Doc nr 04-F-07a EN version 3

FSCA Ref: CAPA39214
FSN Ref: CAPA39214

Date: 09-02-2023

Field Safety Notice (FSN)

Chromogranin A RIA

At the Attention of: the users of the DiaSource Chromogranin A RIA kit (#KIPERB321)

Contact details of local representative*
DiaSource ImmunoAssays; Rue du Bosquet 2, B-1348 Louvain-la-Neuve BELGIUM + 32 10 84 99 11

DiaSource®

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Urgent Field Safety Notice (FSN)

Chromogranin A RIA

1. **Information on Affected Devices***	
1.	**1. Device Type(s)***
	Radioimmunoassay for the in vitro quantitative measurement of chromogranin A in human serum or plasma
1.	**2. Commercial name(s)**
	Chromogranin A RIA
1.	**3. Unique Device Identifier(s) (UDI-DI)**
	N/A
1.	**4. Primary clinical purpose of device(s)***
	Tumours of neuroendocrine origin usually present with increased serum/plasma levels of chromogranin A. The neuroendocrine tumours are derived from the neuroendocrine cells. Typical neuroendocrine tumours are carcinoid tumours, pheochromocytomas, neuroblastomas, small cell lung cancers, hyperparathyroid adenomas, pituitary tumours, prostate cancers and pancreatic islet tumours and including the MEN1 and MEN2 syndromes. This also includes the different neuroendocrine tumour syndromes, namely the gastrinomas, insulinomas, glucagonomas, somatostatinomas, PPomas and the non-functioning neuroendocrine tumours.
1.	**5. Catalogue part number(s)***
	KIPERB321
1.	**6. Software version**
	N/A
1.	**7. Affected lot(s) number(s)**
	222904, 222904/A, 222904/B, 222904/C (expiry 14/10/2022), 223705 (expiry 09/12/2022) 224506, 224506/A (expiry 03/02/2023) 230107, 230107/A (expiry 31/03/2023)
1.	**8. Associated devices**
	N/A

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	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	**1. Description of the product problem***
	Some customers reported the occurrence of false positive patients samples with different kit batches. From the data communicated by these customers, the majority of the patients samples are pathological and have Chromogranin A concentrations located above the reference cut-off (3 nmol/L) corresponding to a healthy population, as described in our Instructions for Use. This overestimation and false positive results potentially concern the laboratories who are using the reference cut-off of 3 nmol/L reported in our Instructions for Use. It is recommended that users establish reference ranges for the populations served by their own laboratories.
2.	**2. Hazard giving rise to the FSCA***
	Overestimation of the Chromogranin A results might lead to an incorrect diagnosis and to further unnecessary clinical examinations. Residual risk for the patients is lower if the laboratories establish and apply their own reference intervals.
2.	**3. Probability of problem arising**
	Probable
2.	**4. Predicted risk to patient/users**
	Severity: serious (3)
2.	**5. Further information to help characterise the problem**
	N/A
2.	**6. Background on Issue**
	Some customers reported the occurrence of false positive patients samples with different kit batches
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 Distributors: - Identify and inform the end-users who received the concerned devices - Destroy the devices of the current un-expired lots 230107 and 230107/A (expiry 31/03/2023). -Complete and send back the Vigilance response form to DiaSource
	☒ The End-users: - Destroy the devices of the current un-expired lots 230107 and 230107/A (expiry 31/03/2023)

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	- Make an assessment of the clinical status of the patients tested with all the concerned batches - Complete and send back the Vigilance response form to DiaSource		
3.	2. By when should the action be completed?	17/02/2023	
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes		
3.	4. Is customer Reply Required? *		Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Inform the distributors and the end-users about the problem ☒ Block the sales of the un-expired kits lots 230107 and 230107/A (expiry 31/03/2023) left in DiaSource's inventory ☒ Stop the production of the Chromogranin A RIA until the end of the investigation ☒Investigation by the Technical teams of DiaSource is ongoing to detect the root cause of the problem		
3	6. By when should the action be completed?	15/03/2023	
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?		
	Not appended to this FSN		

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	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? *	Not planned yet
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	Within 3 months
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	[redacted]

	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.

Field Safety Notice Vigilance Response Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	CAPA39214
FSN Date*	09/02/2023
Product/ Device name*	Chromogranin A RIA
Product Code(s)	KIPERB321
Batch/Serial Number (s)	222904, 222904/A, 222904/B, 222904/C, 223705, 224506, 224506/A, 230107, 230107/A

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	Products.support@diasource.be
Distributor/Importer Helpline	+3210849923
Postal Address	Rue du Bosquet , 2, B-1348 Louvain-la-Neuve, Belgium
Web Portal	https://www.diasource-diagnostics.com/
Fax	+3210849990
Deadline for returning the Distributor/Importer reply form*	17/02/2023

4. Distributors/End-users (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice *	
☐	I have identified and informed the end-users who received the concerned devices	Date of communication:
☐	I have attached customer list	
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected devices – enter the number of kits destroyed and the completion date.	Add quantity, Lot/Serial Number/Date
Print Name*		
Signature*		
Date *		

Mandatory fields are marked with *

It is important that your company takes the actions detailed in the Field Safety Notice and confirms that you have received the Field Safety Notice.

Your company's reply is the evidence we need to monitor the progress of the corrective actions.