



DIAsource ImmunoAssays® S.A.
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FSCA Ref: CAPA34127
FSN Ref: CAPA34127

Date: 12:11:2020

Urgent Field Safety Notice
TPO Ab RIA

At the attention of the users of the DIAsource TPO Ab RIA assay

Contact details of local representative (name, e-mail, telephone, address etc.)*
DIAsource ImmunoAssays , Rue du Bosquet 2, 1348 Louvain-la-Neuve, Belgium



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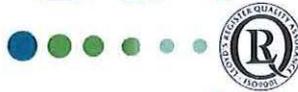
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Urgent Field Safety Notice (FSN)
TPO Ab RIA

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)* Radioimmunoassay for the quantitative determination of anti-thyroperoxidase autoantibodies in human serum
1.	2. Commercial name(s) TPO Ab RIA
1.	3. Unique Device Identifier(s) (UDI-DI) 5400569004207
1.	4. Primary clinical purpose of device(s)* Thyroid autoimmunity is more frequently registered in women. Antibody prevalence in women increases with age, rising from approximately 10% at the age of 18-24 up to 30% at the age of 55-65 for TgAb and from 15% at the age of 18-24 up to 24% at the age of 55-65 for TPOAb
1.	5. Device Model/Catalogue/part number(s)* R-CO-100
1.	6. Software version NA
1.	7. Affected serial or lot number range 203809, 203809/B
1.	8. Associated devices NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* Bad discrimination of the samples concentrations located in the lower part of the calibration curve between 0 and 80 IU/ml. This leads to the risk of an overestimation of the sample's concentration in this zone. Our recent investigations revealed that the use of the tracer lot 20107 might be responsible for a decreased discrimination of the cpm between the calibrators 0, 1 and 2. This leads to a reduced precision in the high-end of



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	the calibration curve and to a potential over-estimation of the patients results, especially the ones whose TPO Ab concentrations are located in this zone (between 0 – 80 IU/ml).
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>This leads to risk of an overestimation of the patient's concentration, especially the ones located in the borderline zone. No risk for users. Residual risk for patients is low if users respect the actions listed in this FSN (re-evaluation of patients samples results).</p>
2.	<p>3. Probability of problem arising</p> <p>Probability : the undesirable event never happened or the cause or circumstances for it happen is exceptionally (1)</p>
2.	<p>4. Predicted risk to patient/users</p> <p>Gravity: serious (3)</p>
2.	<p>5. Further information to help characterise the problem</p> <p>Wrong results leading to a wrong diagnostic of patients are possible if the people in charge of the tests accept/release the final results, taking in account the fact that the controls of the kit are measured within the acceptance range, established by DIAsource. Anti-TPO dosage is always used in combination with other analytes measurements as Tg-Ab,in order to provide a clear view on the health status of the patient. The clinical decision and potential treatments to a patient have to be made on the basis of a combination of clinical parameters and based on the historical file of the patient. That is why the results of TPO themselves cannot be responsible for a critical deterioration of the health of the patient.</p>
2.	<p>6. Background on Issue</p> <p>Two customers' complaints informing us of the issue.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>NA</p>

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input checked="" type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p>



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	<input type="checkbox"/> Other <input type="checkbox"/> None - stop using the kits from lots 203809 and 203809/B, if some boxes are still in inventory. - communicate the number of kits lot 203809 and 203809/B to DIAsource in order to replace by a new lot - re-test the samples located in the region of the cut-off with the new lots 204210 or 204210/A in order to confirm the results generated with the previous lots 203809 and 203809/B.
3.	2. By when should the action be completed? 20-11-2020
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Provide further details of patient-level follow-up if required or a justification why none is required
3.	4. Is customer Reply Required? * Yes (If yes, form attached specifying deadline for return)
3.	5. Action Being Taken by the Manufacturer <input checked="" 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 type="checkbox"/> Other <input type="checkbox"/> None -Discard the impacted tracer and kit batches from DIAsource's inventory -Replace the number of kits requested by the end-users to re-evaluate the patient samples
3	6. By when should the action be completed? Rejection: 23-10-2020 Replacement : 15-01-2021
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? * 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 (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name DIAsource ImmunoAssays
	b. Address Rue du Bosquet, 2 , 1348 Louvain-la-Neuve, Belgium
	c. Website address http://www.diasource-diagnostics.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes
4.	9. List of attachments/appendices: NA
4.	10. Name/Signature

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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<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.