

Urgent Field Safety Notice

SBN-SIS-2019-002

SIS / Laboratory Integration
Version 1
20-Mar-2019

Loose screws on the Tray Input Flap of the cobas p 501 /p 701 post-analytical units

Product Name	cobas p 501 / 701 post-analytical units
Product Description	Instrument stores primary and secondary sample tubes
GMMI / Part No	05158494001, 05349966001
Production Identifier (Lot No./Serial No.)	Serial No. cobas p 501: 1001 - 1044 Serial No. cobas p 701: 1001 - 1037 Serial No. cobas p 701: 502
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

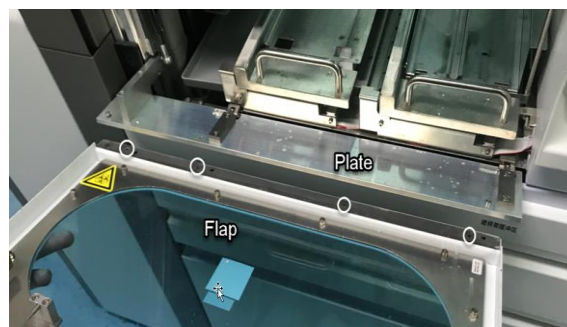
Description of Situation

The Tray Input Flap on the cobas p 501 and cobas p 701 post-analytical units has the potential to become unsecured from the instrument.

The Tray Input Flap screws can become loose on the cobas p 501 or p 701 post-analytical units resulting in the potential detachment from the instrument.

Visual inspection of the Tray Input Flap, plate and screws were performed. As demonstrated in the pictures below, the flap was no longer attached to the instrument and the 4 M3 threads on the Tray Input Flap were worn out resulting in the screws not working as intended.

Loose screws on the Tray Input Flap of the cobas p 501 /p 701 post-analytical units



This design of Tray Input Flap was installed on all instruments with the following Serial Numbers:

cobas p 501, Serial Number 1001 to 1044

cobas p 701, Serial Number 1001 to 1037

cobas p 701, Serial Number 502

Instruments with Serial Numbers higher than 1044 for the cobas p 501 and higher than 1037 for the cobas p 701 are not affected as they have a newer design of Tray Input Flaps.

Actions taken by Roche Diagnostics

The Tray Input Flaps on instruments with the above listed serial numbers must be replaced by Roche Diagnostics with the current design of the tray input flaps with an estimated completion date of 30-September-2019.

Actions to be taken by the customer/user

Prior to the replacement tray input flaps being installed, customers must be informed that they should always inspect their tray input flap to ensure the tray input flap is securely attached to the instrument. If the flap is not fastened securely or becomes loose prior to the tray input flap being replaced, they must contact Roche Diagnostics to repair the instrument.

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. (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).>

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Loose screws on the Tray Input Flap of the cobas p 501 /p 701 post-analytical units

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com