

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/26

Issued: 10 September 2003

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section								
<b>Medical Device/Equipment:</b> Roche Diagnostics Ltd CoaguChek PT test strips (12 strip pack) catalogue number: 1937634-190, lot number: 583	▶ ①								
<b>Problem:</b> Increased risk of falsely high INR results.	▶ ②								
<b>Action by:</b> <ul style="list-style-type: none"> <li>Pharmacists supplying Roche CoaguChek PT test strips (12 strip pack)</li> <li>Anticoagulation service providers (e.g. anticoagulation clinics)</li> <li>Healthcare professionals managing patients using the Roche CoaguChek S monitor</li> </ul>	▶ ③								
<b>Action:</b> See action section on following page.	▶ ④								
<b>Distributed by NIAIC to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <b>For onward distribution see Section 5</b>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
Chief Executive of each HSS Trust	Community Pharmacists								
Chief Executive of each Agency									
NIAIC Liaison Officers									
<b>Contacts</b> Supplier and NIAIC contact details.	▶ ⑥								
<b>Feedback Requirements to NIAIC</b> None required.	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Roche Diagnostics Ltd CoaguChek PT test strips (12 strip pack) catalogue number: 1937634-190, lot number: 583

## 2. PROBLEM:

Roche CoaguChek PT test strips are used in conjunction with the Roche CoaguChek S monitor, and are used by patients on anticoagulation treatment to monitor their prothrombin time. Prothrombin time is expressed as an International Normalised Ratio (INR).

Roche Diagnostics Ltd has identified that a manufacturing problem affecting one batch of test strips has given rise to defects in the packaging of the strips. The company estimates that 3% of test strips from this lot are affected. The manufacturer has stated that this lot has been available in the UK since 29 July 2003.

The packaging defect may give rise to an increased risk of falsely high INR results which may lead to inappropriate anticoagulant treatment and a potentially increased risk of thrombosis/ thromboembolism.

Roche is recalling the affected lot. Other lots are not affected by this recall.

## 3. ACTION BY:

- Pharmacists supplying Roche CoaguChek PT test strips (12 strip pack)
- Anticoagulation service providers (e.g. anticoagulation clinics)
- Healthcare professionals managing patients using the Roche CoaguChek S monitor

## 4. ACTION:

### Pharmacists supplying Roche CoaguChek PT test strips (12 strip pack)

- Do not supply products from lot number 583.
- Quarantine customer returns from this lot together with remaining product from this lot and contact Roche for free-of-charge replacements.
- Please could you:
  - identify patients who have been supplied with the Roche CoaguChek PT test strips (12 strip pack) since 29 July 2003;
  - contact these patients, indicating to them that there has been a problem with a small number of these products from lot number 583;
  - advise the patient to check the lot number that is printed on top of the carton and on the foil packaging;
  - advise patients who have used lot number 583 to repeat the blood test using a new batch of test strips. If the repeat test is outside their therapeutic range, they should seek an appointment with their anticoagulation service provider, taking the test strips and packaging with them.

### Anticoagulation service providers (e.g. anticoagulation clinics)

- Please could you:
  - identify patients who are using the Roche CoaguChek S monitor;
  - contact these patients, indicating to them that there has been a problem with a small number of Roche CoaguChek PT test strips lot number 583, which has been distributed since 29 July 2003;
  - advise the patient to check the lot number that is printed on top of the carton and on the foil packaging;
  - advise patients who have used lot number 583 to repeat the blood test using a new batch of test strips. If the repeat test is outside their therapeutic range, they should seek an appointment with their anticoagulation service provider, taking the test strips and packaging with them.
- If patients attend with Roche CoaguChek PT test strips, check the lot number that is printed on the top of the carton and on the foil packaging.
- If the patient has used the affected lot of test strips, repeat the blood test to check their coagulation status particularly if the recorded INR value is above 4.5 or there have been difficulties in controlling their anticoagulation therapy in the past.
- Advise patients with lot 583 to return products to the pharmacy that supplied them for a free-of-charge replacement.

### Other healthcare professionals managing patients using the Roche CoaguChek S monitor

- If patients present with Roche CoaguChek PT test strips, check the lot number that is printed on the top of the carton and on the foil packaging.

- If the patient has used the affected lot of test strips, repeat the blood test to check their coagulation status. This is particularly important if the recorded INR value is above 4.5 or there have been difficulties in controlling their anticoagulation therapy in the past.
- Advise patients with lot number 583 to return products to the pharmacy that supplied them for a free-of-charge replacement.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Nurse Directors
- All Medical & Nursing Care Staff
- All wards
- Supplies Staff (RSS)
- Trust Pharmacy Managers
- Directors of Pathology
- Anticoagulation service providers
- Haematologists
- Consultant Physicians
- Genitricians
- Anticoagulation therapy nurse specialist
- Practice Nurses
- District Nurses
- HSS Board Pharmaceutical Advisors
- HSS Board Directors of Pharmaceutical Services
- Directors of Public Health
- Independent Health and Social Care Providers including Private Clinics, Residential and Nursing Homes (through R&I Units)

## 6. CONTACTS:

Enquiries to the supplier should be addressed to:

Jas Dhillon, Central Support Manager, Roche Diagnostics Ltd, Bell Lane, Lewes, East Sussex BN7 1LG, Tel: 01273 484 863, Fax: 01273 484 653, E-mail: [jas.dhillon@roche.com](mailto:jas.dhillon@roche.com)

Enquires to NIAIC should quote reference number MDEA(NI)2003/26 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate Stoney Road, Dundonald, Belfast BT16 1US, Tel: 028 9052 3868, Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None required.



Brian Godfrey  
NIAIC Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2003/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*