



PRODUCT ALERT NOTICE

ACTION REQUIRED

Alert Ref No: PA Faulty code chips of CoaguChek PT Control QN-RDS-POC-2023-086

Date: 16/10/23

Product Affected: CoaguChek PT Controls (Levels 1 + 2)

System Affected: CoaguChek Pro II

Expiry Date of Notice: 31/08/24

Product Name	Material No	Lot No
CoaguChek PT Controls (Levels 1 + 2)	06679684190	74569600

Summary of Issue:

Faulty code chips of CoaguChek PT Control

Reason for Notice

Roche regrets to inform customers that we have detected printed circuit boards of some code chips with wrong dimensions, which did not correctly fit into the code chip housing. As a result, these faulty code chips may not be able to be inserted into the CoaguChek Pro II meters and the meter cannot read the data on the code chip.

A random check with a statistically significant number of samples was performed on the affected CoaguChek Controls. The expected error rate of faulty code chips is approximately 2%. Therefore, it cannot be excluded that customers may receive the affected CoaguChek Controls with faulty code chips.

	Immediate Action Required
√	Action Required
	Information Only

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Roche advises customers to immediately check the code chip of the affected lot. If the code chip is faulty, another pack of the CoaguChek Controls from the same or another lot should be checked if this is available. If another unaffected pack or lot number is not available please raise a case via Online Support or contact the technical support hotline for a replacement CoaguChek Control pack.

Workaround in case of QC lockout

In some cases, customers may have set a daily QC lockout and a measurement can be only performed after a successful QC test. If a customer has a faulty code chip, then the QC control cannot be performed. In this situation, the QC lockout can be avoided by performing a STAT test. For this, the customer can preset a number of tests permitted beyond the lockout. For further information on STAT configuration, please refer to the Operator's Manual (OM) of the instrument (CoaguChek Pro II OM V4 page 103-105).

Attachments

None

A copy of this notice can also be found on the [Roche navify® portal](#)

If you have any questions in relation to this notice or require any further information please raise a case via Online Support on the [Roche navify® portal](#)

Alternatively contact our Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

Option 2 – Point of Care

	Immediate Action Required
✓	Action Required
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