Analysis of the potential Microbial cross-reaction

Novel coronavirus (SARS-CoV-2) antigen detection kit

(Colloidal gold immunochromatography)

1 Experimental purpose

To investigate the impact of the test result of the novel coronavirus (SARS-CoV-2) antigen detection kit (colloidal gold immunochromatography) when coexisting other microorganisms in the sample.

2 Experimental materials

2.1 Novel coronavirus (SARS-CoV-2) antigen detection kit (colloidal gold immunochromatography)
2.2 Microbial cross-reaction samples (Detail in Table 1)
2.3 SARS-CoV-2 virus culture

Table 1

Sources	Sample No.	Sample type
Chinese "National controls for SARS-CoV-2 antigen detection kit" N1~N20	N1	Staphylococcus aureus
	N2	Streptococcus pyogenes
	N3	Measles virus
	N4	Paramyxovirus parotitis
	N5	Adenovirus 3
	N6	Mycoplasma pneumoniae
	N7	Parainfluenza virus 2
	N8	Human Metapneumovirus (hMPV)
	N9	Human coronavirus OC43
	N10	Human coronavirus 229E
	N11	Bordetella parapertussia
	N12	Influenza B (Victoria strain)
	N13	Influenza B (Ystrain)
	N14	Influenza A (H1N1, 2009)
	N15	Influenza A (H3N2)
	N16	Avian influenza virus (H7N9)
	N17	Avian influenza virus (H5N1)
	N18	Epstein-Barr virus
	N19	Enterovirus CA16
	N20	Rhinovirus
Zhujiang Hospital of	N21	Respiratory syncytial virus

Southern Medical University	N22	*Streptococcus pneumoniae*
	N23	*Candida albicans*
	N24	*Chlamydia pneumoniae*
	N25	Bordetella pertussis
	N26	Human coronavirus NL63（Recombinant protein）
	N27	*Pneumocystis jirovecii*
	N28	*Mycobacterium tuberculosis*
	N29	Human coronavirus HKU1（Recombinant protein）
	N30	*Legionella pneumophila*

3 Experimental method

Add the SARS-Cov-2 virus culture to the specimens in 2.2, to make the concentration of the virus culture three times of the minimum detection limit (1.5×10^2 TCID50/mL). Use the prepared specimens as samples to test in accordance with the instructions. 3 repeats per specimen, record the results and analyze the data. The sample numbers are as follows:

Table 2 Added sample and its No.

Sources	Sample No.	Added sample	Sample type
Chinese "National controls for SARS-CoV-2 antigen detection kit" N1~N20	N1	N1+	Staphylococcus aureus
	N2	N2+	Streptococcus pyogenes
	N3	N3+	Measles virus
	N4	N4+	Paramyxovirus parotitis
	N5	N5+	Adenovirus 3
	N6	N6+	Mycoplasma pneumoniae
	N7	N7+	Parainfluenza virus 2
	N8	N8+	Human Metapneumovirus (hMPV)
	N9	N9+	Human coronavirus OC43
	N10	N10+	Human coronavirus 229E
	N11	N11+	Bordetella parapertussia
	N12	N12+	Influenza B (Victoria strain)
	N13	N13+	Influenza B (Ystrain)
	N14	N14+	Influenza A (H1N1, 2009)
	N15	N15+	Influenza A (H3N2)
	N16	N16+	Avian influenza virus (H7N9)
	N17	N17+	Avian influenza virus (H5N1)

	N18	N18+	Epstein-Barr virus
	N19	N19+	Enterovirus CA16
	N20	N20+	Rhinovirus
Zhujiang Hospital of Southern Medical University	N21	N21+	Respiratory syncytial virus
	N22	N22+	*Streptococcus pneumoniae*
	N23	N23+	*Candida albicans*
	N24	N24+	*Chlamydia pneumoniae*
	N25	N25+	Bordetella pertussis
	N26	N26+	Human coronavirus NL63（Recombinant protein）
	N27	N27+	*Pneumocystis jirovecii*
	N28	N28+	*Mycobacterium tuberculosis*
	N29	N29+	Human coronavirus HKU1(Recombinant protein）
	N30	N30+	*Legionella pneumophila*

4 Experimental results

Table 3   Test results of interference reaction

Original Sample	Result			Added Sample	Result		
	Batch 1	Batch 2	Batch 3		Batch 1	Batch 2	Batch 3
N1	-	-	-	N1+	+	+	+
N2	-	-	-	N2+	+	+	+
N3	-	-	-	N3+	+	+	+
N4	-	-	-	N4+	+	+	+
N5	-	-	-	N5+	+	+	+
N6	-	-	-	N6+	+	+	+
N7	-	-	-	N7+	+	+	+
N8	-	-	-	N8+	+	+	+
N9	-	-	-	N9+	+	+	+
N10	-	-	-	N10+	+	+	+
N11	-	-	-	N11+	+	+	+
N12	-	-	-	N12+	+	+	+
N13	-	-	-	N13+	+	+	+
N14	-	-	-	N14+	+	+	+
N15	-	-	-	N15+	+	+	+
N16	-	-	-	N16+	+	+	+
N17	-	-	-	N17+	+	+	+
N18	-	-	-	N18+	+	+	+

N19	-	-	-	N19+	+	+	+
N20	-	-	-	N20+	+	+	+
N21	-	-	-	N21+	+	+	+
N22	-	-	-	N22+	+	+	+
N23	-	-	-	N23+	+	+	+
N24	-	-	-	N24+	+	+	+
N25	-	-	-	N25+	+	+	+
N26	-	-	-	N26+	+	+	+
N27	-	-	-	N27+	+	+	+
N28	-	-	-	N28+	+	+	+
N29	-	-	-	N29+	+	+	+
N30	-	-	-	N30+	+	+	+

Note: "+" indicates a positive result, and "-" indicates a negative result.

5 Experimental conclusions

Cross-reaction experiments were conducted on three batches of reagents, and based on the results, the company's novel coronavirus (SARS-CoV-2) antigen detection kit (colloidal gold immunochromatography) was used to detect the novel coronavirus (SARS-CoV-2). There are no false negatives and false positives for the specimens coexisting with other microorganisms. Therefore, the above microorganisms have no impact on the experimental results.