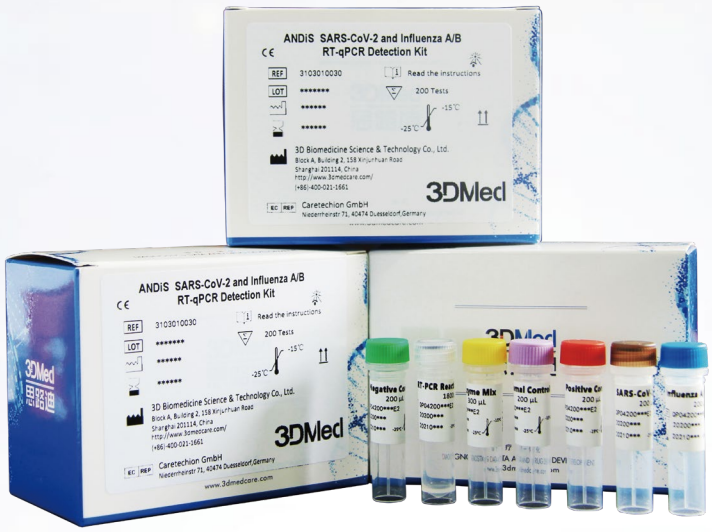
ANDiS SARS-CoV-2 and Influenza A/B RT-qPCR Detection Kit

Concomitant detection of SARS-CoV-2 and Flu-A/B

CE

3DMed

Intended Use: Presumptive qualitative detection of RNA from SARS-CoV-2 (2019-nCoV) and infuenza A/B in specimens from individuals suspected of COVID-19 by their healthcare provider.



THE CHALLENGES

- **Differential Diagnosis:** Since COVID-19 symptoms can be easily confused for other respiratory infections, diagnostics are urgently needed to distinguis SARS-CoV-2 from influenza A/B virus.

- **High Throughput:** With the rapid spread ofCOVID-19, conventional manual nucleic acid extraction can hardly support rapid high-throughput testing.

OUR SOLUTION

- **Multi-target** design to minimize mis-detection.
- **Inclusion of Flu A/B** as targets to facilitate differentiation between COVID-19 and Flu A/B.
- **No cross-reaction** with SARS-CoV or MERS-CoV.

The ANDiS 350 Automated Nucleic Acid Extraction System & the ANDi SARS-CoV-2 and Influenza A/B RT-qPCR Detection Kit increase daily throughput by 5-25 times.

THE IMPACT

• **Multi-target:** With the aim of minimizing false calling, primers and probes are designed to simultaneously target sequences specific of SARS-CoV-2 (ORF1ab and N gene), Flu A (M gene), and FluB (NP gene) in one single assay.

• **LoD= 50 copies/mL:** SARS-CoV-2 could be present at very low viral titers in some specimens,especially those collected from patients with early infection. A virus detection assay with high sensitivity can significantly reduce false negative.

• **Real-world clinical evaluation:** RNA samples extracted from 282 clinical specimens were sent for SARS-CoV-2 testing using both next generation sequencing (NGS) and the ANDiS SARS-CoV-2 and Influenza A/B RT-qPCR Detection Kit. The performance of the kit was evaluated against NGS.

		ANDiS SARS-CoV-2 and Influenza A/B RT-PCRDetection Kit		
		Positive	Negative	Total
Genetic Sequencing result	Positive *	133	1	134
	Negative	0	148	148
	Total	133	149	282
PPA		99.3% [133/(133+1)]		
NPA		100.0% [148/(0+148)]		

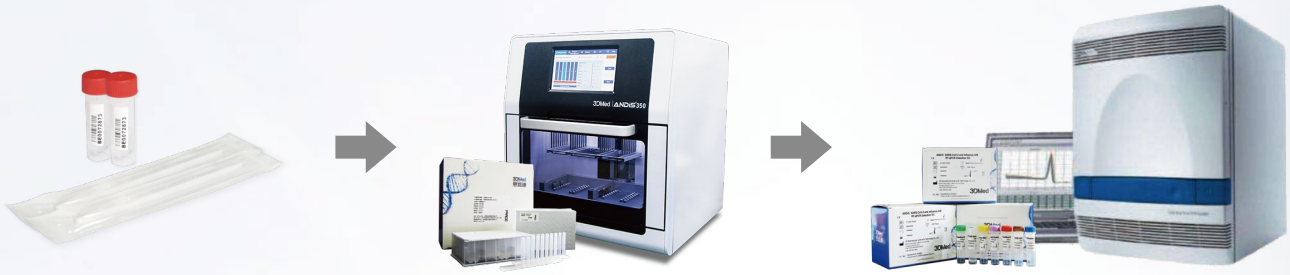
* Read No. requirement: ⩾3 positive reads

• **Inclusivity and specificity:** The test covers 100% of the known SARS-CoV-2 sequences based on NCBI & GISAID database as of February 20, 2020. No cross-reaction was observed with other pathogens commonly found in respiratory specimens.

• **Multiple controls:** A positive control and a negative control are included in each run to ensure that the assay is working properly and to identify potential reagent contamination, respectively. An internal control is included in each reaction to monitor reverse transcription and PCR amplification.

WORKFLOW

The ANDiS SARS-CoV-2 and Influenza A/B RT-qPCR Detection Kit is recommneded to be used in conjunction with the ANDiS 350 Automated Nucleic Acid Extraction System (or QIAamp DSP Viral RNA Mini Kit) and the ABI 7500 Real-Time PCR Instrument. Otherwise, a real-time PCR instrument capable of detecting FAM, ROX, VIC, CY5 and TAMRA is required.



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Technology

Real-time Quantitative Polymerase Chain Reaction (qPCR)

Components

- RT-qPCR Reaction Mix
- Enzyme Mix
- SARS-CoV-2 Assay
- Influenza A/B Assay
- Positive Control, Negative Control and Internal Control

Required Materials (not included)

- RNA Extraction & Purification
- ANDiS 350 Automated Nucleic Acid Extraction System (Instrument + Reagents)
- Or QIAamp DSP Viral RNA Mini Kit
- ABI 7500 Real-Time PCR System (or equivalent)
- Other laboratory supplies for molecular testing
- Personal Protective Equipment

Website WeChat

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