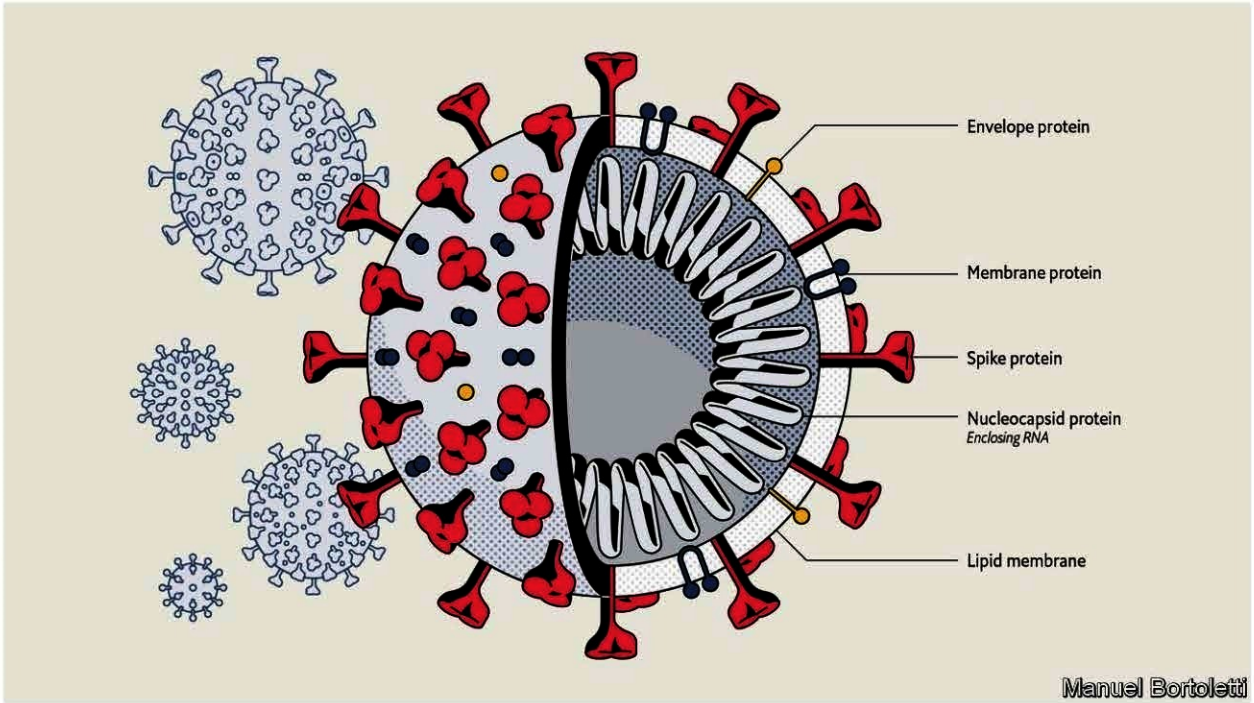
OBTEQ

GenoTec Real-Time RT-PCR SARS-CoV-2



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World Health Organization

WHO COVID-19 LABORATORY

2020 INTERIM GUIDANCE

"PCR TESTING OF ASYMPTOMATIC OR MILDLY SYMPTOMATIC CONTACTS CAN BE CONSIDERED IN THE ASSESSMENT OF INDIVIDUALS WHO HAVE HAD CONTACT WITH A COVID-19 CASE."

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1. KIT INTRODUCTION

- Product specifications
- Product features
- PCR assay
- Diagnostic result

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1. KIT INTRODUCTION

PRODUCT SPECIFICATIONS

A screening and confirmatory kit to detect presence of SARS-CoV-2 (COVID-19) from isolated total RNA

Catalogue No.	Product Name	Detection	Specimen	Compatible Instrument	Test /Kit	Time to Result
G2033	GenoTec Real-Time RT-PCR SARS-CoV-2	SARS-CoV-2 (*RdRP*, *S* and *N* genes)	Bronchoalveolar lavage, tracheal aspirates, sputum, nasopharyngeal swab.	CFX96™, LineGene 9600 series, QuantStudio 5	100	1hr 43mins

Nucleic acid amplification tests (NAAT) for COVID-19 virus.

Routine confirmation of cases of COVID-19 is based on detection of unique sequences of virus RNA by NAAT such as real-time reverse-transcription polymerase chain reaction (rRT-PCR) with confirmation by nucleic acid sequencing when necessary. The viral genes targeted so far include the N, E, S and RdRP genes. Examples of protocols used may be found here. RNA extraction should be done in a biosafety cabinet in a BSL-2 or equivalent facility. Heat treatment of samples before RNA extraction is not recommended.

WHO covid-19 Laboratory
2020 interim guidance

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1. KIT INTRODUCTION

PRODUCT FEATURES

- Real-Time PCR allows quantification of amplification be done at each end of cycle
- One-Step as Reverse Transcription and PCR Amplification processes happen in one tube
- Pre-determined thresholds to guide users in result analysis
- Ready-to-use reagents that simplify assay preparation process
- Multiplex in a single tube
- High analytical sensitivity and specificity

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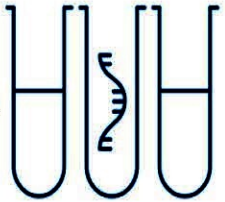
1. KIT INTRODUCTION

PCR ASSAY

Sample Collection



Nucleic Acid Extraction

Preparation of Assay

Run Test

Data Analysis

Diagnostic Result

According to sample type

This assay has been validated with Nucleospin® Virus kit (Macharey-Nagel), QiaAMP® Viral RNA (Qiagen) for RNA extraction.
Refer manufacturer's procedure for RNA extraction process

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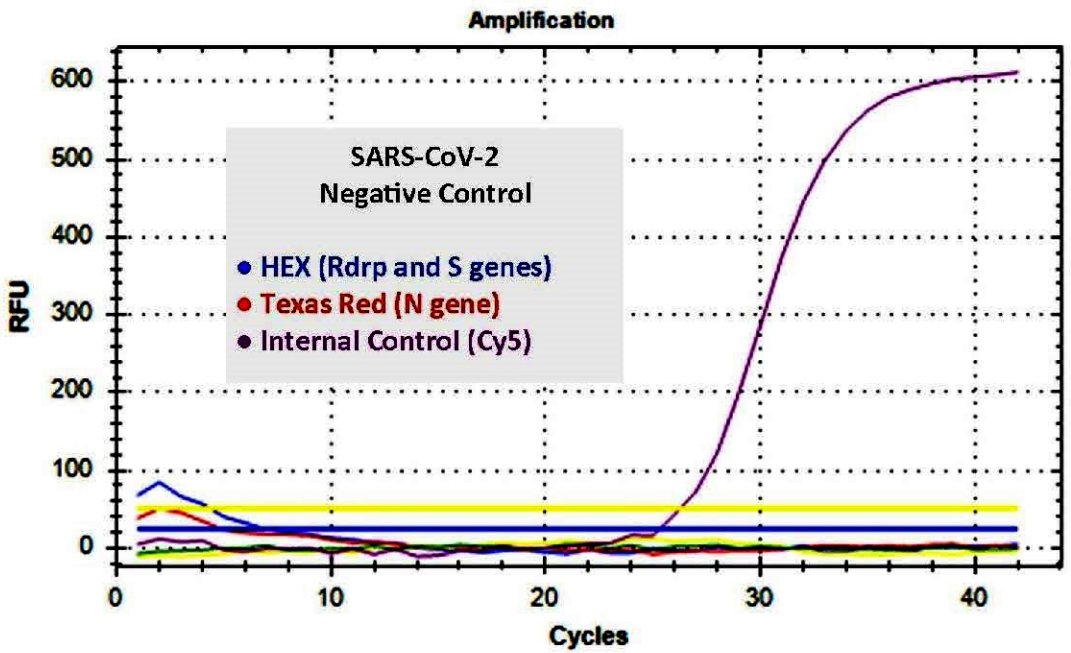
1. KIT INTRODUCTION

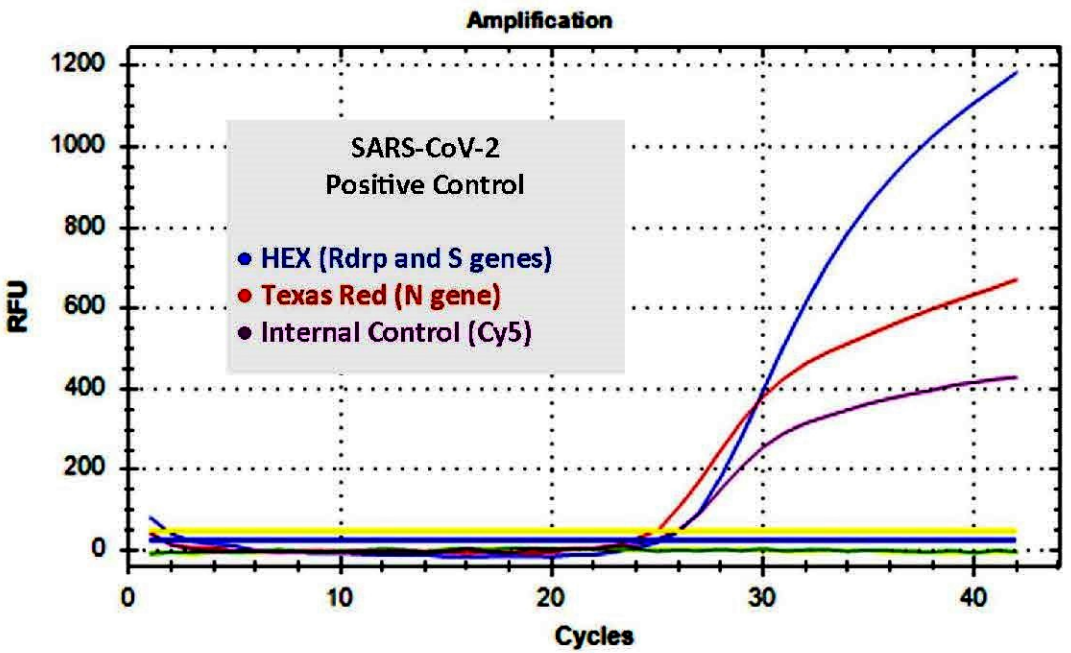
DIAGNOSTIC RESULTS

NEGATIVE COVID-19



VS

POSITIVE COVID-19



GenoTec Platform

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Viral Respiratory Panel	Bacterial Respiratory Panel	Tropical Fever Panel	TB Panel
• Flu A/ H1N1/ H3N2/ Flu B • MERS-CoV • FluA/FluB/ SARS-CoV-2/ MERS-CoV • SARS-CoV-2	• *Bordetella pertussis*	• Dengue 1-4 • Chikungunya • Zika • Dengue/ Chikungunya/Zika • Leptospirosis • Malaria • Malaria/ Leptospirosis/ Salmonella/ *B. pseudomallei*	• MTBC/NTM

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3. SALES INFORMATION

Catalogue No.	Product Name	Detection	Specimen	Compatible Instrument	Test /Kit
G2032	GenoTec Real-Time RT-PCR Flu A / Flu B / SARS-CoV-2 / MERS-CoV	Flu A / Flu B / SARS-CoV-2 / MERS-CoV	Bronchoalveolar lavage, tracheal aspirates, sputum, nasopharyngeal swab.	CFX96™, LineGene 9600 series, QuantStudio 5	100
G2033	GenoTec Real-Time RT-PCR SARS-CoV-2	SARS-CoV-2 (*RdRP*, *S* and *N* genes)			

REAGENTS & MATERIALS SUPPLIED

Ref	Type of Reagents	Volume
1.	Reaction Mix	2 vials of 650 ul
2.	Primer-Probe Mix	2 vials of 50 ul
3.	Internal Control	2 vials of 50 ul
4.	PCR Grade Water	2 vials of 600 ul
5.	Positive Control (20 rxn)	1 vial of 50 ul

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3. SALES INFORMATION

KIT HAS BEEN EVALUATED BY INSTITUTE MEDICAL RESEARCH (IMR) .

Table 1: Evaluation Result by IMR

Test		Tested Kit Assay		Sensitivity/Specificity
		Detected	Not Detected	
IMR In-house Panel	SARS-CoV-2 Positive (n=20)	19	1	Sensitivity = 95.0%
	SARS-CoV-2 Negative (n=20)	20	0	Specificity = 100%

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FREQUENTLY ASKED QUESTIONS (FAQ)

- What are the sensitivity and specificity of the kit?

Type	Limit of Detection (copies/ul)
RdRP	16.5
S	14.5
N	13.2

All the samples tested were negative against these pathogens and the internal control was positive.

Pathogens Tested for Analytical Specificity		
HCoV-229E	SARS-CoV-2 HKU39849	HCoV-NI63
HCoV-OC43	MERS-CoV	

- Has the kit got certification
  - Yes, CE-IVD certificate (DE/CA70/40838-154799)
  - MDA – In-progress
- Kit Specification?
  - Required Instrument for Kit : Real Time PCR Detection System
  - Recommended PCR System a) Bio-Rad CFX96™System b)BioEr Linegene 9600 Series c)QuantStudio 5

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FREQUENTLY ASKED QUESTIONS (FAQ)

- Does the kit requires special storage?
  - -20°C
- How long is the shelf life?
  - One year after the manufacturing date
- What is the time from sample to result?
  - less than 3 hours.
- Payment Terms?
  - 100% T.T. Advanced payment

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CONTACT US

Email *excom@esh-com.de*

www.esh-com.de

ESH GmbH

Address :*Unnauer Weg.7a,50767 Köln,Deutschland*

Phone *+49 221 53 47 43 43*