Doc nr 04-F-07a version 2

DIAsource ImmunoAssays® S.A.
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FSCA Ref: CAPA31527
FSN Ref: CAPA31527

Date: 12 11 2019

Field Safety Notice

17α-HYDROXYPROGESTERONE (17-OHP)-RIA-CT (#KIP1409)

To the attention of the users of the DIAsource 17-OHP RIA-CT assay - **lot 193606**

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Field Safety Notice (FSN)

17α-HYDROXYPROGESTERONE (17-OHP)-RIA-CT

Progesterone Tracer in the kits of 17OHP RIA

	1. Information on Affected Devices*
1.	**1. Device Type(s)***
	Radioimmunoassay
1.	**2. Commercial name(s)**
	17α-HYDROXYPROGESTERONE(17-OHP)-RIA-CT
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 human 17α-hydroxyprogesterone (17-OHP) in serum and plasma
1.	**5. Device Model/Catalogue/part number(s)***
	KIP1409
1.	**6. Software version**
	NA
1.	**7. Affected serial or lot number range**
	193606 (expiry 15/11/2019)
1.	**8. Associated devices**
	NA

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	**1. Description of the product problem***
	A very small proportion of the 17OH-Progesterone RIA kits of the lot 193606 might contain an erroneous tracer reagent corresponding to Progesterone (#3114583) instead of 17OH-Progesterone (#3114063). Both tracers having the same lot number 19H26/01, only the name and the article codes can distinguish them.
2.	**2. Hazard giving rise to the FSCA***
	Using this erroneous tracer would result in abnormally low CPM for the Calibrators, controls and patients. Such profile of the calibration curve, as well as the B/B0 ratio (%)

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	would make the run obviously invalid even if controls might give acceptable concentration values .
2.	**3. Probability of problem arising**
	Low
2.	**4. Predicted risk to patient/users**
	None
2.	**5. Further information to help characterise the problem**
	NA
2.	**6. Background on Issue**
	Coming from a user' complaint showing an erroneous tracer reagent corresponding to Progesterone (#3114583) instead of 17OH-Progesterone (#3114063)
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***
	☒ 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
	Following the Notification sent by DIAsource on the 21/10/2019, we kindly asked you to check the contents of your 17OH Progesterone RIA kits of the lot 193606 in your inventory and let us know if any of them included the erroneous tracer. Now that the kits are close to expiry date (15/11/19), we assume that the content of your kits has been verified. We remind you that the kits which included a tracer of Progesterone, must not be used and have to be replaced.

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3.	**2. By when should the action be completed?**	15/11/2019	
3.	3. **Particular considerations for:** IVD **Is follow-up of patients or review of patients' previous results recommended?** Yes We remind that the kits which included a tracer of Progesterone, by mistake, must not to be used and have to be replaced.		
3.	**4. Is customer Reply Required? ***		Yes (see reply's form)
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.		
3	**6. By when should the action be completed?**	15/11/2019	
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.		

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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?** *	No
4	**5. If follow-up FSN expected, what is the further advice expected to relate to:**	
	NA	
4	**6. Anticipated timescale for follow-up FSN**	NA
4.	**7. Manufacturer information**	
	a. Company Name	DIAsource ImmunoAssays S.A
	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**	[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)

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	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