



SZABO SCANDIC

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Produktinformation



Forschungsprodukte & Biochemikalien



Zellkultur & Verbrauchsmaterial



Diagnostik & molekulare Diagnostik



Laborgeräte & Service

Weitere Information auf den folgenden Seiten!
See the following pages for more information!



Lieferung & Zahlungsart

siehe unsere [Liefer- und Versandbedingungen](#)

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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By correctly setting the standards concentration as a function of the extraction system you can get the quantization of the sample directly in copies / ml:

Alternative Extraction		
RTS 1	500.000 copies	
RTS 2	50.000 copies	
RTS 3	5.000 copies	
RTS 4	500 copies	

When alternative systems are used sample concentration expressed in copies/ml will be obtained using the formula:

$$copie/ml = \frac{1000}{V_e} \times \frac{E_v}{E_a} \times C_{reac}$$

where:

- **V_e**: extracted sample Volume expressed in μ l
- **E_v**: eluted sample Volume during extraction step expressed in μ l
- **E_a**: extracted sample volume used for amplification expressed in μ l
- **C_{reac}**: copies provided by the instrument.

PERFORMANCES

Analytical sensitivity:

It is considered as analytical sensitivity the highest dilution (title) to which a positive sample can be diluted without the system losing the ability to detect with a positivity rate of $\geq 95\%$. The analytical sensitivity of the system was assessed by analyzing synthetic RNA, quantified by spectrophotometric analysis, containing the regions of interest of the virus in serial dilutions.

Target	Copies/ μ l
N1	1 cps/ μ l
N2	1 cps/ μ l
N3	1 cps/ μ l

Clinical sensitivity:

It is considered as clinical sensitivity the ability to detect true positive samples in the totality of the samples screened as positive. The analysis was made on COVID-19 positive samples and the test was performed following the method recommendations. Positive samples were confirmed with another method available on the market.

Obtained results show a clinical sensitivity of 100%: for RNA samples extracted.

Linearity/Proportionality

The system linearity was valued analyzing synthetic RNA, quantified by spectrophotometric analysis, containing the regions of interest N1 of the virus in serial dilutions (1:10) from 500.000.000 copies/reactions to 50 copies/reaction of RNA in 5 μ l of extracted material added in the retro-amplification reaction. The evaluation was performed analyzing 10 calibration curves, that showed these parameters:

RTS conc. 10 ⁸ copie (FAM)	Ct ≤ 25	Medium Ct 22.19
Coefficiente correlazione	$0.990 \leq r^2 \leq 1$	Medium r^2 0.999
Slope	$-3.6 \leq \text{Slope} \leq -3.2$	Medium slope -3.299
Efficienza PCR	$90 \leq \text{Efficiency} \leq 100$	Medium Eff 101%

Diagnostic Specificity:

It is considered as diagnostic specificity the ability of the method to detect true negative samples. The diagnostic specificity of the system was evaluated analyzing human samples tested and confirmed as COVID-19 negative with another method available on the market.

Diagnostic specificity is 100% for RNA samples extracted.

Analytical Specificity:

Test's specificity was guaranteed by the use of specific primers for COVID-19.

The alignment of the chosen regions for specific primers hybridization for COVID-19 with available sequences of the region present in database, demonstrated: their conservation, the absence of significant mutations for the analysed target.

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 absorption of Nucleic Acids) and 280 nm (maximum absorption 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 **quany COVID-19** is tested against predetermined specification to ensure consistent product quality.

BIBLIOGRAPHY









Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases Interim guidance 17 January 2020 WHO/2019 nCoV/laboratory/2020.3

CDC/NCIRD/DVD Effective: 24 Jan 2020

TECHNICAL ASSISTANCE

For any question and support please contact our Technical support:

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

EDMA 15044019
CND: W0105040519



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