Rev 1: September 2018
FSN Ref: FSN2020/01 FSCA Ref: FSCA2020/01

Date: 22-07-2020

Urgent Field Safety Notice
Device Commercial Name

For Attention of*:List of the names of your contact persons or copy this document for each different name

Contact details of local representative (name, e-mail, telephone, address etc.)*
Addresses of the contact person/s

Inzek International Trading BV

Rev 1: September 2018

FSN Ref: FSN2020/01 FSCA Ref: FSCA2020/01

Urgent Field Safety Notice (FSN)
COVID-19 IgG/IgM Rapid Test Cassette (single test)
Some of the performance characteristics stated in the product IFU are incorrect

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Rapid diagnostic serologic test for Covid-19
1.	2. Commercial name(s)
	COVID-19 IgG/IgM Rapid Test Cassette single test
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	4. Primary clinical purpose of device(s)*
	Qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimen
1.	5. Device Model/Catalogue/part number(s)*
	BNCP-402/BNCP-402E
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	Batch numbers BNCP40200074/BNCP40200077/BNCP40200078/BNCP40200080/ BNCP40200083/BNCP40200084/BNCP40200087/BNCP40200088/BNCP40200093/BNCP40200097/BNCP40200098/BNCP40200099/BNCPE40200085/BNCPE40200086
1.	8. Associated devices
	Within context of the FSCA no associated devices

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	There is no problem with the device itself. IFU does not correctly reflect the test performance characteristics
2.	2. Hazard giving rise to the FSCA*
	Test is reliable for the detection of anti-Covid-19 IgG in patients having severe symptoms for at least 10 days. In patients with mild symptoms or showing severe symptoms for less than 10 days, detection with this test is unreliable.
2.	3. Probability of problem arising
	Diagnostic sensitivity for the detection of IgG in patients showing symptoms for less than 10 days is 51.5% whereas it should be > 95%. Diagnostic sensitivity for the detection of IgG in patients with mild symptoms for longer than 10 days is 85.7% whereas it should be > 95%.
2.	4. Predicted risk to patient/users
	Patients might be infected with Covid-19 and the test shows a negative result. However, the current IFU does advice that the test should not be used in the early stages of the disease and that if the test is negative and the symptoms continue, a different test should be used
2.	5. Further information to help characterise the problem
	Diagnostic sensitivity for the detection of IgM in patients infected with Covid-19 is insufficient for diagnosis with this test (<95%)

2.	6. Background on Issue
	The manufacturer became aware of this problem as a result of an investigation by the IGJ. The main root-cause was that the verification by the manufacturer (Inzek) of the supplied tests was insufficient. Inzek's QMS procedures shall be updated to detail the necessary control of newly supplied devices
2.	7. 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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediate after receiving this notice
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Taking into account that the current IFU recommends against the use of the test in early disease stage and advises to use a different test (there are currently several tests in the market based on similar and different technologies) if the results are negative and the symptoms continue, follow-up of the patients is not deemed necessary	
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 Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	Same as in FSCA
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?
	Choose an item. Choose an item.

	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	**Inzek International Trading BV**
	b. Address	**Vissenstraat 32 7324 AL Apeldoorn**
	c. Website address	**www.inzek.nl**
4.	8. The IGJ has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**FSN Customer Reply**
4.	10. Name/Signature	Insert Name and Title here and signature below

	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.