ELITechGroup
MOLECULAR DIAGNOSTICS

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NOTICE of CHANGE dated 08/11/19

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«WNV ELITe Standard»
Ref. STD100PLD

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

- *The volume of the tubes has been modified from 120 µl to 160 µl each.*
- *The number of analytical sessions that could be performed in association with the validated systems has been specified.*

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

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WNV ELITe Standard

plasmid DNA control for quantitative assay

REF STD100PLD CE -20°C

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INTENDED USE

The **«WNV ELITe Standard»** product is intended for use as positive control and as a known-quantity DNA standard to obtain the standard curve in reverse transcription and real time amplification quantitative assays of nucleic acids for **detection** and **quantification of the RNA of human Flavivirus West Nile Virus (WNV, Lineage 1a**, Mediterranean strains included and **Lineage 2)** with the **«WNV ELITe MGB® Kit»** product, manufactured by ELITechGroup S.p.A.

PRODUCT DESCRIPTION

The product supplies the **Q - PCR Standard**, four stabilized plasmid solutions at **known titer***, aliquoted into **two ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient to prepare **8 sessions** in association with the systems validated.

The plasmid contains a region of **NS5 gene**, codifying a regulative protein of WNV. Detection of the target DNA during the real time amplification reaction attests the ability of the product to detect the WNV cDNA and allows calculation of the standard curve.

The product enables **16 separate analysis sessions** using 10 µL for the reaction.

* There are no WHO higher order or approved reference materials for WNV. The standard titre was determined by spectrophotometer by absorbance measurement of the plasmid DNA preparation.

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of hazards
WNV Q-PCR Standard 10^5	Plasmid solution in test tube with **RED cap**	**2 x 160 µL**	-
WNV Q-PCR Standard 10^4	Plasmid solution in test tube with **BLUE cap**	**2 x 160 µL**	-
WNV Q-PCR Standard 10^3	Plasmid solution in test tube with **GREEN cap**	**2 x 160 µL**	-
WNV Q-PCR Standard 10^2	Plasmid solution in test tube with **YELLOW cap**	**2 x 160 µL**	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable latex powder-free gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 RPM).
- Sterile micropipettes and tips with aerosol filter or positive displacement (2-20 µL, 5-50 µL, 50-200 µL, 200-1000 µL).
- Polypropylene micro tube for molecular biology, 1.5 mL.
- Sterile bidistilled water.
- Programmable heater with optical fluorescence detection system 7300 Real-Time PCR System or 7500 Fast Dx Real-Time PCR Instrument calibrated as required by the manufacturer.

OTHER PRODUCTS REQUIRED

The reagents for the extraction of RNA from samples, the Internal Control of extraction and inhibition, the amplification microplates and known-quantity DNA standards **are not** included in this kit.

To perform these analytical steps, the **«WNV ELITe MGB® Kit»** (ELITechGroup S.p.A., code RTS100PLD) product provides the necessary reaction mixtures for reverse transcription of RNA and real time amplification of cDNA with one-step method.

For automatic RNA extraction from samples, it is recommended to use the generic product **«ELITe STAR 200 Extraction Kit»** (ELITechGroup S.p.A., code INT011EX), kit for nucleic acid extraction from biological samples with the instrument **«ELITe STAR»** (ELITechGroup S.p.A., code INT010).

When a 7300 Real-Time PCR System is used, it is recommended to use the generic product **«Q - PCR Microplates»** (ELITechGroup S.p.A., code RTSACC01), microplates with 0.2 mL wells and adhesive sealing sheets for real time amplification.

When a 7500 Fast Dx Real-Time PCR Instrument is used, it is recommended to use the generic product: **«Q - PCR Microplates Fast»** (ELITechGroup S.p.A., code RTSACC02), microplates with 0.1 mL wells and adhesive sealing sheets for real time amplification.

For extraction control and inhibition control, it is necessary to use the generic product «**CPE - Internal Control**» (ELITechGroup S.p.A., code CTRCPE), plasmid DNA and phage RNA template from Internal Control reactions.

WARNINGS AND PRECAUTIONS

This product is exclusively for *in vitro* use.

Warnings and general precautions

Handle and dispose of all biological samples as if they were capable to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with biological samples must be treated with 3% sodium hypochlorite for at least 30 minutes or autoclaved at 121°C for one hour before disposal.

Handle and dispose of all reagents and all assay materials as if they were potentially infective. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be treated and disposed of in compliance with the appropriate safety standards. Disposable combustible materials must be incinerated. Liquid waste containing acids or bases must be neutralised before disposal.

Wear suitable protective clothing and gloves and protect eyes / face.

Never pipette solutions by mouth.

Do not eat, drink, smoke or apply cosmetic products in the work areas.

Wash hands carefully after handling samples and reagents.

Dispose of leftover reagents and waste in compliance with regulations in force.

Carefully read all the instructions provided with the product before running the assay.

Follow the instructions provided with the product while running the assay.

Do not use the product after the expiry date.

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.

Warnings and precautions for molecular biology

Molecular biology procedures, such as extraction, reverse transcription, amplification and detection of nucleic acids, require qualified and trained staff to prevent the risk of erroneous results, especially due to degradation of the nucleic acids contained in the samples or due to sample contamination by amplification products.

It is necessary to have 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 designed for extraction/preparation of amplification reactions.

It is necessary to have lab coats, gloves and tools which are exclusively employed in the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never transfer lab coats, gloves or tools from the area designed for the amplification/detection of amplification products to the area designed 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 displacement type or be used with aerosol filter tips. The tips employed must be sterile, free from DNases and RNases, free from DNA and RNA.

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 used exclusively for this purpose. The pipettes must be of the positive displacement 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. Pipettes used to handle amplification products must be employed exclusively for this specific purpose.

Warnings and precautions specific for the components

The **WNV Q - PCR Standard** can be frozen and thawed for no more than **eight times**. Further cycles of freezing and thawing could cause a reduction in titre.

WNV ELITe Standard
plasmid DNA control for quantitative assay

STD100PLD

PROCEDURE

The **«WNV ELITe Standard»** product must be used with the complete reaction mixture obtained with the product **«WNV ELITe MGB® Kit»**.

Before starting the session, remove and thaw for 30 minutes at room temperature (+18 / 25 °C) the test tubes containing **WNV Q - PCR Standard**. Mix by vortexing for 10 seconds and centrifuge the tubes for 5 seconds to bring the content to the bottom.

The **WNV Q - PCR Standard** is ready to use, hence must be used by adding **10 µL** directly to the reaction mixture.

The complete procedure, the performance characteristics and procedure limitations of the complete assay for detection and quantification of WNV DNA are described in detail in the instruction for use manual enclosed with the **«WNV ELITe MGB® Kit»** product.

N.B.: The **WNV Q - PCR Standard** can be frozen and thawed a maximum of **eight times**.

REFERENCES

F. J. May et al. (2011) *J. Virol.* March vol. 85: 2964-2974
E. M. Botha (2008) *Emerging Infectious Disease* vol. 14: 222-230
T. Bakonyi (2006) *Emerging Infectious Disease* vol. 12: 618-623
J. H. Scherret (2001) *Emerging Infectious Disease* vol. 7: 697-705

SYMBOLS

REF	Catalogue number.
	Upper temperature limit.
LOT	Batch code.
	Use by (last day of month).
IVD	*In vitro* diagnostic medical device.
CE	Fulfilling the requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device.
	Contents sufficient for "N" tests.
	Please refer to the instructions for use.
CONT	Contents.
	Manufacturer.