

Date: DD: MM: YYYY

Product Notification

EliA ANA Positive Control 250, EliA ANA Positive Control 2500/5000

For Attention of

Contact details of local representative

Name	
Address	
Email address	
Telephone number	

Approved by Fredrik Mirenborn 2022-Jun-23 14:58 CET
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Product Notification
EliA ANA Positive Control 250

1. Information of affected device(s)	
1.1	Device Types(s) EliA ANA Positive Control 250 EliA ANA Positive Control 2500/5000
1.2	Commercial name(s) EliA ANA Positive Control 250 EliA ANA Positive Control 2500/5000
1.3	Primary clinical purpose of device(s) EliA ANA Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of antinuclear antibodies (ANA) with Phadia 250 using the EliA IgG method. EliA ANA Positive Control 2500/5000 is intended for laboratory use in monitoring the performance of in vitro measurement of antinuclear antibodies (ANA) with Phadia 2500/5000 using the EliA IgG method.
1.4	Device Model/Catalogue/ part number(s) 83-1033-01 EliA ANA Positive Control 250 83-1073-01 EliA ANA Positive Control 2500/5000
1.5	Affected serial or lot number range 83-1033-01: <i>R1Z7/ C9REF</i> <i>R5CY/ C9REF</i> <i>R65C/ C9REG</i> <i>R7JL/ C9REG</i> <i>R8J8/ C9REH</i> <i>R94T/ C9REH</i> 83-1073-01: <i>R4J7/ CMJEF</i> <i>R5YM/ CMJEG</i> <i>R94R/ CMJEG</i> <i>RAG5/ CMJEH</i>

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2. Reason for Product Notification	
2.1	<p>Description of the problem</p> <p>An issue with the product EliA ANA Positive Control 250 for the dsDNA parameter has been discovered. Complaints have been reported where customers have received results around or over the upper limit for EliA ANA Positive Control 250. During internal review high results for the EliA dsDNA parameter from Bulk lot 0078 (filling C9REF, C9REG, C9REH, C9REJ) was confirmed.</p> <p>The investigation also showed that the EliA ANA Positive Control 2500/5000 is affected by the issue with results around and above the upper limit of the range for dsDNA parameter from Bulk lot 0078 (filling CMJEF, CMJEG, CMJEH).</p> <p>The investigation concluded that it is only the EliA dsDNA parameter for EliA ANA Positive Control 250 and EliA ANA Positive Control 2500/5000 that is affected, all other EliA assays are working as intended within their specified ranges.</p>
2.2	<p>Hazard evaluation</p> <p>No health consequences since this issue does not have an effect on test results. Higher and out of range values for the EliA ANA Pos Control on dsDNA do not have an effect on the correctness of the test results generated for patient samples since EliA dsDNA wells are not affected.</p>
2.3	<p>Probability of problem arising</p> <p>When investigating the incoming complaints and studying customer data for all fillings from Bulk 0078 on Phadia 250, it showed that for EliA dsDNA parameter about 13 % of all values were above the stated higher range limit.</p> <p>The customer data for fillings from Bulk 0078 on Phadia 2500/5000 showed that for EliA dsDNA parameter about 9 % of all values were above the stated higher limit.</p>
2.4	<p>Risk to patient/ users evaluation</p> <p>This does not have an effect on the correctness of the patient test results since the product EliA dsDNA Well is not affected. However, there may be a delay in time to receive test results for EliA dsDNA. No adverse events have been reported.</p>



3. Type of Action to mitigate the risk																																																
3.1	<p>Action(s) to be taken by the user</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of instructions for use (IFU) <input checked="" type="checkbox"/> Other </p> <p>Please use the new EliA dsDNA range for EliA ANA Positive Control 250 and EliA ANA Positive Control 2500/5000 as stated in this Product Notification, PN2022-07.</p> <p>New EliA dsDNA range for EliA ANA Positive Control 250</p> <table border="1"> <thead> <tr> <th>Bulk</th> <th>Filling</th> <th>Lower limit acceptance range</th> <th>Upper limit acceptance range</th> <th>DE: target</th> </tr> </thead> <tbody> <tr> <td rowspan="4">0078</td> <td>C9REF</td> <td>40,5</td> <td>94,5</td> <td>67,5</td> </tr> <tr> <td>C9REG</td> <td>40,5</td> <td>94,5</td> <td>67,5</td> </tr> <tr> <td>C9REH</td> <td>40,5</td> <td>94,5</td> <td>67,5</td> </tr> <tr> <td>C9REJ</td> <td>40,5</td> <td>94,5</td> <td>67,5</td> </tr> </tbody> </table> <p>New EliA dsDNA range for EliA ANA Positive Control 2500/5000</p> <table border="1"> <thead> <tr> <th>Bulk</th> <th>Filling</th> <th>Lower limit acceptance range</th> <th>Upper limit acceptance range</th> <th>DE: target</th> </tr> </thead> <tbody> <tr> <td rowspan="4">0078</td> <td>CMJEF</td> <td>34,8</td> <td>81,2</td> <td>58,0</td> </tr> <tr> <td>CMJEG</td> <td>34,8</td> <td>81,2</td> <td>58,0</td> </tr> <tr> <td>CMJEH</td> <td>34,8</td> <td>81,2</td> <td>58,0</td> </tr> <tr> <td>CMJEJ</td> <td>34,8</td> <td>81,2</td> <td>58,0</td> </tr> </tbody> </table> <p><input type="checkbox"/> None</p>				Bulk	Filling	Lower limit acceptance range	Upper limit acceptance range	DE: target	0078	C9REF	40,5	94,5	67,5	C9REG	40,5	94,5	67,5	C9REH	40,5	94,5	67,5	C9REJ	40,5	94,5	67,5	Bulk	Filling	Lower limit acceptance range	Upper limit acceptance range	DE: target	0078	CMJEF	34,8	81,2	58,0	CMJEG	34,8	81,2	58,0	CMJEH	34,8	81,2	58,0	CMJEJ	34,8	81,2	58,0
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3.2	<p>Particular considerations for IVD</p> <p>Is follow-up of patients or review of patients' previous results recommended?</p> <p>No, this issue does not have an effect on the correctness of the patient test results since the product EliA dsDNA Well is not affected.</p>																																															
3.3	<p>Is customer reply required?</p> <p>Yes</p>																																															
3.4	<p>Action(s) to be taken by the manufacturer</p> <p> <input type="checkbox"/> Product removal <input type="checkbox"/> On-site device modification/ inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labeling change <input checked="" type="checkbox"/> Other </p>																																															

	<p>New ranges for the EliA ANA Positive Control 250 and EliA ANA Positive Control 2500/5000 using EliA dsDNA test have been determined for the affected lots.</p> <p><input type="checkbox"/> None</p>
3.5	<p>Is the Product Notification required to be communicated to the patient/ lay user?</p> <p>No</p>

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4. General information		
4.1	Product Notification type	New
4.2	Further advice or information already expected in follow-up Product Notification?	No
4.3	Manufacturer information	
	Company name	Thermo Fisher Scientific ImmunoDiagnostics
	Address	Rapsgatan 7P, P.O Box 6460 75137 Uppsala, Sweden
4.4	This event has been evaluated against your country's current requirements for reportability to authorities. The conclusion is that this is not a reportable event.	
4.5	Name:	
	Title:	
	Signature:	

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Transmission of this Product Notification
<p>This Product Notification needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this Product Notification to other organizations 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 eventual actions.</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 product Notifications. Others are optional.

Document name QA2022-07 Product Notification (PN) Letter
Number 766393 Version 1.0

Issued by Ingela Eriksson 2022-Jun-23 12:33 CET

Reviewed by Lisa Rohbe 2022-Jun-23 14:46 CET

Reviewed by Isabel Wilhelm 2022-Jun-23 14:25 CET

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