



PRODUCT ALERT NOTICE

ACTION REQUIRED

Alert Ref No: EA Elevated Recovery with Elecsys® anti-TPO on cobas e 402 and e 801 instruments QN-RDS-CoreLab-2024-155

Date: 19/12/24

Product Affected: Elecsys® anti-TPO

System Affected: cobas e 402
cobas e 801

Product Name	Material No	Lot No
Elecsys® anti-TPO cobas e 402/801	07026935190	791515 808202 827071

Summary of Issue:

Elevated Recovery with Elecsys® anti-TPO on **cobas e 402** and **e 801** instruments

Reason for Notice

Roche would like to inform customers about falsely elevated recovery for Elecsys® anti-TPO on **cobas e 402/801** analysers.

During internal investigations with Elecsys® anti-TPO in light of a recent corrective and preventative action (CAPA) it was confirmed that the recovery on **cobas e 402/801** analysers is falsely elevated. This affects all currently available lots in the market (791515, 808202 and 827071).

The recovery on **cobas e 601** was assessed to be correct by analysis of the standardisation data. No drift could be identified for **cobas e 601**. The deviation between both platforms is on average up to approximately 30% (Slope 1.23 - 1.30).

	Immediate Action Required
✓	Action Required
	Information Only

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Standardization					23/1063	24/0153	24/0472	24/0932
	Platform				cobas® e 601	cobas® e 601	cobas® e 601	cobas® e 601
		Lot			769146	784656	806665	827061
			Patho sera		05 May 2023	05 May 2023	26 January 2024	04 August 2024
				CalSet				
24/0203	cobas® e 801	791515	05 May 2023	733046	Intercept 1.99 Slope 1.28 Pearsons r= 0.99	Intercept -4.01 Slope 1.30 Pearsons r= 0.99		
24/0572	cobas® e 801	808202	26 January 2024	733046			Intercept 2.59 Slope 1.23 Pearsons r= 0.99	
24/1078	cobas® e 801	827071	04 August 2024	733046				Intercept -3.58 Slope 1.24 Pearsons r= 0.99

Method comparison between cobas® e 601 and cobas® e 801 module based on pathologic human sera and normal sera (NS)

For corrective action of the elevated recovery, the new reagent lot 837056 for E2G instruments (cobas e 402/801 analysers) will be adjusted with the upcoming standardisation to the newest E1G (cobas e 601) lot 827061.

Action Required

Customers should be aware of the falsely elevated recovery of Elecsys® anti-TPO on cobas e 402/801 analysers and this affects all currently available lots in the market (791515, 808202 and 827071). Since the remaining risk of false positive results with Elecsys® anti-TPO is generally acceptable with respect to the given discrepancy all lots can be used in the customer labs until the specified expiry date. All results should be reviewed in line with local laboratory policies and procedures.

The new reagent lot 837056 is expected to be available from January 2024 onwards. We will send out an updated version of this notice when the new lot number is in stock in our warehouse.

Attachments

None

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