

ELITE InGenius

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EMPOWERING IVD



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NOTICE of CHANGE dated 05/05/22

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

« **ELITE InGenius[®] Waste Box** »
Ref. F2102-000

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 _KOMPATIBLE MIT DER VORIGE VERSION VON DEM KIT

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ELITE InGenius Waste Box
Disposable plastic bags for tip waste

REF F2102-000

MATERIALS PROVIDED

Component	Quantity	Description
Waste Box	20	Plastic box for collecting tip waste.

MATERIALS REQUIRED BUT NOT PROVIDED

The following equipment and reagents are not provided:
- Disposable powder free gloves in nitril or similar material.

OTHER PRODUCTS REQUIRED

This product must be used in association with ELITechGroup Real Time PCR assays, «**ELITE InGenius® SP 200**» (ELITechGroup S.p.A., code INT032SP200), «**ELITE InGenius® SP 1000**» (ELITechGroup S.p.A., code INT033SP1000), «**ELITE InGenius® SP RNA**» (ELITechGroup S.p.A., code INT034SPRNA), «**ELITE InGenius® SP 200 Consumable Set**» (ELITechGroup S.p.A., code INT032CS), «**ELITE InGenius® PCR Cassette**» (ELITechGroup S.p.A., code INT035PCR), «**300 µL Filter Tips Axygen**» (Axygen BioScience Inc., CA, USA, ref. TF-350-L-R-S, for ELITE InGenius only), «**1000 µL Filter Tips Tecan**» (Tecan ref. 30180118, for ELITE BeGenius only), and the «**ELITE InGenius**» (ELITechGroup S.p.A., code INT030) and «**ELITE BeGenius**» (ELITechGroup S.p.A., code INT040) instruments.

WARNING 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 splashing or spraying.

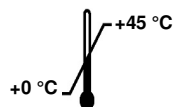
Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards. Disposable combustible material must be incinerated. Liquid waste containing acids or bases must be neutralized before disposal.

After receiving, check the set components for damage. If some are damaged, immediately contact ELITechGroup S.p.A. Technical Services or your local distributor.

The plastic parts are for laboratory use only; they must be stored in the laboratory and are not to be used for purposes other than intended.

ELITE InGenius® Waste Box
Disposable plastic boxes for tip waste

REF F2102-000



UDI 03661540900051

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INTENDED USE

The product «**ELITE InGenius® Waste Box**» (ELITechGroup S.p.A., code F2102-000) provides disposable plastic boxes for collecting tip waste generated during the protocol run for extraction from biological samples, real-time set up and nucleic acid detection in association with the «**ELITE InGenius®**» (ELITechGroup S.p.A., code INT030) and «**ELITE BeGenius®**» (ELITechGroup S.p.A., code INT040) fully automated sample-to-result instruments.

DESCRIPTION

The product «**ELITE InGenius Waste Box**» provides plastic boxes to be used in association with extraction and PCR reagents on the «**ELITE InGenius**» instrument (ELITechGroup S.p.A., code INT030) and «**ELITE BeGenius**» instrument (ELITechGroup S.p.A., code INT040).

The product provides 20 plastic boxes.

Wear suitable protective clothes and gloves and protect eyes and face.
 Discard gloves if they get contaminated.
 Never pipette solutions by mouth.
 Do not eat, drink, smoke or apply cosmetic products in work areas.
 Carefully wash hands after handling samples and reagents.
 Dispose of leftover reagents and waste in compliance with local regulations.
 Carefully read all the instructions provided in the product before running the assay.
 While running the assay, follow the instructions provided with the product.
 Do not use the product after the indicated expiry date.
 Do not use damaged set components.
 Only use the reagents recommended by the manufacturer.

Warnings and precautions for molecular biology

Molecular biology procedures, such as nucleic acid extraction, amplification and detection, 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 contamination of the samples by amplification products.

It is necessary to use lab coats, gloves and tools which are exclusively for the extraction / preparation of amplification reactions and for the amplification / detection of amplification products. Never transfer lab coats, gloves or tools from the area designated for the amplification / detection of amplification products to the area designated for the extraction / preparation of the amplification reactions.

The samples must be exclusively used 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 both DNase and RNase free, and DNA and RNA free.















PROCEDURE

The complete procedure involves DNA and RNA extraction and purification from fresh or frozen cellular and non-cellular fluid samples in association with the «ELiTe InGenius» and «ELiTe BeGenius».

When preparing the session on the «ELiTe InGenius» and «ELiTe BeGenius» instruments, load the «ELiTe InGenius Waste Box» correctly in the space provided. The plastic box can be reused for multiple sessions, however, it is recommended to replace it at least once a month. Dispose of the product according to the instructions reported in this manual in the "Warning and Precautions" paragraph.

The complete procedure is described in detail in the instruction manual enclosed with «ELiTe InGenius» and «ELiTe BeGenius».

SYMBOLS

-  Catalogue Number
-  Temperature limits
-  Batch code
-  Use by (last day of month)
-  *in vitro* diagnostic medical device
-  Fulfilling the requirements of the Regulation IVDR (EU) 2017/746 for *in vitro* diagnostic medical device.
-  Unique Device Identification
-  Do not reuse
-  Contains sufficient for "N" tests
-  Consult instructions for use
-  Contents
-  Keep away from sunlight
-  Manufacturer
-  Country of manufacture

NOTICE TO PURCHASER: LIMITED LICENSE

This product is in compliance with the Regulation IVDR (EU) 2017/746 for *in-vitro* medical devices. *In-vitro* diagnostic use of the product in countries where the Regulation IVDR (EU) 2017/746 is not recognized may be subjected to the fulfilment of registration procedures according to local competent authorities.

ELiTe InGenius® and ELiTe BeGenius® are registered trademark of ELiTechGroup.