

Ö	Immediate Action Required
	Action Required
	Information Only



## URGENT FIELD SAFETY NOTICE

### IMMEDIATE ACTION REQUIRED

**Field Safety Notice Ref No: CCFSN\_04\_16 Rack Trays SBN-CPS-2016-013**

**Document Date: 21/09/2016**

**Type of Action: Field Corrective Action**

**Product Affected:** Refer to CCFSN\_04\_16 Attachment 1

**System Affected:** Refer to CCFSN\_04\_16 Attachment 1

**Summary of Issue:** New Mandatory Cleaning Procedure for Rack Trays

#### Details of Affected

##### Devices:

**Material No:** Refer to CCFSN\_04\_16 Attachment 1

**Reason for Notice:** Roche 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 into contact with rack tray edges and fingers move quickly along the edges of rack tray). We apologise for any inconvenience this may cause and hope for your understanding.

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

Please refer to CCFSN\_04\_16 Attachment 2 for a detailed description of the cleaning procedure.

#### **Actions taken by Roche Diagnostics**

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

Roche Diagnostics  
Charles Avenue  
Burgess Hill  
West Sussex  
RH15 9RY

Registered No 571546

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

**Action Required: Actions to be taken by our customers/users**

It is mandatory to follow the cleaning instructions for rack trays, provided with CCFSN\_04\_16 Attachment 2 to this Field Safety Notice.

Kindly complete the attached fax back form and return the fax back form to us by no later than 3<sup>rd</sup> October 2016 by e mail.

Please accept our apologies for any inconvenience caused by this issue.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

**Attachments:**

CCFSN\_04\_16 Attachment 1  
 CCFSN\_04\_16 Attachment 2  
 CCFSN\_04\_16 Rack Trays SBN-CPS-2016-013 Fax Back Form

**This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.**

***\* Please bring this notice to the attention of all personnel in your hospital/ Health Care facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this letter to them. \****

**If you require any further information please contact our Professional Services Department / Technical Support Hotline on:  
 UK: 0808 100 19 20  
 Ireland : 1800 40 9 564**

**A copy of this notice can also be found on [www.cobas-roche.co.uk](http://www.cobas-roche.co.uk)**

**To enable Roche Diagnostics to fulfil its vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.**

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