Urgent Field Safety Notice

Product description: Gram's Staining Kit
Product code: PL.8055/25
Lot number: K38985
Expiry date: 2025 09 30
# of units: 40

FSCA-identifier: 2025 01 07

Type of action: Recall of affected product

Date: 7th of January 2025

Attention: Dora Ferraro, Quality Assurance Manager, Biolife Italiana S.r.l.

Details on affected devices:

The affected IVD medical device is a Grams Staining Kit (Product code PL.8055/25) which contains the following IVD medical device components:

1 x PL.7000/25; Crystal Violet (ready to use) 250ml
1 x PL.7003/25; Grams Iodine (ready to use) 250ml
1 x PL.7006/25; Grams Differentiator (ready to use) 250ml
1 x PL.7012/25; Safranin (ready to use) 250ml

40 x PL.8055/25 lot # K38985 were shipped to Biolife Italiana on the 25th of September 2024 (ref invoice # 238570).

Description of the problem:

On the 20th of December Pro-Lab Diagnostics received an email from Dora Ferrara at Biolife Italiana. The email explained 12 x PL.8055/25: Grams Staining Kits lot K38985 had been shipped to customers of Biolife Italiana's. The Grams Staining Kit is intended to be used to carry out the Grams Staining procedure for microscopic diagnosis of the presence of Gram-positive and Gram-negative bacteria in smears prepared from human clinical specimens.

One customer reported a mislabelling of two of the Grams Staining Kit components. In at least one kit, the Grams Iodine component had been labelled with a label for 'PL.7012/25; Safranin', and the Safranin component had been labelled with a label for 'PL.7003/25; Grams Iodine'. The error was identified by the difference in the colour of the two products. There was no indication (stated or implied) the products had been used as specified in the instructions for use provided by Pro-Lab Diagnostics. Photographs of the mislabelled products were provided. No information about the other customers who received the affected product and whether or not any attempts had been made to use it were provided.

Pro-Lab Diagnostics admitted liability for the mislabelling of the products which was a result of human error. A Field Safety Corrective Action (product recall) for the 40 x PL.8055/25 lot K38985 will be issued and is considered to be the correct course of action to prevent any misdiagnosis.

The Grams staining procedure is intended to provide results on whether bacteria are present and whether they are Gram-positive or Gram-negative. The product is intended for use by professional users only also. Gram stain results are usually considered preliminary and results of a culture and/or other tests such as antigen or antibody testing for particular types of bacteria are necessary to confirm a diagnosis. There is therefore a low risk associated with the use of the mislabelled product for patients, users or other persons.

Advice on action to be taken by the user:

Biolife Italiana should issue a Field Safety Corrective Action (product recall) to all customers who received the affected product. Affected product should be returned to Biolife Italiana or disposed of by the customer. Biolife Italiana confirmed 28 x PL.8055/25 lot K38985 had not been shipped to customers and had been placed in quarantine. All 28 units should be returned to Pro-Lab Diagnostics. The Field Safety Corrective Action should be carried out with immediate effect. Replacement product will be provided to Biolife Italiana free of charge by Pro-Lab Diagnostics.

Transmission of this Field Safety Notice:

This Field Safety Notice should be forwarded by Biolife Italiana to the customers that received the affected product, and a copy should be sent to the Italian Competent Authority (the Ministry of Health).

A copy of the Field Safety Notice will also be sent to Pro-Lab Diagnostics' EU Authorised Representative (Advena Ltd) by Pro-Lab Diagnostics.

The Field Safety Corrective Action (product recall) recommended by Pro-Lab Diagnostics in this Field Safety Notice meets the criteria of a reportable event in that 'examination of the information supplied with the device' led to the event in question. A 'Report Form Manufacturer's Field Safety Corrective Action Report' is therefore included. A copy should be sent to the Italian Competent Authority (the Ministry of Health) by Biolife Italiana. A copy will also be sent to Pro-Lab Diagnostics' EU Authorised Representative (Advena Ltd) by Pro-Lab Diagnostics.

All units of the affected product were supplied to customers based in the European Union. The UK's competent authority (the MHRA) has no jurisdiction over products supplied in the EEA and will therefore not be notified of the Field Safety Corrective Action.

Contact reference person:

Mark Reed, General Manager, Pro-Lab Diagnostics.
mreed@pro-lab.co.uk

Signed:

Mike Owen, Regulatory Affairs Manager, Pro-Lab Diagnostics.
mowen@pro-lab.co.uk

Signed:

Sophie Schiller, Regulatory Affairs Coordinator, Pro-Lab Diagnostics.
sschiller@pro-lab.co.uk

Signed:

The undersigned confirms that this notice has been used to notify the appropriate Regulatory Agency.

Name:

Job title:

Company:

Signature: