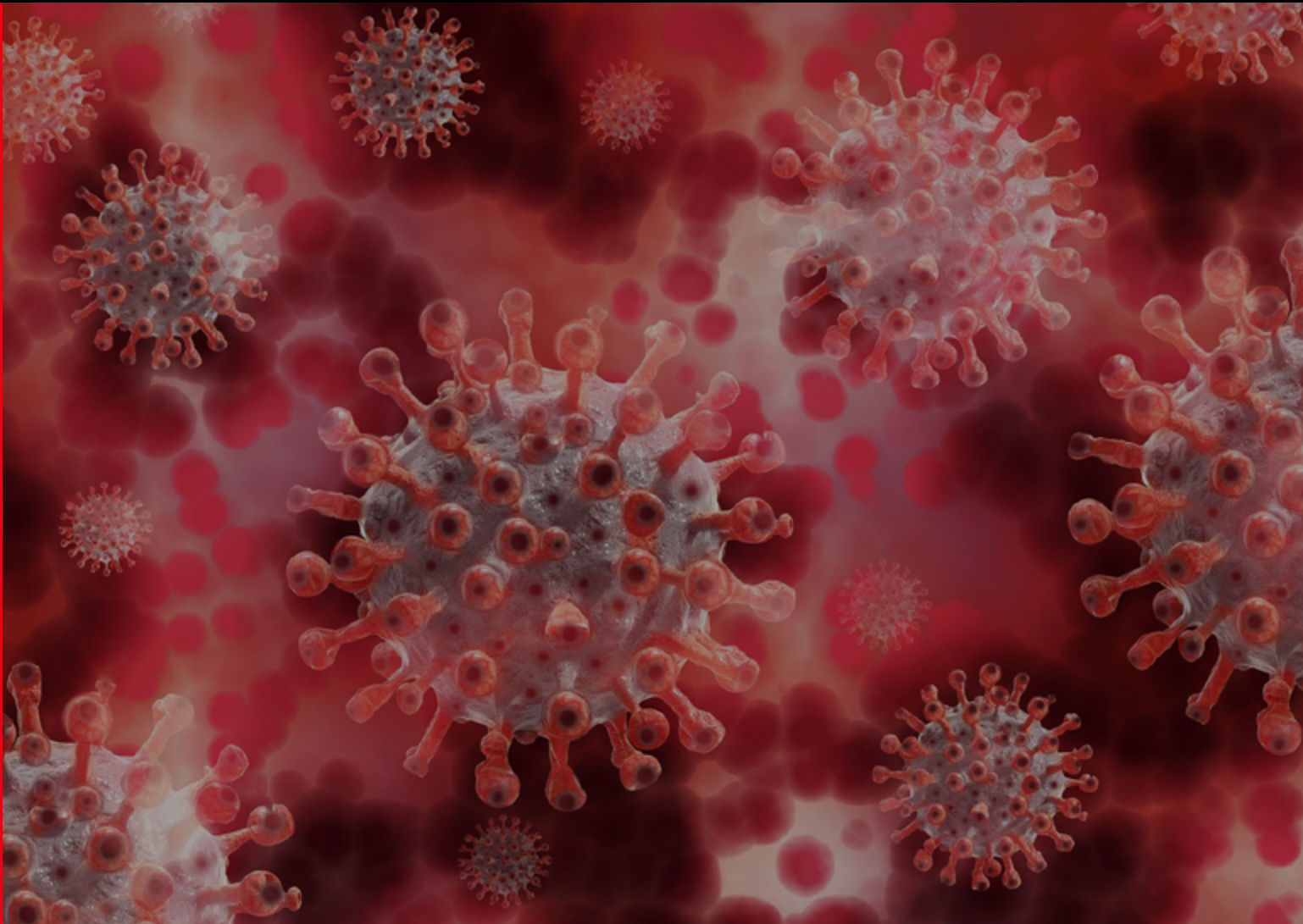


# Coronavirus

Overview on SARS-CoV-2  
detection workflow for research use

Detection Workflow SARS-CoV-2



# Complete Extraction and Detection Workflow

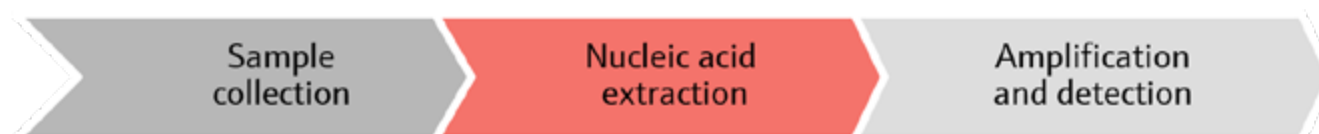
Analytik Jena offers a broad product portfolio in the field of nucleic acid extraction and PCR or real-time PCR with both extraction kits and the necessary equipment.

In December 2019 the novel SARS-CoV-2 (formerly named 2019-nCoV) was identified in Wuhan, the capital of China's province Hubei. Based on its rapid spreading with more than 105,000,000 confirmed cases by beginning of February 2021 the World Health Organization declared the outbreak a public health emergency of international concern<sup>a</sup>.

Basic facts on SARS-CoV-2:

- (+) ss-RNA virus
- Related to SARS-CoV and MERS-CoV
- Detection based on basis of PCR

For research purposes for the detection of SARS-CoV-2 the following workflow is suggested.



## 1. Sample collection

In principle, respiratory material such as nasopharyngeal and oropharyngeal swabs are suitable for the detection of respiratory pathogens. For more detailed information, recommendations of the WHO<sup>b</sup> or other institutions should be observed. Serum can also be used for serological tests, acute and convalescence samples.

## 2. Nucleic acid extraction

Analytik Jena offers a choice of extraction platforms and related extraction kits for extraction of viral RNA from swabs, cell free body fluids (e.g. serum, plasma, cerebrospinal fluid) and more. The product line innuPREP AniPath allows the simultaneous extraction of both bacterial and viral DNA and/or RNA from respective starting materials. A detailed overview is shown in Table 1 below.

Table 1: Overview on Analytik Jena's extraction kits with intended use for isolation of viral RNA.

Handling	Sample throughput	Extraction platform		Extraction kit
		Name	Key features	
Manual	Low	-	Up to 12 samples / 25 min	innuPREP Virus TS RNA Kit innuPREP Virus DNA/RNA Kit
	Middle	InnuPure C16 <i>touch</i>	Up to 16 samples / 31 - 84 min Extraction platform only	innuPREP AniPath DNA/RNA Kit - IPC16, non-filled innuPREP AniPath DNA/RNA Kit - IPC16 innuPREP Virus DNA/RNA Kit - IPC16, non-filled innuPREP Virus DNA/RNA Kit - IPC16
Automated	High	CyBio FeliX	Up to 96 samples / 62 - 73 min Extraction platform + liquid handling (e.g. preparation of PCR)	innuPREP AniPath DNA/RNA Kit - FX <sup>c</sup> innuPREP Virus TS RNA Kit 2.0 - FX innuPREP Virus DNA/RNA Kit - FX
	High	KingFisher Flex	Up to 96 samples / 60 min Extraction platform only	innuPREP AniPath DNA/RNA Kit - KFLX innuPREP RNA Virus PLUS Kit - KFFLX

<sup>a</sup> <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

<sup>b</sup> Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases Interim guidance, WHO, 17 January 2020

<sup>c</sup> Release planned for mid 2021

### 3. Amplification and detection

Molecular assays to detect SARS-CoV-2 have been developed and are accessible through the homepage of the WHO<sup>d</sup>. Furthermore, several commercial kits based on real-time PCR are available. Table 2 below shows all available detection kits which are tested on qTOWER<sup>3</sup> and/or qTOWER<sup>3</sup> 84.

The PCR setup can be pipetted by a liquid handling platform like CyBio Felix. Using PCR workstations or cabinetts offer maximum safety and minimize contamination risks. Single components such as qPCR Master Mixes and Reverse Transcription MasterMix are available via Analytik Jena as well. In general real-time PCR-based assays can be established on real-time thermal cycler of the qTOWER<sup>3</sup> family provided by Analytik Jena or similar.

Please note that products of Analytik Jena GmbH listed here are not explicitly marked as CE IVD and are exclusively intended for research purposes. The validation of the kits was performed by the assay manufacturers themselves on qTOWER devices and was subsequently CE IVD or FDA EUA certified.



Table 2: Overview of molecular detection assays (SARS-CoV-2 detection, SARS-CoV-2 mutation detection only or parallel SARS-CoV-2 and Influenza detection) which are successfully tested on qTOWER<sup>3</sup> and/or qTOWER<sup>3</sup> 84 and/or validated by the assay manufacturer including certification as indicated by footnotes.

Company	Assay Name	Company	Assay Name
<b>Assays detecting SARS-CoV-2</b>		<b>Assays detecting SARS-CoV-2 mutations</b>	
Altona Diagnostic	RealStar® SARS-CoV-2 RT-PCR Kit 1.0 RUO	Shimadzu	2019 Novel Coronavirus Detection Kit
BGI Genomics	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	Siemens healthineers/ Fast-Track Diagnostic	FTD SARS-CoV-2 Assay (RUO)
EuroImmun	EuroRealTime SARS-CoV-2 <sup>e</sup>	SolGent	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit
Fosun Pharma USA	Fosun COVID-19 RT-PCR Detection Kit	TIB MOLBIOL	TIB MOLBIOL LightMix® Modular SARS-CoV-2 (COVID19) RdRP TIB MOLBIOL LightMix® Modular SARS-CoV.2 (COVID19) E-gene
IDEXX	Water SARS-CoV-2 RT-PCR Test	Wells Bio	careGENE™ COVID-19 RT-PCR Kit careGENE™ N-Cov RT-PCR Kit
Ingentix	ViroReal® Kit SARS-CoV-2 & SARS <sup>e</sup>	<b>Assays detecting SARS-CoV-2 and Influenza viruses</b>	
Inno-Train Diagnostik GmbH	Covid-19 FluoGene Q <sup>e</sup>	TIB MOLBIOL	TIB MOLBIOL VirSNIp SARS-CoV-2 Spike 501Y
Mikrogen	ampliCube Coronavirus SARS-CoV-2 ampliCube Coronavirus Panel	Inno-Train Diagnostik GmbH	Covid-19 FluoGene Q N501Y (RUO)
Perkin Elmer	SARS-CoV-2 RT-qPCR Reagent kit New Coronavirus Nucleic Acid Detection Kit <sup>f,9</sup>	<b>Assays detecting SARS-CoV-2 and Influenza viruses</b>	
PrimerDesign	Coronavirus (COVID-19)	EuroImmun	EURORealTime SARS-CoV-2/Influenza A/B <sup>e</sup>
Procomcure Biotech	PhoenixDx® SARS-CoV-2 IVD <sup>e</sup>	Ingentix	ViroReal® Kit SARS Coronavirus & Influenza A/B <sup>e</sup>
R-Biopharm	RIDA®GENE SARS-CoV-2 RUO	Mikrogen	ampliCube Respiratory Flu & SARS-CoV-2
RTA Laboratories	Diagnovital SARS-CoV-2 Multiplex <sup>h</sup>	R-Biopharm	RIDA®GENE Flu & SARS-CoV-2 RUO
Seegene	Allplex™ 2019-nCoV Assay		

<sup>d</sup> <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>

<sup>e</sup> CE IVD (qTOWER<sup>3</sup>)

<sup>f</sup> FDA EUA (qTOWER<sup>3</sup>)

<sup>g</sup> FDA EUA (qTOWER<sup>3</sup> 84)

<sup>h</sup> FDA EUA (qTOWER<sup>3</sup>) pending

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