Plaza de la Verneda, 1
Polígono Industrial La Llana
08191 Rubí (Barcelona) Spain
Tel +34 936 995 000 Fax +34 936 994 512
calidad.deltalab@deltalab.es
www.deltalab.es

SAFETY NOTE / FIELD SAFETY NOTE

Field Safety Note number: FA-25001
Product description: VACUUM CONTAINER 3L BROWN
Reference:408600
Lot number: 32402436
Classification: IVD Class A NON-STERILE, as per Regulation (EU) 2017/746
Legal Manufacturer: DELTALAB, S.L.
Publication date: 27/01/2025
Associated corrective action: N/A
Type of corrective action: N/A

.....

Problem description:

Deltalab has been informed by its customers of an incidence with the expiration date displayed on the labelling of the secondary packaging related to batch 32402436 of reference 408600 UDI-DI 08435263874662, VACUUM CONTAINER 3L BROWN, classified under Regulation (EU) 2017/746 on in vitro diagnostic medical devices as class A NON-STERILE, manufactured by DELTALAB S.L.

Certain units from batch 32402436 show a discrepancy between the expiry date indicated on the product cap (05/2029) and the expiry date indicated on the secondary packaging (box) (06/2029), with the correct expiry date of the product being 05/2029.

The incorrect labelling date represents a one-month extension over the correct expiry date. This one-month increase in the product's expiry date does not pose a direct or indirect health risk to the patient nor does it negatively affect the product's functionality.

The technical characteristics of the materials making up the product, as described in its technical data sheet 408600_FT revision 6, include a polyethylene container and a polypropylene cap, for which the one-month extension of the shelf life does not cause any impact.

Intended use:
Collection of biological urine samples, for the purpose of in vitro diagnostic testing.

Recommended action for the user:
Due to the nature of the described issue, no corrective action is deemed necessary.

We have made extensive this Field Safety Note (FSN) to all customers that have been supplied with this product.

Plaza de la Verneda, 1
Polígono Industrial La Llana
08191 Rubí (Barcelona) Spain
Tel +34 936 995 000 Fax +34 936 994 512
calidad.deltalab@deltalab.es
www.deltalab.es

Contact details:

Email: Calidad.Deltalab@deltalabgroup.com
Tlf:+34 936995000
Address:
DELTALAB S.L Plaza de la Verneda, 1, Pol. Ind. La Llana, 089191 Rubí

We confirm that this note has been communicated to the Spanish Agency of Medicines and Medical Devices (AEMPS), as competent authority related to medical devices in Spain.

Signature:

DELTALAB S.L
Plaza de la Verneda 1, Pol. Ind. La Llana
08191 Rubí - Barcelona
T. +34 936 995 000, F. +34 936 994 152

Firmado digitalmente por:
38083806S ANNA MIR (R:
B63905996)
ND: CN = 38083806S
ANNA MIR (R: B63905996)
C = ES O = DELTALAB SL
Fecha: 2025.01.27 14:26:
52 +01'00'

Anna Mir
Person Responsible for Regulatory Compliance
Technical, Regulatory, Quality and Environment Director