

ELITE InGenius



ELITechGroup S.p.A.
C.so Svizzera, 185
10149 Torino ITALY

Offices: Tel. +39-011 976 191 Fax +39-011 936 76 11
E. mail: emd.support@elitechgroup.com
WEB site: www.elitechgroup.com

NOTICE of CHANGE dated 19/04/2023

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«ELITE InGenius® DNase I» Ref. INT034DNASE

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

- Added 'Do Not Reuse' symbol to list of symbols.

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

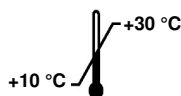
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ELITE InGenius® DNase I reagent for Nucleic Acid Extraction

REF INT034DNASE



UDI 03661540900082

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INTENDED USE

The «ELITE InGenius DNase I» is an endonuclease that cleaves DNA. It acts on single-stranded DNA, double-stranded DNA, and chromatin.

«ELITE InGenius DNase I» (ELITechGroup S.p.A., code INT034DNASE) is used in association with «ELITE InGenius® SP RNA» (ELITechGroup S.p.A., code INT034SPRNA) and the «ELITE InGenius®» (ELITechGroup S.p.A., code INT030) instrument and constitutes, together with ELITechGroup Real Time PCR assays, the **ELITE InGenius System**, fully automated molecular diagnostics systems performing extraction, purification, amplification and detection.

PRODUCT DESCRIPTION

The product supplies the DNase I reagent, a lyophilized endonuclease, aliquoted into 48 ready-to-use test tubes. Each test tube contains DNase I pellet for one sample extraction. The «ELITE InGenius DNase I» tubes must be used with the ELITE InGenius DNase I tube adapter.

ELITE InGenius® DNase I
reagent for Nucleic Acid Extraction

REF INT034DNASE

MATERIALS PROVIDED IN THE PRODUCT

Reagent	Description	Quantity	Classification of Hazard
DNase I	lyophilized endonuclease	48 tubes	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 RPM).

OTHER PRODUCTS REQUIRED

This product must be used in association with the «ELITE InGenius» (ELITechGroup S.p.A., code INT030) instrument, and with the «ELITE InGenius SP RNA» extraction cartridge (ELITechGroup S.p.A., ref. INT034SPRNA), with the «ELITE InGenius DNase tube adapter kit» (ELITechGroup S.p.A., code G6431-000).

WARNINGS AND PRECAUTIONS

This product is intended for *in vitro* use.

Warnings and general 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. The 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. 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.

Carefully read all the instructions provided 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 indicated expiry date.

Only use the reagents provided with 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 acids 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 sample contamination by amplification products.

Laboratory 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 in a Class II Biological Safety Cabinet. Pipettes used to handle samples must be exclusively used for this specific purpose and should be cleaned after each use. 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.

Warnings and precautions specific for the components

The **ELITe InGenius DNase I** must be stored between 10 and 30 °C.

The **ELITe InGenius DNase I** can be left on board on the «**ELITe InGenius**» instrument instrument for up to **one work session of three hours** ("Extract + PCR" mode).

PROCEDURE

The procedure for the use of the «**ELITe InGenius DNase I**» is described in to the manual of the «**ELITe InGenius SP RNA**» extraction cartridge (ELITechGroup S.p.A, ref. INT034SPRNA).

SYMBOLS

REF

Catalogue Number.



Upper limit of temperature.

LOT

Batch code.



Use by (last day of month).

IVD

in vitro diagnostic medical device.



Fulfilling the requirements of the Regulation IVDR (EU) 2017/746 for *in vitro* diagnostic medical device

UDI

Unique Device Identification



Contains sufficient for "N" tests.



Do not reuse



Attention, consult instructions for use.

CONT

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Manufacturer.



Country of manufacture