

Quality Information

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

Purpose:

Quality information about actions to perform due to Product Notification, PN2025-06.

Distribution:

Armenia, Australia, Austria, Bahrain, Belgium, Brazil, Canada, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Great Britain, Hong Kong, Iceland, India, Ireland, Israel, Italy, Japan, Lithuania, Malaysia, Maldives, Malta, Morocco, Netherlands, Netherland Antilles, Norway, Oman, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Ukraine, USA, Taiwan, United Arab Emirates

Product:

Product	Material number	Affected Model/Lot/Serial Number
EliA ANA Positive Control 250	83-1033-01	U1K9/C9RG7, TZUR /C9RG7, U5U7/C9RG8, U4FC/C9RG8, U3DU/C9RG8, U6R0/C9RG9
EliA ANA Positive Control 250	83-1033-41	U4N9/C9RG8
EliA ANA Positive Control 2500/5000	83-1073-01	U1FZ/CMJG7, U4PC/CMJG8

Description of the problem:

An issue of EliA ANA Positive Control 250 and EliA ANA Positive Control 2500/5000 has been discovered. The investigation showed that the acceptance ranges for EliA dsDNA and EliA Ro60 on the control certificates were not correct. Consequently, more results may be found below the limit stated in the certificates.

This does not have an effect on the correctness of the test results generated for patient samples since the EliA dsDNA and EliA Ro60 wells are not affected. No adverse events have been reported.



Actions to be taken by the customer/user:

- 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

Actions to be taken by the manufacturer:

- Corrective Actions have been initiated to prevent this from re-occurring.

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 and EliA ANA Positive Control 2500/5000

- I hereby acknowledge that we have received this QI and PN2025-06:

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 and EliA ANA Positive Control 2500/5000

I hereby confirm that the following has been performed:

- Informed affected customer about the content in PN2025-06.

Yes ☐

No ☐

If No, reason:

- 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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