

PRODUCT NOTIFICATION

ELIA ANA POSITIVE CONTROL 100, 250, 2500/5000

Date: 2018-12-07

Dear Customer,

(cc Chairman Medical Board and Relevant Head of Departments)

We are writing to you regarding an issue affecting the ranges specified for EliA La in the EliA ANA Positive Control and to inform you of the mitigating measures to be taken. The issue does not affect the correctness of the EliA La test results.

Products affected

Article nr	Product name	Kit lots
83-1038-01	EliA ANA Positive Control 100	KWJA, L56S, LAHZ, LK71, LE6Y, LLA8
83-1038-41	EliA ANA Positive Control 100 (Taiwan)	KTLP, L497, L8FB, LK7C, LFWZ, LMLR, KX54, L66G, LADD, LGR0, LOLF
83-1033-01	EliA ANA Positive Control 250	KUH8, KYF9, L45E, L75B, LG57, LBUL, LK6M, L68N, KX7L, L05B, L5TX, L8ZW, LHFZ, LDA8, LL7H, L1LP, LMYR
83-1033-41	EliA ANA Positive Control 250 (Taiwan)	KTRD, L0SE, L35E, L8FA, LEE6, LC67, LLLA, KXLK, LMPJ
83-1073-01	EliA ANA Positive Control 2500/5000	KTB4, KXPK, L5W9, L8ZT, LEW8, LE6Z, LMPG, L68P, KWSW, L8DC, LHD3, LH0Z, LB7E, LKSA

Description of the problem

An issue of EliA ANA Positive Control has been discovered. Customers have received results around the lower limit for the La parameter in EliA ANA Positive Control.

The EliA ANA Positive Control is used for in total 14 assays; EliA dsDNA, U1RNP, RNP70, SmD^P, Ro, Ro60, CENP, Scl-70, Scl-70^S, Jo-1, Symphony, CTD Screen, Symphony^S and La. It is only the EliA La parameter that is affected. All other assays are working within their specified ranges.

The investigation shows that the majority of results is found in the lower half of the expected range for EliA La from the affected lots. As a consequence 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 La wells are not affected. No adverse events have been reported.

As a correction, new ranges for La have been determined for the affected lots and instrument types on the market, see tables in the attachment.

Actions to be taken by the Customer/User

- Please use the new ranges for EliA ANA Positive Control parameter La stated in this Product Notification.

Actions to be taken by the Manufacturer

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

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 may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

If you have any questions, please contact us.

Sherlyn Kon
Business Executive
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ATTACHMENT PHADIA 100

83-1038-01, EliA ANA Positive Control 100

Vial Lot	New La range	Kit lot	Expiry date
CA1CV	22,3 – 52,1 U/ml	KWJA	2018-12-31
CA1CX	22,3 – 52,1 U/ml	L56S	2019-03-31
CA1CZ	23,7 – 55,4 U/ml	LAHZ	2019-05-31
CA1D1	23,7 – 55,4 U/ml	LK71	2019-08-31
CA1D0	23,7 – 55,4 U/ml	LE6Y	2019-07-31
CA1D2	23,7 – 55,4 U/ml	LLA8	2019-09-30

83-1038-41, EliA ANA Positive Control 100 (Taiwan)

Vial Lot	New La range	Kit lot			Expiry date
CA1CV	22,3 – 52,1 U/ml	KTLP	KX54	L0LF	2018-12-31
CA1CX	22,3 – 52,1 U/ml	L497	L66G		2019-03-31
CA1CZ	23,7 – 55,4 U/ml	L8FB	LADD		2019-05-31
CA1D1	23,7 – 55,4 U/ml	LK7C			2019-08-31
CA1D0	23,7 – 55,4 U/ml	LFWZ	LGR0		2019-07-31
CA1D2	23,7 – 55,4 U/ml	LMLR			2019-09-30

ATTACHMENT PHADIA 250

83-1033-01, EliA ANA Positive Control 250

Vial Lot	New La range	Kit lot			Expiry date
C9RCV	19,6 – 45,7 U/ml	KUH8	KX7L		2018-12-31
C9RCW	19,6 – 45,7 U/ml	KYF9	L05B	L1LP	2019-01-31
C9RCX	19,6 – 45,7 U/ml	L45E	L5TX		2019-03-31
C9RCZ	19,1 – 44,7 U/ml	L75B	L8ZW		2019-05-31
C9RD1	19,1 – 44,7 U/ml	LG57	LHFZ		2019-08-31
C9RD0	19,1 – 44,7 U/ml	LBUL	LDA8		2019-07-31
C9RD2	19,1 – 44,7 U/ml	LK6M	LL7H	LMYR	2019-09-30
C9RCY	17,8 – 41,5 U/ml	L68N			2019-05-31

83-1033-41, EliA ANA Positive Control 250 (Taiwan)

Vial Lot	New La range	Kit lot		Expiry date
C9RCV	19,6 – 45,7 U/ml	KTRD	KXLK	2018-12-31
C9RCW	19,6 – 45,7 U/ml	L0SE		2019-01-31
C9RCX	19,6 – 45,7 U/ml	L35E		2019-03-31
C9RCZ	19,1 – 44,7 U/ml	L8FA		2019-05-31
C9RD1	19,1 – 44,7 U/ml	LEE6		2019-08-31
C9RD0	19,1 – 44,7 U/ml	LC67		2019-07-31
C9RD2	19,1 – 44,7 U/ml	LLLA	LMPJ	2019-09-30

ATTACHMENT PHADIA 2500/5000

83-1073-01, EliA ANA Positive Control 2500/5000

Vial Lot	New La range	Kit lot			Expiry date
CMJCV	14,5 – 33,8 U/ml	KTB4	KWSW		2018-12-31
CMJCW	14,5 – 33,8 U/ml	KXPK			2019-01-31
CMJCX	14,5 – 33,8 U/ml	L5W9			2019-03-31
CMJCZ	18,9 – 44,2 U/ml	L8ZT	L8DC	LB7E	2019-05-31
CMJD1	18,9 – 44,2 U/ml	LEW8	LHD3	LKSA	2019-08-31
CMJD0	18,9 – 44,2 U/ml	LE6Z	LH0Z		2019-07-31
CMJD2	18,9 – 44,2 U/ml	LMPG			2019-09-30
CMJCY	15,8 – 37,0 U/ml	L68P			2019-05-31