

10-12-2019

## Field Safety Notice

**Product code: C-1005**  
**Product name: Crypto-Strip**

**Reference: FSN\_NC2072**

**Type of action:**

- Device exchange
- Device destruction

**Details on affected devices:**

The product Crypto-Strip C-1005, strip format, is affected.

The problem is on the batch of strip 1A05A1913.

This strip batch is used in three final batches (packaging):

- 40853D1909 (strip vial: 1A05A1913 and buffer bottle 2A01G1826)
- 40452B1901 (strip vial: 1A05A1913 and buffer bottle 2A01G1826)
- 41175E1927 (strip vial: 1A05A1913 and buffer bottle 2A01B1920)

**Description of the problem:**

The batch of strip 1A05A1913 (final batches # 40853D1909, 40452B1901 and 41175E1927) presents some false positive results.

Some human stool samples shown by cryptosporidium-positive with the kit Crypto-Strip of Coris BioConcept were observed negative PCR and immunofluorescence methods. The origin of this loss in the specificity of this test batch is not known.

QC of this batch was performed at different times of its production and the 150 tests performed gave results that met our quality requirements.

Following this complaint, we carried out a second series of tests with tests kept in archive and it turns out that we confirm that some. False-positives correspond to a background signal that seems to be sample-dependent and that could also come from an excess of samples (> 4% w/v) put in the dilution tube with the buffer provided by the kit.

Coris BioConcept has been aware of this problem with this batch of Crypto-Strip following a complaint from one of our customers. Up to now, we did not receive any other claims.

Nevertheless, we have decided to trigger a vigilance procedure, despite the fact that all criteria for such a procedure are not met according to the MEDDEV 2.12-1.

The potential hazard associated with the continued use of the Crypto-Strip of strip 1A05A1913 (final batches # 40853D1909, 40452B1901 and 41175E1927) is very limited because appropriate treatment is usually not harmful. Our test is only qualitative and as mentioned in the IFU, it should not be taken into consideration alone to establish a diagnosis but that it must be associated with the clinical signs and the anamnesis of the patient.

**Advise on action to be taken by the user:**

- Identifying and quarantining the device
- Confirmation form to be sent back to the manufacturer if an action is required (return of products)

**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:**

M. LAMBOT Michel - Client Care  
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](mailto:client.care@corisbio.com)  
[www.corisbio.com](http://www.corisbio.com)

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

Signature  
Coralie MISSON  
QA Manager



CORIS BIOCONCEPT  
RUE JEAN SONET 4A  
BE-5032 GEMBLOUX



## CUSTOMER REPLY FORM

FSN reference number: FSN\_NC2072

**Crypto-Strip**

**Product code: C-1005**

**Lot numbers: 40853D1909, 40452B1901 and 41175E1927**

Please complete and return this form by email ([client.care@corisbio.com](mailto:client.care@corisbio.com)) or by FAX (+32 81 719 919) as confirmation that you have received this notification before the **17/12/2019**

| Customer details                 |  |
|----------------------------------|--|
| Facility name and address:       |  |
| Reply confirmation completed by: |  |
| Title or function:               |  |
| Telephone number:                |  |
| Email:                           |  |

| Customer action undertaken |                                                                                                             |                                   |                                      |
|----------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------------------------|
| <input type="checkbox"/>   | I confirm receipt of the Field Safety Notice and that I read and understood its content.                    | Customer to complete or enter N/A |                                      |
| <input type="checkbox"/>   | The information and required actions have been brought to the attention of all relevant users and executed. | Customer to complete or enter N/A |                                      |
| <input type="checkbox"/>   | I have used affected devices - enter number of devices used.                                                | Lot Number:                       | Qty:                                 |
|                            |                                                                                                             | Lot Number:                       | Qty:                                 |
|                            |                                                                                                             | Lot Number:                       | Qty:                                 |
|                            |                                                                                                             | Comments:                         |                                      |
| <input type="checkbox"/>   | I have returned affected devices - enter number of devices returned and date complete.                      | Lot Number:                       | Qty:      Date Returned (DD/MM/YY):  |
|                            |                                                                                                             | Lot Number:                       | Qty:      Date Returned (DD/MM/YY):  |
|                            |                                                                                                             | Lot Number:                       | Qty:      Date Returned (DD/MM/YY):  |
|                            |                                                                                                             | Comments:                         |                                      |
| <input type="checkbox"/>   | I have destroyed affected devices – enter number destroyed and date complete.                               | Lot Number:                       | Qty:      Date Destroyed (DD/MM/YY): |
|                            |                                                                                                             | Lot Number:                       | Qty:      Date Destroyed (DD/MM/YY): |
|                            |                                                                                                             | Lot Number:                       | Qty:      Date Destroyed (DD/MM/YY): |
|                            |                                                                                                             | Comments:                         |                                      |
| <input type="checkbox"/>   | No affected devices are available for return/ destruction                                                   | Customer to complete or enter N/A |                                      |

Name \_\_\_\_\_

Date: \_\_\_\_\_

Signature \_\_\_\_\_

| Return acknowledgement to Client Care |                                                                                            |
|---------------------------------------|--------------------------------------------------------------------------------------------|
| Email                                 | <a href="mailto:client.care@corisbio.com">client.care@corisbio.com</a>                     |
| Postal Address                        | Coris BioConcept<br>Science Park CREALYS<br>Rue Jean Sonet 4A<br>5032 - GEMBLOUX - BELGIUM |
| Web Portal                            | <a href="http://www.corisbio.com">www.corisbio.com</a>                                     |
| Tel :                                 | + 32(0)81.719.917                                                                          |
| Fax                                   | +32(0)81.719.919                                                                           |