Date: DD: MM: YYYY

Product Notification

For Attention to customers using EliA™ ANA Positive Control 250 and EliA™ ANA Positive Control 2500/5000

Contact details of local representative	
Name	
Address	
Email address	
Telephone number	

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Product Notification

1. Information of affected device(s)	
1.1	Device Types(s) EliA ANA Positive Control
1.2	Commercial name(s) EliA ANA Positive Control 250; EliA ANA Positive Control 2500/5000
1.3	Unique Device Identifier(s) (UDI-DI) 07333066013824, 07333066019024; 07333066014142
1.4	Primary clinical purpose of device(s) 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. 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.
1.5	Device Model/Catalogue/ part number(s) 83-1033-01, 83-1033-41; 83-1073-01
1.6	Affected serial or lot number range U1K9/C9RG7, TZUR /C9RG7, U5U7/C9RG8, U4FC/C9RG8, U3DU/C9RG8, U6R0/C9RG9, U4N9/C9RG8; U1FZ/CMJG7, U4PC/CMJG8

2. Reason for Product Notification	
2.1	Description of the problem The acceptance ranges on the EliA ANA Positive Control certificates for EliA dsDNA and EliA Ro60 were set incorrectly. Consequently, more results may be found below the limit stated in the certificates. This issue does not have an effect on test results generated for patient samples since EliA dsDNA or EliA Ro60 wells are not affected.

2.2	Health Hazard Evaluation No adverse health consequences are associated with this issue and the probability of serious adverse health consequences is deemed not likely.

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 dsDNA and EliA Ro60 when running EliA ANA Positive Control 250 and/or EliA ANA Positive Control 2500/5000.

Product	Material number	Lot/Batch	EliA assay	Previously reported acceptance range (IU/mL)	Correct acceptance range (IU/mL)
EliA™ ANA Positive Control 250	83-1033-01, 83-1033-41	U1K9/C9RG7, TZUR /C9RG7, U5U7/C9RG8, U4FC/C9RG8, U3DU/C9RG8, U6R0/C9RG9, U4N9/C9RG8	EliA dsDNA	33.0 – 77.1	29.3 – 68.4
			EliA Ro60	31.8 – 74.2	38.1 – 89.0
EliA™ ANA Positive Control 2500/5000	83-1073-01	U1FZ/CMJG7, U4PC/CMJG8	EliA dsDNA	27.4 – 64.0	24.3 – 56.7
			EliA Ro60	34.0 – 79.4	40.8 – 95.2

☐ 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, CA25-00029, has been initiated to prevent this from re-occurring.
☐ None

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	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: • Customer Reply Form, PN2025-06	
4.6	Name:	
	Title:	
	Signature:	

Transmission of this Product Notification
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) 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. *

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