# COVID-2019 RNA Detection kit ( Fluorescent PCR)

## Directive 98/79/EC on Vitro Diagnostic Medical device / CE / Non-Sterile /Medical

## ILB-Product ID-No.: TK DAJ


| Item | Details | Remark |
|---|---|---|
| China Ministry of Commerce White List Producer | Yes | **CE / WHO Emergency use listing of IVDs** |
| CE Certificate | Medical Device Safety Service | **EC-REP** |
| Test Report by | National Institution of Food and Drug Control, China | **CNAS approved Testing lab** |
| Applied standard | **Directive 98/79/EC on Vitro Diagnostic Medical device** | |
| Factory ISO Certificates | **ISO 13485** | |
| Product classification | medical Use | |
| Packaging | 96 pcs / box<br>70 boxes / ctn<br>30 kg / ctn | |

**2019 Novel Coronavirus (2019-nCoV) RNA Detection kit (Fluorescent PCR)**

This product is a qualitative in vitro nucleic acid amplification assay used to detect SARS-CoV-2. The kit is widely used for rapid detection and outbreak control of COVID-19 in China. It's also a WHO Emergency Use Listing of IVD products. Medical Device Safety Service is EU Representative, and the test report is done by National Institution of Food and Drug Control, China.

## TECHNICAL SPECIFICATIONS

- CE EC-REP
- With its high specificity, sensitivity and rapid response
- It can effectively assist the diagnosis of disease and improve the diagnosis efficiency.
- This test needs to be carried out by medical staff only in the hospital PCR laboratory.
- Applicable instruments: Throat Swap, RNA extraction kit, Polymerase chain reaction machine, ABI Prism 7500 Sequence Tection System, Roche LightCycler 480 Instrument Operator, etc
- Accuracy of testing: 99.9%
- Valid Period: -20±5℃，6 months
- Packing unit: box with 96 tests, 70 box in one carton