

Rev 1: September 2018

FSN Ref: Complaint no. 120-2021

FSCA Ref: NA

Date: 28-07-2021

Urgent Field Safety Notice

ImmuView® S.pneumoniae and L. pneumophila Urinary Antigen Test

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
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SSI Diagnostica A/S; Herredsvejen 2; 3400 Hillerød; Denmark
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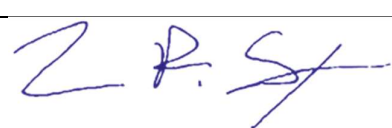
Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Urinary Antigen Test – lateral flow immunochromatographic assay.
1	2. Commercial name(s)
.	ImmuView® S.pneumoniae and L. pneumophila Urinary Antigen Test
1	3. Unique Device Identifier(s) (UDI-DI)
.	GTIN-05713106953891
1	4. Primary clinical purpose of device(s)*
.	The ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test is an in vitro rapid lateral flow test, also known as a lateral flow immunochromatographic assay. The assay is intended for qualitative detection of Streptococcus (S.) pneumoniae and Legionella (L.) pneumophila antigens in urine specimens from patients with symptoms of pneumonia. The ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test can be read visually or used in conjunction with the ImmuView® reader. The assay is intended to aid in diagnosis of S. pneumoniae and of L. pneumophila serogroup 1 infections. The assay is further intended to aid in the diagnosis of S. pneumoniae infections by detection of S. pneumoniae antigen in cerebrospinal fluid (CSF). Results from the ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test should be interpreted in conjunction with the patient's clinical evaluation and other diagnostic methods.
1	5. Device Model/Catalogue/part number(s)*
.	95389
1	6. Software version
.	NA
1	7. Affected serial or lot number range
.	PL20210526
1	8. Associated devices
.	None

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Due to a production error, the positive control is not correct. The test is working as expected. For confirmation of effect, an internal positive control can be used.
2	2. Hazard giving rise to the FSCA*
.	There is no hazard to the patient using the product as the test works as intended.
2	3. Probability of problem arising
.	When following the quality control procedures described in the IFU, the problem will always be detected as the issue is affecting the positive control.
2	4. Predicted risk to patient/users
.	There is no risk to the patient as the test works as intended.
2	5. Further information to help characterise the problem
.	NA
	6. Background on Issue

2	Received an enquiry from a customer which has tested control, and the positive control did not perform as stated in the IFU. The incident has been tested with the lot relevant reference kit which confirmed the incident. The root cause has been narrowed down to not adding S.pneumoniae antigen to the positive control. Measures to the control production process is being implemented to prevent this incident from happening again.
2	7. Other information relevant to FSCA
.	NA

3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* <input checked="" type="checkbox"/> Identify Device <input 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 type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input checked="" type="checkbox"/> Other <input type="checkbox"/> None Replacement of positive control is available upon request.	
3.	2. By when should the action be completed?	No deadline
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	5. Action Being Taken by the Manufacturer <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None Positive control will be replaced on request. Products shipped after the 28 th of July 2021 have been reprocessed and is working as intended.	
3	6. By when should the action be completed?	All actions completed
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	Not relevant
4.	3. For Updated FSN, key new information as follows:	
	New FSN not relevant	
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:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	SSI Diagnostica A/S
	b. Address	Herredsvejen 2, 3400 Hillerød, Denmark
	c. Website address	https://www.ssidiagnostica.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	No attachments
4.	10. Name/Signature	Research scientist Jesper F. Sørensen
		

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>

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