16-117
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Roche

URGENT MEDICAL DEVICE CORRECTION

Multiple Clinical Chemistry, Immunoassay, and Urinalysis Systems – Procedure for Manually Cleaning Sample Rack Trays

Issue

Roche has received two reports of injury caused by the sharp edge of the center guide rail of an analyzer's sample rack tray. This communication provides instructions for effectively cleaning stains and smudges off of sample rack trays, while helping to avoid the risk of injury.

Affected Analyzers/Systems

The sample rack trays used with the following analyzers/systems are affected:

Analyzer/System
cobas® 6000 analyzer series
cobas 8000 modular analyzer series
cobas e 411 analyzer
MODULAR *ANALYTICS* P, D, DAT, and E 170 modules
MODULAR *PRE-ANALYTICS* systems
Urisys 2400® analyzer
COBAS INTEGRA® 800/800 CTS

Clinical Significance

It is unlikely that injury to the operator would occur when performing the maintenance procedure for cleaning the sample rack trays; however, operator injury has been reported. An updated cleaning procedure is being implemented to further avoid the risk of injury.

Materials Required for Cleaning Sample Rack Trays

The following materials are required for properly cleaning the sample rack trays to remove stains or smudges:

- Lint-free gauze
- Cotton swab
- Personal Protective Equipment (PPE) (i.e., lab coat, safety glasses or goggles, gloves)
- 2% Hitergent or 2% EcoTergent solution: dilute 1 part detergent with 49 parts deionized water

over...

☑ **cobas c** 311	☑ **cobas c** 702	☑ **cobas** 8000 ISE
☑ **cobas c** 501	☑ **cobas e** 411	☑ **MODULAR** *PRE-ANALYTICS*
☑ **cobas c** 502	☑ **cobas e** 601	☑ **MODULAR**
☑ **cobas c** 701	☑ **cobas e** 602	☑ **MODULAR** E 170
	☑ URISYS 2400	☑ COBAS INTEGRA 800/800 CTS

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Materials Required for Cleaning Sample Rack Trays, continued

NOTE

Hitergent and EcoTergent are strong alkaline detergents, so always wear PPE when handling them. Refer to the appropriate operator's manual for other suitable cleaning solutions.

Procedure for Cleaning Sample Rack Trays

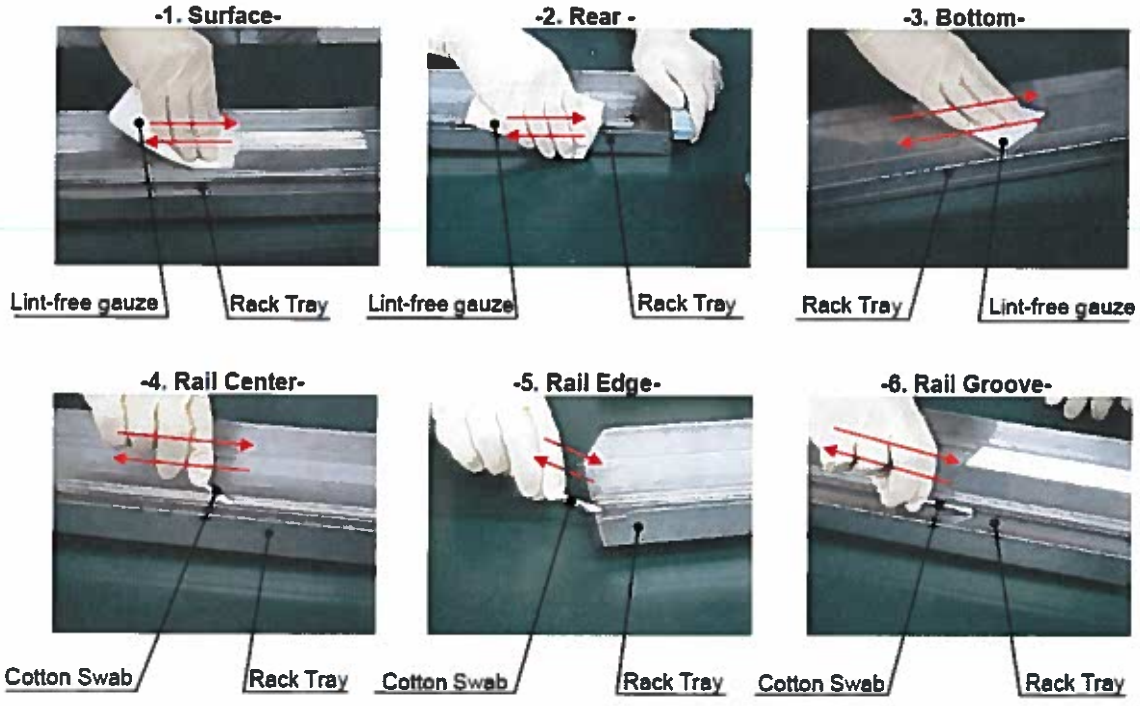
Follow these steps to properly clean the sample rack trays:

Step	Action
1	Dampen lint-free gauze or a cotton swab with 2% Hitergent or 2% EcoTergent solution, or refer to the appropriate operator's manual for other suitable cleaning solutions.
2	Wipe the dirt off of the sample rack tray with the damp lint-free gauze or cotton swab from step 1. Wipe in the direction indicated by the arrows in the pictures below.
3	Wipe off the detergent with lint-free gauze moistened with deionized water.
4	Dry the sample rack tray with dry lint-free gauze.
5	Visually check the sample rack tray for debris (e.g., gauze or cotton fibers) remaining on the tray.

Refer to the figures below for the proper way to clean the sample rack trays with gauze or cotton swabs.

NOTE

This procedure is not effective for removing permanent marker.



Actions Required

- Follow the instructions provided in this Urgent Medical Device Correction (UMDC) to properly clean the affected sample rack trays.
- Complete the enclosed faxback form and fax to number 1-866-462-9888.
- Provide copies of this UMDC to other clinicians who may need to be aware of this cleaning procedure.
- If your facility has distributed the affected product to another site, please ensure this UMDC is provided to that site.
- File this UMDC for future reference.

Enclosure

Faxback form 7061-00-0716

Updated Operator's Manuals

The operator's manuals for the affected analyzers/systems will be updated at a future date.

Questions

Please contact the Roche Support Network Customer Support Center at 1-800-428-2336 if you have questions about the information contained in this UMDC.

This UMDC is being conducted with the knowledge of 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.