



NOTICE of CHANGE dated 18/07/2023

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«CPE - Internal Control» Ref. CTRCPE

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

- *Modified maximum number of freezing/thawing allowed.*

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



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

REF CTRCPE

CPE - Internal Control
Internal Control for nucleic acid extraction

REF CTRCPE

UDI 08033891485139



TABLE OF CONTENTS

INTENDED USE	page 1
PRODUCT DESCRIPTION	page 1
MATERIALS PROVIDED IN THE PRODUCT	page 2
MATERIALS REQUIRED BUT NOT PROVIDED	page 2
OTHER PRODUCTS REQUIRED	page 2
WARNINGS AND PRECAUTIONS	page 3
PROCEDURE	page 4
SYMBOLS	page 6

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.

PRODUCT DESCRIPTION

The product supplies the **CPE**, a stabilised plasmid solution containing two plasmid DNAs and genomic RNA of MS2 phage, **aliquoted in four tubes** and **ready for use**. Each test tube contains **160 µL** of solution.

One 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.

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 of ELITechGroup S.p.A..

The genomic RNA of MS2 phage contains the sequence retro-transcribed amplified as internal control in some products of «**Q - PCR Alert Kit**» and «**ELITE MGB® Kit**» lines of ELITechGroup S.p.A..

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).

CPE - Internal Control
Internal Control for nucleic acid extraction

MANUAL EXTRACTION
When «**EXTRAblood**» is used for DNA and RNA extraction, the product is sufficient for **100 extractions**.

AUTOMATIC EXTRACTION
When «**ELITE STAR 200 Extraction Kit**» is used for DNA and RNA automatic extraction, the product is sufficient for **36 extractions**.

When «**ELITE GALAXY 300 Extraction Kit**» product is used for DNA and RNA automatic extraction, the product is sufficient for **40 extractions**.

When «**ELITE InGenius SP 200**» or «**ELITE InGenius SP 1000**» prefilled unitary extraction cartridge is used for DNA and RNA automatic extraction, the product is sufficient for **48 extractions**.

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of hazards
CPE	Solution of Plasmid DNAs and genomic RNA of MS2 phage	4 x 160 µL	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless gloves in latex or similar material.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (0.5-10 µL, 2-20 µL, 5-50 µL, 50-200 µL, 200-1000 µL).

OTHER PRODUCTS REQUIRED

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

MANUAL EXTRACTION
For manual nucleic acid extraction, use the ELITechGroup S.p.A. generic product «**EXTRAblood**» (code EXTB01) kit for the extraction of DNA from clinical samples.

AUTOMATIC EXTRACTION
For automatic nucleic acid extraction, use the following extraction systems by ELITechGroup S.p.A.:

- «**ELITE STAR 200 Extraction Kit**» (code INT011EX) kit for extraction of nucleic acid from biological samples, in association with the instrument «**ELITE STAR Instrument**» (code INT010).
- «**ELITE GALAXY 300 Extraction Kit**» (code INT021EX) kit for extraction of nucleic acid from biological samples, in association with the instrument «**ELITE GALAXY Instrument**» (code INT020).
- «**ELITE InGenius SP 200**» (code INT032SP200) extraction cartridge for extraction of nucleic acid from biological samples, in association with the instruments «**ELITE InGenius®**» (code INT030) and «**ELITE BeGenius®**» (code INT040).
- «**ELITE InGenius SP 1000**» (code INT033SP1000) extraction cartridge for extraction of nucleic acid from biological samples, in association with the instrument «**ELITE InGenius**» (code INT030).

CPE - Internal Control
Internal Control for nucleic acid extraction

REF CTRCPE

For automatic nucleic acid extraction, it is also possible to use the generic product by bioMérieux SA «**NucliSENS® easyMAG® Reagents**» (codes 280130, 280131, 280132, 280133, 280134, 280135), kits for extraction of DNA and RNA from non-cellular and cellular samples, with the «**NucliSENS® easyMAG®**» instrument (code 200111).

For automatic nucleic acid extraction, it is also possible to use the generic product by QIAGEN GmbH «**QIASymphony® DSP Virus / Pathogen Midi kit**» (code 937055) kit for extraction of DNA and RNA from non-cellular samples or «**QIASymphony® DNA Mini kit**» (code 931236) kit for extraction of DNA from cellular samples, with «**QIASymphony® SP/AS**» instrument (codes 9001297, 9001301) and related disposables (code 997024, 990332, 997120, 997002, 997004, 19588).

For automatic nucleic acid extraction, it is also possible to use the generic product by Roche «**MagNA Pure 24 Total NA Isolation Kit**» (code 07658036001), kit for extraction of DNA and RNA from cellular and non-cellular samples, with «**MagNA Pure 24 System**» instrument (code 07290519001) and related disposables.

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 producing spills or aerosols. Any material coming in contact with the biological samples must be treated for at least 30 minutes with 10% 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 producing spills or aerosols. Waste must be handled and disposed of according to adequate safety measures. 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.

Read all the instructions supplied 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 expiry date provided.

Only use the reagents provided in the product and those recommended by the manufacturer.

Do not mix reagents from different batches.

Do not use reagents from other manufacturers' products.

Warnings and precautions for Molecular Biology

Molecular biology procedures, such as nucleic acid extraction, reverse transcription, amplification and detection, require qualified 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.

It is necessary to have available separate areas for the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never introduce an amplification product in the area designated for extraction/preparation of amplification reactions.

It is necessary to have available lab coats, gloves and tools which are exclusively employed for the extraction/preparation of the amplification reactions and for the amplification/detection of amplification products. Never transfer lab coats, gloves or tools from the area designated for the amplification/detection of amplification products to the area designated for the extraction/preparation of the amplification reactions.

The samples must be exclusively employed for this type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from DNases and RNases, free from DNA and RNA.

CPE - Internal Control
Internal Control for nucleic acid extraction

REF CTRCPE

The reagents must be handled under a laminar flow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. The pipettes employed to handle the reagents must be exclusively used for this purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from DNases and RNases, free from DNA and RNA.

Amplification products must be handled in such a way as to reduce dispersion into the environment as much as possible, in order to avoid the possibility of contamination. The pipettes used to handle amplification products must be exclusively employed for this purpose.

Warnings and precautions specifically meant for components

The **CPE** can be frozen and thawed for a maximum of **6 times**. Further freezing / thawing cycles may cause a loss of titre.

The **CPE** must be used within one month from the first tube opening.

PROCEDURE

The «**CPE - Internal Control**» generic product must be used with «**EXTRAblood**» kits for manual extraction and with «**ELITE STAR 200 Extraction kit**», «**ELITE GALAXY 300 Extraction Kit**», «**ELITE InGenius SP 200**» and «**ELITE InGenius SP 1000**» kits for automatic extraction.

The «**CPE - Internal Control**» generic product can be used «**NucliSENS® easyMAG® Reagents**», «**QIASymphony® DSP Virus / Pathogen Midi kit**» and «**QIASymphony® DNA Mini kit**» and «**MagNA Pure 24 Total NA Isolation Kit**» automatic extraction kits.

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

MANUAL EXTRACTION

When manual nucleic acid extraction is carried out with «**EXTRAblood**» extraction kits, add **5 µL** of **CPE** into each extraction tube as described in the instruction manual of each extraction kit.

AUTOMATIC EXTRACTION

ELITE STAR

When the nucleic acid extraction is carried out with **ELITE STAR System**, use the extraction protocol **UUNI_E100_S200** and follow these directions: prepare the solution containing Proteinase K / Carrier (PKC) adding **600 µL** of ultrapure water and **200 µL** of **CPE** (sufficient for 12 samples) according to the instruction manual of the extraction kit. The extraction setup uses **10 µL** of internal control per sample. Load on **ELITE STAR** the tube containing the solution and proceed with the extraction procedure.

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 to 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.

QIASymphony

When nucleic acid extraction is carried out with «**QIASymphony® DSP Virus / Pathogen Midi kit**» and «**QIASymphony® 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 «**QIASymphony® DNA Mini kit**» and «**QIASymphony® 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 procedures, including the preparation and the execution of DNA or RNA extraction are described in details in the instructions for use of the «**EXTRAblood**», «**ELITE STAR 200 Extraction Kit**», «**ELITE GALAXY 300 Extraction Kit**», «**ELITE InGenius® SP 200**», «**NucliSENS® easyMAG® Reagents**», «**QIASymphony® DSP Virus / Pathogen Midi kit**», «**QIASymphony® DNA Mini kit**» and «**MagNA Pure 24 Total NA Isolation Kit**»products.

The performances characteristics and the procedure limits of the complete assay of «**Q - PCR Alert Kit**» and «**ELITE MGB® Kit**» product lines are described in details in the instructions for use manual annexed to the products.

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.
-  Contents.
-  Attention, consult instructions for use.
-  Manufacturer.

ELITE InGenius® and ELITE BeGenius® are registered trademark of ELITechGroup.