HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

CoaguChek Test Strips for Self-Testing and Point of Care Use

CoaguChek XS PT Test PST
CoaguChek XS PT Test
CoaguChek PT Test

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2018(30) **Issue Date: 30 August 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Roche Diagnostics GmbH	V36870

ISSUE
Roche Diagnostics has identified an increasing positive bias with INR values >4.5 for certain CoaguChek test strips. A medical risk, due to a possible Vitamin K treatment decision, for INR values >4.5 INR, cannot be excluded. Users are advised to confirm INR results >4.5 by a laboratory method (venous blood sample) until replacement lots are available. Roche has confirmed that the impacted lots are safe to use for results between 0.8 to 4.5 INR. Roche has indicated that new lots which are unaffected by this issue are expected to be available to order in early/mid October 2018 for supply to the Irish market in November 2018. Please refer to the accompanying FSN and patient letter for further information.

ACTION OR RECOMMENDATIONS

The HPRA advises that self-testers, carers and family members:

1. Refer to the accompanying patient letter and follow the instructions provided.
2. Please maintain an awareness of this Safety Notice and the actions outlined in the patient letter until replacement unaffected stock is received (November 2018).
3. Report any concerns relating to these devices to the manufacturer and the HPRA as soon as possible.
4. Contact your healthcare professional with any concerns.

The HPRA advises that health care professionals:

1. Refer to the accompanying FSN and follow the instructions provided. For the affected test strips, confirm all INR results >4.5 using a laboratory method (venous blood sample).
2. Contact all self-testers under your care and ensure they are aware of this issue. Please advise the HPRA if you experience any difficulties contacting individuals.
3. Acknowledge receipt of the FSN if you have not already done so.
4. Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation and to any organisation / persons to which / whom these devices have been transferred.
5. Please maintain an awareness of this Safety Notice and actions outlined in the FSN until replacement unaffected stock is received (November 2018).
6. Report any adverse events relating to these devices to the manufacturer and the HPRA as soon as possible.

TARGET GROUPS

Anticoagulation / Warfarin / INR clinics	Medical Scientists
Carers	Patients performing self-testing
Chief Medical Scientists	Pharmacists
Clinical Directors	Point of Care Managers
General practitioners	Practice nurses
Haematology	Private medical practitioners
Hospital Managers / CEOs	Public and Private Hospitals
Hospital personnel	Purchasing Managers
Laboratory Managers	Risk Managers
Laboratory Staff	Supplies Managers

BACKGROUND

A recent change in calibration from WHO reference standard rtf/09 to rTF/16 has been identified as the root cause of this issue. Roche has indicated that affected strips were first placed on the Irish Market in January 2018.

Roche has indicated that the following products and lots are affected by this issue:

- CoaguChek XS PT Test PST, Lots beginning with 272167 - 334498
- CoaguChek XS PT Test, Lots beginning with 272167 - 334498
- CoaguChek PT Test, Lots beginning with 272170 - 353606

New lots which are unaffected by this issue are expected to be available in Ireland in November 2018:

- CoaguChek XS PT PST Test, Lots beginning with 334499
- CoaguChek XS PT Test, Lots beginning with 334499
- CoaguChek PT Test, Lots beginning with 361433

Please refer to the accompanying FSN and patient letter for further information.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY
United Kingdom

Telephone (Patients): 1800 99 28 68
Telephone (HCPs): 1800 40 95 64
Email (Patients): burgesshill.coagpts@roche.com
Email (HCPs): burgesshill.tsgpm@roche.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie