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 – Update

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

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2018(32) **Issue Date: 15th October 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Roche Diagnostics GmbH	V36870

ISSUE
The Health Products Regulatory Authority (HPRA) published a Safety Notice on the 30th of August SN2018(30) to raise awareness of a field safety notice (FSN) issued by Roche relating to an increasing positive bias with INR values >4.5 for certain CoaguChek test strips. Roche limited the use of affected strips to ≤4.5 INR, as a medical risk for INR values >4.5 INR, could not be excluded. Roche has since issued a follow-up FSN advising of additional workaround options available pending release of unaffected lots which are expected to be available to order in early/mid October 2018 for supply to the Irish market in November 2018. The follow-up FSN advises healthcare professionals to confirm INR results >4.5 by either a laboratory method or using unaffected Coaguchek test strips. The follow-up FSN also advises that the frequency of testing should be increased according to local medical guidelines until replacement lots are available. As advised in FSN 1, the impacted lots are safe to use for results ≤4.5 INR. Roche has indicated that the advice provided in the patient letter has not changed. Please refer to the accompanying follow up FSN and patient letter for further information. The follow-up FSN (FSN2) supersede the initial FSN (FSN1).

ACTION OR RECOMMENDATIONS

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

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

The HPRA advises that health care professionals:

1. Refer to the accompanying follow-up FSN and follow the instructions provided. For the affected test strips, confirm all INR results >4.5 using a laboratory method (venous blood sample) or unaffected Coaguchek test strips.
2. Ensure all self-testers under your care are aware of this issue. Please advise the HPRA if you experience any difficulties contacting individuals.
3. Acknowledge receipt of the follow-up FSN if you have not already done so.
4. Forward a copy of this Safety Notice and the follow-up 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 follow-up 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.

The follow-up patient letter reminds users that the instructions for use for the self-test devices state the following:-

- CoaguChek XS PT Test: *"If the measured PT result is unusually high or low repeat the test. If the PT result is still outside the therapeutic range specified by your treating physician, immediately contact your physician and ask for the appropriate (anticoagulant) measures to take in order to reduce risks that could be encountered*

due to excessive anticoagulation (danger of bleeding) or insufficient anticoagulation (risk of thrombosis)."

- CoaguChek XS PT Test PST: *"If the measured result is outside the therapeutic range specified by your treating physician, repeat the test. If the result is still outside the therapeutic range immediately contact your physician and ask for the appropriate (anticoagulant) measures to take."*

The follow-up patient letter also reminds users that the risk of inadequate therapeutic measures due to deviated high INR values (>4.5) is mitigated by the interaction with the physician for patients performing patient self-testing.

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

Users are advised to contact Roche if they have any queries regarding this follow-up FSN.

The HPRA recommends that users do not change therapy without consulting their healthcare professional and ensuring that the out of therapeutic range results are confirmed.

Please refer to the accompanying follow-up 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