

Quality Information

EliA™ ANA Positive Control 250, EliA™ ANA Positive Control 2500/5000 and EliA™ ANA Positive Control 200

Purpose:

Quality information about actions to perform due to Product Notification, PN2025-11.

Distribution:

Australia, Austria, Bahrain, Belgium, Brazil, Canada, Chile, Czech Republic, Denmark, Dutch Antilles and Curacao, Estonia, Finland, France, Georgia, Germany, Great Britain, Hong Kong, Iceland, India, Ireland, Israel, Italy, Japan, Lithuania, Malaysia, Maldives, Malta, Mexico, Morocco, Netherlands, New Zealand, Norway, Philippines, Poland, Portugal, Qatar, Romania, Saudi Arabia, Singapore, Slovenia, South Africa, Spain, Switzerland, USA

Products:

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

Description of the problem:

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.

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 have an impact on previously obtained quality control results.

No adverse events have been reported. No other EliA test ranges on the referenced control certificates are impacted by this action.



Actions to be taken by the customer/user:

- 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

Actions to be taken by the manufacturer:

- Corrective Actions have been initiated to prevent this from recurring.

Actions – Commercial organization

- Scrap any existing stock of affected products and order replacement products free of charge.
- Send the Commercial organization initial report to Global QA as confirmation that the information has been received.
- Send the commercial organization final report to Global QA when communication with customers, and authorities if needed, has been performed.

Transmission of this Notification:

Please ensure that this notice is shared with anyone who needs to be made aware within your organization, or to any organization on which this notification potentially has an impact. We apologize for any inconvenience this event may cause. If you have any questions, please contact us.

Contact/Questions:

vigilance.idd@thermofisher.com



Commercial organization initial report

EliA™ ANA Positive Control 250, EliA™ ANA Positive Control 2500/5000 and EliA™ ANA Positive Control 200

- I hereby acknowledge that we have received this QI and PN2025-11:

Yes ☐

Date: _____

Signature: _____

(Please print name): _____

Country/countries: _____

E-mail a signed, scanned copy to: vigilance.idd@thermofisher.com



Commercial organization final report

EliA™ ANA Positive Control 250, EliA™ ANA Positive Control 2500/5000 and EliA™ ANA Positive Control 200

I hereby confirm that the following has been performed:

- Informed affected customer about the content in PN2025-11.

Yes ☐

No ☐

If No, reason: The affected stock are still at warehouse and no customers are affected by it.

- Customer response rate 100 %

Yes ☐

No ☐

If No, give actual response rate:

Evidence of a minimum of three faith efforts to contact the customers is saved.

- Sent required information to the authority.

Yes ☐

No ☐

If No, reason:

Evidence of communication with authorities is saved.



Date:_____

Signature:_____

(Please print name):_____

Country/countries:_____

E-mail a signed, scanned copy to: vigilance.idd@thermofisher.com

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