

ELITE InGenius



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NOTICE of CHANGE dated 05/05/2022

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«ELITE InGenius® SP 200 Consumable Set» Ref. INT032CS

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.*

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 ALSO COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT



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



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



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

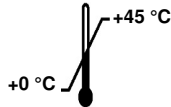


DIE REVIEW VON DIESER IFU IST KOMPATIBLE MIT DER VORIGE VERSION VON DEM TEST-KIT



ELiTe InGenius® SP 200
Consumable Set
Consumables for Nucleic Acid Extraction

REF INT032CS



UDI 03661540900044

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INTENDED USE

The «**ELiTe InGenius® SP 200 Consumable Set**» (ELiTechGroup S.p.A., code INT032CS) provides consumables to be used with «**ELiTe InGenius® SP 200**» (ELiTechGroup S.p.A., code INT032SP200), «**ELiTe InGenius® SP 1000**» (ELiTechGroup S.p.A., code INT033SP1000) or with «**ELiTe InGenius® SP RNA**» (ELiTechGroup S.p.A., code INT034SPRNA) extraction cartridge for nucleic acid extraction from biological samples, in association with the «**ELiTe InGenius®**» (ELiTechGroup S.p.A., code INT030) and «**ELiTe BeGenius®**» (ELiTechGroup S.p.A., code INT040) instruments.

DESCRIPTION

The «**ELiTe InGenius SP 200 Consumable Set**» product provides consumables to be used with the product «**ELiTe InGenius SP 200**», «**ELiTe InGenius SP 1000**» or «**ELiTe InGenius SP RNA**».

The product provides plastic consumables for **48 extractions** (4 runs x 12 samples)

MATERIALS PROVIDED

Component	Quantity	Description
Extraction tubes	48	Disposable tube to be placed in the extraction position. It can also be used as secondary tube for loading samples
Tip cassettes	4 x 12	Cassette containing a piercing tip and a pipette tip used during the extraction procedure
Elution tubes	50	0.5 mL tube and cap used to collect the extracted Nucleic Acid (NA)

MATERIALS REQUIRED BUT NOT PROVIDED

- The following equipment and reagents are not provided:
- Disposable powder free gloves in nitril or similar material.
 - Laminar airflow hood.
 - Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips.

OTHER PRODUCTS REQUIRED

This product must be used in association with the products «**ELiTe InGenius SP 200**» (ELiTechGroup S.p.A., code INT032SP200), «**ELiTe InGenius SP 1000**» (ELiTechGroup S.p.A., code INT033SP1000) or with «**ELiTe InGenius SP RNA**» (ELiTechGroup S.p.A., code INT034SPRNA), «**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.

Extraction and Inhibition Internal Control is not included in this kit. When this extraction kit is used in association with an amplification ELiTe MGB kit by ELiTechGroup S.p.A., for the Extraction and Inhibition Internal Control, please refer to the amplification ELiTe MGB kit IFU.

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. All materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% 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 splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards.

After receiving the set, check the set components for damage. If labware are damaged, contact the 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.

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 provided in the product and those recommended by the manufacturer.
 Do not use reagents from different batches.
 Do not use reagents from other manufacturers.

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.















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».

The complete procedure, the performance characteristics and procedure limitations are described in detail in the instruction manual enclosed with «ELiTe InGenius SP 200», «ELiTe InGenius SP 1000» and «ELiTe InGenius SP RNA».

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® a registered trademark of ELiTechGroup.