

COVID-19 Coronavirus Real Time PCR Kit

Residual Contaminants Test Report

1. Purpose

Examining the possibility of residual contamination by the COVID-19 Coronavirus Real Time PCR Kit

2. Scope of application

COVID-19 Coronavirus Real Time PCR Kit

3. Standards and regulations for reference

(1) FDA 1757 Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices [2016]

(2) ANSI/AMIHE 75:2009/(R)2013 2013 Human factors engineering -Design of Medical Devices [2013]

4. Test materials

4.1 Assessment Reagent

Examination reagents	Specifications	Batch No.	Validity period
COVID-19 Coronavirus Real Time PCR Kit	50 test/kit	20200104	2021.01.20

4.2 Sample

A high concentration of SARS-CoV-2 positive simulated sample (virus-like granule + nasopharyngeal swab sample) was diluted to 1×10^6 copies/mL using a clean nasopharyngeal swab and divided into 40 copies, and 40 negative nasopharyngeal swab samples were added to the group.

Sample type	Number of cases	Nature	Sample marking
Positive samples	40 cases	Sample simulation	1-1 to 1-40
Negative samples	40 cases	Sample	1-41 to 1-80

Source: Taizhou Centers for Disease Prevention and Control, Jiangsu Province

4.3 Instrument

Fluorescent quantitative PCR instrument: ABI7500

Automatic Nucleic Acid Extraction and Separation Instrument: SSNP-3000A

5. Assessment methodology

The above samples were extracted and detected according to the Plum Blossom Method (see figure below), and 1 batch of COVID-19 Coronavirus Real Time PCR Kit was used by 2 operators to analyze the detection results for 3 consecutive days.

1-1	1-41	1-2	1-42	1-3	1-43	1-4	1-44	1-5	1-45
1-46	1-6	1-47	1-7	1-48	1-8	1-49	1-9	1-50	1-10
1-11	1-51	1-12	1-52	1-13	1-53	1-14	1-54	1-15	1-55

1-56	1-16	1-57	1-17	1-58	1-18	1-59	1-19	1-60	1-20
1-21	1-61	1-22	1-62	1-23	1-63	1-24	1-64	1-25	1-65
1-66	1-26	1-67	1-27	1-68	1-28	1-69	1-29	1-70	1-30
1-31	1-71	1-32	1-72	1-33	1-73	1-34	1-74	1-35	1-75
1-76	1-36	1-77	1-37	1-78	1-38	1-79	1-39	1-80	1-40

Pass or not criteria

All the negative samples were negative and the positive samples were positive.

6. Quality control and safety

- (1) This kit is an in vitro test reagent. Operators should be professionally trained and have certain experience.
- (2) The operation of the experiment shall be strictly zoned, and the items and work clothes of each district shall be specially used, and no cross-use shall be allowed to avoid contamination.
- (3) The kit should be fully melted at room temperature, mixed and centrifuged instantaneously.
- (4) Blank and positive controls shall be provided for each experiment. Do not mix reagents of different batch numbers, use the kit within the validity period.
- (5) Frozen RNA samples should be fully melted at room temperature, mixed and used after instantaneous centrifugation.
- (6) The samples to be tested in this kit shall be considered as infectious substances and shall be operated and handled in accordance with the requirements of the Ministry of Health's General Guidelines on Biosafety to Microbiological Laboratories and the Medical Waste Management Regulations.

7. Results

Cross-test results of 40 negative nasopharyngeal swab samples and 40 high-concentration simulated positive samples are shown in Table 1-1.

Table 1-1. Residual contamination detection results

Sample No.	Operator	Day 1			Day 2			Day 3		
		FAM	VIC	CY5	FAM	VIC	CY5	FAM	VIC	CY5
1-1	1	Undet.	Undet.	26.46	Undet.	Undet.	27.43	Undet.	Undet.	27.17
	2	Undet.	Undet.	27.76	Undet.	Undet.	26.28	Undet.	Undet.	26.27
1-2	1	Undet.	Undet.	27.51	Undet.	Undet.	27.81	Undet.	Undet.	27.9
	2	Undet.	Undet.	27.82	Undet.	Undet.	26.14	Undet.	Undet.	26.03
1-3	1	Undet.	Undet.	26.07	Undet.	Undet.	27.42	Undet.	Undet.	27.51
	2	Undet.	Undet.	27.55	Undet.	Undet.	26.24	Undet.	Undet.	27.64
1-4	1	Undet.	Undet.	26.85	Undet.	Undet.	26.39	Undet.	Undet.	27.27
	2	Undet.	Undet.	27.59	Undet.	Undet.	26.4	Undet.	Undet.	27.74
1-5	1	Undet.	Undet.	27.1	Undet.	Undet.	26.85	Undet.	Undet.	27.98
	2	Undet.	Undet.	26.11	Undet.	Undet.	27.31	Undet.	Undet.	26.9
1-6	1	Undet.	Undet.	26.69	Undet.	Undet.	27.33	Undet.	Undet.	27.62
	2	Undet.	Undet.	26.23	Undet.	Undet.	27.16	Undet.	Undet.	26.22
1-7	1	Undet.	Undet.	27.33	Undet.	Undet.	27.46	Undet.	Undet.	26.84
	2	Undet.	Undet.	26.17	Undet.	Undet.	26.39	Undet.	Undet.	26.51
1-8	1	Undet.	Undet.	27.62	Undet.	Undet.	26.82	Undet.	Undet.	27.87
	2	Undet.	Undet.	26.65	Undet.	Undet.	26.39	Undet.	Undet.	26.12
1-9	1	Undet.	Undet.	26.64	Undet.	Undet.	27.11	Undet.	Undet.	27.42

	2	Undet.	Undet.	27.21	Undet.	Undet.	27.9	Undet.	Undet.	27.36
1-10	1	Undet.	Undet.	27.93	Undet.	Undet.	26.31	Undet.	Undet.	27.05
	2	Undet.	Undet.	27.46	Undet.	Undet.	26.9	Undet.	Undet.	27.39
1-11	1	Undet.	Undet.	27.98	Undet.	Undet.	27.67	Undet.	Undet.	27.37
	2	Undet.	Undet.	27.26	Undet.	Undet.	26.76	Undet.	Undet.	26.35
1-12	1	Undet.	Undet.	26.98	Undet.	Undet.	26.45	Undet.	Undet.	26.54
	2	Undet.	Undet.	26.44	Undet.	Undet.	27.11	Undet.	Undet.	27.85
1-13	1	Undet.	Undet.	27.23	Undet.	Undet.	27.56	Undet.	Undet.	27.3
	2	Undet.	Undet.	26.39	Undet.	Undet.	27.79	Undet.	Undet.	26.02
1-14	1	Undet.	Undet.	27.39	Undet.	Undet.	27.85	Undet.	Undet.	26.21
	2	Undet.	Undet.	26.96	Undet.	Undet.	26.09	Undet.	Undet.	26.87
1-15	1	Undet.	Undet.	27.48	Undet.	Undet.	27.7	Undet.	Undet.	26.66
	2	Undet.	Undet.	27.44	Undet.	Undet.	26.88	Undet.	Undet.	27.75
1-16	1	Undet.	Undet.	27.89	Undet.	Undet.	26.78	Undet.	Undet.	27.75
	2	Undet.	Undet.	27.34	Undet.	Undet.	26.06	Undet.	Undet.	27.12
1-17	1	Undet.	Undet.	27.94	Undet.	Undet.	27.56	Undet.	Undet.	27.72
	2	Undet.	Undet.	27.93	Undet.	Undet.	26.19	Undet.	Undet.	27.53
1-18	1	Undet.	Undet.	27	Undet.	Undet.	27.79	Undet.	Undet.	26.09
	2	Undet.	Undet.	27.62	Undet.	Undet.	27.51	Undet.	Undet.	26.16
1-19	1	Undet.	Undet.	26.66	Undet.	Undet.	26.26	Undet.	Undet.	27.24
	2	Undet.	Undet.	27.03	Undet.	Undet.	27.83	Undet.	Undet.	27.57
1-20	1	Undet.	Undet.	26.5	Undet.	Undet.	27.45	Undet.	Undet.	27.62
	2	Undet.	Undet.	27.03	Undet.	Undet.	27.41	Undet.	Undet.	27.23
1-21	1	Undet.	Undet.	27.58	Undet.	Undet.	26.81	Undet.	Undet.	26.12
	2	Undet.	Undet.	27.74	Undet.	Undet.	27.79	Undet.	Undet.	26.5
1-22	1	Undet.	Undet.	26.16	Undet.	Undet.	27.75	Undet.	Undet.	27.23
	2	Undet.	Undet.	26.2	Undet.	Undet.	26.15	Undet.	Undet.	27.85
1-23	1	Undet.	Undet.	27	Undet.	Undet.	26.54	Undet.	Undet.	27.73
	2	Undet.	Undet.	26.98	Undet.	Undet.	26.63	Undet.	Undet.	27.37
1-24	1	Undet.	Undet.	27.92	Undet.	Undet.	27.43	Undet.	Undet.	26.98
	2	Undet.	Undet.	26.72	Undet.	Undet.	26.57	Undet.	Undet.	27.37
1-25	1	Undet.	Undet.	27.93	Undet.	Undet.	26.1	Undet.	Undet.	26.63
	2	Undet.	Undet.	26.7	Undet.	Undet.	27.71	Undet.	Undet.	27.87
1-26	1	Undet.	Undet.	26.07	Undet.	Undet.	26.37	Undet.	Undet.	26.36
	2	Undet.	Undet.	27.88	Undet.	Undet.	26.72	Undet.	Undet.	26.5
1-27	1	Undet.	Undet.	27.14	Undet.	Undet.	27.28	Undet.	Undet.	26.18
	2	Undet.	Undet.	27.48	Undet.	Undet.	27.01	Undet.	Undet.	26.19
1-28	1	Undet.	Undet.	26.86	Undet.	Undet.	26.75	Undet.	Undet.	27.73
	2	Undet.	Undet.	26.19	Undet.	Undet.	27.77	Undet.	Undet.	27.58
1-29	1	Undet.	Undet.	26.72	Undet.	Undet.	27.01	Undet.	Undet.	27.27
	2	Undet.	Undet.	27.9	Undet.	Undet.	27.06	Undet.	Undet.	27.81
1-30	1	Undet.	Undet.	27.11	Undet.	Undet.	27	Undet.	Undet.	27.73
	2	Undet.	Undet.	27.35	Undet.	Undet.	26.14	Undet.	Undet.	27.03

1-31	1	Undet.	Undet.	27.76	Undet.	Undet.	26.08	Undet.	Undet.	27.74
	2	Undet.	Undet.	27.89	Undet.	Undet.	27.21	Undet.	Undet.	26.95
1-32	1	Undet.	Undet.	26.13	Undet.	Undet.	27.45	Undet.	Undet.	26.35
	2	Undet.	Undet.	27.83	Undet.	Undet.	27.12	Undet.	Undet.	26.27
1-33	1	Undet.	Undet.	26.78	Undet.	Undet.	27.37	Undet.	Undet.	26.41
	2	Undet.	Undet.	27.51	Undet.	Undet.	27.05	Undet.	Undet.	27.24
1-34	1	Undet.	Undet.	26.89	Undet.	Undet.	26.18	Undet.	Undet.	26.77
	2	Undet.	Undet.	27.24	Undet.	Undet.	26.51	Undet.	Undet.	26.59
1-35	1	Undet.	Undet.	27.42	Undet.	Undet.	27.16	Undet.	Undet.	27.43
	2	Undet.	Undet.	27.73	Undet.	Undet.	26.75	Undet.	Undet.	27.33
1-36	1	Undet.	Undet.	27.04	Undet.	Undet.	26.09	Undet.	Undet.	26.49
	2	Undet.	Undet.	27.89	Undet.	Undet.	27.79	Undet.	Undet.	26.41
1-37	1	Undet.	Undet.	26.31	Undet.	Undet.	26.92	Undet.	Undet.	26.58
	2	Undet.	Undet.	27.46	Undet.	Undet.	26.88	Undet.	Undet.	27.29
1-38	1	Undet.	Undet.	26.08	Undet.	Undet.	27.96	Undet.	Undet.	27.66
	2	Undet.	Undet.	26.02	Undet.	Undet.	27.88	Undet.	Undet.	27.41
1-39	1	Undet.	Undet.	26.39	Undet.	Undet.	26.71	Undet.	Undet.	27.07
	2	Undet.	Undet.	27.27	Undet.	Undet.	26.11	Undet.	Undet.	27.23
1-40	1	Undet.	Undet.	27.66	Undet.	Undet.	26.14	Undet.	Undet.	26.22
	2	Undet.	Undet.	27.97	Undet.	Undet.	26.02	Undet.	Undet.	27.23
1-41	1	22.42	22.70	26.72	22.65	22.95	26.26	22.90	23.22	26.67
	2	22.60	22.61	26.95	22.46	23.36	26.43	22.21	22.60	26.71
1-42	1	22.10	23.31	26.67	22.16	22.64	26.32	22.50	22.64	26.21
	2	22.20	22.85	26.44	22.60	23.15	26.52	22.91	22.57	26.13
1-43	1	22.21	23.22	26.03	22.02	23.43	26.38	22.22	23.43	26.96
	2	22.08	22.82	26.69	22.66	22.57	26.86	22.41	22.98	26.77
1-44	1	22.53	23.20	26.49	22.31	22.71	26.94	22.83	23.20	26.31
	2	22.44	23.37	26.34	22.38	23.06	26.30	22.08	23.28	26.42
1-45	1	22.71	23.10	26.55	22.78	22.95	26.19	22.63	22.67	26.25
	2	22.08	23.15	26.59	22.94	22.55	26.94	22.34	23.29	26.53
1-46	1	22.80	22.70	26.88	22.46	23.18	26.48	22.94	22.63	26.92
	2	22.32	23.16	26.44	22.05	22.60	26.08	22.49	23.24	26.27
1-47	1	22.63	23.04	26.56	22.77	23.43	26.92	22.15	23.47	26.12
	2	22.84	22.75	26.27	22.19	23.46	26.16	22.89	22.50	26.09
1-48	1	22.60	23.29	26.52	22.04	22.68	26.48	22.45	23.28	26.50
	2	22.19	22.68	26.23	22.58	23.46	26.41	22.35	22.56	26.59
1-49	1	22.97	23.14	26.74	22.41	23.41	26.89	22.68	23.41	26.36
	2	22.87	22.88	26.97	22.10	23.27	26.20	22.48	23.42	26.92

1-50	1	22.02	22.78	26.14	23.00	23.13	26.82	22.34	23.13	26.29
	2	22.86	23.47	26.94	22.40	22.81	26.01	22.75	23.28	26.74
1-51	1	22.62	23.02	26.90	22.44	22.55	26.42	22.98	23.06	26.29
	2	22.57	22.92	26.53	22.94	23.09	26.89	22.10	23.33	26.52
1-52	1	22.75	23.20	26.64	22.24	22.74	26.52	22.79	23.12	26.88
	2	22.85	22.97	26.39	22.06	23.27	26.07	22.36	22.77	26.89
1-53	1	22.10	22.57	26.71	22.46	23.41	26.47	22.30	22.94	26.66
	2	22.74	23.12	26.14	22.10	22.96	26.65	22.95	23.41	26.01
1-54	1	22.76	22.64	26.89	22.06	22.81	26.87	22.23	22.95	26.86
	2	22.27	22.95	26.44	22.42	23.47	26.45	22.95	23.30	26.98
1-55	1	22.83	23.27	26.75	22.27	22.51	26.30	22.53	22.71	26.05
	2	22.16	22.88	26.10	22.09	23.32	26.61	22.53	23.08	26.96
1-56	1	22.30	22.58	26.73	22.99	22.75	26.80	22.15	23.42	26.30
	2	22.27	23.21	26.26	22.45	23.25	26.91	22.50	23.29	26.80
1-57	1	22.44	23.00	26.55	22.68	23.09	26.05	22.78	22.87	26.97
	2	22.46	23.04	26.10	22.88	23.39	26.58	22.22	23.04	26.99
1-58	1	22.42	22.73	26.40	22.58	22.58	26.20	22.43	23.01	26.40
	2	22.30	23.44	26.12	22.96	23.31	26.11	22.83	22.80	26.64
1-59	1	22.15	22.61	26.02	22.35	23.05	26.49	22.79	22.73	26.42
	2	22.60	23.11	26.90	22.25	22.91	26.65	22.05	22.54	26.85
1-60	1	22.50	23.23	26.45	22.98	23.40	26.28	22.15	22.65	26.43
	2	22.82	22.66	26.53	22.15	23.12	26.38	22.60	23.02	26.45
1-61	1	22.66	22.56	26.04	22.44	22.97	26.01	22.85	22.89	26.87
	2	22.59	23.09	26.68	22.28	22.63	26.00	22.83	22.63	26.48
1-62	1	22.38	23.45	26.61	22.62	23.26	26.44	22.44	23.38	26.59
	2	22.84	23.34	26.37	22.35	23.45	26.53	22.46	23.37	26.11
1-63	1	22.23	23.27	26.09	22.62	22.71	26.33	22.06	23.02	26.55
	2	22.00	22.51	26.60	22.86	23.36	26.92	22.70	22.65	26.67
1-64	1	22.82	22.84	26.93	22.49	22.91	26.30	22.56	23.33	26.57
	2	22.85	22.72	26.70	22.96	22.76	26.07	23.00	22.99	26.29
1-65	1	22.27	23.13	26.61	22.09	23.49	26.50	22.45	22.98	26.43
	2	22.27	22.77	26.17	22.84	22.58	26.45	22.65	23.03	26.03
1-66	1	22.05	22.87	26.25	22.06	23.11	26.01	22.29	22.64	26.59
	2	22.82	22.65	26.87	22.96	23.07	26.81	22.38	23.14	26.90
1-67	1	22.73	22.82	26.57	22.20	23.44	26.08	22.82	23.26	26.93
	2	22.44	22.65	26.43	23.00	22.76	26.80	22.10	22.88	26.84
1-68	1	22.37	23.43	26.67	22.74	23.21	26.66	22.52	23.22	26.53
	2	22.87	22.84	26.28	22.76	22.56	26.80	22.48	23.09	26.28
1-69	1	22.21	22.57	26.25	22.91	22.89	26.14	22.22	22.94	26.93
	2	22.94	22.70	26.17	22.23	22.93	26.21	22.45	22.59	26.60

1-70	1	22.92	22.59	26.37	22.57	22.98	26.03	22.96	22.87	26.50
	2	22.71	22.71	26.68	22.68	23.44	26.85	22.40	22.77	26.76
1-71	1	22.65	23.01	26.06	22.90	23.37	26.94	22.25	22.80	26.68
	2	22.80	23.22	26.87	22.66	23.32	26.83	22.75	23.37	26.24
1-72	1	22.61	22.55	26.39	22.39	23.33	26.17	22.16	22.76	26.03
	2	22.91	23.04	26.61	22.70	23.31	27.00	22.97	23.44	26.15
1-73	1	22.08	22.61	26.46	22.03	22.78	27.00	22.20	23.39	26.64
	2	23.00	22.73	26.39	22.82	23.46	26.57	22.54	22.87	26.25
1-74	1	22.33	23.12	26.54	22.69	22.84	26.12	22.41	22.81	26.24
	2	22.05	22.75	26.96	22.77	23.32	26.31	22.33	22.63	26.96
1-75	1	22.79	23.23	26.14	22.70	23.23	26.35	22.70	22.71	26.90
	2	22.84	22.70	26.26	22.68	23.00	26.19	22.98	23.47	27.00
1-76	1	22.14	23.26	26.33	22.23	23.38	26.34	22.35	22.55	26.48
	2	22.62	22.67	26.50	22.68	22.58	26.92	22.59	22.93	26.45
1-77	1	22.64	23.48	26.95	22.61	23.24	26.31	22.36	23.09	26.92
	2	22.78	23.47	26.11	22.02	22.73	26.14	22.29	22.72	26.99
1-78	1	22.33	22.98	26.54	22.50	23.49	26.57	22.00	22.70	26.67
	2	22.20	23.24	26.48	22.01	23.47	26.34	22.24	23.19	26.81
1-79	1	22.76	22.54	26.56	22.97	23.45	26.75	22.87	22.91	26.41
	2	22.61	23.34	26.14	22.09	23.06	26.11	22.82	22.65	26.40
1-80	1	22.03	22.76	26.57	22.13	23.42	26.08	22.79	22.52	26.85
	2	22.89	23.45	26.32	22.82	22.89	26.22	22.27	23.26	26.93

The results of 40 negative nasopharyngeal swab samples were all negative, and the positive samples were all positive, that is, the cross contamination rate was 0%.

8. Conclusions

No residual contamination in the COVID-19 Coronavirus Real Time PCR Kit.