Urgent Field Safety Notice

SBN-RDS-Corelab-2025-005

RDS CoreLab
Version 1

Missing functional Layer from Leu Pad in Combur[10] Test® M Lot 84639701

Product Name	Combur10 Test M u 411 Visual 100 Str
BASIC UDI-DI/GMMI / Part No **Device Identifier (UDI)**	GMMI: 09587624190 UDI: 4015630000838
Production Identifier **(Lot No./Serial No.)**	Lot 84639701
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We have received complaints in which customers alleged that the color for Leucocytes on one specific lot of the Combur10 Test M strip cannot be assessed (blue/green shade instead of expected violet colors) or false negative results by meter reading have been observed.
Our investigation of returned material confirmed this issue and showed that one of three expected strip layers is missing. Therefore the expected color for Leucocytes cannot develop and the cobas u 411 will display a false negative result for a positive sample.
The root cause was a temporary insufficiency in the production process leading to a limited number of strips of lot 84639701 missing the Diazonium layer. There are no reports of patient harm linked to this issue.

The Combur10 Test M is intended for the in vitro determination of multiple parameters in urine, including leukocytes. Leukocyturia is often the only early indicator of inflammatory renal diseases and Urinary Tract Infections (UTIs), especially in the population at greatest risk (e.g., those with chronic pyelonephritis or urinary catheters).
In specific clinical scenarios, it is possible that clinical care could be influenced by false negative leukocyturia,

especially in the population at greatest risk. Given a false negative result, required further diagnostic and appropriate therapeutic measures might not be made until characteristic clinical signs and symptoms become evident when the underlying disease aggravates, potentially causing adverse health consequences.

Actions taken by Roche Diagnostics

A Corrective and Preventive Action (CAPA) investigation has been initiated, and the root cause investigation continues. Once the root cause analysis is complete, appropriate corrective and preventive measures will be defined and communicated, as needed.

Actions to be taken by the customer/user

- Please immediately discontinue the use of and discard any inventory of affected lot 84639701 of Combur10 Test M strips used with the cobas u 411 urine analyzer.
- The affected lot of Combur10 Test M strips is still suitable for visual reading. The issue is easily detectable during visual reading due to the incorrect color code. It is important to note that this issue does not affect the entire lot.
- A replacement can be requested for discarded products of the affected lot.
- No general recommendations with respect to the review of previous results can be given. Customers should follow their standard laboratory operating procedures. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

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

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

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

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Include if applicable: 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 your support.

<closing salutations>,

Contact Details

To be completed locally:

Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

Roche Diagnostics GmbH - SRN: DE-MF-000006260 (legal manufacturer)