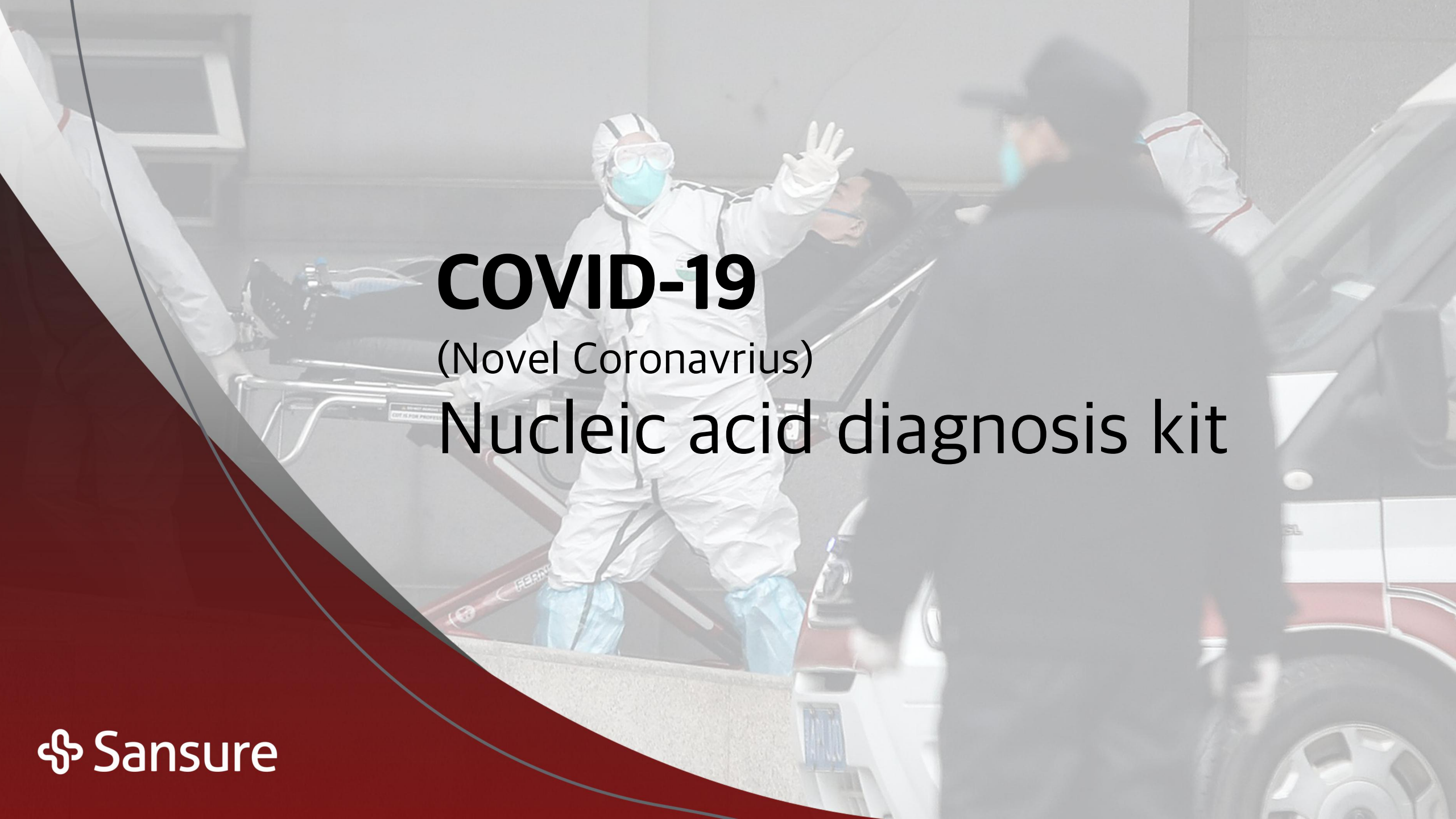


COVID-19

(Novel Coronavrius)

Nucleic acid diagnosis kit

Sansure

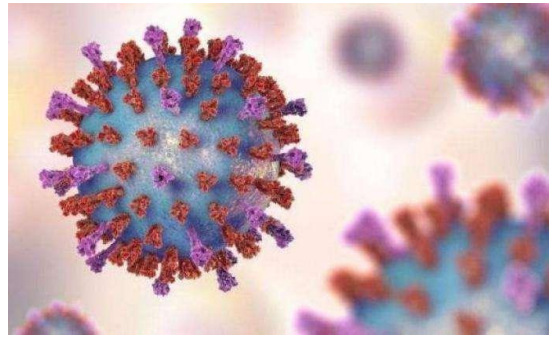
About the coronaviruses

01

Recognize coronaviruses

- Single-stranded positive-strand RNA virus, Orthocoronavirinae of the family Coronaviridae of the order Nidovirales.

- Divided into four genera α, β, γ, and δ.



- Can infect many species

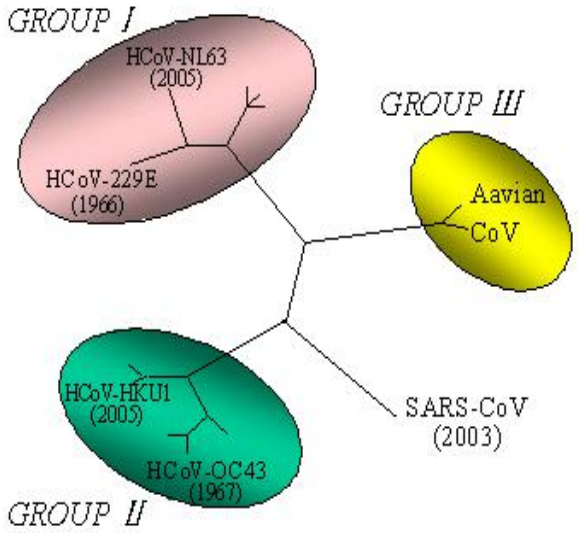
✓ Bat, dog, pig, mouse, bird, cow, whale, horse, goat, monkey, etc.

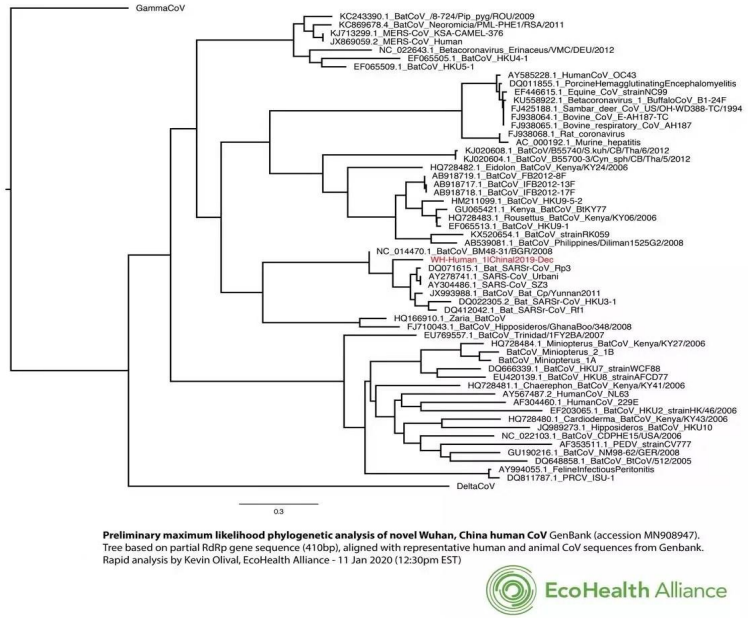
✓ Human.

- Sensitive to heat and UV-ray, it can be also effectively inactivated by 56 ℃ for 30 minutes, ether, 75% ethanol, chlorine-containing disinfectant, lipid solvents such as peracetic acid and chloroform.

Six known coronaviruses that infect humans

- Alpha 229E, NL63.
- β-OC43, HKU1,
  MERSr-CoV, SARSr-CoV.
- HKU1, SARS-CoV,
  MERS-CoV: May cause pneumonia.
- This is a new type of coronavirus
  (β gene)
  (WHO named COVID-19).





Preliminary maximum likelihood phylogenetic analysis of novel Wuhan, China human CoV GenBank (accession MN908947).
Tree based on partial RdRp gene sequence (410bp), aligned with representative human and animal CoV sequences from Genbank.
Rapid analysis by Kevin Olival, EcoHealth Alliance - 11 Jan 2020 (12:30pm EST)

EcoHealth Alliance

Features of COVID-19 infection cases

Epidemiological characteristics

- ✓ At present, most patients are centralized in Wuhan.
- ✓ Some cases are clustered in families.

Clinical manifestation

- ✓ Fever, fatigue, respiratory symptoms are mainly dry cough, and gradually have difficulty breathing. In severe cases, acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis and coagulopathy.
- ✓ Some patients have mild onset symptoms without a fever.
- ✓ Most patients have a good prognosis, and a few patients are critically ill and even die.

Features of COVID-19 infection cases

Existing data display

- ✓ The median time from incubation period to symptom appearance is 9 days
- ✓ In some cases, the disease spread rapidly, and the onset of dyspnea is only about 7 days.
- ✓ Covering all age of the patients
- ✓ Critical illness accounts for about 15%. Most of them are elder people with basic diseases and obesity.

Features of COVID-19 infection cases

laboratory examination

- ✓ In the early stage of the disease, the total number of leukocytes was normal or decreased, and the lymphocyte count was decreased.
- ✓ The liver enzyme, muscle enzyme, and myoglobin increased in some patients.
- ✓ In most patients, C-reactive protein and ESR increased, and procalcitonin was normal. D-dimer increased in severe cases.
- ✓ The samples of the upper respiratory tract (including nasopharynx and oropharynx) and lower respiratory tract (including sputum, endotracheal aspirates or bronchoalveolar lavage fluid) were collected and the COVID-19 was detected by RT-PCR.
- ✓ Serology is recommended for diagnosis when RT-PCR is not available.

Differential diagnosis

- ✓ It is mainly distinguished from other known viral pneumonia such as influenza virus, parainfluenza virus, adenovirus, respiratory syncytial virus, rhinovirus, human metapneumovirus, SARS, MERS virus, etc.
- ✓ It should also be distinguished from non-infectious diseases such as vasculitis, dermatomyositis, and organizing pneumonia.

COVID-19 worldwide

South Korea

Till 9 am on 26th, Feb, 169 new cases of COVID-19 infection had been tested in South Korea, with a total of 1146 confirmed cases, 11 deaths and 22 cured cases, the Ministry of the central anti-epidemic strategy of South Korea announced.

구분	총계	확진환자현황				검사현황		
		계	격리해제	격리 중	사망	계	검사 중	결과 음성
2.25.(화) 16시 기준	40,304	977	22	945	10	39,327	13,880	25,447
2.26.(수) 09시 기준	46,127	1,146	22	1,113	11	44,981	16,734	28,247
증감	+5,823	+169	0	+168	+1*	+5,654	+2,854	+2,800

COVID-19 worldwide

Japan

According to NHK reported, There were 11 new COVID-19 infections cases on the 25th. Till 26th midnight, there were 862 confirmed cases in Japan, including 691 confirmed cases on the "Diamond Princess cruise line".

コロナウイルス 国内の感染確認862人（クルーズ船含む）

COVID-19 worldwide

Iran

Till 25th Feb afternoon, A total of 95 COVID-19 infection cases were identified in Iran, and 15 cases died. Even the Deputy Minister of the health of Iran was diagnosed.

As of 24th Feb, all six of Iran's land neighbors, except Azerbaijan, had closed their borders with Iran. Iraq, the United Arab Emirates, and other important neighboring countries have also issued decrees banning flights to and from Iran. According to statistics, 12 countries in the Middle East temporarily shut downland or air traffic to Iran.

COVID-19 worldwide

Italy

On the 26th, 147 new cases of COVID-19 pneumonia were confirmed. As of 00:00 on the 27th local time, a total of 470 cases of COVID-19 pneumonia infection have been confirmed in Italy and a total of 12 deaths. Neighboring Greece, North Macedonia, and other European countries have confirmed cases for the first time on the 26th. Patients have recently visited Italy.

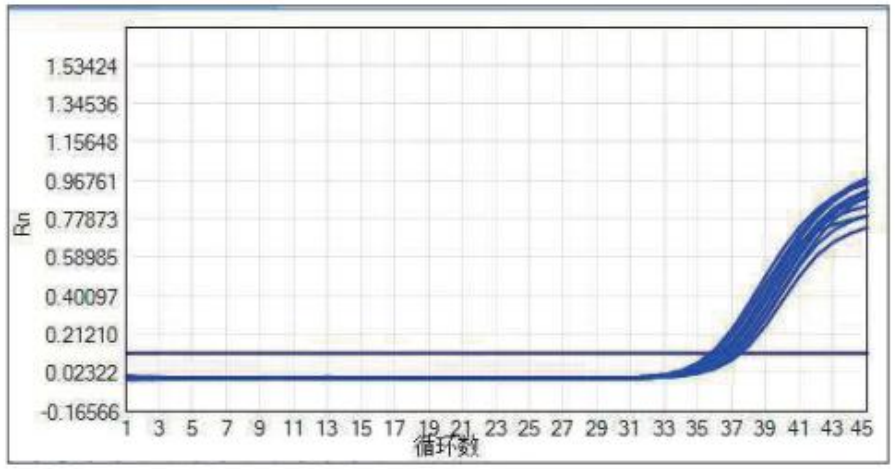
Currently, more than 20 countries have adopted measures such as restricting entry, banning travel, and suspending flights to Italy.

About Sansure's solutions

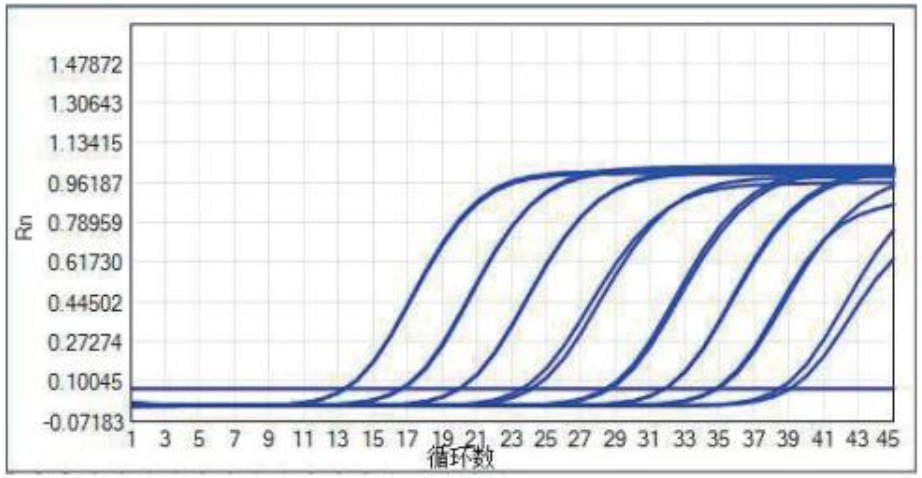
02

Sansure Biotech COVID-19 Nucleic Acid Detection Kit

Developed a reagent that combines three genetic loci of the COVID-19 with fluorescent PCR and multiplex PCR



Sensitivity: 200 copies / mL



Plasmid test linear range: 10^2 to 10^9 copies / mL

Product features

- Easy operation: no heating, tube replacement, nucleic acid extraction, and am
- plification detection can be achieved in a simple step. One person, one machine and one day is able to achieve over 1200 samples, greatly improving detection efficiency.

- The pathogen is inactivated after sampling and reach a high level of biological safety.

- The housekeeping gene and internal standard are monitored throughout to ensure the accuracy of the test results.

- High sensitivity, 200 copies/ml

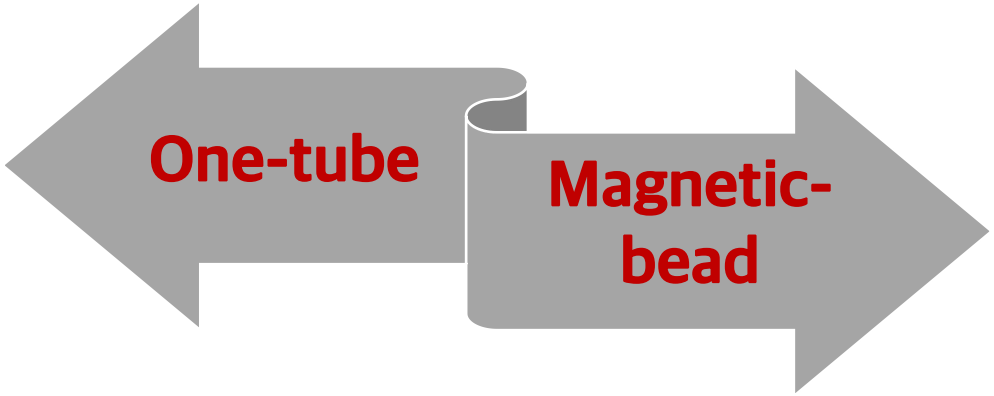
Applicable specimen type

- ✓ Pharyngeal swab
- ✓ Alveolar wash
- ✓ Sputum

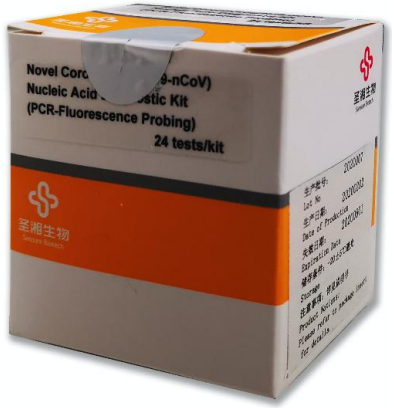
Sansure's advantages of nucleic acid detection technology

Accurate, simple, efficient and full-scenario to meet the needs of detection at all levels of epidemic prevention and control.

- Nucleic acid extraction technology platform



Sansure Biotech COVID-19 Laboratory Solution (1)



COVID-19 Kit

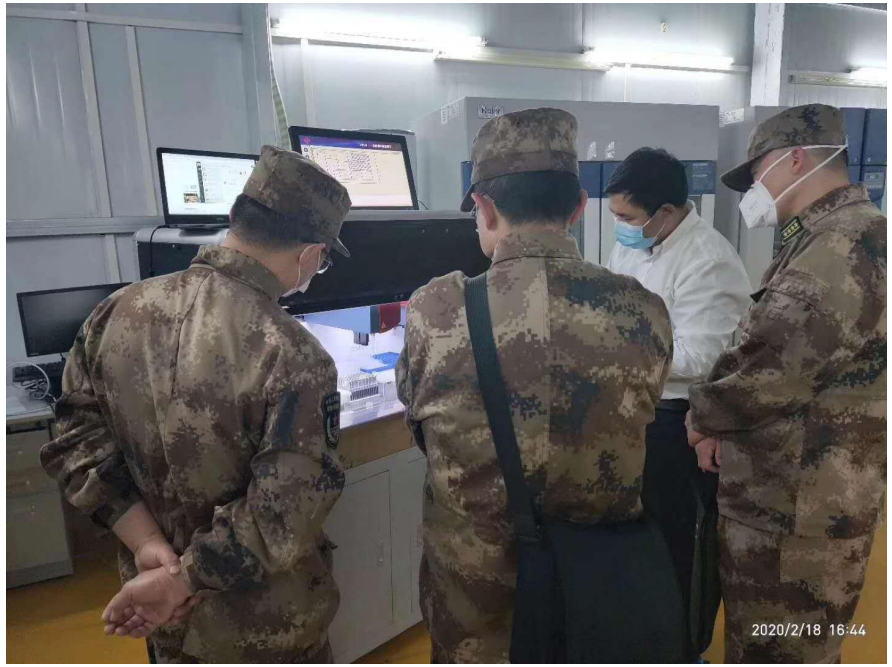
Natch CS fully automated extraction system

Slan 96 PCR

- ✓ Suitable for hospitals and users with large sample volume.
- ✓ No manual operation, high throughput, suitable for large-scale population screening.

Note: applicable for both one-tube and magnetic-bead

Laboratory application scenarios



✓ Medical institutions and disease control centers at all levels

This set of pictures comes from the front-line shooting, all of which are solutions proposed by Sansure in Wuhan

Sansure Biotech COVID-19 Laboratory Solution (2)

World's premier "One-Step RNA" Technology Platform

- ✓ Suitable for medium-sized hospitals, or customers who require fast results.
- ✓ Easy to operate, high throughput, suitable for screening of a certain size population.

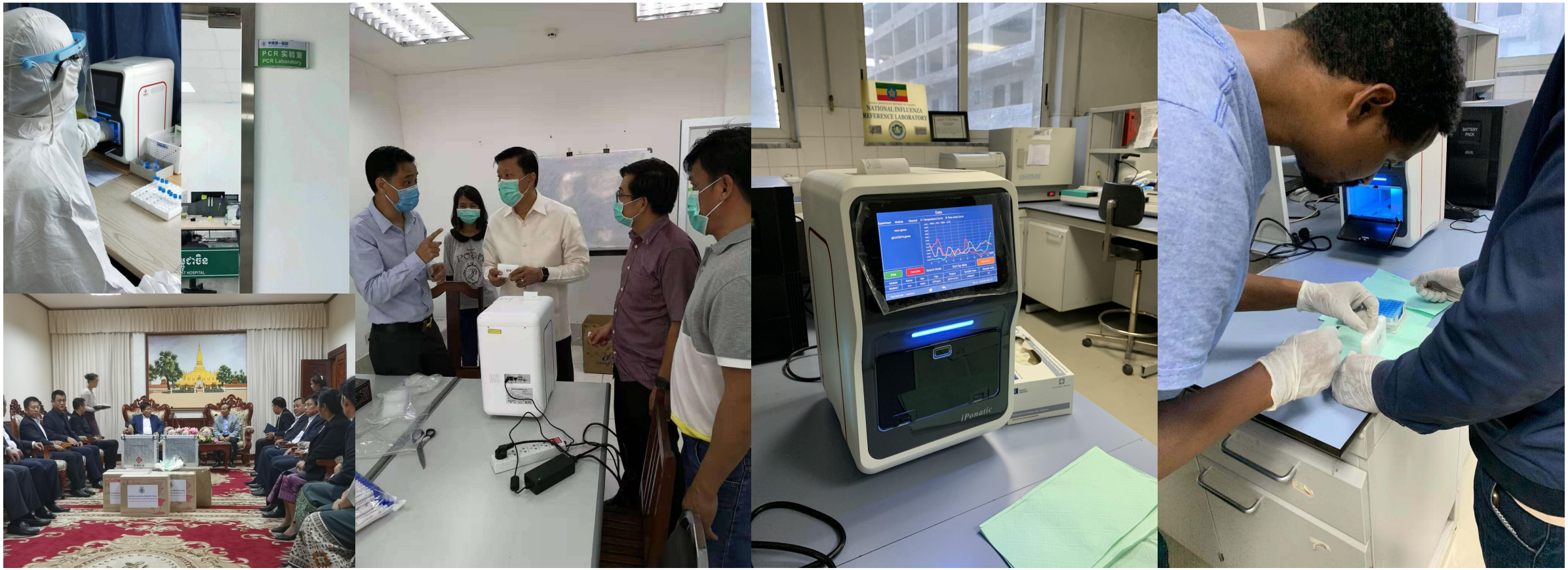
For field use

COVID-19 Kit

iPonatic portable molecular workstation

- ✓ Suitable for disease control, hospital, customs, etc.
- ✓ Simple operation, rapid report results.

Laboratory application scenarios



Sansure has already adopted the COVID-19 test program in health ministries and hospitals over 10 countries, including Ethiopia, Thailand, Malaysia, Laos, UAE and Cambodia.etc.

Product comparision

	Sansure	Company A	Company B	Company C	Company D
Certificate	CFDA	CFDA	CFDA	CFDA	CFDA
Detection Method	(PCR-Fluorescence Probing)	(PCR-Fluorescence Probing)	(PCR-Fluorescence Probing)	(PCR-Fluorescence Probing)	(PCR-Fluorescence Probing)
Sample Type	Pharyngeal swabs and alveolar lavage samples	Pharyngeal swabs,sputum, alveolar lavage sample	Pharyngeal swabs, sputum	Nasopharyngeal swab, sputum	Pharyngeal swabs and alveolar lavage samples
Target Gene	ORF1ab and N gene	ORF1ab and N gene, E gene	ORF1ab gene N gene	ORF1ab gene N gene	ORF1ab
Sensitivity	200 copies/mL	1000 copies/mL	1000 copies/mL	1000 copies/mL	1000 copies/mL
Amplification Time	90 min	90 min/60 min	100 min	80 min	120 min
Internal control	Endogenous internal control	Plasmid internal control	Endogenous internal control	Internal control	Internal control
Validity	6month	6month	6month	6month	6month
Specification	24 test/kit	25/50 test/kit	24/48/96 test/kit	50 test/kit	50 test/kit
Features	One Step fast release time, quick/easiest operation, 30-40 Minutes to report result.Highest Sensitivity 3.Endogenous internal control, monitor sampling ,extration and amplification	Three target gene complicated and long extraction time;Low sensitivity;Non-endogenous internal control, cannot monitor sampling accuracy.	RNA reverse transcription time is short,Complex operation of column extraction and magnetic bead extraction, long extraction time and long overall time;Low sensitivity	RNA reverse transcription time and amplification time is short.complicated and long extraction time;Low sensitivity;Non-endogenous internal control, cannot monitor sampling accuracy.	Only 1 target gene, Easy .complicated and long extraction time; More than 4 hours in all ; Low sensitivity;Non-endogenous internal control, cannot monitor sampling accuracy.

Analysis of the advantages

According to the above table, the advantages and disadvantages of Sansure products are listed as follows:

1. RNA one-step nucleic acid extraction free technology: a unique nucleic acid release agent, which can rapidly lyse pathogens at room temperature and inactivate pathogens to reduce bio-safety hazards. Without boiling and tube changing, rapid extraction of sample nucleic acid can be achieved through a simple operation. It is the only product of all manufacturers that does not need to be heated or cracked by boiling.

2. Higher sensitivity: 200 copies/mL. while other certified products were 1000 copies/mL.

3. Internal standard whole-process monitoring: endogenous housekeeper gene monitoring is adopted for the whole process, including sampling, testing, and other processes, to better avoid false-negative results. There is no internal standard in other licensed products.

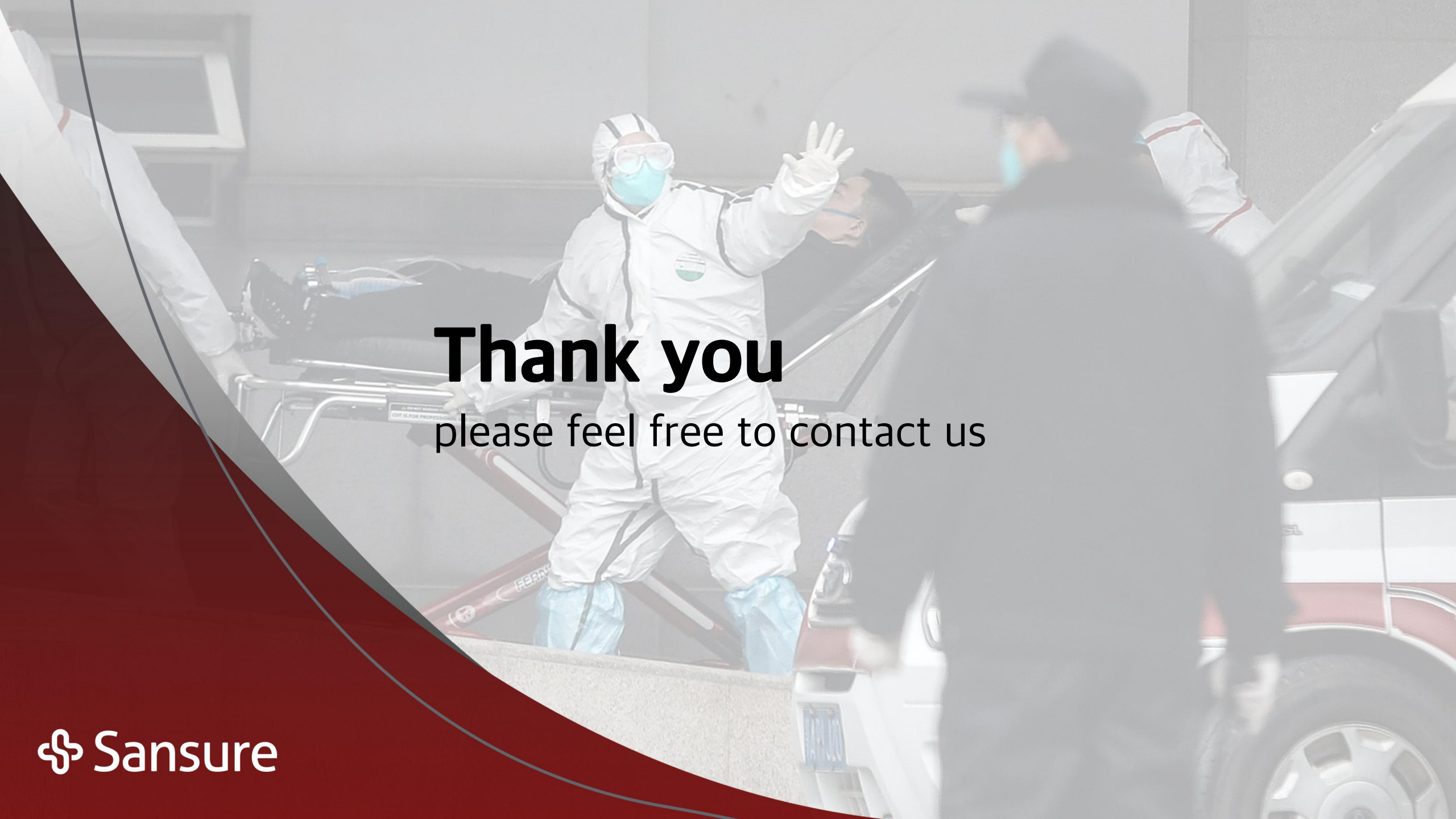
4. Fast reporting time: pre-processing of 96 samples of nucleic acid was completed by the one-step method of RNA in 30 minutes, and the results were reported within 2 hours.The shortest extraction time in all manufacturers.

Analysis of the advantages

5.High degree of automation and high detection flux: among the mainstream manufacturers, Some do not have a fully automatic nucleic acid extraction instrument, so it cannot realize high-throughput automatic detection. In the automatic manufacturers, Sansure automatic extraction speed is the fastest, can achieve 1 person 1 machine 1-day detection of 1000 people. while other products are unable to reach.

6. Diversified extraction and matching methods: the reagent can match the one-step method, magnetic bead method or other manufacturers' extraction methods, and the instrument can match iPonatic and Natch CS.

7. Detecting targets: national health council general office issued the new coronavirus pneumonia infection prevention and control program (second edition) "pointed out that for nucleic acid detection method, the novel coronavirus genome open reading code box 1 a/b 1 ab (ORF) and core-shell protein N gene, the same specimens new coronavirus in the two target specificity of real-time fluorescent RT-PCR test results for positive can be confirmed. Therefore, the nucleic acid detection kit only needs to cover these two targets to meet the detection needs.



Thank you

please feel free to contact us

Sansure