

ELITE InGenius

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EMPOWERING IVD



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NOTICE of CHANGE dated 05/05/2022

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«ELITE InGenius® PCR Cassette» Ref. INT035PCR

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



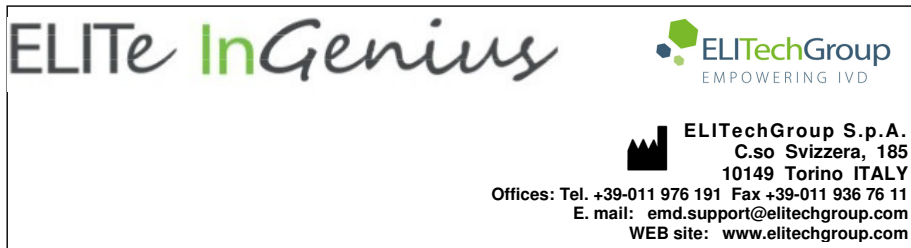
LA REVISIÓN DE ESTE IFU ES COMPATIBLE CON LA VERSIÓN ANTERIOR DEL KIT



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



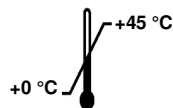
DIE REVIEW VON DIESER IFU IST _KOMPATIBLE MIT DER VORIGE VERSION VON DEM KIT



ELITE InGenius® PCR Cassette

Consumables for Real Time PCR assays

REF INT035PCR



UDI 03661540900037

TABLE OF CONTENTS

INTENDED USE	page 1
DESCRIPTION	page 1
MATERIALS PROVIDED	page 2
MATERIALS REQUIRED BUT NOT PROVIDED	page 2
OTHER PRODUCTS REQUIRED	page 2
WARNINGS AND PRECAUTIONS	page 2
PROCEDURE	page 3
SYMBOLS	page 4
NOTICE TO PURCHASER: LIMITED LICENSE	page 4

INTENDED USE

The product «**ELITE InGenius® PCR cassette**» (ELITechGroup S.p.A., code INT035PCR) provides consumables to be used in association with the «**ELITE InGenius®**» instrument (ELITechGroup S.p.A., code INT030) and «**ELITE BeGenius®**» instrument (ELITechGroup S.p.A., code INT040) for Real Time PCR reactions.

DESCRIPTION

The product «**ELITE InGenius PCR cassette**» provides consumables to be used in association with Real Time PCR reagents to perform Real Time PCR reactions on the «**ELITE InGenius**» instrument (ELITechGroup S.p.A., code INT030) and «**ELITE BeGenius®**» instrument (ELITechGroup S.p.A., code INT040).

Each «**ELITE InGenius PCR cassette**» is composed of a PCR tube and cap which is used by the instrument to seal the tube immediately before performing the PCR reaction.

To avoid contamination each cassette is individually covered on top.

The product «**ELITE InGenius PCR cassette**» provides plastic consumables for **192 Real Time PCR reactions**.

ELITE InGenius PCR cassette

Consumables for Real Time PCR assays

REF INT035PCR

MATERIALS PROVIDED

Component	Quantity	Description
PCR cassette	4 x 48	Sealed PCR tubes and caps.

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 ELITechGroup Real Time PCR assays on the «**ELITE InGenius**» (ELITechGroup S.p.A., code INT030) and «**ELITE BeGenius®**» (ELITechGroup S.p.A., code INT040) instruments.

This product can be used in association with «**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), «**300 µL Filter Tips Axygen**» (Axygen BioScience Inc., CA, USA, ref. TF-350-L-R-S, for ELITE InGenius only) and «**1000 µL Filter Tips Tecan**» (Tecan, ref. 30180118, for ELITE BeGenius only), when performing extraction plus PCR runs.

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, 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.

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.

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.

Warnings and precautions specific to components

The product does not carry GHS Hazard and Precautions phrases.















PROCEDURE

Remove the rack from the **ELITE InGenius** or **ELITE BeGenius** instrument and place the rack on a stable workbench to perform the following steps:

1. Carefully place the **ELITE InGenius PCR cassette** in the rack, making sure that it is fastened.
2. Remove the seal just before loading the rack.
3. Load the rack to the «**ELITE InGenius**» or **ELITE BeGenius** instrument following the instruction on the screen of the instrument.
4. After completion of the PCR reaction, discard the cassette without removing the PCR cap to avoid the risk of contamination.

The complete procedure is detailed in the operator's manual enclosed with «**ELITE InGenius**» and «**ELITE BeGenius**» instruments.

SYMBOLS

-  Catalogue Number
-  Temperature limits
-  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
-  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* diagnostic 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.