

Urgent Field Safety Notice

SBN-CPS-2016-013

CPS / Serum Work Area
Version 1
12-September-2016

New mandatory cleaning procedure for rack trays

Product Name	Refer to Attachment 1 <i>(or list Instruments/Systems)</i>
GMMI / Part No Device Identifier	Refer to Attachment 1 <i>(or list Instruments/Systems)</i>
Instrument/System Affected	Refer to Attachment 1 <i>(or list Instruments/Systems)</i>
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We would like to inform you about an update of the cleaning procedure for rack trays. It is mandatory to follow this cleaning procedure which contains instructions for safe handling of the parts to avoid the risk of injury (edges may cause cuts of skin during rack tray cleaning when fingers come in contact with rack tray edges and fingers move quickly along the edges of rack tray). We apologize for any inconvenience this may cause and hope for your understanding.

This is applicable to all Instruments/Systems using rack trays.

Please find attached the detailed description of the cleaning procedure.

Actions taken by Roche Diagnostics

Recently we have become aware of in total 5 cases of injuries (cut of skin) caused by edges on rack trays during cleaning. The following action was taken:

- Creation of a consolidated cleaning procedure to be included into user documentation of all Instruments/Systems using rack trays

New mandatory cleaning procedure for rack trays

Actions to be taken by the customer/user

It is mandatory to follow the cleaning instructions for rack trays, provided with attachment 2 to this Field Safety Notice.

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

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.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com