



NOTICE of CHANGE dated 24/02/2023

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«IC500 - Internal Control» Ref. IC500

This new revision of the Instruction for Use (IFU) contains the following changes:

- *Update to be in compliance with the Regulation (EU) 2017/746 and the Standard ISO 15223-1:2021 requirements.*

Composition, use and performance of the product remain unchanged.

PLEASE NOTE



LA REVISIONE DI QUESTO IFU E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT



THE REVIEW OF THIS IFU IS COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT



CET IFU MIS A JOUR ANNULE ET REMPLACE ET C'EST COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT



LA REVISIÓN DE ESTE IFU ES COMPATIBLE CON LA VERSIÓN ANTERIOR DEL KIT



A REVISÃO DO ESTE IFU É COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT



DIE REVIEW VON DIESER IFU IST KOMPATIBEL MIT DER VORIGE VERSION VON DEM KIT



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REF IC500

500-Internal Control
Internal Control for nucleic acid extraction

MATERIALS PROVIDED IN THE PRODUCT

Complete size product, code IC500

Component	Description	Quantity	Classification of hazards
500 Internal Control	murine CMV (mCMV), brome mosaic virus (BMV) and <i>Streptococcus equi</i> (Sequi)	3 x 450 µL	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless gloves in latex or similar material.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (0.5-10 µL, 2-20 µL, 5-50 µL, 50-200 µL, 200-1000 µL).

OTHER PRODUCTS REQUIRED

The reagents for the extraction of DNA and/or RNA from samples to be tested **are not** included in this product.

For automatic nucleic acid extraction, use the following extraction system by ELITechGroup S.p.A.:

- **ELITE InGenius SP 200** (code INT032SP200) extraction cartridge for extraction of nucleic acid from biological samples, in association with the instrument **ELITE InGenius** (code INT030).

WARNINGS AND PRECAUTIONS

This product is exclusively designed for *in-vitro* use.

General warnings and precautions

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid producing spills or aerosols. Any material coming in contact with the biological samples must be treated for at least 30 minutes with 10% sodium hypochlorite or autoclaved for one hour at 121°C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid producing spills or aerosols. Waste must be handled and disposed of according to adequate safety measures. Disposable combustible material must be incinerated. Liquid waste containing acids or bases must be neutralised before disposal.

Wear suitable protective clothes and gloves and protect eyes and face.

Never pipette solutions by mouth.

Do not eat, drink, smoke or apply cosmetic products in the work areas.

Carefully wash hands after handling samples and reagents.

Dispose of leftover reagents and waste in compliance with the regulations in force.

Read all the instructions supplied with the product before running the assay.

While running the assay, follow the instructions provided with the product.

Do not use the product after the expiry date provided.

Only use the reagents provided in the product and those recommended by the manufacturer.

Do not mix reagents from different batches.

Do not use reagents from other manufacturers' products.

500-Internal Control

Internal Control for nucleic acid extraction

REF IC500



IVD



UDI 0803389148626

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INTENDED USE

The product **500-Internal Control** (extraction and inhibition control) is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as internal control template for DNA and RNA extraction from clinical samples with the ELITechGroup S.p.A. product **ELITE InGenius® SP 200** in association with the **ELITE MGB® Panel** products real-time PCR assays.

PRODUCT DESCRIPTION

The product supplies the **Internal Control**, a solution containing the sequences of the murine CMV (mCMV), of the brome mosaic virus (BMV), of the equine arteritis virus(EAV) and the *Streptococcus equi* (S.equi), aliquoted in **three tubes** and **ready for use**. Each test tube contains 450 µL of solution.

The presence of the specific product in the amplification reaction of the internal control indicates the correctness of the extraction procedure (presence of DNA/RNA and absence of inhibitors in the extraction product).

When **ELITE InGenius SP 200** prefilled unitary extraction cartridge is used for DNA and RNA automatic extraction, the product is sufficient for **96 extractions**.

Warnings and precautions for Molecular Biology

Molecular biology procedures require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

Lab coats, gloves and tools dedicated to work session setup are needed.

The samples must be suitable and, if possible, dedicated for this type of analysis. Samples must be handled under a laminar airflow hood. Pipettes used to handle samples must be exclusively used for this specific purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips used must be sterile, free from DNases and RNases, free from DNA and RNA.

The PCR Cassettes must be handled in such a way to reduce as much as possible amplification product diffusion into the environment in order to avoid sample and reagent contamination.

Warnings and precautions specifically meant for components

The **500-Internal Control** can be frozen and thawed for a maximum of **nine times**. Further freezing / thawing cycles may cause a loss of product performance.

The product must be stored at -20 °C.

The **500-Internal Control** must be used within one month from the first tube opening.

PROCEDURE

The **500-Internal Control** generic product must be used with **ELITE InGenius SP 200** kit for automatic extraction.

Thaw the **500 Internal Control** tubes for the session. Each tube is sufficient for **32 extractions**. Mix gently, spin down the content for 5 seconds before any session.

The **500 Internal Control** is ready for use, therefore it has to be used directly with the specific CE-IVD assay protocol associated to the **ELITE MGB Panel products** and the sample matrix. The extraction setup is included in the assay protocol and it uses **10 µL** of internal control per sample. Load on the instrument reagents and disposable material and proceed with the extraction procedure.

SYMBOLS



Catalogue Number.



Upper limit of temperature.



Batch code.



Use by (last day of month).



in vitro diagnostic medical device.



Fulfilling the requirements of the IVDR Regulation 2017/746/EC for *in vitro* diagnostic medical device.



Unique Device Identification



Contains sufficient for "N" tests.



Contents.



Attention, consult instructions for use.



Manufacturer.

NOTICE TO THE USERS

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and /or the patient is established. At the moment of the current revision of the IFU, no serious incident or recall of the device has occurred.

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