Brescia, [*enter day*] October 2021

URGENT: FILED SAFETY NOTICE

eSwab®

FSN-2021-001 Ref. FSCA-2021-001

All eSwab® lots on the market and with an expiry date previous than or equal to 12/2022.

Dear Customer,

We hereby inform you about the **Copan eSwab® device instructions for use update and communicate the required actions**, following the report of false positive results for *Bordetella parapertussis* in molecular biology procedures based on PCR protocols.

Products involved:

eSwab®

REF: [*enter list of impacted REF numbers*]

All lots on the market and with an expiry date previous than or equal to 12/2022.

Problem description:

Copan has received some reports of *Bordetella parapertussis* false positives observed at high cycle threshold values (Ct, Cycle threshold) when combining eSwab® with some in-house PCR protocols and the Pathofinder BV-RealAccurate Quadruplex Bordetella PCR kit.

The investigation revealed the presence, inside the eSwab® device, of non-viable *Bordetella parapertussis* nucleic acid residues derived from raw materials used in the production process. These fragments can potentially be amplified with PCR methods, and in some cases, they could be detectable, giving false positive results (weak positive at high Ct) depending on the analytical sensitivity of the commercial kit or the in-house protocol used.

Since it is not currently possible to exclude the presence inside the eSwab® device of nucleic acid fragments coming from non-viable microorganisms other than *Bordetella parapertussis*, nor to exclude that these fragments are amplifiable and detectable with the combined use of eSwab® with PCR protocols, Copan considered it appropriate to **integrate the instructions for use with the following warnings and precautions**:

-Traces of nucleic acids from non-viable microorganisms could be contained into eSwab® that may be amplified by PCR-based tests depending on the analytical sensitivity of the assay. Refer to the

assay manufacturers' instructions for useand internal laboratory procedures to manage results from specimen providing low amplification (high Ct value) of the target microorganism.
-The compatibility of eSwab® as collection and transport device suitable for use with PCR-based tests must be qualified according to internal laboratory procedures.

- **The indications for use of the device has been reformulated** to better describe the function of collect, transport, and store the sample:

Copan Liquid Amies Elution Swab (eSwab®) Collection and Transport System is intended for the collection and transport of clinical specimens containing aerobes, anaerobes, fastidious bacteria, viruses, and Chlamydia from the collection site to the testing laboratory.
eSwab® medium preserves the viability of aerobes, anaerobes, fastidious bacteria from swab specimens for bacterial culture purposes and can be used for the preservation of bacterial, viral, or chlamydial antigens and nucleic acids from swab specimens.

The presence of nucleic acid fragments from non-viable microorganisms does not affect the intended function of the device: collection and transport of clinical specimens containing aerobic, anaerobic, and facultative anaerobic bacteria, viruses, and Chlamydia.
The revision of the instructions for use has no impact on the clinical sample collection and transport procedures.

Actions taken by Copan:

- Update of the instructions for use with warnings and precautions.
- A corrective and preventive action to reduce the risk of microbial nucleic acid fragments from raw materials.

Actions to be taken by the recipient of this communication:

- Read the additional warnings and precautions listed above.
- Complete the acknowledgment form – ATTACHMENT 1 – and return it via email [*enter appropriate email address*] as soon as possible and no later than three working days from the receipt of this communication.
- Temporarily block the distribution of the product currently stocked, giving evidence by filling in the form ATTACHMENT 1. Copan will contact you to provide information on the management of the blocked material.
- Distribute this communication to all interested personnel in your facility, keep copies in your records, and forward it to all who use or may use this product, including third-party users who may have received the product.

- For diagnostic laboratories: it is suggested to discuss the appropriate course of action on any suspicious positive samples identified through the combined use of eSwab® with PCR methods with the medical director of your laboratory.

Copan has informed the appropriate Regulatory Agency of these actions and constantly renews its commitment to provide safe and quality products.
We apologize for any inconvenience this problem may cause to your organization, and please don't hesitate to contact our customer service [*enter appropriate email address and phone number*] for any further request or need for clarification.

Kind regards,

Elisabetta Zanella

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