swab manufacturer and confirmed that there were no problems with the product sterilization process. Therefore, the severity of the risk is very low, as swabs with incorrectly labelling are unlikely to cause problems with performance and safety and health effects in Field.
2 .	5. Further information to help characterise the problem
	N/A
2 .	6. Background on Issue
	1. How the manufacturer became aware; brief details of relevant incidents; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc. We received feedback from European representative that there is an incorrect labelling component. After recognizing the incident, we tracked the Lot. Number of the Nowcheck Covid-19 Ag test kit that had a problem. And investigated the history of labelling inappropriate swabs. After the Lot.no tracking was completed, an official document was forwarded to the distributor, to stop using and selling the product. Since then, We have discontinued the use of the incorrectly labelled swabs, reviewed the labelling specifications and CE conformity for replaceable swabs, and It was replaced by the sterile swab from Noble Biosciences, Inc. The affected products that have already been investigated will be reworked and re-QC to replace them with new swabs. We analyzed the root cause as follows and took the following actions. 2. root cause if known; Corrective action; There was no process to review the compliance with the requirements when selecting the accessories which is a medical device to include in our product. Internal procedure of BIONOTE will be revised to review the compliance with the requirements when selecting the components
2 .	7. Other information relevant to FSCA
	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

Dispose of the lot below lot below.
1901D001
1901D002
1901D003
1901D004
1901D005

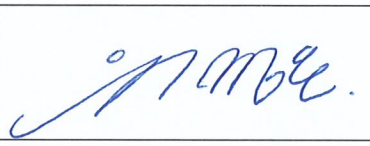
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety Up to 2020-11-15
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No It is unlikely that the use of the issue swab affects the diagnostic result of the IVD product.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes (Statement of handling of recalled product, D410-8)

3. 5. Action Being Taken by the Manufacturer

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

Provide further details of the action(s) identified.
Although there are no quality problems, it is going to dispose of products that have already been shipped.

3	6. By when should the action be completed?	Up to 2020-11-15
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	

	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:	
	Product Removal	
4	6. Anticipated timescale for follow-up FSN	Up to 2020-11-15
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Bionote, Inc.
	b. Address	22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449, Republic of Korea
	c. Website address	www.bionote.co.kr
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No	
4.	9. List of attachments/appendices:	Statement of handling of recalled product, D410-8
4.	10. Name/Signature	Jung Eun Yoo / QMR
		

	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.