



# Antibody Test for COVID-19

*International Marketing Dept.*

*2020-04-03*

# CONTENTS

**01** The Significance of Antibody Test

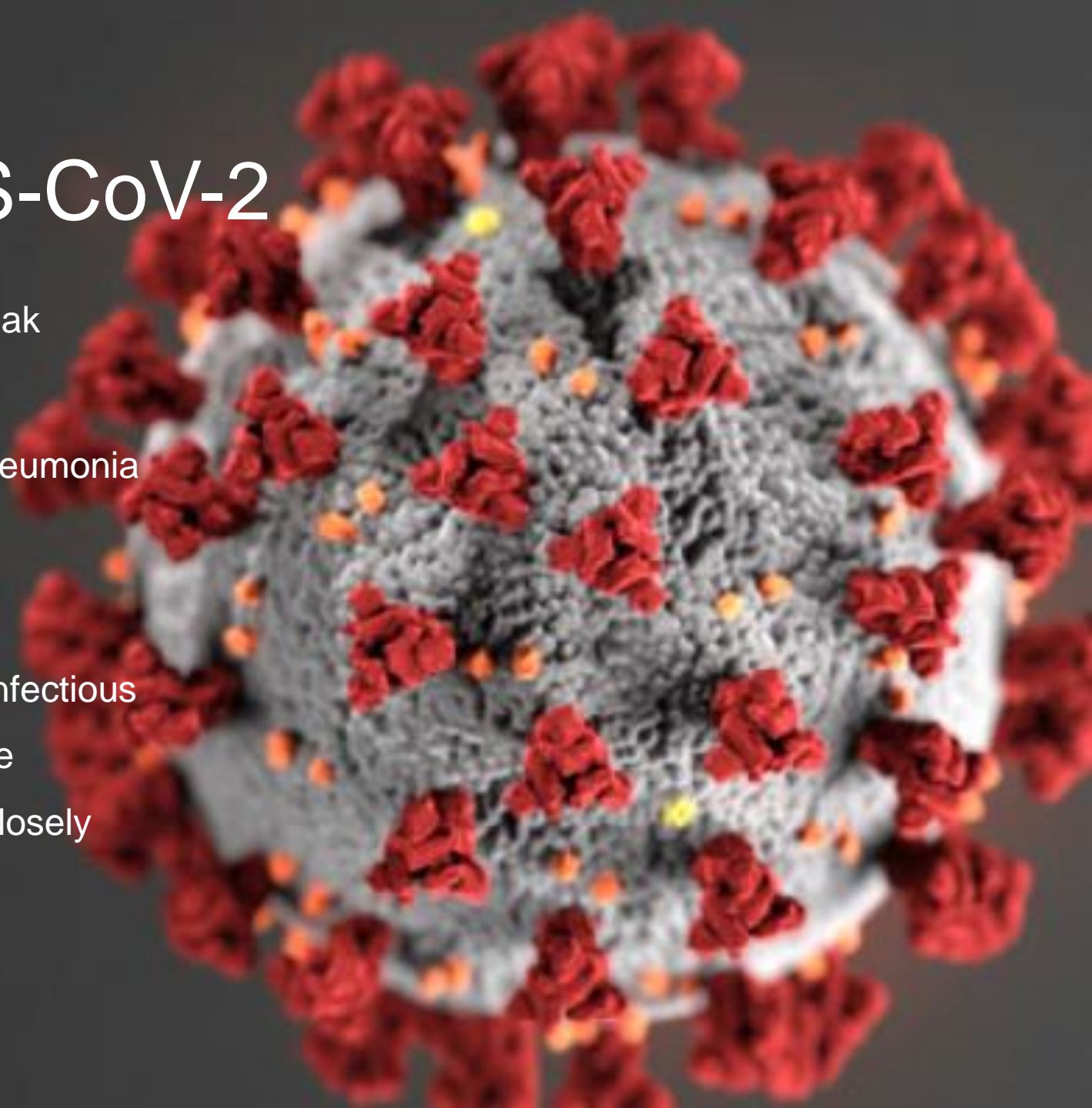
**02** The COVID-19 Diagnosis Guideline

**03** Wondfo SARS-CoV-2 Antibody Test



# COVID-19 and SARS-CoV-2

- China experienced a novel coronavirus outbreak starting from Dec, 2019.
- On 11<sup>th</sup> Feb, WHO has officially named the pneumonia caused by novel coronavirus 'COVID-19'.
- The virus has been named 'SARS-CoV-2'.
- COVID-19 (Coronavirus disease 2019) is an infectious disease caused by SARS-CoV-2,(severe acute respiratory syndrome coronavirus 2 ) a virus closely related to the SARS virus.



# Confirmed cases of COVID-19



Updated by 2<sup>nd</sup> Apr 2020

# Two methods for COVID-19 diagnosis

## RT-PCR Test

(aka. Nucleic acid , molecular test)



## Antibody Test

(aka. serological test, blood test)



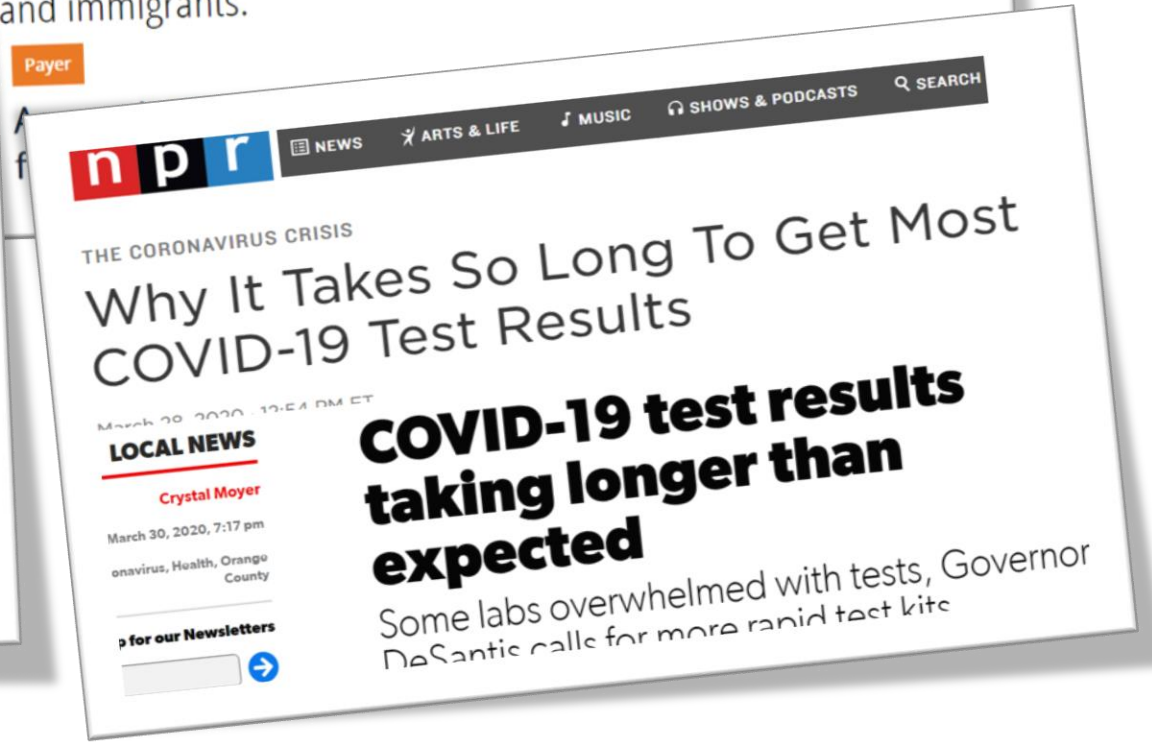
# RT-PCR Test for COVID-19

## RT-PCR Method:


- Directly detect the virus RNA from a swab or other specimen,
- A positive result of RT-PCR is a golden standard for virus infection



# Limitations of RT-PCR Test for COVID-19



# Limitations of RT-PCR Test for COVID-19



*Long turn  
around time*



*High Cost*



*High  
false-negative rate*

*Delay  
Treatment*

*Increase the  
Transmission*

*Endanger  
Medical Staff*

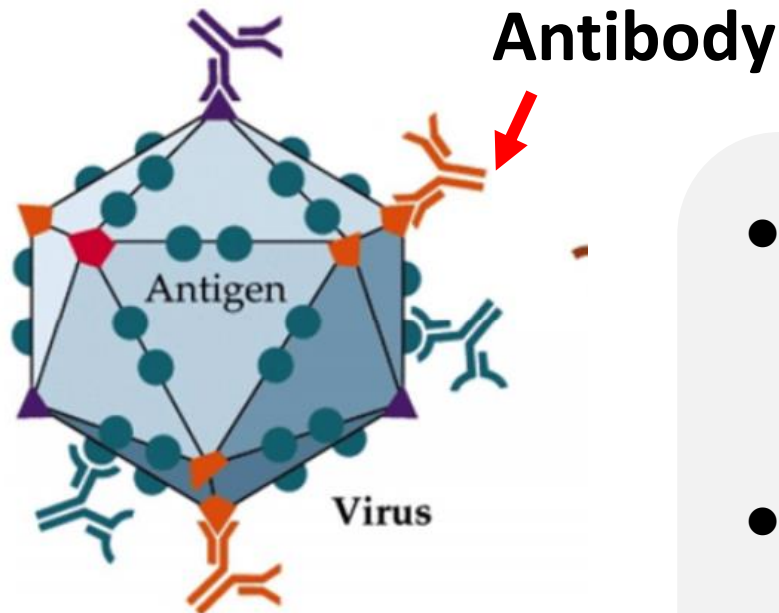


# *How to make a better diagnosis?*

***RT-PCR  
combines with  
Antibody Rapid Test !***

# What is Antibody Test? (Serological test, Blood test)

Antibody generation is the first line of defense.



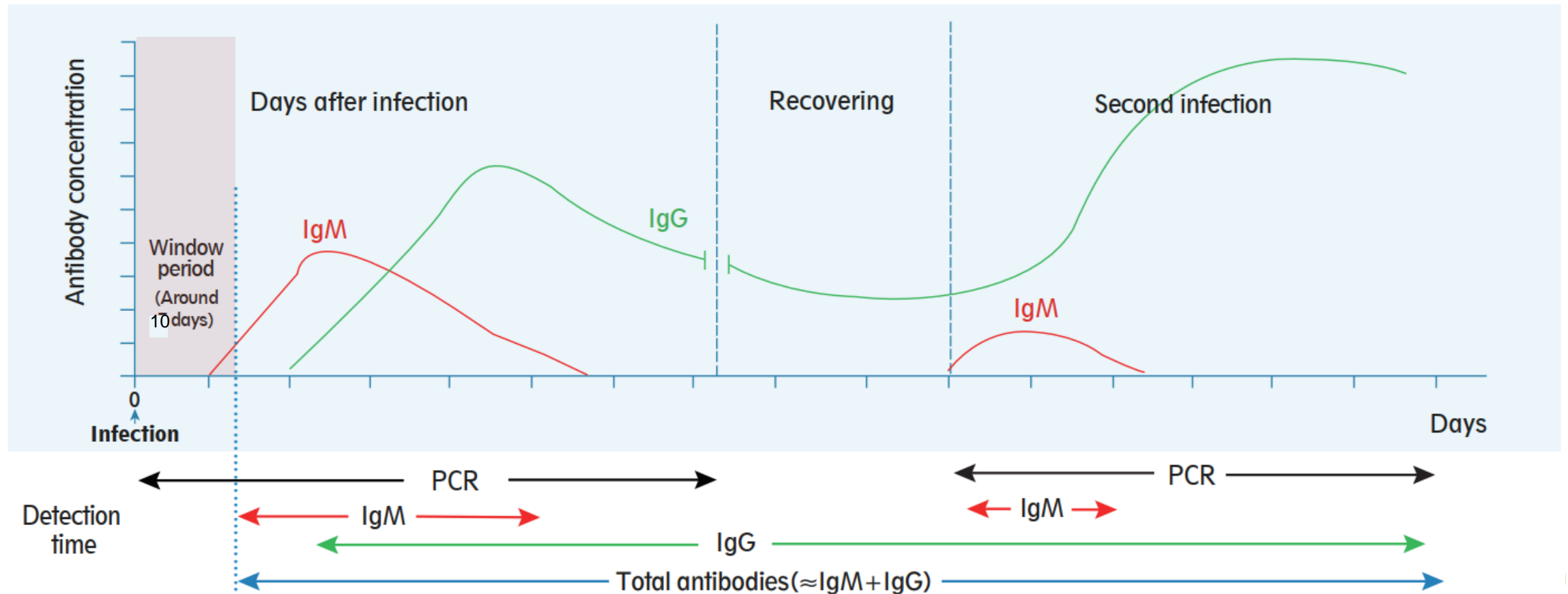
- **Detection method:** Colloidal gold immuno-chromatography, ELISA, CLIA, etc.
- **Sample type:** whole blood, serum or plasma
- **Detected target:** IgG, IgM, IgA

# What is Antibody Test? (Serological test, Blood test)



IgM is the **EARLIEST** antibody produced by human body after infection

IgG is the most abundant antibody in the human serum ( 75% ~ 80%)





Report of the WHO-China Joint Mission  
on Coronavirus Disease 2019 (COVID-19)

**WHO + China**

*“ **Rapid IgM and IgG antibody testing are also important ways to facilitate early diagnosis.** Standard serologic testing can be used for retrospective diagnoses in the context of serosurveys that help better understand the full spectrum of COVID-19 infection. ”*

国家卫生健康委员会办公厅  
国家中医药管理局办公室

国卫办医函〔2020〕184号

Diagnosis and Treatment Protocol for  
COVID-19 (Trial Version 7) -China

**National Health Commission  
of China**

- **Serological test** is added as one of the diagnostic standards of confirmed cases
- **Serological test** is added into the exclusion criteria for suspected cases



## Diagnosis and treatment

COVID-19 Prevention and Control

**Chinese Centre for Disease  
Control and Prevention (CDC)**

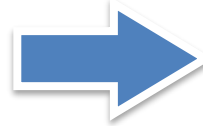
Confirmed case: suspected case with one of the following etiology or serological evidences:

- 1) The result of RT-PCR used to detect the nucleic acid of 2019-nCoV is positive;
- 2) The result of virus gene sequencing analysis is highly homologous with the known 2019-nCoV.
- 3) Serum IgM antibodies and IgG antibodies to 2019-nCov are positive; serum IgG antibodies to 2019-nCov turn from negative to positive or the IgG antibody titers of recovery period are 4 times or more higher than that of acute phase.

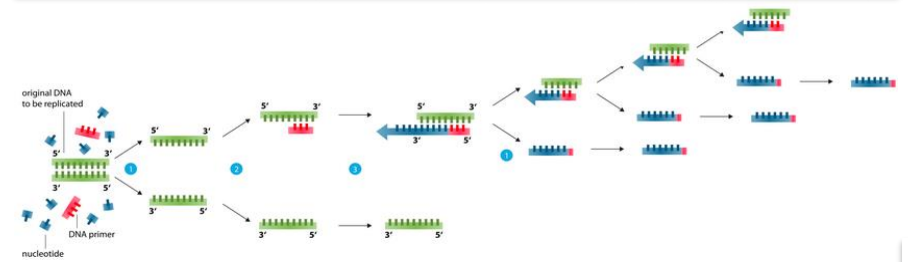
# 1<sup>st</sup> Application Scenarios

## ➤ For Suspected Cases Confirmation and Exclusion

For suspected cases confirmation and exclusion, should be used **in combination with nucleic acid test** or for re-confirming the nucleic acid negative test result suspected patients.

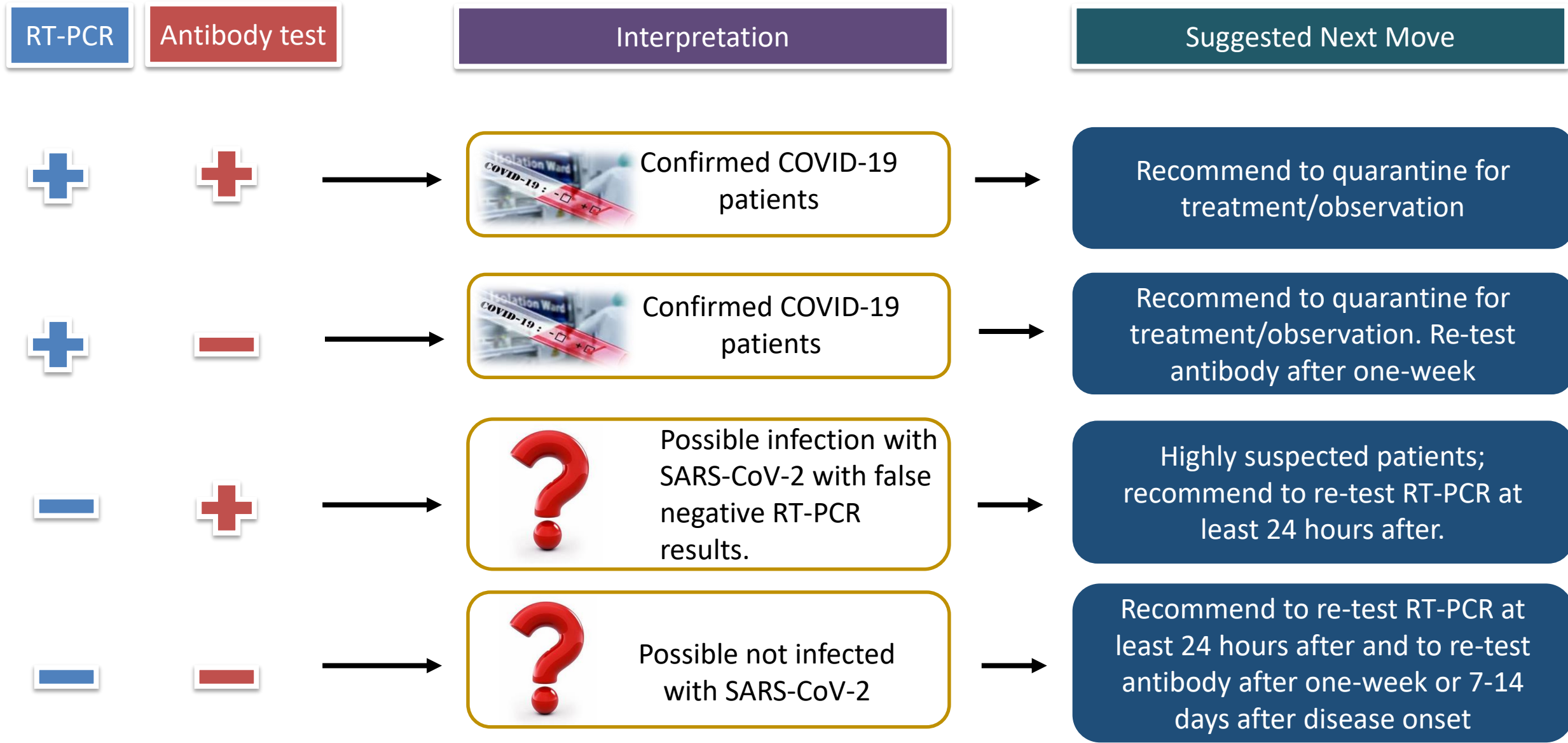


### RT-PCR Test



### Antibody test



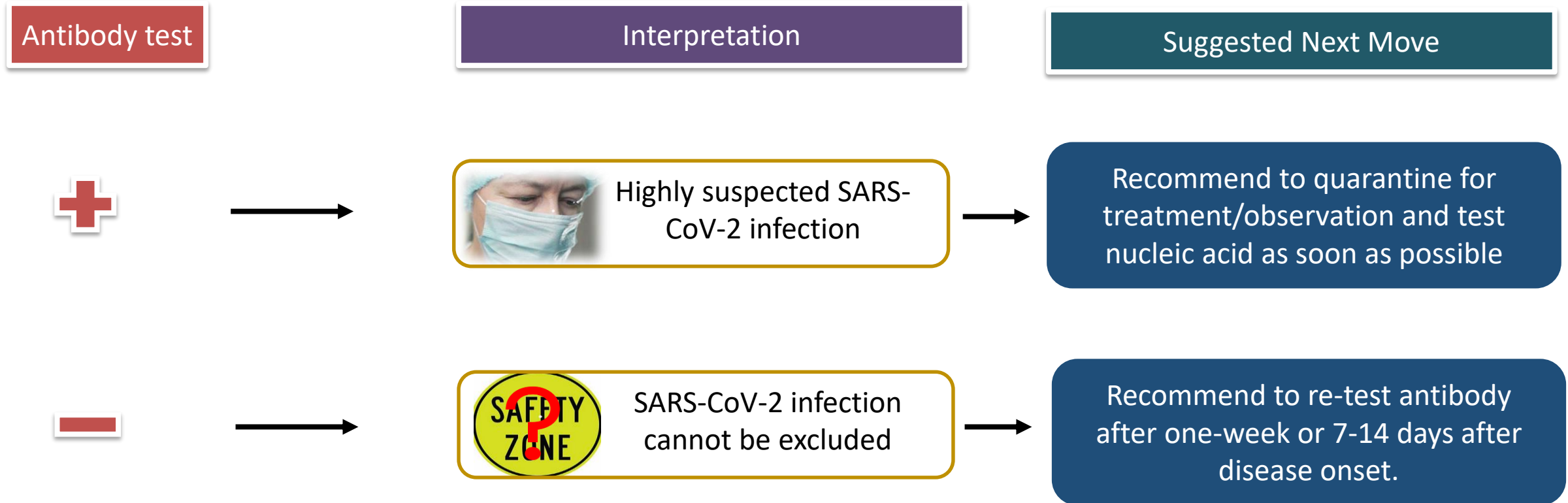


*For Suspected Patients Under the Situation When PCR is Available*



## For Suspected Patients Under the Situation When PCR is NOT Available

In case of the nucleic acid test of SARS-CoV-2 cannot be completed in a short time or nucleic acid test resources are insufficient, the following supplementary suggestions are made.



# 2<sup>nd</sup> Application Scenarios

## ➤ For Asymptomatic population with high risk

The antibodies detected by this test indicate that a person had an immune response to SARS-CoV-2, whether symptoms developed from infection or the infection was asymptomatic. Antibody test results are important in detecting infections with few or no symptoms.



Healthcare workers



Close contact for confirmed cases



## Antibody test



# PCR resources may not be available for asymptomatic patients

Antibody test

Interpretation

Suggested Next Move



Possible infection with SARS-CoV-2



Possible no infection with SARS-CoV-2

Recommend to quarantine for observation and to test nucleic acid twice consecutively

PCR:-

PCR:+

Possible past infection or false positive results of antibody test.

Either one of the test shows positive, COVID-19 patients confirmed.

Recommend to quarantine for observation and retest antibody after one week.

Antibody:+

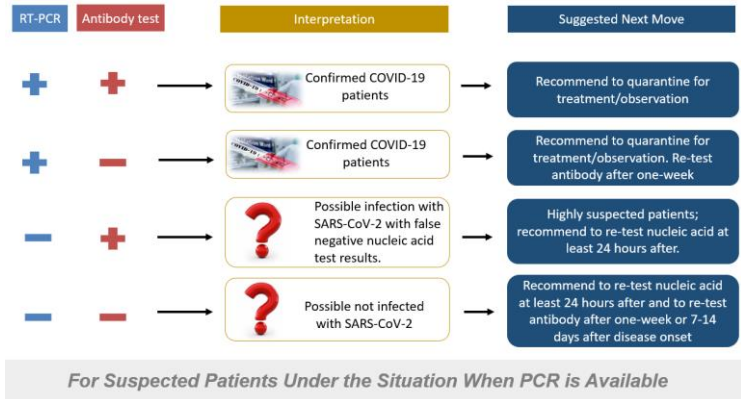
Antibody:-

Possible infection with SARS-CoV-2

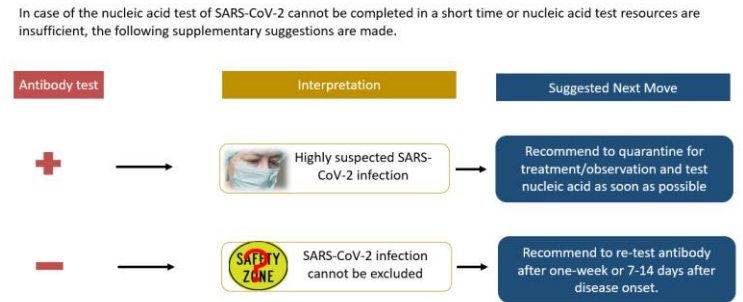
Recommend to continue isolation until 14 days



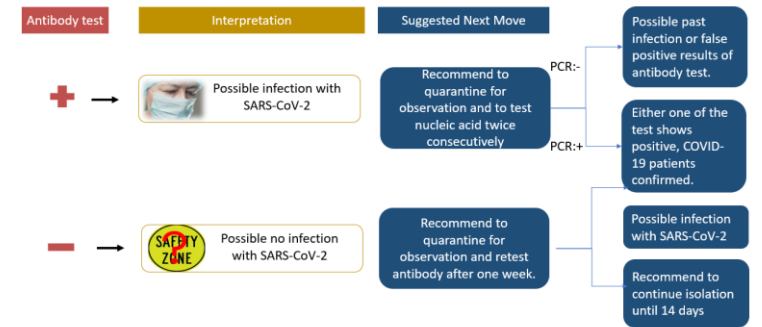
# Only for Professional Use!



### For Suspected Patients Under the Situation When PCR is NOT Available



### PCR resources may not be available for asymptomatic patients



Not for General Population Screening



Not for Home testing

# Combine **Antibody Test** with Nucleic Acid Test is highly recommended

Table 2. Performance of different detections in samples at different time since onset of patients.

Days after onset	n	RNA		Ab		IgM		IgG		RNA+Ab	
		n(+)	Sensitivity (% , 95%CI)	n(+)	Sensitivity (% , 95%CI)	n(+)	Sensitivity (% , 95%CI)	n(+)	Sensitivity (% , 95%CI)	n(+)	Sensitivity (% , 95%CI)
Total	173	112 <sup>§</sup>	67.1 (59.4, 74.1)	161	93.1 (88.2, 96.4)	143	82.7 (76.2, 88)	112	64.7 (57.1, 71.8)	172	99.4 (96.8, 100.0)
1-7	94	58 <sup>§</sup>	66.7 (55.7, 76.4)	36	38.3 (28.5, 48.9)	27	28.7 (19.9, 39.0)	18	19.1 (11.8, 28.6)	74	78.7 (69.1, 86.5)
8-14	135	67 <sup>§</sup>	54.0 (44.8, 63.0)	121	89.6 (83.2, 94.2)	99	73.3 (65.0, 80.6)	73	54.1 (45.3, 62.7)	131	97.0 (92.6, 99.2)
15-39	90	25 <sup>§</sup>	45.5 (32.0, 59.5)	90	100.0 (96.0, 100.0)	83 <sup>*</sup>	94.3 (87.2, 98.1)	71 <sup>#</sup>	79.8 (69.9, 87.6)	90	100.0 (96.0, 100.0)

**Higher Sensitivity**

**Nucleic Acid Test alone**

**Antibody Test + Nucleic Acid Test**

\* Two patients missed IgM tests due to inadequate plasma samples. # One patient missed IgG tests due to inadequate plasma samples. § There were

7, 11 and 35 patients had not been performed RNA testing during the 1-7 onset day, 8-14 onset day and 15-39 onset day, respectively.

Zhao, Juanjuan, et al. "Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019." (2020).

# Combine **Antibody Test** with Nucleic Acid Test is highly recommended



## Using Antibody Test to Re-confirm the Nucleic Acid Negative Samples

**Table 3. Presence of antibodies against SARS-CoV-2 in cases with undetectable viral nucleic acid in their throat swabs specimens**

d.a.o	No of cases with undetectable RNA	IgM		IgG	
		n <sup>+</sup>	Sensitivity	n <sup>+</sup>	Sensitivity
0-7	4	2	50.0%	4	100.0%
8-14	6	2	33.3%	6	100.0%
≥15	20	9	45.0%	18	90.0%

**Reducing the Rate Missing Detection**

**Nucleic acid false-negative patients**

**Antibody test in nucleic acid false-negative patients**

Reference: Gao Y, Yuan Y, Li T T, et al. Evaluation the auxiliary diagnosis value of antibodies assays for detection of novel coronavirus (SARS-Cov-2) causing an outbreak of pneumonia (COVID-19)[J]. medRxiv, 2020.

# SARS-CoV-2 Antibody Test

## (Lateral Flow Method)

 *The 1<sup>st</sup> officially approved antibody test in China!*

- Easy to use, no equipment required
- Multiple sample types, including fingerstick blood
- Instant result in 15 minutes
- Total antibody test, higher detection rate comparing with single IgG/IgM test
- CFDA and CE certified



# Operation Procedure



Fingerstick  
Whole Blood

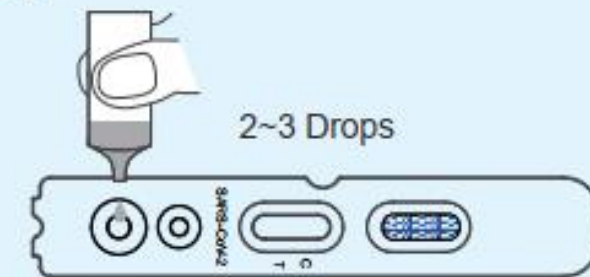


Venous Whole  
Blood/Serum/Plasma

01.



02.

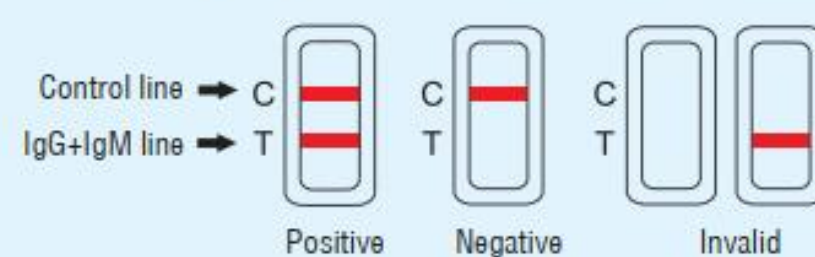


03.



15 minutes

04.





Reagents		Clinical cases		Total
		Confirmed case samples	Excluded case samples	
Wondfo SARS-CoV-2 Antibody Test (Laberal Flow Method)	Positive	312	1	313
	Negative	49	234	283
<b>Total</b>		361	235	596

Sensitivity: 86.43% (95%CI: 82.51%~89.58%)

Specificity: 99.57% (95%CI: 97.63%~99.92%)

Total consistent: 91.61% (95%CI: 89.10%~93.58%)

# Biosafety Requirements

- **Lab technician**



## Sampling personnel:

Collected by qualified technicians who have received biosafety training, equipped with the corresponding laboratory skills



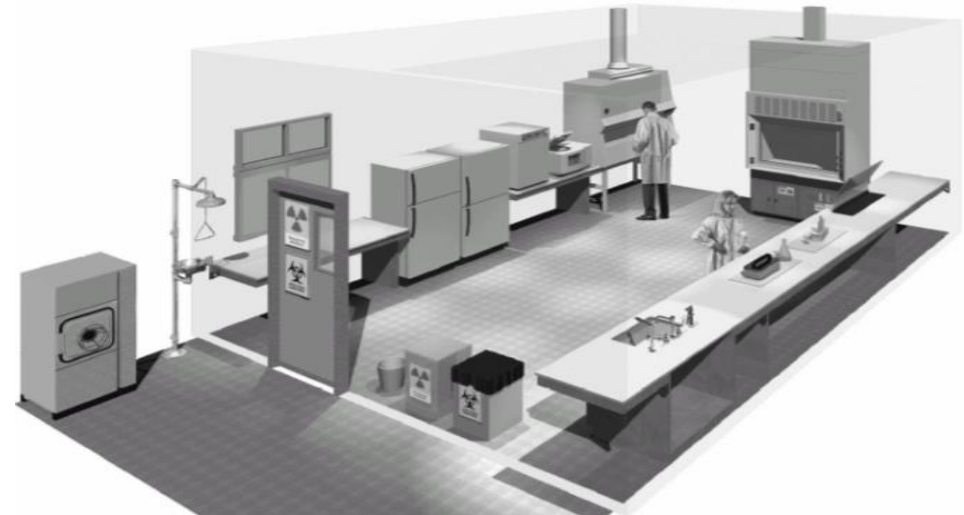
## PPE requirements :

N95 masks or masks with higher filtration efficiency, goggles, protective clothing ,double-layer latex gloves ,waterproof boot covers, If exposed to patients' blood, body fluids, secretions or excretions, the outer layer of the latex gloves should be changed in time



- **Laboratory**

Operations of nucleic acid extraction and serological testing, should be performed in a **BSL-2 laboratory** with personal protective equipment subject to **BSL-3 laboratory protection requirements**



# THANK YOU



## Battle with COVID-19

Wondfo, being with people, fighting as a hero