

Instructions for use

CPE — Internal Control

Internal control for nucleic acid extraction



REF CTRCPE

UDI 08033891485139



CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
11	Update of the Paragraph "Product Description": better description of the genomic RNA of MS2 phage Update to the current instruments on the market New graphics and content setting of the IFU.	04/06/25
10	Modified maximum number of freezing/thawing allowed	18/07/23
09	Update to be in compliance with the Regulation (EU) 2017/746 and the Standard ISO 15223-1:2021 requirements	11/07/22
08	Update for the use of the product in association with «ELITE BeGenius®» instrument (REF INT040).	30/08/21
00–07	new product development and succeeding changes	-

NOTE

The revision of this IFU is also compatible with the previous version of the kit

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1 INTENDED USE

The product **CPE — Internal Control** is an in vitro diagnostic medical device intended to be used by healthcare professionals as internal control template for DNA and RNA extraction and amplification monitoring (presence of nucleic acids and absence of inhibitors in the extraction product) in association with the ELITechGroup S.p.A. nucleic acids amplification assays, extraction reagents and instruments.

2 PRODUCT DESCRIPTION

The product supplies the **CPE**, a stabilised solution containing two plasmid DNAs and genomic RNA of MS2 phage, **aliquoted in four tubes** and **ready for use**.

A first plasmid DNA contains promoter and 5' UTR regions of the human beta Globin gene, amplified as internal control in some products of «**Q - PCR Alert Kit**» and «**ELITE MGB® Kit**» lines f ELITechGroup S.p.A.

A second plasmid DNA contains an artificial DNA sequence, that is the target of the internal control amplification for some products of the «**ELITE MGB Kit**» line.

The genomic RNA of MS2 phage contains the protein-A gene, that is the target of internal control system in some products of «**ELITE MGB Kit**» line.

The presence of the specific product in the amplification reaction of the internal control indicates the correctness of the extraction procedure (presence of DNA/RNA and absence of inhibitors in the extraction product).

The product contains sufficient reagents for **48 extractions** with **ELITE InGenius®** or **ELITE BeGenius®** when **ELITE InGenius SP 200** or **ELITE InGenius SP 1000** prefilled unitary extraction cartridge are used for DNA and RNA automatic extraction, with 10 µL used per reaction.

The product contains sufficient reagents for **40 extractions** when «**ELITE GALAXY 300 Extraction Kit**» product is used for DNA and RNA automatic extraction, with 10 µL used per reaction.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
CPE ref. CTRCPE	Solution of Plasmid DNAs and genomic RNA of MS2 phage in 2mL tube with NATURAL cap	4 x 160 µL	-

4 MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (~13,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (volume range: 0.5-1000 µL).

5 OTHER PRODUCTS REQUIRED

The reagents for the extraction of DNA and/or RNA from samples to be tested **are not** included in this product.

Please refer to the Instruction for Use manuals of the reagents ELITE MGB Kit for details.

To perform the nucleic acid extraction the following extraction systems are required:

Table 2

Instruments and softwares	Products and reagents
ELiTe InGenius (ELiTechGroup S.p.A., EG SpA, ref. INT030) ELiTe InGenius Software version 1.3.0.19 (or later) Assay Protocols with parameters for samples analysis.	ELiTe InGenius Waste Box (EG SpA, ref. F2102-000) 300 µL Filter Tips Axygen (Corning Life Sciences Inc., ref. TF-350-L-R-S) with ELiTe InGenius only 1000 µL Filter Tips Tecan (Tecan, Switzerland, ref. 30180118) with ELiTe BeGenius only ELiTe InGenius SP 200» (ref. INT032SP200) ELiTe InGenius SP 200 Consumable Set (EG SpA, ref. INT032CS) ELiTe InGenius SP 1000» (ref. INT033SP1000) Specific ELiTe MGB Kit products (EG SpA)
ELiTe BeGenius (EG SpA, ref. INT040) ELiTe BeGenius Software version 2.2.1 (or later) Assay Protocols with parameters for samples analysis.	
ELiTe GALAXY (EG SpA, ref. INT020) QIAasymphony® SP/AS (QIAGEN GmbH, ref. 9001297, 9001301) «NucliSENS®easyMAG®» instrument (bioMérieux SA, ref. 200111). MagNA Pure 24 System» instrument (Roche, ref. 07290519001)	ELiTe GALAXY 300 Extraction Kit» (EG SpA, ref. INT021EX) «NucliSENS® easyMAG® Reagents» (bioMérieux SA, ref. 280130, 280131, 280132, 280133, 280134, 280135), «QIAasymphony® DSP Virus / Pathogen Midi kit» (ref. 937055) QIAasymphony® DNA Mini kit» (QIAGEN GmbH, ref. 931236) MagNA Pure 24 Total NA Isolation Kit» (Roche, ref. 07658036001) Specific ELiTe MGB Kit products (EG SpA)

6 WARNINGS AND PRECAUTIONS

This product is designed for *in-vitro* use only.

6.1 General warnings and precautions

Handle and dispose of all biological samples as if they were infectious. Avoid direct contact with biological samples. Avoid splashing or spraying. Tubes, tips and other materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite (bleach) 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 infectious. 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. Do not allow extraction reagents to contact sodium hypochlorite (bleach).

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 before running the assay.

While running the assay, follow the product instructions provided.

Do not use the product after the indicated expiry date.

Only use 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.

6.2 Warnings and precautions for molecular biology

Molecular biology procedures require qualified and trained staff to avoid the risk of erroneous results, especially due to sample nucleic acid degradation or sample contamination by PCR 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 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, and free from DNA and RNA.

The reagents must be handled under a laminar airflow hood. The pipettes used to handle the reagents must be exclusively used for this 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 and free from DNA and RNA.

The extraction products must be handled in such a way as to minimize dispersion into the environment in order to avoid the possibility of contamination.

6.3 Warnings and precautions specific for the components

Table 3

Component	Storage temperature	Use from first opening	Freeze / thaw cycles
CPE	-20°C or below	30 days	up to six

* with intermediate freezing.

7 PROCEDURE

The **CPE** is ready for use and it has to be used as follows:

ELITe GALAXY

When the nucleic acid extraction is carried out with **ELITe GALAXY System**, use the extraction protocol **xNA Extraction (Universal)** and follow these directions: prepare **Carrier** adding **450 µL** of Carrier buffer and prepare a solution of 1/3 of Carrier and 2/3 of CPE according to the instruction manual of the extraction kit. The extraction setup uses **10 µL** of internal control per sample. Load on the instrument reagents and disposable material and proceed with the extraction procedure.

ELITe InGenius and ELITe BeGenius

When the nucleic acid extraction is carried out with **ELITe InGenius** and **ELITe BeGenius Systems**, use the specific IVD assay protocol associated with the ELITe MGB Kit and the sample matrix. The extraction setup is included in the assay protocol and it uses **10 µL** of internal control per sample. Load on the instrument reagents and disposable material and proceed with the extraction procedure.

NucliSENS

When the nucleic acid extraction from non cellular samples is carried out with «**NucliSENS® easyMAG® Reagents**» and «**NucliSENS® easyMAG®**» instrument, use the extraction protocol **Generic 2.0.1** and follow these directions: add **5 µL / sample** of **CPE** for internal control before adding the **EasyMAG® Magnetic Silica** to the 8 well Strip by the supplied multichannel pipette using the program number 3. Then proceed with the extraction.

QIA Symphony

When nucleic acid extraction is carried out with «**QIA Symphony® DSP Virus / Pathogen Midi kit**» and «**QIA Symphony® SP/AS**» instrument with **software version 3.5**, use the extraction protocol "**Virus Cell free 500_V3_DSP_default IC**" and follow these directions: prepare the solution containing AVE buffer and RNA carrier, according to the instruction manual of the extraction kit. Add **6 µL / sample** of **CPE** to the solution. Load on the instrument, in the "internal control" slot, the tubes containing the solution.

When nucleic acid extraction is carried out with «**QIA Symphony® DNA Mini kit**» and «**QIA Symphony® SP/AS**» instrument with **software version 3.5**, use the extraction protocol "**Virus Blood_200_V4_default IC**" and follow these directions: prepare aliquots of ATE buffer according to the instruction manual of the extraction kit. Add **6 µL / sample** of **CPE** to the solution. Load on the instrument, in the "internal control" slot, the tubes containing the solution.

MagNA Pure

When nucleic acid extraction is carried out with **MagNA Pure 24 System** use the extraction protocol **Pathogen200** and follow these directions: dilute the **CPE** 1:2 in ultra-pure molecular biology grade water. The extraction uses **20 µL** of Internal Control/sample. Load on the instrument reagents and consumables and proceed with the extraction procedure.

The complete assay procedures, including the preparation and the execution of DNA or RNA extraction, are described in details in the instructions for use of the of the products **ELITe MGB Kit**. The performances characteristics and the procedure limitations of the complete assay are described in details in the instructions for use of the products **ELITe MGB Kit**.

8 SYMBOLS



Catalogue Number.



Upper limit of temperature.



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



Contains sufficient for "N" tests.



Consult instructions for use.



Contents.



Manufacturer.

9 NOTICE TO THE USERS

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and /or the patient is established. At the moment of the current revision of the IFU, no serious incident or recall with impact on product performance and safety of the device has occurred.



ELITechGroup S.p.A.
C.so Svizzera, 185, 10149 Torino ITALY
Tel. +39-011 976 191
Fax +39-011 936 76 11
E. mail: emd.support@elitechgroup.com
WEB site: www.elitechgroup.com