

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 2 – Warning

HPRA Safety Notice: SN2018(38)

Issue Date: 18th December 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 Diagnostics relating to an increasing positive bias with INR values >4.5 for certain CoaguChek test strips. Roche Diagnostics limited the use of affected test strips to ≤ 4.5 INR, as a medical risk for INR values >4.5 INR, could not be excluded.

A follow-up Safety Notice was issued in October [SN2018\(32\)](#) highlighting a follow-up FSN in which Roche Diagnostics advised of additional workaround options pending release of unaffected test strips.

Roche Diagnostics has confirmed that unaffected test strips are now available in Ireland.

The HPRA recommends that users source unaffected test strips at the earliest opportunity. In the interim, the affected test strips can be used with the known limitations for values >4.5 INR.

ACTION OR RECOMMENDATIONS

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

1. Contact your pharmacy to source unaffected test strips. In the interim, the affected test strips can be used with the known limitations for values >4.5 INR.
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. Advise users to contact their local pharmacy to obtain unaffected test strips. In the interim, the affected test strips can be used with the known limitations for values >4.5 INR.
2. Source unaffected test strips for professional use. In the interim, the affected test strips can be used with the known limitations for values >4.5 INR.
3. Report any adverse events relating to these devices to the manufacturer and the HPRA as soon as possible.

TARGET GROUPS

Anticoagulation / Warfarin / INR clinics
Carers
Chief Medical Scientists
Clinical Directors
General practitioners
Haematology
Hospital Managers / CEOs
Hospital personnel
Laboratory Managers
Laboratory Staff

Medical Scientists
Patients performing self-testing
Pharmacists
Point of Care Managers
Practice nurses
Private medical practitioners
Public and Private Hospitals
Purchasing Managers
Risk Managers
Supplies Managers

BACKGROUND

Roche Diagnostics has confirmed that test strips which are unaffected by this issue are now available in Ireland. Unaffected test strips can be identified as follows:-

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

The HPRA recommends that users source unaffected test strips at the earliest possible opportunity. In the interim, the affected test strips can be used with the known limitations for values >4.5 INR.

Users are advised to contact Roche Diagnostics if they experience any problems sourcing unaffected test strips.

The HPRA recommends that users do not change therapy without consulting their healthcare professional.

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