Rev 1: September 2018

FSN Ref: Non-conformity No.:023-2021

Date: 2021.03.24

Urgent Field Safety Notice
Product nr 16996 Pneumococcus Factor 42a serum, 1 mL

Product with non-intended cross-reactions
(REF): 16996 Pneumococcus Factor 42a serum, lot M42a12F1, exp. date 24-01-2025

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.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Field Safety Notice (FSN)

Product with non-intended cross-reactions
(REF): 16996 Pneumococcus Factor 42a serum, lot M42a12F1, exp. date 24-01-2025.

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Antiserum product: Pneumococcus Factor 42a antiserum, 1 mL
1.	2. Commercial name(s)
	Product nr 16996 Pneumococcus Factor 42a serum, 1 mL
1.	3. Unique Device Identifier(s) (UDI-DI)
	GTIN13: GMDN:
1.	4. Primary clinical purpose of device(s)*
	Intended use is qualitative serotyping of the bacteria pneumococci (Streptococcus pneumoniae) by use of the capsular reaction test (Neufeld test).
1.	5. Device Model/Catalogue/part number(s)*
	REF: 16996
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	M42a12F1
1.	8. Associated devices
	N/A

2 **Reason for Field Safety Notice**	
2.	1. Description of the product problem*
	The Pneumococcus Factor 42a antiserum reacts specifically with pneumococcus serotype 35C and is used to distinguish serotype 35C from the other serotypes within serogroup 35. This lot has a non-intended cross-reaction and reacts in addition to serotype 35C also with serotype 35A. Serotype 35A can therefore with this lot be mistaken to be serotype 35C.
2.	2. Hazard giving rise to the FSCA*
	Minor hazard as only 3 vials of this lot has been sold within the last week before the error was found. It is therefore likely that the customers have not started using the product yet. Serotypes of group 35 are not common and this factor serum will only be used after encountering a group 35.
2.	3. Probability of problem arising
	As the error has been discovered fast, it is likely that no problem will arise. Also serotypes of group 35 are not common and this factor serum will only be used after encountering a group 35.
2.	4. Predicted risk to patient/users
	No risk to patients/users
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Upon producing this lot of antiserum this cross-reaction was not present and it therefore passed the laboratory QC tests. When the serum was retested the cross-reaction was present, so for some unknow reason it seems to be difficult to fully remove all cross-reactions in this particular factor serum lot. This is probably due to high similarity between the antigens within group 35 that the factor sera need to be specific to.
2.	7. Other information relevant to FSCA

	No FSCA have been issue, this FSN is for information only

	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	
3.	2. By when should the action be completed?	As soon as possible and latest
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? N/A	
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	
3	6. By when should the action be completed?	2021-04-09
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?	
	N/A	

	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	No follow up necessary
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	www.ssidiagnostica.com
4.	8. The Competent (Regulatory) Authority of your country is being informed about this communication to customers.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Lotte Lambertsen** *Cand Scient, Ph.D.* **Team leader**
		2021-03-24 

	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.

Customer Acknowledgment form

Please read this document in conjunction with Field Safety Notice **16996**
Pneumococcus Factor 42a serum, lot M42a12F1, exp. date 24-01-2025
and return the completed and signed form as soon as possible but no later than 2021-04-09 to SSI Diagnostica A/S
By completing the form, you confirm you have destroyed, returned and/or used all vials of the lot covered by the FSN.

Name of Site	
Name of organization covered by this response	
Email address	
Telephone Number	
Name	
Signature	
Date	