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Produktinformation

- Forschungsprodukte & Biochemikalien
- Zellkultur & Verbrauchsmaterial
- Diagnostik & molekulare Diagnostik
- Laborgeräte & Service

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Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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Clonit'*nGo* Zika, Dengue & Chikungunya

Detection of the genome of Zika, Dengue & Chikungunya using *Real Time PCR*

IVD	*In vitro* diagnostic device
	Revision 2 –15th November 2022
	Range of temperature
	Use within (dd/mm/yyyy: year-month)
LOT	Lot (xxxx)
REF	CLNG-96-73
	CLONIT srl Via Umberto Saba 25 - 20081 Abbiategrasso (MI) Via Varese 20 – 20121 Milano (MI)
Σ	96Tests

INTRODUCTION AND PURPOSE OF USE

Clonit'ngo Zika, Dengue & Chikungunya is designed for specific detection and differentiation of Zika, Dengue and/or Chikungunya viruses in clinical samples from patients with signs and symptoms of Zika, Dengue and/or Chikungunya viruses infection. The procedure involves the detection of the target RNA of interest by means of a genomic amplification reaction in a microplate. The analysis of the results is carried out using a real time pcr tool, composed of a thermal cycler equipped with a fluorescence detection system.

CONTENT

The kit contains reagents enough to perform 96 amplification tests

	Quantity	Description
R1	12 x 8 well strips	Zika, Dengue & Chikungunya Virus 8-well strips
R2	1 vial	Zika, Dengue & Chikungunya – Controllo positivo
R3	1 vial x 1.8ml	Rehydratation Buffer (Buffer B)
R4	1 vial x 1ml	Negative control (Buffer C)
R5	1 vial x 1ml	Water RNAse/DNAse free (Buffer A)
R6	12	8-cap strips

Instructions for Use: **ST. CLNG-9673.ENG.2**

MATERIALS AND STRUMENTATION REQUIRED BUT NOT SUPPLIED

Disposable latex powder-free gloves or similar material;
Bench microcentrifuge (12,000 - 14,000 rpm);
Micropipettes and Sterile tips with aerosol filter;
Vortex;
Plastic materials (microplate and optical adhesive cover);
Heat block (only for extraction)

INSTRUMENT

Clonit'nGo Zika, Dengue & Chikungunya is compatible with the following real time PCR instruments:

7500 Fast fornito da Lifetechnologies
7500Dx Fast fornito da Lifetechnologies
QuantStudio™12 Flex fornito da Lifetechnologies
QuantStudio™6 Flex fornito da Lifetechnologies
QuantStudio™7 Flex fornito da Lifetechnologies
QuantStudio™5 Flex fornito da Lifetechnologies
CFX 96TM Real Time PCR fornito da BioRad
LightCycler 480 fornito da Roche
Cobas z480 Analyzer 480 fornito da Roche
Rotor Gene Q MDx fornito da QIAGEN

Please ensure that the instruments have been installed, calibrated, checked and maintained according to the manufacturer's instruction and recommendations

SAMPLE AND STORAGE

The product **Clonit'nGo Zika, Dengue & Chikungunya** is designed to be used with RNA extracted from biological samples. Perform sample preparation according to the recommendations in the "instructions for use" of the extraction kit used. The kit has been tested and validated with the following product: QIAamp Viral RNA Mini Kit (QIAGEN).

PREACAUTION USE

This kit is for in v*itro* diagnostic (IVD), for professional use only and not for in vivo use.
At all times follow Good Laboratory Practice (GLP) guidelines.
Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
Avoid any contact between hands and eyes or nose during specimens collection and testing.
Handle and dispose all used materials into appropriate bio-hazard waste containers. It should be discarded according to local law.
Keep separated the extraction and the reagents preparation.
Never pipette solutions by mouth.
Avoid the air bubbles during the master mix dispensing. Eliminate them before starting amplification.
Wash hands carefully after handling samples and reagents.
Do not mix reagents from different lots.
It is not infectious and hazardous for the health (see Material Safety data Sheet – MSDS).
Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
Read carefully the instructions notice before using this test.
Do not use beyond the expiration date which appears on the package label.
Do not use a test from a damaged protective wrapper.

LIMIT OF THE METHOD

The extreme sensitivity of gene amplification may cause false positives due to cross-contamination between samples and controls. Therefore, you should:

- physically separate all the products and reagents used for amplification reactions from those used for other reactions, as well as from post-amplification products;
- use tips with filters to prevent cross-contamination between samples;
- use disposable gloves and change them frequently;
- carefully open test tubes to prevent aerosol formation;
- close every test tube before opening another one.

The proper functioning of the amplification mix depends on the correct collection, correct transportation, correct storage and correct preparation of a biological sample.

As with any diagnostic device, the results obtained with this product must be interpreted taking in consideration all the clinical data and other laboratory tests done on the patient.

A negative result obtained with this product suggests that the RNA was not detected in nuclei acid extracted from the sample, but it may also contain RNA at a lower titre than the detection limit for the product (detection limit for the product, see paragraph on Performance Characteristics); in this case the result would be a false negative.

As with any diagnostic device, with this product there is a residual risk of obtaining invalid, false positives or false negatives results

STORAGE AND STABILITY

The kits can be shipped and stored from 2 to 40 °C until the expiration date which is stated on the label. Once the positive control has been re-suspended, store it at -20 °C. We recommend to separate it in aliquots to minimize freeze and thaw cycles. Keep components away from sunlight.

ANALYTICAL PROCEDURE

RNA EXTRACION

Manual Extraction
Ref. 52906. QIAmp Viral RNA Mini Kit
Follow the instructions in the qiamp viral rna mini kit. Elute the sample 50 µl of AVEbuffer.

POSITIVE CONTROL

Clonit'nGo Zika, Dengue & Chikungunya Positive Control contains high copies of the template, the recommendation is to open and manipulate it in a separate laboratory area away from the other components. Reconstitute the lyophilized Positive Control (red vial) by adding 100 µL of the supplied Water RNAse/DNAse free (white vial) and vortex thoroughly.

Once the positive control has been re-suspended, store it at -20°C. We recommend to separate it in aliquots to minimize freeze and thaw cycles.

PRECEDURE

Determine and separate the number of required reactions including samples and controls.
One positive and negative control must be included in each run for each assay.
Peel off protective aluminium seal from plates or strips.
Reconstitute the number of wells you need. Add 15 µL of Rehydration Buffer (blue vial) into each well.
Adding 5 µl of DNA extracted for each sample, 5 µl of positive control and 5 µl of negative control in different wells and close them with provided caps.
It is recommended to briefly centrifuge
Load the strips in the thermocycler.
Set up the thermocycler. Program the thermocycler following the conditions listed below and start the run:

SOFTWARE SETTINGS

Set the right thermal cycling:

Cycles	***Retrotrascription***			
1	*45°C 15 min*			
Cycles	***Denaturation***		***Annealing/ extension***	
1	*95°C 2 min*		*Reading stage*	
45	*95°C*	*10 sec*	*60°C*	*50 sec*

Fluorogenic data should be collected during the extension step following the instruction in the table:

	Zika Virus	***Dengue***	***Chikungunya***	***Interna control***
7500 Lifetech.	*Cy5*	*FAM*	*ROX*	*VIC*
CFX 96	*Cy5*	*FAM*	*ROX*	*HEX/JOE*
RotorGene Q	Red	*Green*	*Orange*	*Yellow*
QS5 *Lifetech.*	*Cy5*	*FAM*	*ROX*	*VIC*

Depending on the equipment used select the proper detection channel. In Applied Biosystems 7500 Fast Real-Time PCR System, StepOne Plus™ Real Time PCR System and Stratagene Mx3005P ™ Real Time PCR System check check for information purposes only that passive reference option ROX is none.

Reaction Volume: 20 µl

RESULTS INTERPRETATION

The use of positive and negative controls in each run, validate the reaction by checking the absence of signal in the negative control well and the presence of signal for Zika virus, Dengue Virus e Chikungunya.
in the positive control well. Check Internal Control signal to verify the correct functioning of the amplification mix. The analysis of the samples is done by the
software of the used real time PCR equipment itself according to manufactureŕ s instructions.

Interpretation of results:

Zika Virus	*Dengue*	*Chikungunya*	*Internal control*	*Negative*	*Positive*	*Interpretation*
+	+	+	+/-	-	+	*Zika, dengue & Chikungunya positive*
-	-	-	+/-	-	+	*Zika, dengue & Chikungunya Negative*
+	-	-	+/-	-	+	*Zika virus Positive Dengue & Chikungunya Negative*
+	+	-	+/-	-	+	*Zika virus e Dengue Positive Chikungunya Negative*
+	-	+	+/-	-	+	*Zika virus e Chikungunya Positive Dengue Negative*
-	+	-	+/-	-	+	*Dengue virus Positive Zika & Chikungunya Negative*
-	+	+	+/-	-	+	*Dengue virus & Chikungunya Positive Zika Negative*
-	-	+	+/-	-	+	*Chikungunya Positive Dengue virus & Zika Negative*
+	+	+	+	+	+	*Fail*
-	-	-	-	-	-	*Fail*

PERFORMACES

Analytical sensitivity:
For the purposes of this evaluation, the greater dilution (titre) to which a positive sample can be diluted without the system losing its ability to detect it as positive is considered analytical sensitivity. **Clonit'nGo Zika Dengue** & **Chikungunya** has a detection limit> 10 copies of RNA per reaction.

Analytical specificity:
Test's specificity is guaranteed by the use of specific primers for the target
The alignment of the choose regions for specific primers' hybridization with available sequences of present in database, demonstrated: their conservation and the complete specificity for the analyzed targets.

Crossreactivity
An analysis was also performed on samples positive for other pathogens and the test was performed following the indications reported in the method.

ZIKA VIRUS:

Samples	Results
Chikungunya virus strain S27 Petersfield	-
Dengue 1 Virus Strain Hawaii	-
Dengue 2 Cuìirus strain new Guinea C	-
Dengue 3 Virus strain H87	-
Dengue virus 4 strain H241	-
St Louis Enchephalitis virus strain 17D	-
WNV Strain H160/99	-
WNV Heja	-
WNV UG37	-
Yellow Fever virus	-

DENGUE VIRUS:

Samples	Results
Chikungunya virus strain S27 Petersfield	-
ZIKA virus strain MR 766	-
St Louis Enchephalitis virus strain 17D	-
WNV Strain H160/99	-
WNV Heja	-
WNV UG37	-
Yellow Fever virus	-

CHIKUNGUNYA VIRUS:

Samples	Results
ZIKA virus strain MR 766	-
Dengue 1 Virus Strain Hawaii	-
Dengue 2 Cuìirus strain new Guinea C	-
Dengue 3 Virus strain H87	-
Dengue virus 4 strain H241	-
St Louis Enchephalitis virus strain 17D	-
WNV Strain H160/99	-
WNV Heja	-
WNV UG37	-
Yellow Fever virus	-

INTERFERENCES

Verify that in the RNA extracted from the sample there is no contamination from mucoproteins and haemoglobin, to exclude possible inhibition of PCR reaction. The interference due to contaminants can be detected through a spectrophotometric analysis, verifying the ratio between the absorbance readings at 260 nm (maximum absorbtion of Nucleic Acids) and 280 nm (maximum absorbtion of Proteins). A pure RNA should have a ratio of approximately 2.

QUALITY CONTROL

It is recommended to include in each analytical run, as quality control of every extraction, amplification and detection step, an already tested negative and positive sample, or a reference material with known concentration

In accordance with the Clonit srl ISO EN 13485 Certified quality Management System, each lot of **Clonit'nGo Zika, Dengue & Chikungunya** is tested against predetermined specification to ensure consistent product quality.

TECHNICAL ASSISTANCE

For any question and support please contact our Technical support:

e-mail: info@clonit.it
phone: +39 02 56814413

IVD	*In vitro* diagnostic device
	Read the instruction's manual
	Range of temperature
	Use within (dd/mm/yyyy: year-month)
LOT	Lot (xxxx)
REF	Code
	Manufacturer
	Contains sufficient for <n> tests

Clonit'nGo Zika, Dengue & Chikungunya is CE marked diagnostic kit according to the European *in vitro* diagnostic directive 98/79/CE

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CE IVD

for *in vitro* diagnostic use