One-stop solutions for SARS-CoV-2 diagnostics

From extraction to detection

INVITEK Molecular

ALS Oligonucleotides

Products for SARS-CoV-2 diagnostics - from extraction to detection

ALS Life Sciences Portugal and Invitek Molecular are highly dedicated to the development of innovative biotechnological solutions. Together, both companies offer a comprehensive portfolio of SARS-CoV-2 viral RNA extraction and detection solutions to meet the demands of clinical diagnostics and research. Invitek is expert in nucleic acid extraction since almost 30 years and offers high quality kits, for manual as well as for automated viral RNA extraction. ALS Life Sciences Portugal offers SARS-CoV-2 RT-PCR and RT-LAMP detection kits for human diagnostics (CE-IVD) and environmental testing, particularly surface swab, and wastewater samples, as there is an increasing concern in monitoring the presence of SARS-CoV-2 in the environment.

- CE-certified products, recommended for in-vitro diagnostic use (IVD)
- One-stop solution
- Fast and easy protocols

RNA Extraction from upper respiratory tract samples

The Universal and Ready-to-Prep (RTP®) product lines for infectious diseases cover all requirements of daily laboratory routine and guarantee an excellent performance in all downstream applications such as Real-Time PCR.

1. Ready-To-Prep - RTP® Pathogen Kit

- One-step sample lysis with lyophilized extraction buffer containing Proteinase K/Lysozyme and Carrier RNA
- Simplifies manual extraction: Save handling steps, waste, and time compared to traditional manual extraction protocols

Extraction Tube
with lyophilized components

- Lysis Buffer
- Proteinase K / Lysozyme
- Carrier nucleic acids

- stable at RT

2. Universal Kit series - Invisorb® Spin Universal Kit & InviMag® Universal Kit/KF96

- For every lab: From manual (spin column) to fully automated (magnetic beads) purification
- High throughput: established protocols available for common extraction platforms such as the KingFisher™ Flex (Thermo Scientific)

SARS-CoV-2 detection

For all ALS SARS-CoV-2 detection kits the choice of the genomic regions used as targets and the sequences of the primers and probes were based on WHO, CDC and DGS recommendations. All kits can detect all known SARS-CoV-2 variants.

Kit	**ALS SARS-CoV-2 RT-LAMP Kit** (CE-IVD)	**ALS SARS-CoV-2 RT-PCR 4G** (CE-IVD)	**ALS SARS-CoV-2 Multiplex RT-PCR Test** (CE-IVD)	**ALS SARS-CoV-2 RT-PCR Test for Surfaces** (RUO)	**ALS SARS-CoV-2 RT-PCR Test for Wastewater** (RUO)
Sample type	native respiratory or extracted RNA from clinical samples	clinical samples from the upper respiratory tract	clinical samples from the upper respiratory tract	surface swabs	wastewater
Target	Nsp3 gene (located in the ORF1ab region) and the N gene	ORF1ab and N genes (specific for SARS-CoV-2); E gene (*Sarbecovirus* subgenus); RNase P (human endogenous control gene for full-process monitoring)	RdRp and N genes (specific for SARS-CoV-2); RNase P (human endogenous control gene for full-process monitoring)	RdRp and N genes (specific for SARS-CoV-2); Internal Amplification Control (IAC) to exclude false negatives due to PCR inhibition	N gene (specific for SARS-CoV-2); Infectious Bronchitis Virus (IBV), used as extraction control
Technique	LAMP	Real-Time PCR	Real-Time PCR	Real-Time PCR	Real-Time PCR
Operation/ Detection	colorimetric and fluorimetric	compatible with open qPCR platforms	compatible with open qPCR platforms	compatible with open qPCR platforms	compatible with open qPCR platforms
Sensitivity	LOD = 10 copies/µL	LOD = 2.5 copies/µL	LOD = 10 copies/µL	LOD = 10 copies/µL	LOD = 100 copies/100 ml

The ALS SARS-CoV-2 RT-LAMP Kit is an especially easy and ready-to-use solution, that can be used as a screening method for individuals with or without suspected COVID-19 disease, and as an alternative to Real-Time PCR-based methods for diagnosing COVID-19.

- Results obtained in 40 min. (colorimetric)
- Simple colorimetric visualization of results
- Suitable for point-of-care
- No need of expensive equipment
- Comparable sensitivity/sensibility to RT-PCR

ALS SARS-CoV-2 RT-PCR 4G and **ALS SARS-CoV-2 Multiplex RT-PCR** kits are in vitro diagnostic medical devices (CE-IVD) that use real-time PCR nucleic acid amplification technology for the detection of SARS-CoV-2 in clinical samples. Both kits provide results in about 1 hour with optimized amplification protocols.

These kits must be used by properly trained health professionals and laboratory technicians with specific training in IVDs, in clinical labs or in hospital or clinical settings.

The **ALS SARS-CoV-2 RT-PCR 4G** kit simplifies lab routine with its inert plate loading dye to avoid pipetting errors and allows for improved detection efficiency.

The **ALS SARS-CoV-2 RT-PCR Test for Surfaces** and the **ALS SARS-CoV-2 RT-PCR Test for Wastewater** kits are two solutions that can help trained laboratory technicians on SARS-CoV-2 continuous monitoring.

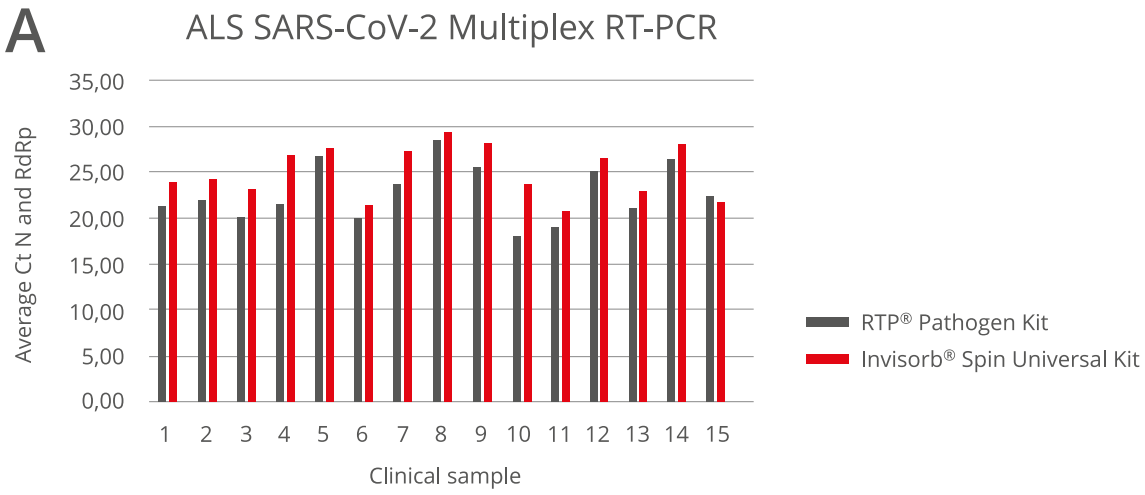
Systematic surveillance of SARS-CoV-2, especially in wastewater, is very helpful in evaluating the effectiveness of measures taken to mitigate virus transmission, as published in the EU Commission Recommendation (EU)2021/472.

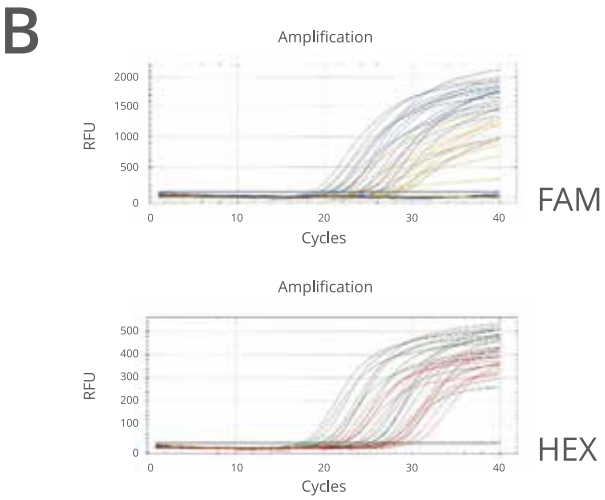
Environmental surveillance allows regular monitorization of the community, detection of asymptomatic individuals, anticipation and/or identification of outbreaks, reduction of testing costs, and finally, a quick activation of contingency plans.

Clinical performance evaluation

The diagnosis of COVID-19 in human upper respiratory tract clinical samples has been performed using the ALS SARS-CoV-2 Multiplex RT-PCR test kit. Total viral RNA was extracted with the RTP® Pathogen and Invisorb® Spin Universal kits, using 400 µL and 200 µL of starting material, respectively.

Detection of SARS-CoV-2 viral RNA extracts by real-time PCR was performed using 5 µL of total RNA eluate. The results obtained demonstrate 100% agreement with the expected results, and both COVID-19 positive and negative samples could be reliably detected regardless of the extraction method used and clinical samples viral load.





COVID-19 diagnosis in human upper respiratory tract clinical samples using the ALS SARS-CoV-2 Multiplex RT-PCR Test kit.

A: Average Ct of N- and RdRP-Genes for positive SARS-CoV-2 samples extracted with RTP® Pathogen and Invisorb® Spin Universal kits. (Twice the sample volume was extracted with the RTP® Pathogen Kit.)

B: PCR amplification curves for the RdRp-Gene in FAM (RTP® Pathogen: blue, Invisorb® Spin Universal: yellow) and for the N-Gene in HEX (RTP® Pathogen: green, Invisorb® Spin Universal: red).

Ordering Information

Product	Package size	Catalogue number
RNA extraction kits		
RTP® Pathogen Kit (CE-IVD)	50 preps 250 preps	1040500200 1040500300
Invisorb® Spin Universal Kit (CE-IVD)	50 preps 250 preps	1050100200 1050100300
InviMag® Universal Kit/ KF96 (CE-IVD) (for use on KingFisher™ 96 and KingFisher™ Flex, Thermo Fisher Scientific)	5 x 96 preps	7450300200
InviMag® Universal Kit/ KF96 w/o plastic (CE-IVD) (for use on KingFisher™ 96 and KingFisher™ Flex, Thermo Fisher Scientific, without KingFisher™ plastic)	5 x 96 preps	7450300250
Real-Time PCR kits		
ALS SARS-CoV-2 RT-LAMP (CE-IVD)	100 reactions	6010003200
ALS SARS-CoV-2 RT-PCR 4G (CE-IVD)	100 reactions	6010002200
ALS SARS-CoV-2 Multiplex RT-PCR Test (CE-IVD)	100 reactions	6010001200
ALS SARS-CoV-2 RT-PCR Test for Surfaces (RUO)	100 reactions	6011001200
ALS SARS-CoV-2 RT-PCR Test for Wastewater (RUO)	100 reactions	6011002200

For more information and data on the Invitek Molecular products for Infectious diseases, please see the brochure.

For more information and data on the ALS Life Sciences Portugal products, please visit https://alsmolecular.com/

CE IVD

Compliance with EU Directive 98/79/EC on in vitro medical devices.
Not for in-vitro diagnostic use in countries where the EU Directive 98/79/EC on in vitro medical devices is not recognized.

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