Roche

URGENT MEDICAL DEVICE CORRECTION

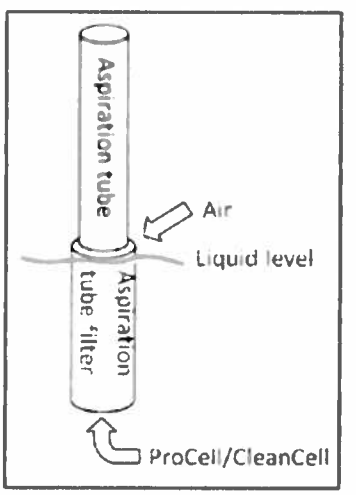
14-122
05/20/14

MODULAR *ANALYTICS* E 170 module and cobas e 601 and 602 analyzers — Loose ProCell/CleanCell Filter May Lead to Air Aspiration

Issue

Currently, the Operator's Manuals for the **MODULAR** *ANALYTICS* E 170 module and the **cobas e** 601 and 602 analyzers recommend that you check the ProCell/CleanCell (PC/CC) aspiration tube filter as needed. If the ProCell/CleanCell aspiration tube filter is not properly tightened after this maintenance step, it may lead to loosening of the filter. When a filter is loose, it is possible for air to be aspirated through the thread of the aspiration tube and aspiration filter when the liquid level drops below the joint between the aspiration tube and the aspiration filter. If air is aspirated, this air generates foam in the reservoirs, and the foam could then be aspirated by the sippers into the measuring cells, therefore affecting assay results. This can also cause sipper and system reagent alarms.

All assays run on the MODULAR *ANALYTICS* E 170 module and cobas e 601 and 602 analyzers are affected.



NOTE

To mitigate the potential for a loose filter to cause air aspiration, refer to the "Precautions Regarding Handling the Aspiration Tube Filter" section on page 3 and stop performing the ProCell/Clean Cell aspiration tube filter check as explained in the "Revised Maintenance Action and Updated Operator's Manuals and Maintenance Logs" section on page 3 of this Urgent Medical Device Correction (UMDC).

over...

☑ **MODULAR** E 170
☑ **cobas e** 601
☑ **cobas e** 602

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Root Causes

There are two root causes that have been identified that can lead to loose ProCell/CleanCell aspiration tube filters:

1. ***Improper tightening of the ProCell/CleanCell aspiration tube filters after performing maintenance.***

The Operator's Manuals recommend checking the ProCell/CleanCell aspiration tube filter "as needed." If the ProCell/CleanCell aspiration tube filter is not tightened correctly, the ProCell/CleanCell aspiration tube filter may loosen.

2. ***Dropping the aspiration tube lifter after exchange of a ProCell/CleanCell bottle.***

The aspiration tube lifter should not be dropped after the replacement of the ProCell/CleanCell bottle. If the aspiration tube lifter is dropped, the following may occur:

- The aspiration tube filter may hit the bottom of the ProCell/CleanCell bottle.
- The ProCell/CleanCell bottle opening and the rubber piece of the aspiration tube lifter will collide.

Both causes were identified to increase the likelihood of loosening the ProCell/CleanCell aspiration tube filter.

Clinical Significance

Under or over-estimation of parameters may lead to incorrect diagnosis and to incorrect treatment in the worst case. Particularly, severe consequences could result during emergency treatment or for patients at greatest risk. Parameter-specific implications begin on page 4 of this UMDC.

In a rare scenario, loose ProCell/CleanCell aspiration tube filters cause air and system reagent mixture. Consecutive, conspicuous results may occur.

In case of ProCell this may lead to discrepant results: High for competitive and low for sandwich assays. The ranges of bias are unpredictable. Therefore, no bias-related assessment is possible.

All laboratory results should always be interpreted in combination with the patient's clinical status, medical history, and further medical testing such as medical imaging. The risk to patients is mitigated as laboratory results of non-stand-alone parameters are to be seen in context with other parameters.

Contact the physician or pathologist at your facility to determine specific clinical implications for your patients.

The probability of undetected discrepant patient results which appear valid is reduced by the necessity of conditions (a), (b), and (c) to coincide:

a) Discrepant results are generated consecutively. Up to 200 consecutive measurements may be affected. No single outlier occurs. It is unlikely that a continuous sequence of discrepant results would remain undetected.

b) The issue occurs only after maintenance of filters is performed.

c) The liquid level in the ProCell/CleanCell bottle must drop below the joint between aspiration tube and aspiration filter before air might be aspirated through the thread of the ProCell/CleanCell aspiration tube filter.

Precautions Regarding Handling the Aspiration Tube Filter

1. When exchanging bottles of ProCell/CleanCell:

- Handle the tube lifters gently; do not drop them.
- Verify the ProCell/CleanCell aspiration tube filters are tightly fixed.

The following verbiage will be added to the operator system documentation:

CAUTION! Make sure the aspiration tube is pulled up and hooked on to its notch before removing the bottle. After replacing the bottle, unhook the aspiration tube and lower it slowly into the bottle. Do not let it drop into the bottle.

2. If the ProCell/CleanCell aspiration tube filter is blocked and needs to be cleaned, please ensure that the filter is properly tightened when placing it back after the cleaning process.

Revised Maintenance Action and Updated Operator's Manuals and Maintenance Logs

The PC/CC aspiration tube filter check will now be performed by your Roche Field Service Representative (FSR) as a part of service maintenance. The Operator's Manuals and System Maintenance Logs will be updated accordingly and will be available on usdiagnostics.roche.com in the future.

Enclosure

Faxback Form, 5370-00-0514

Actions Required

- Follow the instructions in the "Precautions Regarding Handling the Aspiration Tube Filter" section in this UMDC.
- Discontinue performing ProCell/Clean Cell aspiration tube filter check as this maintenance item will be performed by your Roche FSR as a part of service maintenance.
- If you have distributed the products listed within this UMDC to other sites or facilities, please provide them with a copy of the UMDC.
- Complete the faxback form enclosed with this UMDC and fax it to 1-888-410-6620.
- File this UMDC for future reference.

Questions

Please contact the Roche Support Network Customer Support Center, 24 hours a day, seven days a week at 1-800-428-2336 if you have questions about the information contained in this UMDC.

This UMDC is being conducted in cooperation with the U.S. Food and Drug Administration (FDA).

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Events Reporting Program: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call FDA 1-800-FDA-1088.