Doc nr 04-F-07a version 2

DIAsource ImmunoAssays® S.A.
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FSCA Ref: CAPA30680
FSN Ref: CAPA30680

Date: 04.06.2019

Urgent Field Safety Notice

VIP RIA (#RB311/#RB311RUO)

To the attention of the users of DIAsource VIP RIA assay (#RB311/RB311RUO) - lot 191601

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

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Urgent Field Safety Notice (FSN)

VIP RIA (#RB311/#RB311RUO)

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Radioimmunoassay
1.	2. Commercial name(s)
	VIP RIA
1.	3. Unique Device Identifier(s) (UDI-DI)
	NA
1.	4. Primary clinical purpose of device(s)*
	Radioimmunoassay for the in vitro quantitative measurement of vasoactive intestinal polypeptide (VIP) in human plasma. For professional use within a laboratory
1.	5. Device Model/Catalogue/part number(s)*
	RB311/RB311RUO
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	Lot 191601 (expiry 28/06/2019)
1.	8. Associated devices
	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Low CPM values measured for the calibrators and kit controls generated with the kit lot 191601, which might lead to an unexpected flat calibration curve and a loss of discrimination between the calibrators. For that reason, the values of the 2 kit controls might fall out of the acceptable ranges defined by DIAsource, leading to invalid assays.
2.	2. Hazard giving rise to the FSCA*
	The results generated with that batch 191601 do not meet the performances expected in the Instructions for Use. Despite this problem, no risk of patient misdiagnosis is being expected in the case the kit controls measured by the laboratories are out of the

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	acceptable range. As indicated in the Instruction for use, " In order to enable the laboratory to completely monitor the consistent performance of the assay, the following important factors should be checked. 1.The found concentrations of the controls should be within the limits given on the labels of the vials".
2.	3. Probability of problem arising
	Moderate.
2.	4. Predicted risk to patient/users
	None
2.	5. Further information to help characterise the problem
	NA
2.	6. Background on Issue
	DIAsource registered some customers' complaints related to low CPM values measured for the calibrators and kit controls generated with the kit lot 191601. DIAsource's preliminary investigations highlighted that the tracer lot 19D08 could be responsible for this issue, which leads to a flat calibration curve and a loss of discrimination between the calibrators.
2.	7. Other information relevant to FSCA
	A follow-up will be provided by the end of the week 23.

	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
	1. Stop the use of the un-opened VIP RIA boxes from lot 191601 in customers' inventory until DIAsource provides new tracers to the customers in replacement for on-site device modification;

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	2. Discard the tracer 19D08 from the kits lot 191601 and use the remaining reagents only in combination with the new tracer that DIAsource will provide 3. Communicate to DIAsource the number of un-opened kits lot 191601 in the end-users facilities 4. Communicate to DIAsource the number of kits who failed. 5. Complete and send back the Field Safety Notice Customer Reply Form provided on the following pages	
3.	2. By when should the action be completed?	- 11/06/19
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No No risk for the patients as far as the kit controls have been measured out of the acceptance criteria. The runs who have achieved correct kit controls values can be validated and the patients samples can be released	
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 1) Pursue the tests to find the root cause and to correct the problem 2) Discard the incriminated lot cited above from inventory; 3) Analyze the risks for the patient health. 4) Offer replacements materials to the customers	
3	6. By when should the action be completed?	14/06/19
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?	
	NA NA	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	**3.** For Updated FSN, key new information as follows:	
	NA	
4.	4. Further advice or information already expected in follow-up FSN? *	YES
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Delivery timeframe of the replacements products	
4	6. Anticipated timescale for follow-up FSN	By 07/06/2019
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	DIAsource ImmunoAssays
	b. Address	Rue du Bosquet 2 , B-1348 Louvain-la-Neuve
	c. Website address	www.diasource.be
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	NA
4.	10. Name/Signature	Preud'homme Valérie Technical Support Specialist

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	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.

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Field Safety Notice Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	CAPA30680
FSN Date*	CAPA30680
Product/ Device name*	VIP RIA
Product Code(s)	RB311 & RB311RUO
Batch/Serial Number (s)	191601

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	Valerie.Preudhomme@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*	11/06/2019

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4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory – enter number of un-opened kits and date complete.	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I need …. new Tracers in replacement for on-site modification of the lot 191601	Distributor/Importer to enter quantity
☐	I need …. new kits in replacement for the kits lot 191601 that failed	Distributor/Importer to enter quantity
Print Name*		
Signature*		
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

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