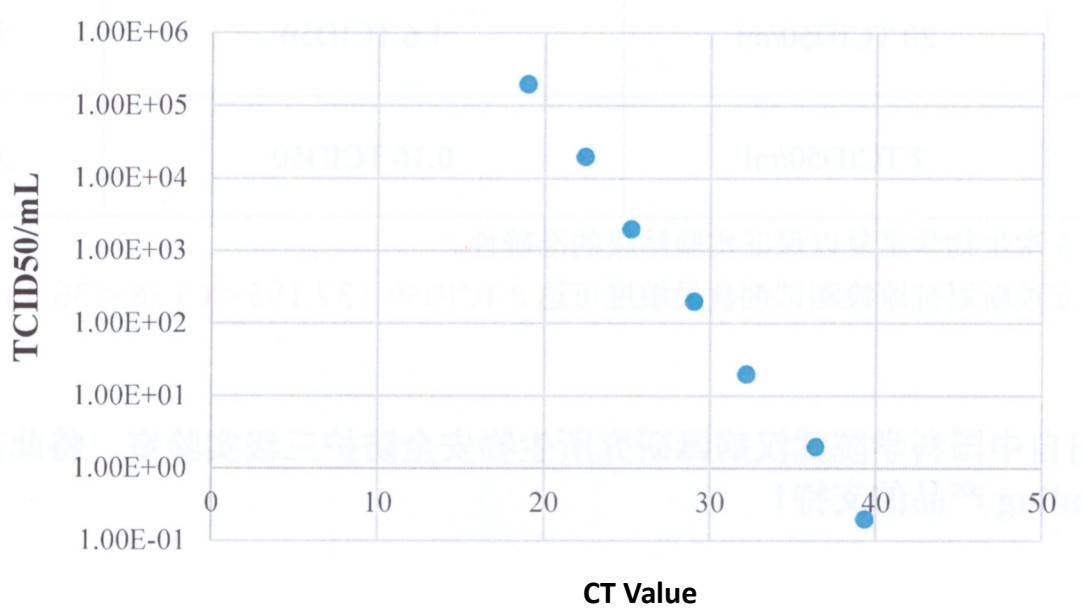
Technical data

PART ONE
Evalution

1. CT Value and TCID50 Conversion

CT Value	19.01	22.46	25.225	29.03	32.195	36.385	39.35
TCID 50	200,000	20,000	2,000	200	20	2	0.2



2. SARS-CoV-2 virus evaluation procedure and results

2.1 **Location**: Biological safety protection third-level laboratory

2.2 **Virus**: SARS-CoV-2 WIV04

2.3 **Virus amplification cell**: Vero E6

2.4 **Titer detection**: limiting dilution assay, the origin virus' titer 2 x $10^6$$TCID_{50}$/ml

2.5 **Test Kit**: **BALLYA Covid 19 Antigen Rapid Test Kit**

2.6 **Virus dilution**:

2 x $10^5$$TCID_{50}$/ml
2 x $10^4$$TCID_{50}$/ml
2 x $10^3$$TCID_{50}$/ml
2 x $10^2$$TCID_{50}$/ml
2 x $10^1$$TCID_{50}$/ml
2 $TCID_{50}$/ml

2.7 **Sample add**: 80μl / cassette

2.8 **Dection time**: 15 minutes

2.9 **Repeat**: each sample repeat 3 times

Results

No.	Virus Concentration	Sample added volume (80μl / cassette)	Results
1	2 x $10^5$$TCID_{50}$/ml	1.6 x $10^4$$TCID_{50}$/ml	High Brightness line
2	2 x $10^4$$TCID_{50}$/ml	1.6 x $10^3$$TCID_{50}$/ml	High Brightness line
3	2,000 $TCID_{50}$/ml	160 $TCID_{50}$	Medium brightness line
4	200 $TCID_{50}$/ml	16 $TCID_{50}$	Weak line
5	100 $TCID_{50}$/ml	8 $TCID_{50}$	Weak line
6	20 $TCID_{50}$/ml	1.6 $TCID_{50}$	No line
7	2 $TCID_{50}$/ml	0.16 $TCID_{50}$	No line

Conclusion:
The sensitivity **8 $TCID_{50}$ (32.195< CT value < 36.385)**

PART TWO
National Reference & Company Standard

National reference (China)

Negative reference: total 20
(N1,N2,N3,N4,N5,N6,N7,N8,N9,N10,N11,N12,N13,N14,N15,N16,N17,N18,N19 N20)
Positive reference: total 8 (P1,P2,P3,P4,P5,P6,P7,P8)
Minimum detection reference: total 1 (**S**)
Repeat reference: total 2 (**R1, R2**)

Company Standard
BALLYA

1. **Minimum detection** : **7 $TCID_{50}$/ml**
   Use **National Reference Panel for 2019-nCoV Antigen Detection Kit** (**S**) , **1:140,000** dilution or titer 7 $TCID_{50}$/ml as company reference, 20 times detection in same batch, positive results not less than 95%
2. **Positive rate**: 100% (detection P1-P8, all positive)
3. **Negative rate**: 100% (detection N1-N20)
4. **Repeat**: all postive results (R1= 10 times detection, R2= 10 times detection); color band of cassette in same brightness
5. **Batch CV%**: use three different batches to detect R1 & R2, each reference 10

times detection, all positive results; color band of cassette in same brightness

6. **Stability**: Accelerated test, 55℃ for 100 days (equivalent to); then detect according to No.1 - No.4; all results are match.
7. **Hook effect**: dilute 1:1 national reference (S) or company reference $0.5x10^6$ $TCID_{50}$/ml, no hook effect

Cross reactivity:

There is no cross-reaction with pathogens at the following concentrations.

No.	Phathogen	Concentration
1	HCoV-HKU1	$1.5x10^6$copies/mL
2	HCoV-OC43	$1.1x10^6$copies/mL
3	HCoV-NL63	$1.0x10^6$copies/mL
4	HCoV-229E	$3.8x10^6$copies/mL
5	Novel influenza A(h1n1) virus(2009)	$1.8x10^7$copies/mL
6	Seasonal h1n1 influenza virus	$8x10^7$copies/mL
7	Influenza A virus(h3n2)	$1.2x10^7$copies/mL
8	Influenza A virus(h5n1)	10^6copies/mL
9	Influenza A virus(h7n9)	10^6copies/mL
10	Influenza B (yamagata)	$2.8x10^7$copies/mL
11	Influenza B (victoria)	$2.0x10^7$copies/mL
12	Respiratory syncytial virus type A	10^6copies/mL
13	Respiratory syncytial virus type B	$1.2x10^6$$TCID_{50}$/mL
14	Parainfluenza virus type 1	10^6copies/mL
15	Parainfluenza virus type 2	10^6copies/mL
16	Parainfluenza virus type 3	10^6copies/mL
17	Rhinovirus A	10^6copies/mL
18	Rhinovirus B	10^6copies/mL
19	Rhinovirus C	10^6copies/mL
20	Adenovirus 1	10^6copies/mL
21	Adenovirus 2	10^6copies/mL
22	Adenovirus 3	10^6copies/mL
23	Adenovirus 4	10^6copies/mL
24	Adenovirus 5	10^6copies/mL
25	Adenovirus 7	10^6copies/mL
26	Adenovirus 55	10^6copies/mL
27	Human metapneumovirus	10^6copies/mL
28	Enterovirus A	10^6copies/mL
29	Enterovirus B	10^6copies/mL
30	Enterovirus C	10^6copies/mL
31	Enterovirus D	10^6copies/mL
32	EB virus	10^6copies/mL
33	Measls virus	10^6copies/mL

34	Human cytomegalovirus	10^6copies/mL
35	Rotavirus	10^6copies/mL
36	Norovirus	10^6copies/mL
37	Mumps virus	10^6copies/mL
38	Herpes zoster virus	10^6copies/mL
39	Mycoplasma pneumoniae	10^6CFU/mL

Interfering substances:

The kit is not affected with the substances at the following concentrations

No.	Interference substances	Concentration
1	Mucin	60mg/dL
2	Whole blood	20%(v/v)
3	Phenylephrine	2mg/mL
4	Oxymetazoline	2mg/mL
5	Sodium chloride (with preservative)	0.1%
6	Beclomethasone	20mg/mL
7	Dexamethasone	20mg/mL
8	Flunisolide	20μg/mL
9	Triamcinolone acetonide	2mg/mL
10	Budesonide 2mg/mL 23 Ceftriaxone	40μg/mL
11	Mometasone	2mg/mL
12	Fluticasone	2mg/mL
13	Zanamivir	20mg/mL
14	Peramivir	1mg/mL
15	Lopinavir	500mg/mL
16	Ritonavir	60mg/mL
17	Interferon-α	800IU/mL
18	Ribavirin	10mg/mL
19	Oseltamivir	60ng/mL
20	Arbidol	700ng/mL
21	Levofloxacin	10μg/mL
22	Azithromycin	1mg/L
23	Ceftriaxone	40μg/mL
24	Meropenem	200mg/mL
25	Tobramycin	0.6mg/mL
26	Histamine dihydrochloride	5mg/mL