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Produktinformation

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Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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Clonit'*nGo* Flu A + Flu B

Detection and identification of the genome of Influenza A (Flu A), Influenza B (Flu B) using Real Time PCR.

IVD	*In vitro* diagnostic device
	Revision X –25th May 2020
	Range of temperature
	Use within (dd/mm/yyyy: year-month)
LOT	Lot (xxxx)
REF	CLNG-96-31
	CLONIT srl Via Lombardia 6 – 27010 Siziano (PV) Via Varese 20 – 20121 Milano (MI)
Σ	96 Tests

INTRODUCTION AND PURPOSE OF USE

Clonit'^{nGo} Flu A + Flu B is designed for the specific detection and differentiation of Influenza A (Flu A), and Influenza B (Flu B) in respiratory samples from patients with signs and symptoms of respiratory 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	Flu A + Flu B - 8-well strips
R2	1 vial	Flu A + Flu B – Positive Control
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)
	12	8-cap strips

Instructions for Use: **ST. CLNG-9631.ENG.1**

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} Flu A + Flu B is compatible with the following real time PCR instruments:

AriaMx/AriaDx Real-Time PCR System
7500 Fast supplied from Lifetechnologies (1)
7500Dx Fast supplied from Lifetechnologies (1)
QuantStudio™12 Flex supplied from Lifetechnologies
QuantStudio™6 Flex supplied from Lifetechnologies
QuantStudio™7 Flex supplied from Lifetechnologies
QuantStudio™ 3 Fast supplied from Lifetechnologies
QuantStudio™ 5 Fast supplied from Lifetechnologies
StepOne Plus™ /StepOne™ supplied from Lifetechnologies (4)
ViiA™ 7 Fast supplied from Lifetechnologies
Exicycler™ 96 supplied from Lifetechnologies
CFX 96™ Real Time PCR supplied from BioRad

Mini Opticon™ supplied from BioRad
SmartCycler® supplied from Cepheid (2)
Rotor-Gene Q MDx® supplied from Qiagen (2)
LightCycler ®480 Real-Time PCR System supplied from Roche (3)
LightCycler ®96 Real-Time PCR System supplied from Roche (3)
Cobas z480 Analyzer supplied from Roche (3)

(1)Select Ramp Speed "**Standard**".
(2)The product should be reconstituted following the appropriate procedure (see Test Procedure) and transferred into the specific Rotor-Gene® Q or SmartCycler® tubes.
(3)Shell Frame grid plate which fits in these Roche qPCR System is necessary.
(4)No detection in Cy5 channel.

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 Flu A + Flu B 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.

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 EXTRACTION

Perform the sample preparation according to the recommendations appearing in the instructions for use of the extraction kit used.

For RNA extraction from respiratory samples you can use your manual or automatic routine optimized system. Also, you can use any commercially available RNA extraction kit and follow the manufacturer´s instructions. We have validated the following extraction kits:

- RIDA® Xtract (r-Biopharm).
- Maxwell® 16 Viral Total Nucleic Acid Purification Kit, using the Maxwell® 16 instrument (Promega).
- Total Nucleic Acid Isolation (TNAI) Kit, using COBAS® AmpliPrep (ROCHE).

POSITIVE CONTROL

Clonit´nGo Flu A + Flu B 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 Flu A, Flu B 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 -20ºC. 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 RNA 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:

	Flu A	***Flu B***	***Internal Control***
7500 Lifetech.	*FAM*	*ROX*	*VIC*
CFX 96	*FAM*	*ROX*	*HEX/JOE*
RotorGene Q	*Green*	*Orange*	*Yellow*
QS5 *Lifetech*.	*FAM*	*ROX*	*VIC*
Roche LightCycler	*465/510*	*533/610*	*533/580*

Depending on the equipment used select the proper detection channel. In Applied Biosystems 7500 Fast Real-Time PCR System check for information purposes only that passive reference option ROX is none. In the Applied Biosystems 7500 Fast Real-Time PCR System select Ramp Speed Standard in Select New Experiment/Advanced Setup/Experiment Properties.

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 negative control well and the presence of signal in Flu A and Flu B Positive Control well. The analysis of the samples is done by the software itself of the used real time PCR equipment according to manufacturer´s instructions.

Interpretation of results:

Flu A FAM	***Flu B ROX***	***Internal Control HEX***	***Negative Control***	***Positive Control***	***Interpretation***
+	*+*	*+/-*	*-*	*+*	*Flu A + Flu B Positive*
-	*-*	*+*	*-*	*+*	*Flu A + Flu B Negative*
+	*-*	*+/-*	*-*	*+*	*Flu A positive and Flu B negative*
-	*+*	*+/-*	*-*	*+*	*Flu B positive and Flu A negative*
+	*+*	*+*	*+*	*+*	*Fail*
-	*-*	*-*	*-*	*-*	*Fail*

PERFORMACES

Clinical sensitivity ancd specificity

The clinical performance of **Clonit'nGo Flu A + Flu B** was tested using 109 respiratory specimens (throat swabs) from symptomatic patients. These results were compared with those obtained with a commercial Real Time PCR kit.

The results show a high sensitivity and specificity to detect Flu A+B using **Clonit'nGo Flu A + Flu B** kit

Analytical sensitivity:

For the purposes of this evaluation, the greater dilution (titer) 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 **Flu A + Flu B** Real Time PCR Detection Kit has a detection limit of ≥10 RNA copies per reaction for Flu A and Flu B.

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.

Samples	Results	Samples	Results	Samples	Results
Bordetella pertussis	-	Human metapneumovirus A and B	-	Influenza A/DE-SH/Reiherente/AR8444/ 2013 (H5N8) virus	-
Bordetella bronchiseptica	-	Human coronavirus 229E, OC43 and NL63	-	Influenza A/Anhui/1/2013 (H7N9) virus	-
Bordetella holmesii	-	Human rhinovirus	-	Influenza A/Mallard/Netherlands/2/2009 (H7N7) virus	-
Bordetella bronchiseptica	-	Human coronavirus 229E, OC43 and NL63	-	Influenza A/Anhui/1/2013 (H7N9) virus	-
Bordetella holmesii	-	Human rhinovirus	-	Influenza A/Mallard/Netherlands/2/2009 (H7N7) virus	-
Bordetella parapertussis	-	Bocavirus	-	Influenza A/turkey/Virginia/2002 x PR8- IBCDC-5 (H7N2)	-
Legionella bozemanii	-	Human Adenovirus	-	Influenza A/chicken/Hong Kong/G9/1997 x PR8-IBCDC-2 (H9N2)	-
Legionella micdadei	-	MERS Coronavirus	-	Influenza A/mallard/Netherlands/12/2000 (H7N7) - IBCDC-1	-
Legionella dumoffii	-	Influenza A/New Caledonia/20/99(H1N1) virus	-	Influenza A/pheasant/New Jersey/1355/1998 (H5N2)-PR8-IBCDC-4	-
Legionella longbeachae	-	Influenza A/California/7/2009(H1N1)pdm09-like virus	-	Influenza A/Singapore/INFIMH-16-0019/2016 (H3N2)	-
Legionella pneumophila	-	Influenza A/Netherlands/1250/2016 (H1N1)pdm09 virus (clade 6B.1)	-	Influenza A/South Australia/55/2014	-
Mycoplasma pneumoniae	-	Influenza A/Michigan/45/2015 (H1N1)pdm09 virus	-	Influenza A/Uruguay/716/2007 (H3N2)(NYMC-175C)	-
Streptococcus pneumoniae	-	Influenza A/Singapore/GP1908/2015, IVR-180 (H1N1)pdm09 virus	-	Influenza B/Brisbane/60/2008-like virus	-
Staphylococcus aureus subsp. aureus	-	Influenza A/Perth/16/2009(H3N2)-like virus	-	Influenza B/Netherlands/207/06 virus	-
Methicillin-resistant Staphylococcus aureus	-	Influenza A/Thüringen/5/17 (H3N2) virus	-	Influenza B/Florida/04/06 virus	-
Haemophilus influenzae	-	Influenza A/Switzerland/9715293/2013 (H3N2)	-	Influenza B/Phuket/3073/2013 virus	-

Samples	Results	Samples	Results	Samples	Results
MinnA		virus			
Moraxella catarrhalis	-	Influenza A/Hong Kong/4801/2014, NYMC X-263B (H3N2) virus	-	Influenza B/Netherlands/2518/2016 (clade 1A) virus	-
Chlamydia caviae	-	Influenza A/Netherlands/398/2014 (H3N2) virus (clade 3C.3a)	-	Influenza B/Netherlands/365/2016 (clade 3)	-
Chlamydia psittaci genotype A and C	-	Influenza A/Netherlands/2393/2015 (H3N2) virus (clade 3C.2a)	-	Influenza B/Colorado/6/2017	-
Chlamydophila pneumoniae	-	Influenza A/Hong Kong/213/2003 (H5N1) virus	-	Influenza B/Maryland/15/2016	-
Human parainfluenza 1, 2, 3 and 4 viruses	-	Influenza A/Turkey/Germany R2485+86/2014 (H5N8) virus	-	Respiratory syncytial virus (RSV)	-

INTERFERENCES

Check that in the RNA extracted from the starting sample there are no mucoproteins and hemoglobin so as to exclude any inhibitions in the PCR reaction. The interference due to contaminants can be highlighted by spectrophotometric analysis and ratio of the data obtained at 260 nm (Maximum absorption of Nucleic Acids) and 280 nm (Maximum absorption of proteins). Pure RNA should have a ratio of about 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} Flu a + Flu B** 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
Σ	Contains sufficient for <n> tests

Clonit'nGo Flu A + Flu B 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