

NOTICE of CHANGE dated 01/02/2022

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«SARS-CoV-2 ELITe Standard» Ref. STD170ING

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

- *Introduction of new International Unit*

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 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
	DIESE FASSUNG DER GEBRAUCHSANLEITUNG IST KOMPATIBEL MIT DER VORHERIGEN VERSION DES TESTKITS



SARS-CoV-2 ELITE Standard

plasmid DNA control for quantitative assay

REF STD170ING



IVD

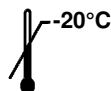


TABLE OF CONTENTS

INTENDED USE	page 1
PRODUCT DESCRIPTION	page 1
MATERIALS PROVIDED IN THE PRODUCT	page 2
MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT	page 2
OTHER PRODUCTS REQUIRED	page 2
WARNINGS AND PRECAUTIONS	page 2
PROCEDURE	page 3
REFERENCES	page 4
SYMBOLS	page 4

INTENDED USE

The «SARS-CoV-2 ELITE Standard» product is intended for use as known quantity DNA standard in quantitative nucleic acids amplification assays for the detection and quantification of RNA of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) with «SARS-CoV-2 ELITE MGB® Kit» product (ELITechGroup S.p.A.).

PRODUCT DESCRIPTION

The product supplies the **Q - PCR Standard**, four stabilized solutions of plasmid DNA at **known titre***, each aliquoted into two **ready to use test tubes**. Each tube contains 160 µL of solution, sufficient for 4 sessions.

The plasmid DNA solution contains the regions of **RdRp gene** and **ORF8 gene** of SARS-CoV-2. The detection of plasmid DNA in the real time amplification reaction with the product «SARS-CoV-2 ELITE MGB® Kit» attests the product ability to detect the SARS-CoV-2 cDNA and allows to calculate the standard curve for SARS-CoV-2 quantification in the samples.

The product is sufficient for **8 separate analytic sessions**, by using 10 µL for reaction.

* The calculation of the conversion factor from gEq / mL to International Units (IU) / mL using the new certified WHO reference material is currently under study. The standard titre was determined by spectrophotometer by absorbance measurement of the plasmid DNA preparation.

SARS-CoV-2 ELITE Standard

plasmid DNA control for quantitative assay

REF STD170ING

MATERIALS PROVIDED IN THE PRODUCT

Components	Description	Quantity	Classification and Labelling
CoV-2 Q - PCR Standard 10 ⁵	plasmid solution in tube with RED cap	2 x 160 µL	-
CoV-2 Q - PCR Standard 10 ⁴	plasmid solution in tube with BLUE cap	2 x 160 µL	-
CoV-2 Q - PCR Standard 10 ³	plasmid solution in tube with GREEN cap	2 x 160 µL	-
CoV-2 Q - PCR Standard 10 ²	plasmid solution in tube with YELLOW cap	2 x 160 µL	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

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

OTHER PRODUCTS REQUIRED

The reagents for the amplification reaction and the consumable **are not** included in this product.

To perform these analytical steps, the use of the product «SARS-CoV-2 ELITE MGB® Kit» (ELITechGroup S.p.A, EG SpA, ref. RTS170ING or RTS170ING-96) is required. The product provides the reaction mixtures for reverse transcription of RNA and real-time amplification of cDNA by one-step method.

For automatic sample analysis, the «ELITE InGenius®» instrument (EG S.p.A., ref. INT030) is required together with the specific Assay Protocol «SARS-CoV-2 ELITE_QT_STD» (EG S.p.A.), parameters for the amplification of standard DNA and standard curve calculation.

The automatic sample analysis with the instrument «ELITE InGenius®» also requires the following generic products:

- amplification cartridges «ELITE InGenius® PCR Cassette» (ELITechGroup S.p.A, ref. INT035PCR),
- tips «300 µL Filter Tips Axygen» (Axygen BioScience Inc., CA, USA, ref. TF-350-L-R-S),
- boxes «ELITE InGenius® Waste Box» (ELITechGroup S.p.A, ref. F2102-000).

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 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.

SARS-CoV-2 ELite Standard
plasmid DNA control for quantitative assay

REF STD170ING

Dispose of leftover reagents and waste in compliance with the regulations in force.
Carefully read all the instructions provided in the product before running the assay.
While running the assay, follow the instructions provided in the product.
Do not use the product after the indicated expiry date.
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 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 specific for the components

The **Q - PCR Standard** must be stored at -20 °C.

The **Q - PCR Standard** can be frozen and thawed for no more than **four times**: further freezing / thawing cycles may cause a loss in titre.

The **Q - PCR Standard** can be kept on board on «ELite InGenius» up to **four work sessions of two hours each** ("PCR Only" run mode).

PROCEDURE

The «**SARS-CoV-2 ELite Standard**» product must be used with the complete reaction mixture of the «**SARS-CoV-2 ELite MGB® Kit**» product.

Before use, thaw the **CoV-2 Q - PCR Standard** tubes at room temperature (+18 / 25°C) for 30 minutes. Mix gently, spin down the contents for 5 seconds and keep them on ice.

The **CoV-2 - PCR Standard** is ready to use: a volume of **10 µL** is directly added to the reaction mixture.

The complete procedure involves setup and carrying out of a real-time amplification reaction and is described in detail in the instructions for use of the «**SARS-CoV-2 ELite MGB® Kit**» product.

The performance characteristics and procedure limitations of the complete assay for the detection of the RNA of the SARS-CoV-2 are described in detail in the instructions for use of the «**SARS-CoV-2 ELite MGB® Kit**» product.

Note: The results of the CoV-2 Q - PCR Standard amplification will be stored by the instrument «**ELite InGenius®**». For each batch of product «**SARS-CoV-2 ELite MGB® Kit**» the calibration curve is required. The stored results of the Q - PCR Standard amplification will expire **after 60 days**.

Note: The **CoV-2 Q - PCR Standard** can be frozen and thawed for no more than **four times**. The **CoV-2 Q - PCR Standard** can be kept on board on «ELite InGenius» up to **four work sessions of two hours each** ("PCR Only" run mode).

SARS-CoV-2 ELite Standard
plasmid DNA control for quantitative assay

REF STD170ING

REFERENCES

Zhou P. et al. (2020) *Nature* 579: 270 – 273
Y. C. F. Su et al. (2020) *Mbio* 11: e01610-20
B. E. Young et al. (2020) *The Lancet* 396: 603 - 611

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 European Directive 98/79/EC for *in vitro* diagnostic medical.



Contains sufficient for "N" tests.



Attention, consult instructions for use.

CONT

Contents.



Manufacturer.

ELite MGB®, the ELite MGB® logo, ELite InGenius® and ELite BeGenius® device are registered as trademarks within the European Union.