

Urgent Field Safety Notice

SBN-CPS-2016-017

CPS / Urinalysis
Version 2
6-September-2016

Error in Combur-Test/Chemstrip/ChoiceLine 10 test Method Sheets

Product Name	Combur-Test / Chemstrip / ChoiceLine 10 test
Product	GMMI
Combur ¹⁰ Test [®] UX	11544373 049
Combur ¹⁰ Test [®] UX	11544373 173
Combur ¹⁰ Test [®] UX	11544373 191
Combur ¹⁰ Test [®]	04510062 171
Combur ¹⁰ Test [®]	04510089 056
Combur ⁹ Test [®]	04510038 191
Combur ⁹ Test [®]	04510046 040
Combur ⁹ Test [®]	04510054 056
Combur ⁷ Test [®]	11008552 173
Combur ⁷ Test [®]	11008552 191
Combur ⁶ Test [®]	11896962 257
Combur ⁵ Test [®]	11893467 255
Combur ⁴ Test [®] N	11896822 191
Combur ² Test [®] LN	11896890 191
Chemstrip [®] GP	10200743 119 (Canada only)
Chemstrip [®] 5	11893467 119 (Canada only)
Chemstrip [®] 7	11008552 119 (Canada only)
Chemstrip [®] 9	10398411 119 (Canada only)
Chemstrip [®] 10	11203479 119 (Canada only)
ChoiceLine 10 test	03504379 023
Production Identifier (Lot No./Serial No.)	See attachment 1 V02
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Error in Combur-Test/Chemstrip/ChoiceLine 10 test Method Sheets

Dear Valued Customer,

Description of Situation

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. Specifics 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.

If applicable for customers: Please see attachment 1 (V02) for affected products and corresponding material numbers. All not yet expired lots of the listed material are affected by the issue.

Actions taken by Roche Diagnostics (if applicable)

We work with highest priority on appropriate corrective actions to rectify the mistake.

Affected lots on stock are blocked for sale on global and affiliate level until a printed note, informing about the correct wording, has been added to the packages.

Actions to be taken by the customer/user

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

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.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the affected products have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and support.

Best regards,

Error in Combur-Test/Chemstrip/ChoiceLine 10 test Method Sheets

Contact Details

To be completed locally:

Name

Title

Company Name

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