Urgent Field Safety Notice

SBN-RDS-NPC-2024-003

RDS / NPC
Version 1
19-Sep-2024

CoaguChek PT Deviation % Quick

Product Name	CoaguChek PT 2x24 Test (es/pt/hu/el) CoaguChek PT 2x24 Test (de/it/fr/nl) CoaguChek PT 2x24 Test (en/fr/pl/sl)		
Product Description	CoaguChek PT 2x24 Test		
BASIC UDI-DI/GMMI / Part No **Device Identifier (UDI)**	CoaguChek PT 2x24 Test (es/pt/hu/el) CoaguChek PT 2x24 Test (de/it/fr/nl) CoaguChek PT 2x24 Test (en/fr/pl/sl)	06688721070 06688721016 06688721019	UDI-04015630933495 UDI-04015630933471 UDI-04015630933488
Production Identifier **(Lot No./Serial No.)**	06688721070 - lot 77409111 06688721016 - lot 77409112 06688721019 - lot 77409113		
SW Version	n/a		
Type of Action	Field Safety Corrective Action (FSCA)		

Dear Valued Customer,

Description of Situation

During internal testing it was observed that the %Quick values were out of specification (false low) in the above-mentioned lots. The discrepant %Quick values in the specific INR range 2.87 - 3.0 INR may have a maximum deviation of -5 %Quick, displaying a faulty range of 14.72 - 12.88 %Quick. The CoaguChek PT Test is an in vitro assay for the determination of prothrombin time (PT) using the CoaguChek Pro II meter. The described issue of false low %Quick values is related to a calculation error and occurs in a small %Quick range only.

INR values generated from the affected lots remain unaffected, and all results produced are valid and acceptable.

So far, no customer complaints have been received.

Actions taken by Roche Diagnostics (if applicable)

Due to the potential safety risk related to the issue, customers of the impacted lots must be informed of the issue.

SBN-RDS-NPC-2024-003 CoaguChek PT Deviation %Quick

The CAPA investigation is ongoing and after its completion, if needed appropriate corrective/preventive actions will be defined and implemented.

Actions to be taken by the customer/user

For only these impacted lots, 77409111, 77409112, and 77409113 only the INR value can be used for therapy decisions. Customers can continue using the affected lots because the INR value is correct.

For customers who only report in %Quick, please discontinue using the impacted lots.

Customers should follow their standard laboratory operating procedures for any suspected erroneous results. Any specific questions raised by the users should be addressed individually considering all relevant clinical information.

Communication of this Field Safety Notice (if appropriate)

For only these impacted lots, 77409111, 77409112, and 77409113, customers must be informed to use only the INR value for therapy decisions.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

Roche Diagnostics GmbH - SRN: DE-MF-000006260 (legal manufacturer)