

Analytical Specificity – Cross Reactivity Studies

Product Name: Rapid SARS-CoV-2 Antigen Test Card

Catalog No.: 1N40C5

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Xiamen Boson Biotech Co., Ltd.

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1. Purpose

To analyze whether common microorganisms would cause cross reactivity on the test results of the Rapid SARS-CoV-2 Antigen Test Card, and evaluate the product specificity.

2. References

	Document No.	Document
1	BS EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices

3. Personnel and Responsibility

Name	Position	Education	Responsibility
Haolong Shen	Management Representative	B.S.	Approval of study report
Zhijuan Jia	R&D Manager	M.S.	Review of study report
Kesai Liu	R&D Engineer	M.S.	Study implementation, recording, analysis of results, and report drafting
Mengjuan Wu	R&D Vice Manager	M.S.	Study implementation, recording, analysis of results, and report drafting

4. Materials

4.1. Evaluated Reagent

Rapid SARS-CoV-2 Antigen Test Card (1N40C5)		
	Lot Number	Manufacturer
1	H20061502	Xiamen Boson Biotech Co., Ltd.

4.2. Other Materials

	Name	Lot No. (Catalog No.)	Notes
1	SARS-CoV-2 viral culture	NR-52281 (USA-WA1/2020)	ZeptoMetrix Corporation
2	Human coronavirus 229E	R20051235	ZeptoMetrix Corporation
3	Human coronavirus OC43	R20051233	ZeptoMetrix Corporation
4	Human coronavirus NL63	R20051234	ZeptoMetrix Corporation
5	Parainfluenza virus 1	R20051715	ZeptoMetrix Corporation
6	Parainfluenza virus 2	R20051716	ZeptoMetrix Corporation
7	Parainfluenza virus 3	R20051717	ZeptoMetrix Corporation
8	Enterovirus EV71	R20051718	ATCC
9	Respiratory syncytial virus	R20051612	ZeptoMetrix Corporation
10	Rhinovirus	R20051714	ATCC
11	Influenza A virus (H1N1)	R19101301	National Institute for the Control of Pharmaceutical and Biological Products (NICPBP)
12	Influenza A virus (H3N2)	R19101302	NICPBP
13	Influenza B virus	R19101303	NICPBP

	(Yamagata)		
14	Influenza B virus (Victoria)	R19101304	NICPBP
15	Adeno virus 71	R20051719	ATCC
16	MERS-coronavirus	R20051232	ZeptoMetrix Corporation
17	Chlamydia pneumoniae	R20062510	ATCC
18	Streptococcus pneumoniae	R20062511	ATCC
19	Streptococcus pyogenes	R20121823	ATCC
20	Bordetella pertussis	R20062513	ZeptoMetrix Corporation
21	Mycobacterium tuberculosis	R20062514	ATCC
22	Legionella pneumophila	R20062515	ATCC
23	Mycoplasma pneumoniae	R20121502	ATCC
24	Haemophilus influenzae	R20062506	ATCC
25	Candida albicans	Q18071804	CMCC(F)98001
26	Staphylococcus aureus	Q19072903	CMCC(B)26003
27	Pseudomonas aeruginosa	Q18071806	CMCC(B)10104
28	Escherichia coli	Q19072901	CMCC(B)44102
29	Human Metapneumovirus (hMPV)	R20082113	ZeptoMetrix Corporation
30	Human coronavirus HKU1	R20121852	BioVector NTCC Inc.
31	Pneumocystis jirovecii (PJP)	R20082115	ATCC
32	SARS-coronavirus	R20082116	ZeptoMetrix Corporation
33	Parainfluenza virus 4	R20121850	ZeptoMetrix Corporation
34	Staphylococcus epidermidis	R20121822	ATCC
35	Nasal wash	R20122308	The Alkalol Company

5. Methods

5.1. Matrix Preparation

Use the nasopharyngeal swabs to collect nasopharyngeal swabs from healthy individuals, and add to the extraction tube with sample extraction buffer. Mix well and use as the negative matrix.

5.2. Sample Preparation

1) Preparation of Microorganism Samples

Add the microorganisms into the negative control samples and prepare samples with concentrations shown in Table 1.

Table 1. Testing concentrations of cross reactivity substances

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0×10^6 TCID ₅₀ /mL	MERS-coronavirus	1.0×10^5 PFU/mL

Human coronavirus OC43	2.0×10^6 TCID ₅₀ /mL	Chlamydia pneumoniae	2.0×10^6 IFU/mL
Human coronavirus NL63	2.0×10^6 TCID ₅₀ /mL	Streptococcus pneumoniae	2.0×10^6 CFU/mL
Parainfluenza virus 1	2.0×10^6 TCID ₅₀ /mL	Streptococcus pyogenes	2.0×10^6 CFU/mL
Parainfluenza virus 2	2.0×10^6 TCID ₅₀ /mL	Bordetella pertussis	2.0×10^6 CFU/mL
Parainfluenza virus 3	2.0×10^6 TCID ₅₀ /mL	Mycobacterium tuberculosis	2.0×10^6 CFU/mL
Enterovirus EV71	2.0×10^6 TCID ₅₀ /mL	Legionella pneumophila	2.0×10^6 CFU/mL
Respiratory syncytial virus	2.0×10^6 TCID ₅₀ /mL	Mycoplasma pneumoniae	2.0×10^6 U/mL
Rhinovirus	2.0×10^6 TCID ₅₀ /mL	Haemophilus influenzae	2.0×10^6 CFU/mL
Influenza A virus (H1N1)	2.0×10^6 TCID ₅₀ /mL	Candida albicans	2.0×10^6 CFU/mL
Influenza A virus (H3N2)	2.0×10^6 TCID ₅₀ /mL	Staphylococcus aureus	2.0×10^6 CFU/mL
Influenza B virus (Yamagata)	2.0×10^6 TCID ₅₀ /mL	Pseudomonas aeruginosa	2.0×10^6 CFU/mL
Influenza B virus (Victoria)	2.0×10^6 TCID ₅₀ /mL	Escherichia coli	2.0×10^6 CFU/mL
Adeno virus 71	2.0×10^6 TCID ₅₀ /mL	Pneumocystis jirovecii (PJP)	2.0×10^6 Copies/mL
Human Metapneumovirus(hMPV)	2.0×10^6 TCID ₅₀ /mL	Human coronavirus HKU1	2.0×10^6 TCID ₅₀ /mL
SARS-coronavirus	2.0×10^6 TCID ₅₀ /mL	Parainfluenza virus 4	2.0×10^6 TCID ₅₀ /mL
Staphylococcus epidermidis	2.0×10^6 CFU/mL	Pooled human nasal wash	N/A

2) Preparation of pooled human nasal wash samples: use nasal wash to rinse the nasal cavity of healthy individuals. Collect 5 samples, mix well and add into the negative matrix (1:1 volume ratio) to prepare the pooled human nasal wash sample.

5.3. Sample Testing

Use the Rapid SARS-CoV-2 Antigen Test Card to test the samples. Perform 3 parallel tests for each sample, and read results 15-20 min after sample addition.

Carry out the test procedures and interpretation of results according to the instructions for use.

6. Results

Table 2. Test results for cross reactivity samples

Microorganisms	1	2	3
Human coronavirus 229E	-	-	-
Human coronavirus OC43	-	-	-
Human coronavirus NL63	-	-	-

Parainfluenza virus 1	-	-	-
Parainfluenza virus 2	-	-	-
Parainfluenza virus 3	-	-	-
Enterovirus EV71	-	-	-
Respiratory syncytial virus	-	-	-
Rhinovirus	-	-	-
Influenza A virus (H1N1)	-	-	-
Influenza A virus (H3N2)	-	-	-
Influenza B virus (Yamagata)	-	-	-
Influenza B virus (Victoria)	-	-	-
Adeno virus 71	-	-	-
MERS-coronavirus	-	-	-
Chlamydia pneumoniae	-	-	-
Streptococcus pneumoniae	-	-	-
Streptococcus pyogenes	-	-	-
Bordetella pertussis	-	-	-
Mycobacterium tuberculosis	-	-	-
Legionella pneumophila	-	-	-
Mycoplasma pneumoniae	-	-	-
Haemophilus influenzae	-	-	-
Candida albicans	-	-	-
Staphylococcus aureus	-	-	-
Pseudomonas aeruginosa	-	-	-
Escherichia coli	-	-	-
Human Metapneumovirus(hMPV)	-	-	-
Human coronavirus HKU1	-	-	-
Pneumocystis jirovecii(PJP)	-	-	-
SARS-coronavirus	+	+	+
Parainfluenza virus 4	-	-	-
Staphylococcus epidermidis	-	-	-
Pooled human nasal wash	-	-	-

7. Analysis of Results

The test results for SARS-coronavirus samples were positive, indicating cross reactivity. The test results for other pathogen samples were all negative and no cross reactivity was found. The test results for pooled human nasal wash samples were negative, and no cross

reactivity was found.

8. Conclusion

Using the Rapid SARS-CoV-2 Antigen Test Card, the test results for SARS-coronavirus samples were positive, indicating cross reactivity. The test results for other pathogen samples were all negative and no cross reactivity was found. The test results for pooled human nasal wash samples were negative, and no cross reactivity was found.