Shenzhen Reagent Technology Co.,Ltd.
R7777,Hangcheng Wisdom Science Park, Hangcheng street,Bao'an District Shenzhen 518128,China
0755-23006622 Email: reagenkits@gmail.com
Web :www.reagen.cn
www.reagen.us

Medical & Drug ● IVD & POCT ● Food & Safety

SARS-CoV-2 antigen IVD kit SALIVA

Clinic Evaluation Report

1 Product Review

Product Name: SARS-CoV-2 antigen IVD kit SALIVA

Specification:1 test/kit, 25tests/kit

Manufacturer: Shenzhen Reagent Technology Co.,Ltd.

2 Intended Use

This product is used for qualitative detection of coronavirus-19 antigen in saliva samples. The SARS-CoV-2 belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a fewcases.

3 Technical Principles

SARS-CoV-2 Antigen IVD Kit SWAB is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to qualitatively determine the presence of nucleocapsid protein (N-Protein) antigen from SARS-CoV-2 in direct nasopharyngeal swab. When the sample is dropped into the sample well, SARS-CoV-2 antigens in the sample are bound by colloidal gold-labeled monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2. This complex migrates on the membrane via capillary action to the test region (T), where it is captured by the mouse monoclonal anti-SARS-CoV-2. If the SARS-CoV-2 antigens are present in the sample, a colored test line becomes visible in the T line. To serve as a procedural control, a colored line always appears in the control region (C), if the test has performed properly..

4 Background of Clinical Evaluation

Typical symptoms: fever, fatigue and dry cough are the main manifestations, and dyspnea may occur in severe cases.

Common symptoms: the incubation period of this disease is generally 3 ~ 7 days,and the longest is not more than 14 days. Fever,fatigue and dry cough are the main manifestations. A few patients have nasal obstruction, runny nose, diarrhea and other symptoms. Severe cases usually have dyspnea after 1 week. Severe cases rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis which is difficult to correct, and coagulation dysfunction.

Other symptoms: Some patients showed only low fever, slight fatigue, etc., no pneumonia, and recovered after 1 week.

5 Selection of Clinical Assessment Data

5.1 Overview of the Clinical Evaluation Phase Clinically evaluate according to the flow chart 1.

5.2 Literature Retrieval

5.2.1 Scope of document retrieval

Literature covering the clinical application, performance, safety and adverse events of the product.

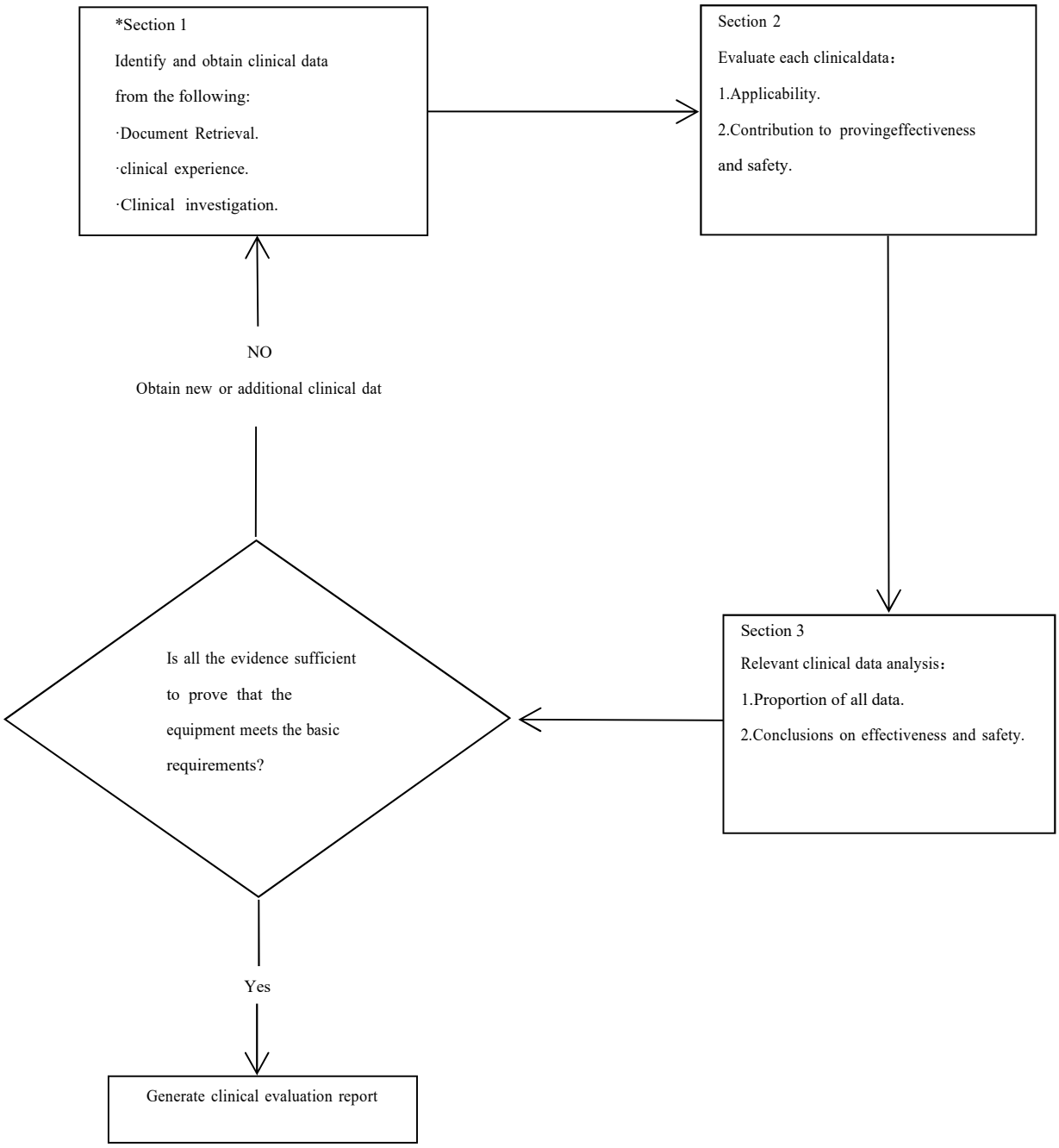
5.2.2 The year-range of document retrieval

2019~ present.

5.2.3 Literature resources: CNKI; Lilei Database; PUBMED;NMPA.

Flow Chart 1

Meeting the requirements of the coordination standards can be considered to fully meet the relevant basic requirements.



6 Analysis And Evaluation of Clinical Data

6.1 Applicability Evaluation

The applicability of the retrieved literature was identified by flow chart 2 and table 1. Flow Chart 2

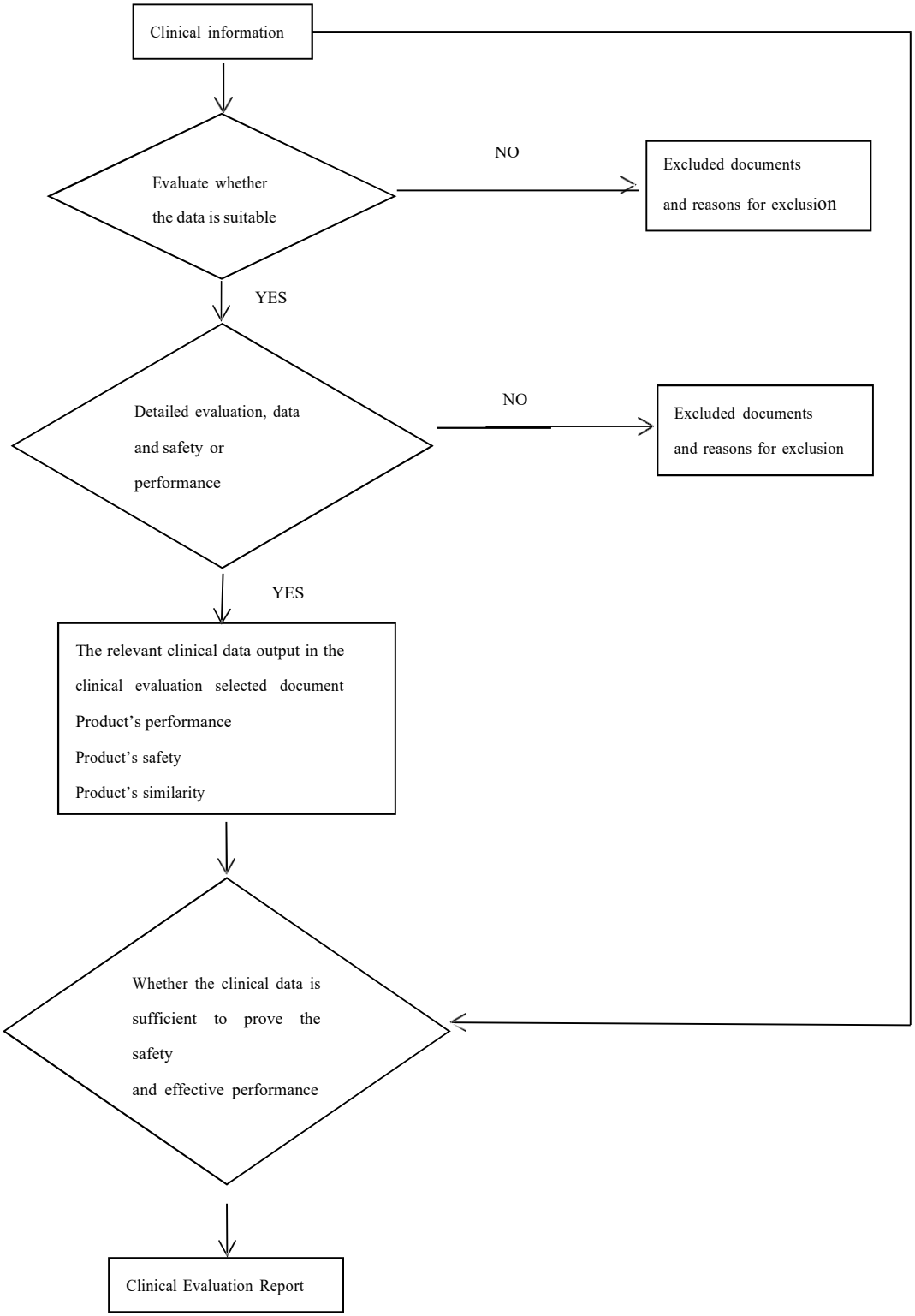


Table 1: Literature Applicability Evaluation Criteria

Applicability Standard	Description	Classification System
Proper product	Is the data generated from the product to be evaluated?	□ D1 Actual instrument ■ D2 Equal instrument □ D3 Other instrument
Proper clinical application	Is the intended use of the product same?	□ A1 Same usage ■ A2 Nuance □ A3 Great difference
Proper patient population	Does the patient population collecting data represent the intended application population?	□ P1 Applicable ■ P2 Partially applicable □ P3 Different
Proper patient population	Does the patient population collecting data represent the intended application population?	□ P1 Applicable ■ P2 Partially applicable □ P3 Different
Selection report/data sorting	Does the report or data include enough information for a rational and objective evaluation?	■ R1 High quality □ R2 Minor defect □ R3 Lack of information

6.2 Literature Search Results

The literature related to the intended evaluation of the device is as follows：

1) Test report
2) 5 pcs of reference
3) Adverse Event Report

The kit is found to have no adverse events for similar products within the range of retrieval.

6.3 Data Evaluation

6.3.1 Evaluation Criteria of Data Contribution Rate

Table 2: Evaluation Criteria of Data Contribution Rate

Data Contribution Criteria	Description	Classification System
Data source type	Is the research method appropriate?	■ T1 Yes □ T2 No
Result measurement	Does the reported result reflect the expected performance of the product?	■ T1 Yes □ T2 No
Statistical significance	Have the statistical analysis been done? Is the statistical analysis method appropriate?	■ S1 Yes □ S2 No
Clinical significance	Is the significance of clinical observation important?	■ C1 Yes □ C2 No

6.4 Data Contribution Rate Evaluation

Table3:

Draft evaluation content	Cited References	Data Source	Description	Classification system
1. Analytical performance	Analytical Performance Study	Shenzhen Reagent Technology Co.,Ltd.	Performance research includes testing and verification studies of technical requirements indicators.	D1 Draft evaluation Device D2 Similar Device D3 Other
	QAQC Process Control File	Shenzhen Reagent Technology Co.,Ltd.	Inspect the product to ensure that the product meets performance requirements.	D1 Draft evaluation Device D2 Similar Device D3 Other
	Stability Study Report	Shenzhen Reagent Technology Co.,Ltd.	Verify the stability of the product's packaging, transportation and storage life to ensure the safety and effectiveness of the product.	■ D1 Draft evaluation device □ D2 Similar Device □ D3 Other
2.Post-marketing adverse events	Adverse event report	Website of national adverse drug reaction monitoring center.	No adverse events were reported	□D1 Draft evaluation Device D2 Similar Device D3 Other
3. Residual risk and potential risk	Risk analysis and Control Summary	Shenzhen Reagent Technology Co.,Ltd.	It was suitable for the analysis of the product	D1 Draft evaluation Device D2 Similar Device D3 Other

7. **Introduction of Clinical Trials**

7.1 To prove the Kits' safety and effectiveness, clinical trials are necessary.

7.2 Clinical trials were conducted in May 15,2020~Jun 21,2020

7.3 The clinical trial medical unit is Zhongshan Hospital, Shenzhen No.3 People's Hospital.

8. Performance

8.1 Sensitivity,Specificity and Accuracy

Saliva:

A total of 260 various types of samples are tested. Compared with the COVID-19 Real Time PCR Kit (RT-PCR), the SARS-CoV-2 antigen IVD kit SALIVA (See below Table fordetails) .

Clinical Sample		COVID-19 Real Time PCR Kit (RT-PCR)		Total
		Positive	Negative	
SARS-CoV-2 antigen IVD kit SALIVA	Positive	99	4	103
	Negative	6	151	157
Total		105	155	260

Clinical Sensitivity = 99/105= 94.29 % （95%CI:85.94%-98.20%）
Clinical Specificity =151/155=97.42% （95%CI:86.28%-98.96%）
Accuracy: (99+151)/ (99+4+6+151) *100%=96.15%

Please see the attachment<Clinic Evaluation Report> for more details.

9 Conclusion

The kit which its working principle is clear, the design is finalized, the process is mature, the clinical application is extensive, and no serious adverse event records and/or product defectshave been found. The performance indicators of the product's safety and effectiveness have been established in the test report and have been fully verified without passing the clinical trial. Atthe same time, the product is of the same clinical use and the same operating object with the samekind of registered and marketed products, and is substantially equivalent in terms of basic principle, structure composition, product manufacturing materials, main performance indicators, application scope, use method and so on.

Therefore, compared to other similar products, The kit does not reduce the clinical effectiveness, nor increase the clinical safety risk. The production and application technology of this product is mature, and its functional principle, expected clinical use effect have been fully affirmed in the relevant clinical application field.

In conclusion,The kit can meet the expected use and ensure the safety and effectiveness of its clinical use.

Attachment 1 Test result of Saliva samples

Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
1	3+	21	positive	17	2+	23	positive	33	-	26	positive
2	-	/	negative	18	3+	22	positive	34	2+	25	positive
3	-	/	negative	19	1+	25	positive	35	2+	24	positive
4	-	/	negative	20	-	/	negative	36	-	/	negative
5	-	/	negative	21	-	/	negative	37	-	/	negative
6	3+	23	positive	22	3+	22	positive	38	-	/	negative
7	2+	25	positive	23	3+	20	positive	39	3+	21	positive
8	3+	21	positive	24	3+	20	positive	40	3+	20	positive
9	-	/	negative	25	-	/	negative	41	-	/	negative
10	-	/	negative	26	-	/	negative	42	-	/	negative
11	-	/	negative	27	-	/	negative	43	-	/	negative
12	3+	20	positive	28	-	/	negative	44	-	/	negative
13	3+	22	positive	29	3+	20	positive	45	2+	24	positive
14	1+	/	negative	30	-	/	negative	46	-	/	negative
15	-	/	negative	31	-	/	negative	47	-	/	negative
16	-	/	negative	32	2+	24	positive	48	-	/	negative

Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
49	-	/	negative	67	3+	21	positive	85	1+	26	positive
50	2+	/	negative	68	-	/	negative	86	-	/	negative
51	1+	26	positive	69	-	/	negative	87	2+	25	positive
52	-	/	negative	70	-	/	negative	88	-	/	negative
53	3+	20	positive	71	1+	29	positive	89	-	/	negative
54	-	/	negative	72	3+	21	positive	90	3+	22	positive
55	-	/	negative	73	3+	20	positive	91	-	/	negative
56	-	/	negative	74	-	/	negative	92	-	/	negative
57	2+	28	positive	75	-	/	negative	93	3+	23	positive
58	3+	21	positive	76	-	/	negative	94	-	/	negative
59	-	19	positive	77	3+	22	positive	95	-	/	negative
60	-	/	negative	78	2+	21	positive	96	3+	20	positive
61	2+	24	positive	79	3+	20	positive	97	-	/	negative
62	-	/	negative	80	-	/	negative	98	-	/	negative
63	-	/	negative	81	-	/	negative	99	-	/	negative
64	-	/	negative	82	-	/	negative	100	3+	19	positive
65	3+	21	positive	83	2+	23	positive	101	3+	21	positive
66	-	/	negative	84	3+	21	positive	102	-	/	negative

Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
103	3+	18	positive	120	2+	23	positive	137	1+	29	positive
104	3+	19	positive	121	-	/	negative	138	-	/	negative
105	-	/	negative	122	2+	25	positive	139	-	/	negative
106	3+	21	positive	123	2+	24	positive	140	+	31	positive
107	1+	28	positive	124	-	/	negative	141	3+	22	positive
108	-	/	negative	125	-	/	negative	142	2+	23	positive
109	-	29	positive	126	2+	23	positive	143	-	/	negative
110	-	/	negative	127	-	/	negative	144	-	/	negative
111	-	/	negative	128	1+	27	positive	145	1+	29	positive
112	3+	21	positive	129	-	/	negative	146	-	/	negative
113	-	/	negative	130	-	/	negative	147	-	/	negative
114	3+	20	positive	131	-	/	negative	148	-	/	negative
115	2+	/	negative	132	-	/	negative	149	1+	31	positive
116	3+	18	positive	133	-	19	positive	150	3+	20	positive
117	1+	27	positive	134	3+	21	positive	151	-	/	negative
118	-	/	negative	135	-	/	negative	152	-	/	negative
119	-	/	negative	136	-	/	negative	153	3+	21	positive

Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
154	2+	23	positive	171	-	/	negative	188	2+	24	positive
155	2+	23	positive	172	2+	26	positive	189	-	/	negative
156	-	/	negative	173	-	/	negative	190	-	/	negative
157	-	33	positive	174	-	/	negative	191	3+	18	positive
158	-	/	negative	175	3+	20	positive	192	2+	23	positive
159	-	/	negative	176	-	/	negative	193	-	27	positive
160	1+	29	positive	177	-	/	negative	194	-	/	negative
161	-	22	positive	178	-	/	negative	195	-	/	negative
162	-	/	negative	179	-	/	negative	196	-	/	negative
163	-	/	negative	180	3+	21	positive	197	3+	21	positive
164	-	/	negative	181	-	/	negative	198	-	/	negative
165	-	/	negative	182	3+	21	positive	199	3+	22	positive
166	3+	21	positive	183	-	/	negative	200	-	/	negative
167	-	/	negative	184	-	/	negative	201	3+	/	negative
168	-	/	negative	185	-	/	negative	202	-	/	negative
169	3+	24	positive	186	3+	24	positive	203	3+	24	positive
170	-	/	negative	187	-	/	negative	204	-	/	negative

Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit		Sample No.	SARS-CoV-2 antigen IVD kit SALIVA	COVID-19 Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
205	-	/	negative	224	-	/	negative	243	-	/	negative
206	3+	21	positive	225	3+	19	positive	244	3+	22	positive
207	-	/	negative	226	-	/	negative	245	3+	21	positive
208	-	/	negative	227	1+	26	positive	246	-	/	negative
209	2+	23	positive	228	-	/	negative	247	3+	21	positive
210	3+	20	positive	229	1+	/	negative	248	-	/	negative
211	-	/	negative	230	-	/	negative	249	-	/	negative
212	-	/	negative	231	-	/	negative	250	-	/	negative
213	-	/	negative	232	3+	21	positive	251	-	/	negative
214	3+	22	positive	233	1+	27	positive	252	3+	21	positive
215	-	/	negative	234	3+	22	positive	253	-	/	negative
216	-	/	negative	235	-	/	negative	254	-	/	negative
217	3+	23	positive	236	-	/	negative	255	3+	24	positive
218	-	/	negative	237	-	/	negative	256	-	/	negative
219	-	/	negative	238	1+	29	positive	257	-	/	negative
220	-	/	negative	239	-	/	negative	258	-	/	negative
221	-	/	negative	240	-	/	negative	259	3+	21	positive
222	-	/	negative	241	-	/	negative	260	-	/	negative
223	3+	22	positive	242	3+	24	positive				

Note:"-" indicates the negative result, "1+, 2+, 3+" indicate positive result, the intensity increases from "1+" to "3+". Ct Value： Cycle threshold