新型冠状病毒（2019-nCoV）抗原检测试剂盒（胶体金法）

SARS-CoV-2 Antigen Test Kit (colloidal gold method)

性能报告

Performance Study

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1.1 最低检测限的确认 Validation of LoD

选取 3 份阴性鼻咽拭子样本与 2019-nCoV 假病毒混合并进行梯度稀释，每份样本得到 1600, 800, 400, 200, 100 $TCID_{50}$/ml 浓度的 2019-nCoV 人造样本，分别用 3 批本试剂盒检测，每批试剂盒均对每一梯度的每一份样本重复检测 20 次，如此，对于每一份样本，3 批合计检测 60 次，故每个梯度均进行了 3 批试剂盒合计 180 次重复检测。结果如下表。阴性鼻咽拭子样本为我司返岗健康人员捐献（经 PCR 检测鼻咽拭子阴性）。

We selected three negative nasopharyngeal swab samples mixed with 2019-nCoV pseudovirus for serial gradient dilution, then 2019-nCoV contrived swab samples at the concentration of 4000, 2000, 1000, 500, 250 pfu/ml of each sample were obtained. Three batches of the kit were used for testing, and each batch was tested 20 times for each sample of each gradient. Thus, for each sample, three batches were tested for 60 times in total, so three batches of kit were tested for 180 times in total for each gradient. Results are shown in the table below. Negative nasopharyngeal swab samples were donated by health personnel returning to work of our company (negative nasopharyngeal swab detected by PCR method).

样本编号 Sample No.	浓度 Concentration $TCID_{50}$/ml	第一批		第二批		第三批		检出率≥90%的最低浓度 The lowest virus concentration that was detected ≥ 90%
		结果 Results	检出率 Detection rate	结果 Results	检出率 Detection rate	结果 Results	检出率 Detection rate	
N1	1600	20/20(+)	100%	19/20(+)	95%	20/20(+)	100%	200 $TCID_{50}$/ml
	800	20/20(+)	100%	20/20(+)	100%	19/20(+)	95%	
	400	19/20(+)	95%	19/20(+)	95%	20/20(+)	100%	
	200	19/20(+)	95%	20/20(+)	100%	18/20(+)	90%	
	100	15/20(+)	75%	14/20(+)	70%	12/20(+)	60%	
N2	1600	20/20(+)	100%	20/20(+)	100%	19/20(+)	95%	200 $TCID_{50}$/ml
	800	20/20(+)	100%	19/20(+)	95%	20/20(+)	100%	
	400	19/20(+)	95%	20/20(+)	100%	20/20(+)	100%	
	200	18/20(+)	90%	19/20(+)	95%	20/20(+)	100%	

	100	13/20(+)	65%	14/20(+)	70%	14/20(+)	70%	
N3	1600	20/20(+)	100%	20/20(+)	100%	19/20(+)	95%	200 $TCID_{50}$/ml
	800	19/20(+)	95%	20/20(+)	100%	20/20(+)	100%	
	400	20/20(+)	100%	20/20(+)	100%	19/20(+)	95%	
	200	18/20(+)	90%	20/20(+)	100%	19/20(+)	95%	
	100	14/20(+)	70%	15/20(+)	65%	16/20(+)	80%	

结论：因此，最低检测限初步确定为 200 $TCID_{50}$/ml。

Conclusion: From the results showed above, the limit of detection was preliminarily determined as 200 $TCID_{50}$/ml.

1.2 最低检测限的验证 Verification of LoD

选取 3 份阴性鼻咽拭子样本与 2019-nCoV 假病毒混合并进行梯度稀释，每份样本得到 350, 175, 87.5 $TCID_{50}$/ml 浓度的 2019-nCoV 人造样本，分别用 3 批本试剂盒检测，每批试剂盒均对每一梯度的每一份样本重复检测 20 次，如此，对于每一份样本，3 批合计检测 60 次，故每个梯度均进行了 3 批试剂盒合计 180 次重复检测。结果如下表。阴性鼻咽拭子样本为我司返岗健康人员捐献（经 PCR 检测鼻咽拭子阴性）。

We selected three negative nasopharyngeal swab samples mixed with 2019-nCoV pseudovirus for serial gradient dilution, then 2019-nCoV contrived swab samples at the concentration of 350, 175, 87.5 $TCID_{50}$/ml of each sample were obtained. Three batches of the kit were used for testing, and each batch was tested 20 times for each sample of each gradient. Thus, for each sample, three batches were tested for 60 times in total, so three batches of kit were tested for 180 times in total for each gradient. Results are shown in the table below. Negative nasopharyngeal swab samples were donated by health personnel returning to work of our company (negative nasopharyngeal swab detected by PCR method).

样本编号 Sample No.	浓度 Concentration pfu/ml	第一批		第二批		第三批		检出率≥95%的最低浓度 The lowest virus concentration that was detected ≥ 95%
		结果 Results	检出率 Detection rate	结果 Results	检出率 Detection rate	结果 Results	检出率 Detection rate	
N4	350	20/20(+)	100%	20/20(+)	100%	19/20(+)	95%	175

	175	20/20(+)	100%	20/20(+)	100%	19/20(+)	95%	$TCID_{50}$/ml
	87.5	17/20(+)	85%	16/20(+)	80%	14/20(+)	70%	
N5	350	20/20(+)	100%	20/20(+)	100%	20/20(+)	100%	175 $TCID_{50}$/ml
	175	20/20(+)	100%	19/20(+)	95%	20/20(+)	100%	
	87.5	14/20(+)	70%	15/20(+)	75%	13/20(+)	65%	
N6	350	19/20(+)	95%	20/20(+)	100%	20/20(+)	100%	175 $TCID_{50}$/ml
	175	20/20(+)	100%	19/20(+)	95%	20/20(+)	100%	
	87.5	15/20(+)	75%	16/20(+)	80%	14/20(+)	70%	

结论：因此，最低检测限确定为 1.75×10^2 $TCID_{50}$/ml。

Conclusion: From the results showed above, the limit of detection was confirmed as 1.75×10^2 $TCID_{50}$/ml.

2. 分析特异性 Analytical specificity

2.1 交叉反应 Cross reactivity

采用 3 批试剂盒，对抗原结构相近或临床症状相似的其他病原体进行交叉反应研究，每份样本检测 1 次。结果均为阴性。试验用阳性样本通过将阴性鼻咽拭子样本与 2019-nCoV 假病毒混合得到。

Three batches of kits were used to study the cross-reaction of other pathogens with similar antigen structure or similar clinical symptoms, and each sample was tested once. The results were all negative. Positive samples for testing were obtained by mixing negative nasopharyngeal swab samples with 2019-nCoV pseudovirus.

序号 No.	可能引起交叉反应的病原体 Pathogens that may cause cross-reaction	第一批	第二批	第三批
1	冠状病毒 HKU1 Coronavirus HKU1	-	-	-
2	冠状病毒 OC43 Coronavirus OC43	-	-	-
3	冠状病毒 NL63 Coronavirus NL63	-	-	-

4	冠状病毒 229E Coronavirus 229E	-	-	-
5	甲型流感病毒 2009H1N1 Influenza A virus 2009H1N1	-	-	-
6	甲型流感病毒季节性 H1N1 Influenza A virus seasonal H1N1	-	-	-
7	甲型流感病毒 H3N2 Influenza A virus H3N2	-	-	-
8	甲型流感病毒 H5N1 Influenza A virus H5N1	-	-	-
9	甲型流感病毒 H7N9 Influenza A virus H7N9	-	-	-
10	乙型流感病毒 Yamagata Influenza B virus Yamagata	-	-	-
11	乙型流感病毒 Victoria Influenza B virus Victoria	-	-	-
12	呼吸道合胞病毒 Respiratory syncytial virus	-	-	-
13	鼻病毒（A 组） Rhinovirus (group A)	-	-	-
14	鼻病毒（B 组） Rhinovirus (group B)	-	-	-
15	鼻病毒（C 组） Rhinovirus (group C)	-	-	-
16	呼吸道腺病毒（1 型） Respiratory adenovirus type 1	-	-	-
17	呼吸道腺病毒（2 型） Respiratory adenovirus type 2	-	-	-
18	呼吸道腺病毒（3 型）	-	-	-

	Respiratory adenovirus type 3			
19	呼吸道腺病毒（4 型） Respiratory adenovirus type 4	-	-	-
20	呼吸道腺病毒（5 型） Respiratory adenovirus type 5	-	-	-
21	呼吸道腺病毒（7 型） Respiratory adenovirus type 7	-	-	-
22	呼吸道腺病毒（55 型） Respiratory adenovirus type 55	-	-	-
23	肠道病毒（A 组） Enterovirus (group A)	-	-	-
24	肠道病毒（B 组） Enterovirus (group B)	-	-	-
25	肠道病毒（C 组） Enterovirus (group C)	-	-	-
26	肠道病毒（D 组） Enterovirus (group D)	-	-	-
27	EB 病毒衣壳抗原 Epstein-barr virus capsid antigen	-	-	-
28	麻疹病毒 Measles virus	-	-	-
29	人巨细胞病毒 Human cytomegalovirus	-	-	-
30	轮状病毒 Rotavirus	-	-	-
31	诺如病毒 Norovirus	-	-	-
32	腮腺炎病毒 Mumps virus	-	-	-
33	水痘-带状疱疹病毒 Varicella zoster virus	-	-	-
34	副流感病毒 Parainfluenza virus	-	-	-
35	肺炎支原体	-	-	-

	Mycoplasma pneumoniae			
36	肺炎衣原体 Chlamydia pneumoniae	-	-	-
37	血杆菌 Haemophiluspamsuis	-	-	-
38	MERS	-	-	-

结论：以上结果表明，本试剂盒与冠状病毒（HKU1、OC43、NL63、229E）、MERS、甲型流感病毒（2009H1N1、季节性 H1N1、H3N2、H5N1、H7N9）、乙型流感病毒（Yamagata、Victoria）、呼吸道合胞病毒、鼻病毒（A、B、C 组）、呼吸道腺病毒（1~5、7、55 型）、肠道病毒（A、B、C、D 组）、EB 病毒衣壳抗原、麻疹病毒、人巨细胞病毒、轮状病毒、诺如病毒、腮腺炎病毒、水痘-带状疱疹病毒、副流感病毒、肺炎支原体、肺炎衣原体、血杆菌不发生交叉反应。

Conclusion: The results show that there is no cross-reactivity with the following pathogens: Coronavirus (HKU1, OC43, NL63, 229E); MERS; Influenza A virus (2009H1N1, seasonal H1N1, H3N2, H5N1; H7N9); Influenza B virus (Yamagata, Victoria); Respiratory syncytial virus; Rhinovirus (group A, B, C); Respiratory adenovirus (type 1~5, 7, 55); Enterovirus (group A, B, C, D); Epstein-barr virus capsid antigen; Measles virus; Human cytomegalovirus; Rotavirus; Norovirus; Mumps virus; Varicella zoster virus; Parainfluenza virus; Mycoplasma pneumoniae; Chlamydia pneumoniae; Haemophiluspamsuis.

2.2 干扰物质 Interfering substance

以 2019-nCoV 假病毒与阴性鼻咽拭子样本混合得到人造样本，以弱阳性鼻咽拭子人造样本作为基础样本，分成若干等分后，分别添加下表所示的干扰物成为试验样本。每份样本用 3 批试剂盒检测，每份样本均检测 2 次。

Contrived samples were obtained by mixing 2019-nCoV pseudovirus and negative nasopharyngeal swab samples. The weakly positive nasopharyngeal swab of contrived sample was taken as the basic sample, divided into several equal parts, and then the interferences shown in the following table were added respectively as the test samples. Each sample was tested with 3 batches of kit, and each sample was tested twice.

干扰物 Interfering substance		试验浓度 Test concentration
粘蛋白 Mucins		1%
血液 Human blood		5%
鼻腔喷雾剂 Nasal spray	羟甲唑啉 Oxymetazoline	1.125mg/mL

鼻用皮肤类固醇 Nasal corticosteroids	地塞米松 Dexamethasone	0.009mg/mL
	氟尼缩松 Flunisolide	0.75mg/mL
鼻用凝胶 Zicam Cold Remedy Nasal Gel	硫磺 Sulphur	335mg/mL
过敏性症状缓解药物 Allergic symptom relief drug	金英 Kim Anh	4.5mg/mL
口服麻醉剂 Oral anesthetic	苯佐卡因 Benzocaine	1.875mg/mL
抗病毒药物 Antiviral drug	扎那米韦 Zanamivir,	75mg/mL
抗生素、鼻用软膏 Antibiotics, nasal ointments	莫匹罗星 Mupirocin	33.5mg/mL
全身性抗菌药 Systemic antibiotics	妥布霉素 Tobramycin	0.3mg/mL
免疫系统用药 Immune system medication	穿琥宁 Kalii Dehydrographolidi Succinas	3.8mg/mL
退烧药 Antipyretic	阿司匹林（肠溶片） Aspirin (enteric-coated tablets)	0.04g/L
	布洛芬（颗粒） Ibuprofen (granules)	0.2g/L
	对乙酰氨基酚（缓释片） Acetaminophen (slow-release tablets)	450mg/L
	尼美舒利片 Nimesulide Tablets	0.05g/L

实验结果：

Results:

干扰物 Interfering substance	试验浓度	第一批	第二批	第三批

		Test concentration			
粘蛋白 Mucins		1%	2/2（+）	2/2（+）	2/2（+）
血液 Human blood		5%	2/2（+）	2/2（+）	2/2（+）
鼻腔喷雾剂 Nasal spray	羟甲唑啉 Oxymetazoline	1.125mg/mL	2/2（+）	2/2（+）	2/2（+）
鼻用皮肤类固醇 Nasal corticosteroids	地塞米松 Dexamethasone	0.009mg/mL	2/2（+）	2/2（+）	2/2（+）
	氟尼缩松 Flunisolide	0.75mg/mL	2/2（+）	2/2（+）	2/2（+）
鼻用凝胶 Zicam Cold Remedy Nasal Gel	硫磺 Sulphur	335mg/mL	2/2（+）	2/2（+）	2/2（+）
过敏性症状缓解药物 Allergic symptom relief drug	金英 Kim Anh	4.5mg/mL	2/2（+）	2/2（+）	2/2（+）
口服麻醉剂 Oral anesthetic	苯佐卡因 Benzocaine	1.875mg/mL	2/2（+）	2/2（+）	2/2（+）
抗病毒药物 Antiviral drug	扎那米韦 Zanamivir,	75mg/mL	2/2（+）	2/2（+）	2/2（+）
抗生素、鼻用软膏 Antibiotics, nasal ointments	莫匹罗星 Mupirocin	33.5mg/mL	2/2（+）	2/2（+）	2/2（+）
全身性抗菌药 Systemic antibiotics	妥布霉素 Tobramycin	0.3mg/mL	2/2（+）	2/2（+）	2/2（+）
免疫系统用药 Immune system medication	穿琥宁 Kalii Dehydrographolidi Succinas	3.8mg/mL	2/2（+）	2/2（+）	2/2（+）
退烧药 Antipyretic	阿司匹林（肠溶片） Aspirin (enteric-coated tablets)	0.04g/L	2/2（+）	2/2（+）	2/2（+）
	布洛芬（颗粒） Ibuprofen (granules)	0.2g/L	2/2（+）	2/2（+）	2/2（+）

	对乙酰氨基酚（缓释片） Acetaminophen (slow-release tablets)	450mg/L	2/2（+）	2/2（+）	2/2（+）
	尼美舒利片 Nimesulide Tablets	0.05g/L	2/2（+）	2/2（+）	2/2（+）

结论：以上结果表明，人血液，粘蛋白，以及以下常用药物不会干扰本试剂盒的检测结果：羟甲唑啉、地塞米松、氟尼缩松、硫磺、金英、苯佐卡因、扎那米韦、莫匹罗星、妥布霉素、穿琥宁、阿司匹林（肠溶片）、布洛芬（颗粒）、对乙酰氨基酚（缓释片）、尼美舒利片。各测试卡的显色线清晰可见，与基础样本的显色无肉眼可见变化。

Conclusion: The results show that human blood and mucins will not interfere with the results of the kit. The following common drugs will not interfere with the results of the kit: Oxymetazoline, Dexamethasone, Flunisolide, Sulphur, Kim Anh, Benzocaine, Zanamivir, Mupirocin, Tobramycin, Kalii Dehydrographolidi Succinas, Aspirin (enteric-coated tablets), Ibuprofen (granules), Acetaminophen (slow-release tablets), Nimesulide Tablets. The color line of each test card is clearly visible, there is no visible change in color rendering compared with the basic samples.