

COVID-19 Nucleic Acid Detection Solution





Principle

The kit is used to qualitatively detect the S gene and N gene of the new coronavirus from the suspected cases of pneumonitis, patients with suspected clustering cases, and other kinds of pharyngeal swabs and sputum samples from patients undergoing diagnosis or differential diagnosis of new coronavirus infection.

The samples could be the throat swab, sputum, alveolar lavage fluid or stool.

Application

At present, the Automatic Nucleic Acids Detection System and supporting detection kits are used in CDCs and some clinical units in China.

There has more than 30 sets of the system installed in the hospitals and clinical units. And LifeReal supplies around 5000 tests per day.





Innovation advantages



The sealed kit to prevent the detection of pathogen leakage, reduce contact with infectious samples, and protect medical personnel



manual sample operation in 2 minutes, training to the medical staff just in 10 minutes



No PCR laboratory is required, no contamination



critical state multiphase microfluidic technology is used to effectively improve the efficiency of nucleic acid extraction, and the sensitivity is high up to 50 virus copies.

Validated clincial data by Chinese authoritative institute

(January 24, 2020-February 02, 2020)

| Sample type | Specimen quantity | | | |
|----------------------|-------------------|----------|-------|--|
| | Positive | Negative | Total | |
| Throat swab | 27 | 106 | 133 | |
| Nasal swab | 4 | 5 | 9 | |
| Sputum | 7 | 16 | 23 | |
| Lung Lavage fluid | 3 | 0 | 3 | |
| Nucleic acid extract | 1 | 0 | 1 | |
| Total | 42 | 127 | 169 | |

The test results of the instrument's verification kit are in complete agreement with the confirmed and excluded results from the clinical diagnosis.

The sensitivity, specificity, and total coincidence rate of the kit detection method and the clinical diagnosis method are all 100%, indicating that the consistency of the two detection methods is good.

> Workflow



Judgment result



GMP Workshop



GMP standard class 100,000 clean workshop automatic filling production line ISO13485 certified

CE IVD Certification



AIGS in German: DECA5919352019-RFs





AIGS in German: DE202018006254 AIGS in China: 2017 1 0428548.X, 2017 1 0429121.1, 2017 1 0863330.7

Order No.& specifications

AIGS Instrument

| Model/Order No. | LifeReady 1000 | | | | |
|-------------------------------|---|--|--|--|--|
| Sample capacity | 4 Samples | | | | |
| Block temperature range | 40°C-99. 9℃ | | | | |
| Block temperature fluctuation | ≤±0. 5°C | | | | |
| Block temperature accuracy | ≪0. 5°C | | | | |
| Temperature display accuracy | 0. 1°C | | | | |
| Dyes | F1: FAM,SYBR Green I;F2:HEX,VIC; F3: TAMRA,CY3;F4: TEX RED,ROX;F5: Cy5 | | | | |
| Data connector | USB,WiFi | | | | |
| Size | 380mm*305mm*343mm | | | | |

Detection Kit

| Name | Storage | Package | Order. No | Note |
|--|---------|---------|-----------|-------------------------------------|
| COVID-19 nucleic acid POCT detection kit (AIGS real-time fluorescent PCR method) | 2-8°C | 24T | C0011-E | AIGS-LifeReady 1000 |
| COVID-19 nucleic acid detection kit(Real-time fluorescent PCR method) | -20°C | 96T | C0011-b | Traditional realtime PCR machine |





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