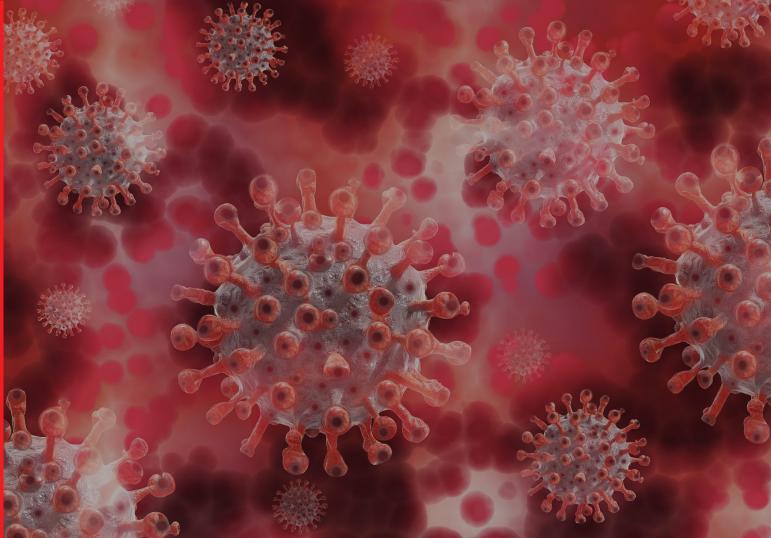
Coronavirus

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





Complete Extraction and Detection Workflow

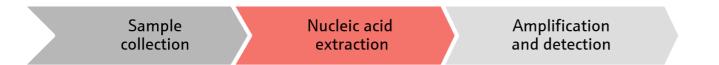
Analytik Jena offers a broad product portfolio in the field of nucleic acid extraction and PCR or real-time PCR with both extraction kits and the necessary equipment.

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^a.

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^b 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 plaforms InnuPure C16 touch and CyBio FeliX for automated nucleic acid extraction according to sample throughput. For both systemsextraction procedures for dedicated virus DNA/ RNA extraction kits have been established and ready-touse 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 | Extraction platform | | Ready-to-use protocols for corresponding extraction kits. ^d | |
|------------|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| throughput | Name | Key features | Extraction kit | Kit supplier |
| Middle | InnuPure C16 touch | Up to 16 samples / 31 - 84 min Closed extraction system for dedicated extraction kits 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 | Innuscreen GmbH |
| High | CyBio FeliX & CyBio FeliX Extraction Set | Up to 96 samples / 62 - 73 min Open extraction platform with dedicated pre-established extraction kits Open liquid handling platform (e.g. qPCR setup, serial dilution) | innuPREP AniPath DNA/RNA Kit - FX ^c innuPREP Virus TS RNA Kit 2.0 - FX innuPREP Virus DNA/RNA Kit - FX | Innuscreen GmbH |

^a https://www.who.int/emergencies/diseases/novel-coronavirus-2019

^b Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases Interim guidance, WHO, 17 January 2020 ^c Release planned for autumn 2021

^d 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^e. Furthermore, several commercial kits based on real-time PCR are available. Table 2 below shows all available detection kits which are tested on qTOWER³ and/or qTOWER³ 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 qTOWER³ 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.

CoV-2 and Influenza detection) which are successfully tested on qTOWER³ and/or qTOWER³ 84 and/or validated by the assay manufacturer including certification as indicated by footnotes.

| Company | Assay Name | | | |
|---------------------------------------------|---------------------------------------------------------------------------------------------|--|--|--|
| Assays detecting SARS-CoV-2 | | | | |
| 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 | | | |
| Eurolmmun | EuroRealTime SARS-CoV-2 ^f | | | |
| 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 ^f | | | |
| Inno-Train Diagnostik GmbH | Covid-19 FluoGene Q ^f | | | |
| Mikrogen | ampliCube Coronavirus SARS-CoV-2 / ampliCube Coronavirus Panel | | | |
| Perkin Elmer | SARS-CoV-2 RT-qPCR Reagent kit / New Coronavirus Nucleic Acid Detection Kit ^{9, h} | | | |
| PrimerDesign | Coronavirus (COVID-19) | | | |
| Procomcure Biotech | PhoenixDx [®] SARS-CoV-2 IVD ^f | | | |
| R-Biopharm | RIDA®GENE SARS-CoV-2 RUO | | | |
| RTA Laboratories | Diagnovital SARS-CoV-2 Multiplex ⁱ | | | |
| Seegene | Allplex™ 2019-nCoV Assay | | | |
| Shimadzu | 2019 Novel Coronavirus Detection Kit | | | |
| Siemens healthineers/ 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 / | | | |
| | TIB MOLBIOL LightMix [®] Modular SARS-CoV.2 (COVID19) E-gene | | | |
| Wells Bio | careGENE™ COVID-19 RT-PCR Kit / careGENE™ N-Cov RT-PCR Kit | | | |

tps://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance f CE IVD (aTOWER³) 9 FDA EUA (qTOWER³)

^h FDA EUA (qTOWER³ 84) ¹FDA EUA (qTOWER³) pending



Table 2: Overview of molecular detection assays (SARS-CoV-2 detection, SARS-CoV-2 mutation detection only or parallel SARS-

| Company | Assay Name | | | |
|-----------------------------------------------|-------------------------------------------------------------------------|--|--|--|
| Assays detecting SARS-CoV-2 mutations | | | | |
| TIB MOLBIOL | TIB MOLBIOI VirSNiP SARS-CoV-2 Spike 501Y | | | |
| Inno-Train Diagnostik GmbH | Covid-19 FluoGene Q N501Y (RUO) | | | |
| Assays detecting SARS-CoV-2 and Influenza v | iruses | | | |
| Eurolmmun | EURORealTime SARS-CoV-2/Influenza A/B ^f | | | |
| Ingentix | ViroReal [®] Kit SARS Coronavirus & Influenza A/B ^f | | | |
| Mikrogen | ampliCube Respiratoty Flu & SARS-CoV-2 | | | |
| R-Biopharm | RIDA®GENE Flu & SARS-CoV-2 RUO | | | |
| Assays particularly tested for wastewater sam | nples* | | | |
| Eurolmmun | EuroRealTime SARS-CoV-2 | | | |
| IDEXX | Water SARS-CoV-2 RT-PCR Test | | | |
| Inno-Train Diagnostik GmbH | Covid-19 FluoGene Q | | | |
| Inno-Train Diagnostik GmbH | Covid-19 FluoGene Q N501Y (RUO) | | | |
| Zymo Research | Quick SARS-CoV-2 Multiplex Kit | | | |

* Wastewater samples were preparaed according to the workflow established by Analytik Jena. Real-time PCR using the indicated assay was implemented on qTOWER³.

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More Information ►

www.analytik-jena.com/cov

