

Rev 1: September 2018

FSN Ref: FSN2020/01

FSCA Ref: FSCA2020/01

Date: 22-07-2020 (Initial FSN) 10-09-2020 (rev1)

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.)*
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Addresses of the contact person/s

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/BNCP40200082/BNCP40200083/BNCP40200084/BNCP40200087/BNCP40200088/BNCP40200093/BNCP40200097/BNCP40200098/BNCP40200099/BNCP402E00084/BNCPE40200085/BNCP40200086/BNCPE40200092
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
	5. Further information to help characterise the problem

2	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 Dutch Competent Authority, 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*	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> 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	<input type="checkbox"/> Product Removal <input checked="" type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> 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	Zeki Hamid
		Inzek International Trading BV

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

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Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.