

Date: DD: MM: YYYY

Product Notification

For Attention to customers using EliA™ ANA Positive Control 250, EliA™ ANA Positive Control 2500/5000 or EliA™ ANA Positive Control 200

Contact details of local representative	
Name	
Address	
Email address	
Telephone number	

Approved by Fredrik Mirenborn, 2025-Dec-17 10:51 CET
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Product Notification

1. Information about affected device(s)	
1.1	<p>Device Types(s)</p> <p>EliA ANA Positive Control</p>
1.2	<p>Commercial name(s)</p> <p>EliA ANA Positive Control 250 EliA ANA Positive Control 2500/5000 EliA ANA Positive Control 200</p>
1.3	<p>Unique Device Identifier(s) (UDI-DI)</p> <p>07333066013824 07333066019024 07333066014142 07333066016382</p>
1.4	<p>Primary clinical purpose of device(s)</p> <p>83-1033-01/41: 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 products are to be used in clinical laboratories by trained professionals only.</p> <p>83-1073-01: 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 and Phadia 5000 series using the EliA IgG method. EliA products are to be used in clinical laboratories by trained professionals only.</p> <p>83-1148-01: EliA ANA Positive Control 200 is intended for laboratory use in monitoring the performance of in vitro measurement of antinuclear antibodies (ANA) with Phadia 200 using the EliA IgG method. EliA products are to be used in clinical laboratories by trained professionals only.</p>
1.5	<p>Device Model/Catalogue/ part number(s)</p> <p>83-1033-01 83-1033-41 83-1073-01 83-1148-01</p>
1.6	<p>Affected serial or lot number range</p>

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Product	Material number	Affected Model/Lot/Serial Number
EliA ANA Positive Control 250	83-1033-01	UN41/C9RGJ, UNJW/C9RGJ, UNKG/C9RGK, UPMT/C9RGK, UT0T/C9RGL, UTP9/C9RGL
	83-1033-41	UMXS/C9RGJ
EliA ANA Positive Control 2500/5000	83-1073-01	UPHP/CMJGJ, UNJT/CMJGK, UTAJ/CMJGM, UUBC/CMJGM
EliA ANA Positive Control 200	83-1148-01	UNLY/E06GJ

2. Reason for Product Notification	
2.1	<p>Description of the problem</p> <p>An issue relating to EliA ANA Positive Control 250, EliA ANA Positive Control 2500/5000 and EliA ANA Positive Control 200 has been discovered. The investigation confirmed that the acceptance ranges for EliA La on the control certificates required revision following initial publication. Consequently, additional results may be found above/outside the limit stated in the control certificates.</p> <p>This does not have an effect on the correctness of the test results generated for patient samples since the EliA La wells are not affected, and this will not impact previously obtained quality control results.</p> <p>No adverse events have been reported. No other EliA test ranges on the referenced control certificates are impacted by this action.</p>
2.2	<p>Health Hazard Evaluation</p> <p>No adverse health consequences are associated with this issue and the probability of serious adverse health consequences are deemed not likely.</p>

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3. Type of Action to mitigate the risk

3.1 Action(s) to be taken by the user

Identify Device Quarantine Device Return Device Destroy Device
 On-site device modification/inspection
 Follow patient management recommendations
 Patient follow up
 Review of patients' previous results
 Take note of amendment/reinforcement of instructions for use (IFU)
 Other: Please use the below updated acceptance ranges for EliA La when running EliA ANA Positive Control 250, EliA ANA Positive Control 2500/5000 or EliA ANA Positive Control 200.

Product	Material number	Lot/Batch	EliA Assay	Previously reported acceptance range (U/mL)	Updated acceptance range (U/mL)
EliA™ ANA Positive Control 250	83-1033-01	UN41/C9RGJ UNJW/C9RGJ	EliA La	21.9 – 51.1	24.9 – 58.1
	83-1033-01	UNKG/C9RGK UPMT/C9RGK	EliA La	21.9 – 51.1	24.9 – 58.1
	83-1033-01	UT0T/C9RGL UTP9/C9RGL	EliA La	24.2 – 56.6	24.9 – 58.1
	83-1033-41	UMXS/C9RGJ	EliA La	21.9 – 51.1	24.9 – 58.1
EliA™ ANA Positive Control 2500/5000	83-1073-01	UPHP/CMJGJ	EliA La	28.5 – 66.4	35.5 – 82.7
	83-1073-01	UNJT/CMJGK	EliA La	28.5 – 66.4	35.5 – 82.7
	83-1073-01	UTAJ/CMJGM UUBC/CMJGM	EliA La	31.5 – 73.6	35.5 – 82.7
EliA™ ANA Positive Control 200	83-1148-01	UNLY/E06GJ	EliA La	22.3-52.1	25.4 – 59.3

None

3.2 Is customer reply required?
Yes

3.3 Action(s) to be taken by the manufacturer

Product removal (partial recall) Product removal (full recall)
 On-site device modification/ inspection
 Software upgrade IFU or labeling change
 Customer information only
 Other: A CAPA, CA25-00071, has been initiated to prevent this from re-occurring.
 None

4. General information

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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	Phadia AB
	Address	Rapsgatan 7P, P.O Box 6460 75137 Uppsala, Sweden
	SRN	SE-MF-000014170
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	List of attachments/ appendices: <ul style="list-style-type: none"> • Customer Reply Form, PN2025-11 	
4.6	Name:	
	Title:	
	Signature:	

Transmission of this Product Notification

This Product Notification needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this Product Notification to other organizations 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 eventual actions.

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.



Document name Product Notification (PN) Letter, PN2025-11
Number 858886 Version 1.0

Issued by Erle Skovlund, 2025-Dec-17 09:12 CET

Reviewed by Henrik Schiöld, 2025-Dec-17 09:29 CET

Approved by Fredrik Mirenborn, 2025-Dec-17 10:51 CET

Release Date 2025-Dec-17 10:51 CET

