√	**Immediate Action Required**
	Action Required
	Information Only

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: SB-RPD_2013_06
Document Date: 16/05/2013
Type of Action: Field Corrective Action

Product Affected:	**CoaguChek XS; CoaguChek XS Plus; CoaguChek XS Pro**
System Affected:	**CoaguChek XS; CoaguChek XS Plus; CoaguChek XS Pro**
Summary of Issue:	**ERROR 6 might require an urgent alternative INR measurement due to possibly high INR values**

Material No:	04625412017 - CoaguChek XS Kit 04625412019 - CoaguChek XS Kit 04800842190 - CoaguChek XS Plus Kit 04826051001 - CoaguChek XS Patient Care Kit 04826108001 - CoaguChek XS Professional Care Kit 05530199190 - CoaguChek XS Pro Kit
Serial: No:	All serial numbers for CoaguChek XS serial numbers < UQ 90000 for CoaguChek XS Plus serial numbers < U7 6011000 for CoaguChek XS Pro

Reason for Notice:	The CoaguChek® XS Plus, CoaguChek® XS Pro, and CoaguChek® XS instruments measures patients' coagulation status up to an INR value of 8.0. It is known that, in very rare situations, INR values greater than 8.0 can occur – for example if the patient is undergoing antibiotic treatment or chemotherapy. The CoaguChek® XS Plus, CoaguChek® XS Pro, and CoaguChek® XS instruments detect these very high values and display the following messages for the patients' protection: **CoaguChek® XS Plus and CoaguChek® XS Pro:**

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

√	**Immediate Action Required**
	Action Required
	Information Only

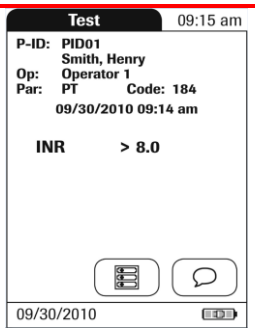


Fig 1.

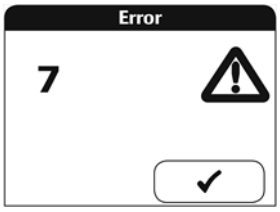


Fig 2.

The user manual informs you that an "error 7" (Fig. 2) could indicate a very high INR value and that, after repeating the test with the same result, you should try an alternative test method.

CoaguChek® XS:

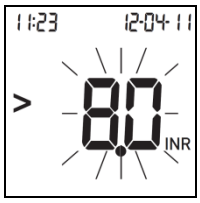


Fig 1.

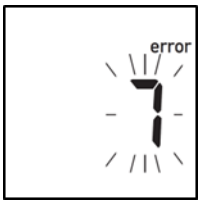
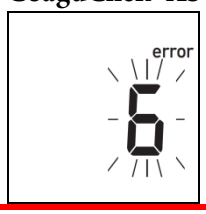


Fig 2.

In both cases, the user manual advises you to consult your doctor immediately.

In April 2013, we were made aware of a case in Norway in which antibiotic treatment resulted in a patient having an INR value greater than 10. However, the CoaguChek® XS instrument being used at the time displayed an "error 6". A patient looking up this error code in the user manual receives the information that an error has occurred in the measurement process. Although a very high INR value is practically excluded as a reason for this error message, we consider it wise to point out that a very high INR value (greater than 10) could be another reason for this error message being displayed.

CoaguChek® XS error 6 message:



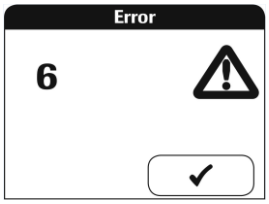
Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

√	**Immediate Action Required**
	Action Required
	Information Only

We are so far unaware of any single case, anywhere in the world, in which this error has been produced on a CoaguChek® XS Plus or CoaguChek® XS Pro instrument, but we cannot exclude the possibility that this could occur on CoaguChek® XS Plus instruments with serial numbers lower than UQ 0090000 and CoaguChek® XS Pro instruments with serial numbers lower than U7 6011000. In this event, you would see the following error message:

CoaguChek® XS Plus/CoaguChek® XS Pro error 6 message:



The CoaguChek® XS Plus instruments with a serial number equal to or higher than UQ 0090000 and the CoaguChek® XS Pro instruments with a serial number equal to or higher than U7 6011000 are not affected!

Action Required:

What do you have to do if your CoaguChek® XS instrument (all serial numbers) CoaguChek® XS Plus instrument (<UQ 0090000) or your CoaguChek® XS Pro instrument (<U7 6011000) displays "error 6"?

If this happens, the most likely cause is that an error has occurred in the measurement process. Please turn off the The CoaguChek® XS Plus, CoaguChek® XS Pro, or CoaguChek® XS instrument, remove the test strip and repeat the measurement with a new test strip. Make sure that you do not squeeze the patients' finger while taking the blood and that you do not touch the test strip during the measurement – these are the two most frequent causes of an "error 6". If you follow the correct procedure and "error 6" is displayed again, please contact our Point of Care Technical Service Team (telephone number at the end of the letter) and use a different test method to check the result.

This is particularly important for you:
All CoaguChek® instruments continue to effectively measure patients' INR values – even if they are undergoing antibiotic

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

√	**Immediate Action Required**
	Action Required
	Information Only

	treatment or chemotherapy. 99.99% of cases in which an "error 6" is displayed result from an incorrect measurement process. Since the CoaguChek® XS instrument was introduced in 2006, the Norwegian case is the only case anywhere in the world in which an INR value greater than 10 has produced an "error 6". Our Point of Care Technical Service Team will be happy to answer any questions you may have regarding this letter. You can call on the telephone number below Mon-Fri 09:00-17:30.
	To assist with compliance to the IVD Directive 98/79/EC, please complete the enclosed faxback form and return within 7 days
Attachments:	Fax back

This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Irish Medicines Board (IMB), and other International Regulatory Agencies.

** Please bring this notice to the attention of all personnel in your hospital/ Health Care facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, hospital, or end user, please provide a copy of this letter to them. **

If you require any further information please contact our
Point of Care Technical Services on:
UK: 0808 100 19 20
Ireland : 1800 40 9 564

A copy of this notice can also be found on www.cobas-roche.co.uk

To enable Roche Diagnostics to fulfil it's vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546