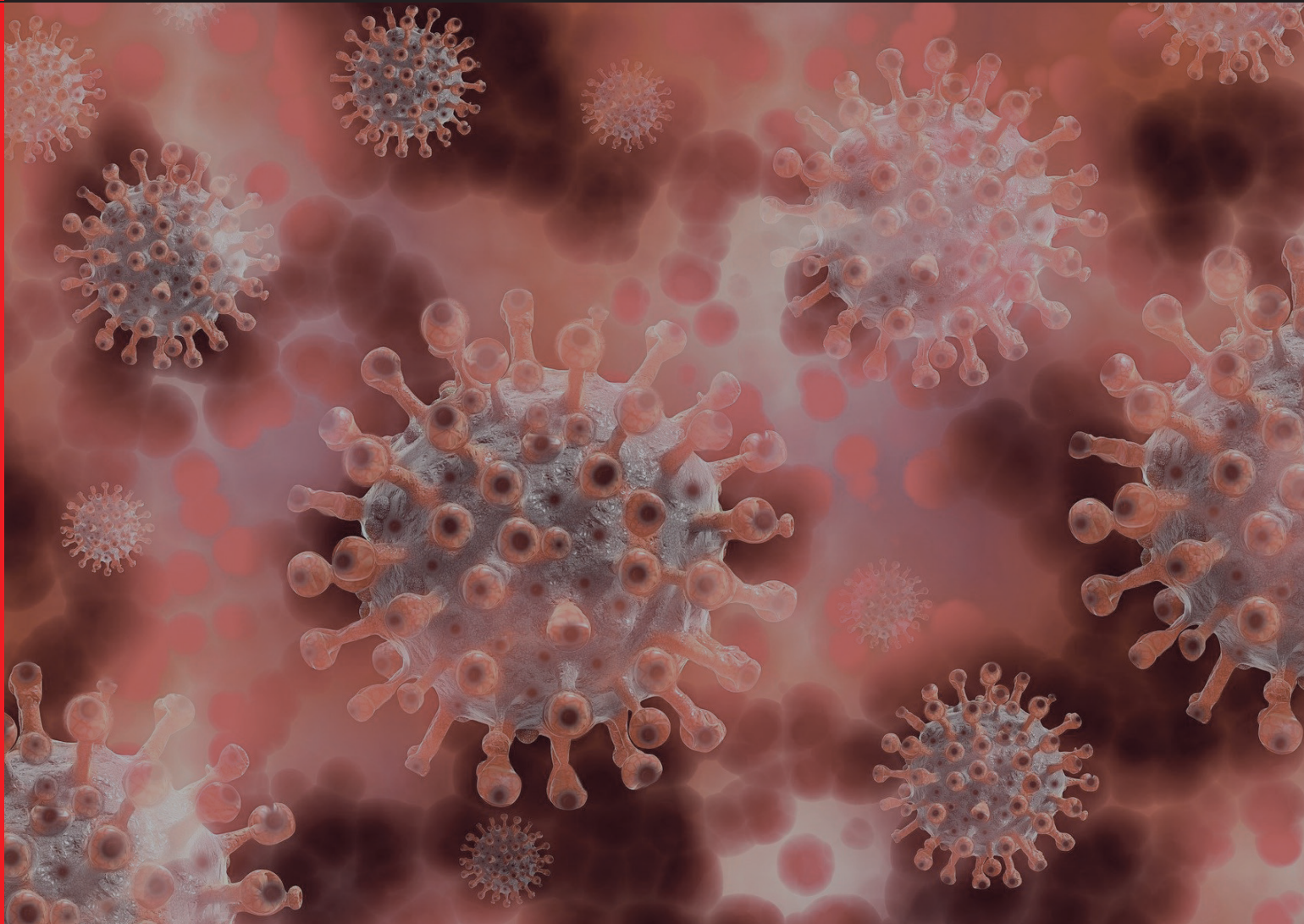


# Coronavirus

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

Detection Workflow SARS-CoV-2



# Complete Extraction and Detection Workflow

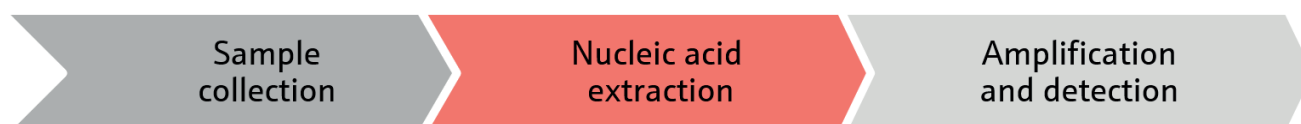
Analytik Jena offers a broad product portfolio in the field of nucleic acid extraction and PCR or real-time PCR with both extraction kits and the necessary equipment.

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 the liquid handling platforms InnuPure C16 touch and CyBio FeliX for automated nucleic acid extraction according to sample throughput. For both system extraction procedures for dedicated virus DNA/RNA extraction kits have been established and ready-to-use extraction protocols are included in the pre-installed software. A detailed overview is shown in Table 1 below.

Table 1: Overview on Analytik Jena's liquid handling platforms for automated nucleic acid extraction with corresponding pre-established kits for extraction of virus DNA/RNA.

| Sample throughput | Extraction platform                      |   | Ready-to-use protocols for corresponding extraction kits. <sup>d</sup>   |                 |
|-------------------|--|---|--|-----------------|
|                   | Name                                     | Key features  | Extraction kit   | Kit supplier    |
| Middle            | InnuPure C16 <i>touch</i>                | Up to 16 samples / 31 - 84 min<br>Closed extraction system for dedicated extraction kits only   | innuPREP AniPath DNA/RNA Kit - IPC16, non-filled<br>innuPREP AniPath DNA/RNA Kit - IPC16<br>innuPREP Virus DNA/RNA Kit - IPC16, non-filled<br>innuPREP Virus DNA/RNA Kit - IPC16 | Innuscreen GmbH |
| High              | CyBio FeliX & CyBio FeliX Extraction Set | Up to 96 samples / 62 - 73 min<br>Open extraction platform with dedicated pre-established extraction kits<br>Open liquid handling platform (e.g. qPCR setup, serial dilution) | innuPREP AniPath DNA/RNA Kit - FX <sup>c</sup><br>innuPREP Virus TS RNA Kit 2.0 - FX<br>innuPREP Virus DNA/RNA Kit - FX  | Innuscreen GmbH |

<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 autumn 2021

<sup>d</sup> Please note that extraction kits are available via the corresponding supplier.

### 3. Amplification and detection

Molecular assays to detect SARS-CoV-2 have been developed and are accessible through the homepage of the WHO<sup>e</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. 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   |
|------------------------------------|--|
| <b>Assays detecting SARS-CoV-2</b> |  |
| Altona Diagnostic                  | RealStar® SARS-CoV-2 RT-PCR Kit 1.0 RUO  |
| BGI Genomics                       | Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV                                |
| EuroImmun                          | EuroRealTime SARS-CoV-2 <sup>f</sup>   |
| Fosun Pharma USA                   | Fosun COVID-19 RT-PCR Detection Kit  |
| IDEXX                              | Water SARS-CoV-2 RT-PCR Test   |
| Ingentix                           | ViroReal® Kit SARS-CoV-2 & SARS <sup>f</sup>   |
| Inno-Train Diagnostik GmbH         | Covid-19 FluoGene Q <sup>f</sup>   |
| Mikrogen                           | ampliCube Coronavirus SARS-CoV-2<br>ampliCube Coronavirus Panel                              |
| Perkin Elmer                       | SARS-CoV-2 RT-qPCR Reagent kit<br>New Coronavirus Nucleic Acid Detection Kit <sup>g, h</sup> |
| PrimerDesign                       | Coronavirus (COVID-19)   |
| Procomcure Biotech                 | PhoenixDx® SARS-CoV-2 IVD <sup>f</sup>   |
| R-Biopharm                         | RIDA®GENE SARS-CoV-2 RUO   |
| RTA Laboratories                   | Diagnovital SARS-CoV-2 Multiplex <sup>i</sup>  |
| Seegene                            | Allplex™ 2019-nCoV Assay   |

| Company  | Assay Name   |
|--|--|
| Shimadzu   | 2019 Novel Coronavirus Detection Kit   |
| Siemens healthineers/<br>Fast-Track Diagnostic           | FTD SARS-CoV-2 Assay (RUO)   |
| SolGent  | DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit   |
| TIB MOLBIOL  | TIB MOLBIOL LightMix® Modular SARS-CoV-2 (COVID19) RdRP<br>TIB MOLBIOL LightMix® Modular SARS-CoV.2 (COVID19) E-gene |
| Wells Bio  | careGENE™ COVID-19 RT-PCR Kit<br>careGENE™ N-Cov RT-PCR Kit  |
| <b>Assays detecting SARS-CoV-2 mutations</b>             |  |
| TIB MOLBIOL  | TIB MOLBIOL VirSnIP SARS-CoV-2 Spike 501Y  |
| Inno-Train Diagnostik GmbH                               | Covid-19 FluoGene Q N501Y (RUO)  |
| <b>Assays detecting SARS-CoV-2 and Influenza viruses</b> |  |
| EuroImmun  | EURORealTime SARS-CoV-2/Influenza A/B <sup>f</sup>   |
| Ingentix   | ViroReal® Kit SARS Coronavirus & Influenza A/B <sup>f</sup>  |
| Mikrogen   | ampliCube Respiratory Flu & SARS-CoV-2   |
| R-Biopharm   | RIDA®GENE Flu & SARS-CoV-2 RUO   |

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

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

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

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

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

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Subject to changes in design and scope of delivery as well as further technical development.

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