

√	Immediate Action Required
	Action Required
	Information Only



URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: U_FSN_16_ Error in Combur-Test/Chemstrip/ChoiceLine 10 test Method Sheets_SBN-CPS-2016-017_ V2
Document Date: 08/09/2016
Type of Action: Field Corrective Action

Product Affected:	Combur-Test
System Affected:	Combur
Summary of Issue:	Error in Combur-Test Method Sheets

Details of Affected Devices:

Material No:	Combur10Test® UX 11544373 049
	Combur10Test® UX 11544373 191
	Combur10Test® 04510062 171
	Combur9Test® 04510038 191
	Combur9Test® 04510046 040
	Combur7Test® 11008552 191
	Combur5Test® 11893467 255
	Combur4Test® N 11896822 191

Lot: No: See attachment 1

Reason for Notice: We regret to inform you that we have identified an error in some languages in the method sheets of some urine test strips providing a test field for nitrite (NIT). The error appears in the sections “Limitations - interferences” or section/table “Accuracy” in different language versions however not all languages are always affected. Specific germs which are clearly gram-negative are falsely classified as gram-positive. Chemistry of strip measurement system is not affected. No risk of erroneous measurement is related.

Please see attachment 1(V02) for affected products and corresponding material numbers. All current lots that have not yet expired of the listed materials are affected by the issue.

Action Required: Please take note of the following correct wording and communicate the information as appropriate.

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

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In the section/table "Accuracy" of the Method Sheet, the classification of bacteria should correctly read:

Nitrite: $\geq 90\%$ for 10^7 gram-**negative** organisms compared with Griess test.

In the "Limitations - interferences" section of the Method Sheet, the classification of bacteria should correctly read:

Nitrite: Prolonged urinary retention in the bladder (4-8 hours) is essential in order to obtain an accurate result. Administration of antibiotics or chemical drugs should be discontinued 3 days before the test. 95 % of all bacteria responsible for urinary tract infections are gram-**negative** rods (E.coli, Proteus mirabilis, Klebsiella pneumoniae), present as singular bacteria or in short chains, usually in large numbers. In hospitalized patients gram-positive cocci (enterococci) are of significance. ...

The result performance of the products is not affected by the wrong information in the method sheets, thus the products can still be used as specified.

Kindly complete the attached Fax Back form and return by no later than 23rd Sept 2016 by fax or email.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation/individual where the potentially affected devices have been distributed/supplied.

Attachments:

Attachment 1(V02). Lot numbers affected
 U_FSN_16_ Error in Combur-Test/Chemstrip/ChoiceLine 10 test
 Method Sheets_SBN-CPS-2016-017 Faxback

This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), 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, please provide a copy of this letter to them. **

**If you require any further information please contact our
 Professional Services Department / Technical Support Hotline 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 its 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.

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