

Augustus 22, 2014

Urgent Field Safety Notice

Product code : C-1081
Product name : Rotavirus Positive Control
Reference : Batch number 1081G1408

Type of action:

- Advice regarding the use of the device
- Return of a MEDICAL DEVICE to the supplier

Details on affected devices:

Coris BioConcept Rotavirus positive control C-1081 (0,7 mL vial) with the lot number 1081G1408.

Description of the problem:

Rota positive control intended use is to control the functionalities of Coris Bioconcept's *in vitro* diagnostic devices Rota-Strip, Combi-Strip and Combi K-SeT, GastroVir-Strip.

The intensity of the Rotavirus test line signals generated by the incriminated Rota positive control could be judged too weak.

As a consequence, one may erroneously conclude that the tested diagnostic kit quality is beyond the expectations and that weak positive signals could be missed with clinical samples.

Advise on action to be taken by the user:

- Evaluation of the device
Verify that the Rotavirus Positive Control meets the expectations of your laboratory considering the given signal intensities.
- Return the device to the supplier
If the Rotavirus test line signal intensities are considered as too weak, please discard the entire batch you may possess or return it back to Coris BioConcept or to your local distributor.
- Acknowledge form
Please send the attached acknowledge form back to Coris BioConcept or your local distributor.

Transmission of this Field Safety Notice:

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

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Dr. Ir. Laurent Ferrière
QA-RA Manager
Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
5032 - GEMBLoux - BELGIUM
TEL : + 32(0)81.719.917
FAX : +32(0)81.719.919
e-mail : client.care@corisbio.com
www.corisbio.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Signature

A handwritten signature in blue ink, appearing to read 'L. Ferrière', is written over a faint, light blue circular stamp or watermark.

L. Ferrière
QA-RA Manager
Coris BioConcept

CUSTOMER REPLY FORM

(Product recall letter dated Augustus 22, 2014)

Rotavirus Positive Control

Product code : C-1081 – lot number : 1081G1408

Please complete and return this form by email (client.care@corisbio.com) or by FAX (+32 81 719 919) as confirmation that you have received this notification.

- We do not have any of the potentially affected devices in our inventory
- We do have potentially affected devices in our inventory

Product code	Lot	Quantity	We have decided to
C-1081	1081G1408		<input type="checkbox"/> Keep the product <input type="checkbox"/> Discard the product <input type="checkbox"/> Return the product back

Facility name and address:	
Reply confirmation completed by:	
Title:	

We have received the above mentioned letter and have disseminated this information to our staff and to other accounts.

Signature / date:
REQUIRED FIELD
