新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）性能评估

Performance Evaluation Study of SARS-CoV-2 Antigen Rapid Test (Saliva)

目录 contents

第一节 概述
Section 1 Overview

依据《EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices》对新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）的产品性能进行评估。
The SARS-CoV-2 Antigen Rapid Test (Saliva) was evaluated according to the 《EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices》.

对新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）的性能主要进行以下内容的研究：
The performance of the SARS-CoV-2 Antigen Rapid Test (Saliva) is mainly studied in the following aspects:

1.内部全性能评估：选择试生产三个批次的试剂盒，采用企业制定的企业参考品进行检测，评估验证试生产三批试剂物理性能、阴性参考品符合率、阳性参考品符合率、最低检出限、重复性，进而评估目前产品生产的有效性及可靠性。
Evaluation of Internal whole performance: Select three batches of reagents for trial production, the enterprise reference prepared by the company were used for testing, the physical properties, the compliance rate of negative reference, the compliance rate of positive reference, the limit of detection, and the precision repeatability of the reagents are comprehensively evaluated, and then the effectiveness and reliability of the current product production were evaluated.

2.HOOK 效应：当试剂盒采用夹心法（双抗体夹心法或双抗原夹心法）原理时，当待检测物质浓度很高时，由于无法形成有效的夹心模式，导致检测结果数值下降或颜色显色变浅。通过试剂盒 HOOK 效应的研究，明确本产品是否存在 HOOK 效应，用于提醒客户存在 HOOK 效应的影响。
HOOK effect: The reagent adopts the principle of the sandwich method (double antibody sandwich method or double antigen sandwich method). At this time, the concentration of the substance to be tested is very high, the effective sandwich pattern cannot be formed, resulting in lower detection results or shallow color. Through the research of the reagent's HOOK effect, it is clear whether this product has HOOK effect, so as to remind customers of the influence of the HOOK effect.

3.交叉反应：通过评估与新型冠状病毒感染症状类似疾病的病毒/细菌或同源的病毒，是否会与新型冠状病毒检测产生交叉反应，用于评估本产品的特异性。
Cross-reaction: It is used to evaluate the specificity of this product by evaluating whether the virus/bacteria with similar symptoms to the SARS-CoV-2 infection or a homologous virus will cross-react with the detection of the SARS-CoV-2.

4.不同区域感染者及感染者不同感染期的研究：评估不同区域病毒检测能力是否存在差异，从而明确试剂检测能力，同时评估不同患者在不同感染期试剂的检测能力。
Study on infected persons in different regions and samples of infected persons in different infection periods: Evaluate whether there are differences in the detection capabilities of the reagents in different regions, so as to clarify the detection capabilities of the reagents. And evaluate the reagent's ability to detect different patients in different infection stages.

5.干扰物质研究：评估样本中常见物质或可能存在物质或患者可能服用的相关药物对项目检测是否存在影响。
Research of Interfering substances: Evaluate whether common or possible substances in the sample or related drugs that the patient may take have an impact on the testing of this item.

6.最低检出限研究：通过最低检出限的研究明确本产品的灵敏度，同时通过培养物稀释进行验证，明确确定的灵敏度的可靠性。

The limit of detection study: The sensitivity of this product is clarified by studying the limit of detection, and the reliability of the obtained sensitivity is clarified by verifying the culture dilution.

第二节 人员、试验地点和时间
Section 2 Personnel, Test Site and Time

性能评估研究负责人及职责 Co-ordinator of a performance evaluation study and Duty	林志铿； 5.1.2e 对新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）的整个性能评估研究过程负责。 Responsible for the entire performance evaluation study of SARS-CoV-2 Antigen Rapid Test (Saliva).
研究者及职责 Investigator and Duty	余俊森； 5.1.2e 负责对新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）进行性能评估。 Responsible for the performance evaluation of SARS-CoV-2 Antigen Rapid Test (Saliva).
试验地点 Test Site	厦门为正生物科技股份有限公司试验室、病毒研究所、临床机构。 Laboratory of Xiamen WizBiotech CO., LTD; INSTITUTE OF VIROLOGY; Clinical Institutions
时间 Time	2020.02～2020.06

第三节 评估内容及评估结果
Section 3 Evaluation Contents And Results

内部全性能评估资料
Evaluation documentation of Internal whole performance

1 研究依据
Research basis

参考厦门为正生物科技股份有限公司制定的新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）技术要求。

Refer to the Product quality standards of SARS-CoV-2 Antigen Rapid Test (Saliva) formulated by Xiamen WIZ Biotech Co., LTD.

2 研究目的
Research purpose

通过试生产三批新型冠状病毒抗原（唾液）检测试剂盒（胶体金法），采用企业制定的企业参考品进行检测，评估验证试生产三批试剂性能的准确性，进而评估目前产品生产的有效性及可靠性。

Through the trial production of three batches of SARS-CoV-2 Antigen Rapid Test (Saliva) , the enterprise reference prepared by the company were used for testing, and the accuracy of the performance of the three batches of reagents was evaluated and verified, and then the effectiveness and reliability of the current product production were evaluated.

3 研究材料
Research materials

3.1 试剂盒

Reagent

名称 Name	批号 Batch code	生产厂家 Manufacturer	备注 Remarks
新型冠状病毒抗原（唾液）检测试剂盒（胶体金法） SARS-CoV-2 Antigen Rapid Test (Saliva)	Lot 01: 2020030405 Lot 02: 2020030505 Lot 03: 2020030606	厦门为正生物科技股份有限公司 Xiamen WIZ Biotech Co., LTD.	规格：25 人份/盒 Specification: 25 tests/kit

3.2 企业参考品
Enterprise Reference

（1）批号 Batch code：ZK2020012801

（2）制备厂家：厦门为正生物科技股份有限公司

Manufacturer：Xiamen WIZ Biotech Co., LTD.

（3）企业参考品组成

The composition of Enterprise reference

类别 Category	编号 Serial number
阴性参考品 Negative references	N1, N2, N3, N4, N5, N6, N7, N8, N9, N10
阳性参考品 Positive references	P1, P2, P3, P4
最低检测限参考品 Limit of detection references	DL1, DL2, DL3
重复性参考品 Repeatability references	CV1, CV2

4 研究方法
Research method

选择试生产三个批次的试剂盒，依据技术要求对试剂盒的物理性能、阴性参考品符合率、阳性参考品符合率、最低检出限、重复性进行全面评估。

Select three batches of reagents for trial production, according to the Product quality standards, the physical properties, the compliance rate of negative reference, the compliance rate of positive reference, the limit of detection, and the repeatability of the reagents are comprehensively evaluated.

4.1 物理性能
Physical properties

（1）外观检查：取本产品 1 人份，在自然光下目视检查。

Appearance inspection: Take 1 test of this product and inspect it visually under natural light.

（2）液体移行速度：取本产品 1 人份，按说明书操作，加 3 滴稀释液至加样孔，以秒表计时，计算液体移行速度。

The moving speed of liquid: Take 1 test of this product, according to the instructions for use; add

3 drops of diluent to the sample hole, time with a stopwatch to calculate the moving speed of liquid.

计算公式：v=l/t

Calculation formula: v=l/t

计算公式中：

In the calculation formula:

v—液体移行速度；

The moving speed of liquid;

l—加样孔中间位置至观察窗口上沿之间的距离。

The distance from the middle position of the sample hole to the upper edge of the observation window;

t—以滴加稀释液于加样孔时开始计时，沿反应膜移行至观察窗口上沿所需的时间。

The time required to start timing when the diluent is added to the sample hole and move along the reaction membrane to the upper edge of the observation window.

（3）膜条宽度：取本产品 1 人份，使用游标卡尺检测。

Width of strip: Take 1 test of this product and use Vernier caliper to detect.

4.2 性能检测

Performance test

（1）阴性参考品符合率：取本产品 10 人份，按照说明书操作步骤检测，对 10 份阴性企业参考品（N1~N10）检测，阴性企业参考品符合率应为 10/10。

Coincidence rate of negative reference: Take 10 tests of this product and test according to the operating steps of the instructions for use. For 10 negative enterprise references (N1~N10), coincidence rate of negative reference should be 10/10.

（2）阳性参考品符合率：取本产品 4 人份，按照说明书操作步骤检测，对 4 份阳性企业参考品（P1~P4）检测，阳性企业参考品符合率应为 4/4。

Coincidence rate of positive reference: Take 4 tests of this product and test according to the operating steps of the instructions for use. For 4 positive enterprise references (P1~P4), coincidence rate of positive reference should be 4/4.

（3）最低检测限：取本产品 3 人份，按照说明书操作步骤检测，对 3 份最低检测限企业参考品（DL1~ DL3）检测，DL1、DL2 企业参考品应均为阳性，DL3 企业参考品可为阳性或阴性。

Limit of detection: Take 3 tests of this product and test according to the operating steps of the instructions for use. Test 3 limit of detection enterprise references (DL1~DL3), DL1, DL2

enterprise reference should all be positive, DL3 enterprise reference can be positive or negative.

（4）重复性：取本产品 20 人份，按照说明书操作步骤检测，对 2 份重复性企业参考品（CV1、CV2）进行检测，各重复检测 10 次，结果应均为阳性且显色均一。

Repeatability: Take 20 tests of this product and test according to the operating steps of the instructions for use. Test 2 the Repeatability enterprise references (CV1, CV2), repeat the test 10 times separately, and the results should all be positive and uniform in color.

5 检验标准
Inspection standards

5.1 物理性能
Physical properties

（1）外观检查：外观应平整，标识应清晰，各组分应牢固附着，内容应齐全，液体无渗漏。

Appearance inspection: The appearance should be flat, the identification should be clear, the components should be firmly attached, the content should be complete, and no liquid leakage.

（2）液体移行速度：液体移行速度应不低于 10mm/min。

The moving speed of liquid: The moving speed of liquid should not be less than 10mm/min.

（3）膜条宽度：膜条宽度应不小于 2.5mm。

Width of strip: The width of the strip should not be less than 2.5mm.

5.2 性能检测
Performance test

（1）阴性参考品符合率：对 10 份阴性企业参考品检测，阴性企业参考品符合率应不低于 10/10。

Coincidence rate of negative reference: For 10 negative enterprise references were tested, coincidence rate of negative reference should not be less than 10/10.

（2）阳性参考品符合率：对 4 份阳性企业参考品检测，阳性企业参考品符合率应不低于 4/4。

Coincidence rate of positive reference: For 4 positive enterprise references were tested, coincidence rate of positive reference should not be less than 4/4.

（3）最低检测限：对 3 份最低检测限企业参考品检测，DL1、DL2 企业参考品应均为阳性，DL3 企业参考品可为阳性或阴性。

The limit of detection: For 3 the limit of detection enterprise references were tested, DL1 and DL2 enterprise references should all be positive, and DL3 enterprise reference products can be positive or negative.

（4）重复性：对 2 份重复性企业参考品进行检测，CV1、CV2 各重复检测 10 次，结果应均为阳性。

Repeatability: For 2 repeatability enterprise references were tested, CV1 and CV2 were tested 10 times separately, and the results should all be positive.

6 研究结果
Research results

按照技术要求对试剂盒进行全性能评估，详细研究数据汇总如下：

The whole performance evaluation of the reagent is carried out in accordance with the Product quality standards. The detailed research data is summarized as follows:

6.1 物理性能
Physical properties

表 1 物理性能研究结果

Tab.1 The research results of Physical properties

批号/类别 Batch code/category	Lot1	Lot2	Lot3
外观检查 Appearance inspection	符合要求 Meet the requirements	符合要求 Meet the requirements	符合要求 Meet the requirements
液体移行速度 The moving speed of liquid (mm/min)	15.0	15.1	14.9
膜条宽度 Width of strip（mm）	4.1/4.0/3.9	4.0/4.0/4.1	4.1/3.9/4.1

6.2 性能检测
Performance tests

表 2 性能研究结果

Tab.2 The research results of Performance

类别 category	编号/次数 Serial number/time	Lot1	Lot2	Lot3
阴性符合率 Negative coincidence rate	N1	—	—	—
	N2	—	—	—
	N3	—	—	—
	N4	—	—	—

	N5		—	—	—
	N6		—	—	—
	N7		—	—	—
	N8		—	—	—
	N9		—	—	—
	N10		—	—	—
	符合率 Coincidence rate		10/10	10/10	10/10
阳性符合率 Positive coincidence rate	P1		+	+	+
	P2		+	+	+
	P3		+	+	+
	P4		+	+	+
	符合率 Coincidence rate		4/4	4/4	4/4
最低检出限 Limit of detection	DL1		+	+	+
	DL2		+	+	+
	DL3		—	—	—
重复性 Repeatability	CV1	1	+	+	+
		2	+	+	+
		3	+	+	+
		4	+	+	+
		5	+	+	+
		6	+	+	+
		7	+	+	+
		8	+	+	+
		9	+	+	+
		10	+	+	+
		均一无色差 Uniform and	符合要求 Meet the	符合要求 Meet the	符合要求 Meet the

		no color difference	requirements	requirements	requirements
	CV2	1	+	+	+
		2	+	+	+
		3	+	+	+
		4	+	+	+
		5	+	+	+
		6	+	+	+
		7	+	+	+
		8	+	+	+
		9	+	+	+
		10	+	+	+
		均一无色差 Uniform and no color difference	符合要求 Meet the requirements	符合要求 Meet the requirements	符合要求 Meet the requirements

研究结果可见，三批产品按照技术要求进行全性能评估，试剂盒检测结果均能满足相关检验标准（技术要求）的要求。

The research results show that the three batches of products according to Product quality standards carried out whole performance evaluation, and the test results of the reagent can meet the requirements of relevant inspection standards (Product quality standards).

7 研究结论
Research conclusions

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）按照技术要求进行三批产品的全性能评估，产品能够满足相关要求。

The SARS-CoV-2 Antigen Rapid Test (Saliva) has been evaluated for the whole performance of the three batches of products according to the Product quality standards, and the products can meet the relevant requirements.

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）
HOOK 效应研究资料
SARS-CoV-2 Antigen Rapid Test (Saliva)
Research documentation of HOOK effect

1 研究依据
Research basis

当试剂盒采用夹心法（双抗体夹心法或双抗原夹心法）原理时，当待检测物质浓度很高时，由于无法形成有效的夹心模式，导致检测结果数值下降或颜色显色变浅。

The reagent adopts the principle of the sandwich method (double antibody sandwich method or double antigen sandwich method). At this time, the concentration of the substance to be tested is very high, the effective sandwich pattern cannot be formed, resulting in lower detection results or shallow color.

2 研究目的
Research purpose

通过试剂盒 HOOK 效应的研究，明确本产品是否存在 HOOK 效应，用于提醒客户存在 HOOK 效应的影响。

Through the research of the reagent's HOOK effect, it is clear whether this product has HOOK effect, so as to remind customers of the influence of the HOOK effect.

3 研究材料
Research materials

3.1 试剂盒

Reagent

名称 Name	批号 Batch code	生产厂家 Manufacturer	备注 Remarks
新型冠状病毒抗原（唾液）检测试剂盒（胶体金法） SARS-CoV-2 Antigen Rapid Test (Saliva)	Lot 01: 2020030405	厦门为正生物科技股份有限公司 Xiamen WIZ Biotech Co., LTD.	规格：25 人份/盒 Specification: 25tests/Kit

3.2 新冠病毒培养物

SARS-CoV-2 culture

通过热灭活的新型冠状病毒培养物，浓度 3.4×10^5 $TCID_{50}$/mL。

The heat-inactivated SARS-CoV-2 culture with concentration of 3.4×10^5 $TCID_{50}$/mL.

3.3 稀释溶液

Dilution solution

试剂盒的样本提取液，磷酸盐缓冲液（PH7.4±0.2）。

Extraction solution of the reagent kit, Phosphate Buffer Solution (pH7.4±0.2)

4 研究方法
Research method

（1）将热灭活的新型冠状病毒培养物（浓度：3.4×10^5 $TCID_{50}$/mL）按照两倍倍比进行稀释；

Diluting the heat-inactivated SARS-CoV-2 culture (concentration: 3.4×10^5 $TCID_{50}$/mL) at two-fold ratio.

（2）稀释后的样本溶液取 50μL 至一次性取样棒（每个稀释梯度制备三份），待稀释液被一次性取样棒吸收后，按照样本处理方法将一次性取样棒进行处理，处理后的样本根据检测卡说明书的检测方法进行检测。

Drawing 50μL from each diluted sample to disposable sampling rod(Prepare three for each dilution gradient). After the diluent is absorbed by the disposable sampling rod, the disposable sampling rod is treated according to the sample processing method, and the treated sample is tested according to the test method of reagent Instructions for Use.

5 检验标准
Inspection standards

检测结果颜色随着培养物中新型冠状病毒浓度的增加而变强，或者达到一定强度后保持不变，而未见颜色随着病毒增加而变浅。

The color intensity of the test results will become stronger as the concentration of the SARS-CoV-2 in the culture increases. The color intensity of the test result will remain unchanged after reaching certain intensity, and will not become shallow as the virus increases.

6 研究结果
Research results

表 1　HOOK 效应研究结果

Tab.1 Research results of the HOOK effect

序号 No.	浓度 concentration	检测结果 1 Test results 1	检测结果 2 Test results 2	检测结果 3 Test results 3	显色情况 Color
1	3.40×10^5 $TCID_{50}$/mL	++++	++++	++++	
2	1.70×10^5 $TCID_{50}$/mL	++++	++++	++++	
3	8.50×10^4 $TCID_{50}$/mL	++++	++++	++++	

4	4.25×10^4 $TCID_{50}$/mL	++++	++++	++++	显色强度未见随浓度上升而呈现减弱的状况。 The color intensity does not decrease with the increase of concentration.
5	2.13×10^4 $TCID_{50}$/mL	++++	++++	++++	
6	1.06×10^4 $TCID_{50}$/mL	++++	++++	++++	
7	5.31×10^3 $TCID_{50}$/mL	+++	+++	+++	
8	2.66×10^3 $TCID_{50}$/mL	+++	+++	+++	
9	1.33×10^3 $TCID_{50}$/mL	++	++	++	
10	6.64×10^2 $TCID_{50}$/mL	+	+	+	

研究结果表明，新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）在病毒浓度为3.40×10^5 $TCID_{50}$/mL 范围内未见 HOOK 效应。

The results of the study showed that the SARS-CoV-2 Antigen Rapid Test (Saliva) testing sample has no hook effect below the virus concentration of 3.40×10^5 $TCID_{50}$/mL.

7 研究结论
Research conclusions

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）在病毒浓度为3.40×10^5 $TCID_{50}$/mL 范围内未产生 HOOK 效应。

There is no Hook effect when SARS-CoV-2 Antigen Rapid Test (Saliva) tests sample below the virus concentration of 3.40×10^5 $TCID_{50}$/mL.

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）
交叉反应研究资料
SARS-CoV-2 Antigen Rapid Test (Saliva)
Research documentation of Cross-reaction

1 研究依据
Research basis

依据中国国家药品监督管理局医疗器械技术审评中心发布的《2019 新型冠状病毒抗原/抗体检测试剂注册技术审评要点（试行）》中关于分析特异性部分进行研究。

The research base on the analysis specificity study in the《The Technical Key Points for Coronavirus (COVID-19) Antigen-antibody Detection Reagent Registration Review (Trial)》formulated by The Center For Medical Device Evaluation Of The National Medical Products Administration(NMPA).

2 研究目的
Research purposes

通过评估与新型冠状病毒感染症状类似疾病的病毒/细菌或同源的病毒，是否会与新型冠状病毒检测产生交叉反应，用于评估本产品的特异性。

It is used to evaluate the specificity of this product by evaluating whether the virus/bacteria with similar symptoms to the SARS-CoV-2 infection or a homologous virus will cross-react with the detection of the SARS-CoV-2.

3 研究材料
Research materials

3.1 试剂盒
Reagent

名称 Name	批号 Batch code	生产厂家 Manufacturer	备注 Remarks
新型冠状病毒抗原（唾液）检测试剂盒（胶体金法） SARS-CoV-2 Antigen Rapid Test (Saliva)	Lot 01: 2020030405	厦门为正生物科技股份有限公司 Xiamen WIZ Biotech Co., LTD.	规格：25 人份/盒 Specification: 25tests/Kit

3.2 交叉反应微生物
Cross-reactive microorganisms

通过企业内部/疾控中心/保藏中心/美国模式培养物集存库保藏的病毒或细菌，具体如下：

Viruses or bacteria preserved through the company's internal/CDC/preservation center/U.S. model culture repository, as follows:

名称（微生物） Name (microorganism)	毒株编号 Preservation code
乙型流行性感冒 B/Y amagata Influenza B/Y amagata	BY055
乙型流行性感冒 B/Voctoria Influenza B/Voctoria	BV/江西修水/32/2000 BV/Jiangxixiushui/32/2000
甲型流行性感冒 H1N1 Influenza A H1N1	A/布里斯班/5/2007 A/Brisbane/5/2007
甲型流行性感冒 H3N2 Influenza A H3N2	A/布里斯班/10/2007 A/Brisbane/10/2007
甲型流行性感冒 H5N1 Influenza A H5N1	/
H7N9 型禽流感 H7N9 Avian Influenza	/
SARS 冠状病毒 SARS Coronavirus	/
腺病毒 1 型 Adenovirus 3	/
腺病毒 3 型 Adenovirus 3	VR-3
腺病毒 7 型 Adenovirus 7	VR-7
人冠状病毒 229E 型 Human coronavirus 229E	VR-740
人冠状病毒 OC43 型 Human coronavirus OC43	/
人冠状病毒 NL63 型 Human coronavirus NL63	/
人冠状病毒 HKU1 型 Human coronavirus HKU1	/
MERS 冠状病毒 MERS-coronavirus	/
巨细胞病毒 Cytomegalovirus	VR-538
肠道病毒 71 型 Enterovirus 71	VR-1775
人副流行性感冒病毒 1 型 Human parainfluenza virus 1	VR-94
人副流行性感冒病毒 2 型 Human parainfluenza virus 2	VR-92
人副流行性感冒病毒 3 型 Human parainfluenza virus 3	VR-93
人副流行性感冒病毒 4 型 Human parainfluenza virus 4	/
麻疹病毒 Measles virus	VR-24
流行性腮腺炎病毒 Mumps virus	VR-106
呼吸道合胞病毒	VR-2542

Respiratory syncytial virus	
鼻病毒 1A 型 Rhinovirus 1A	VR-1559
诺如病毒 Norovirus	/
EB 病毒 Epstein Barr Virus	/
水痘—带状疱疹病毒 Varicella zoster virus	/
百日咳杆菌 Bacillus pertussis	BAA-589
肺炎衣原体 Chlamydophila pneumoniae	VR-2282
埃希氏大肠杆菌 Escherichia coli	25922
流感嗜血杆菌 Haemophilus influenzae	10211
结合分枝杆菌 Mycobacterium binding	25177
肺炎支原体 Mycoplasma Pneumoniae	39505
白色念珠菌 Candida Albicans	10231
奈瑟氏脑膜炎球菌 Neisseria meningococcus	13077
奈瑟氏淋球菌 Neisseria gonorrhoeae	19424
铜绿假单胞菌 Pseudomonas aeruginosa	9721
金黄色葡萄球菌 Staphylococcus aureus	12598
肺炎链球菌 Streptococcus pneumoniae	55143
化脓链球菌 Streptococcus pyogenes	21060
唾液链球菌 Streptococcus salivarius	14485
嗜肺军团菌 Iegionella Pneumophila	/

4 研究方法
Research method

（1）通过企业内部/疾控中心/保藏中心/美国模式培养物集存库保藏的病毒或细菌，通过合作中心或企业内部进行培养，培养物及相应最高浓度如下：

Viruses or bacteria preserved through the company's internal/CDC/preservation center/U.S. model culture repository, or through the cooperation center or internal company for microbial cultivation. The culture and the corresponding maximum concentration are as follows:

名称（微生物） Name (microorganism)	毒株编号 Preservation code	浓度 Concentration
乙型流行性感冒 B/Yamagata	BY055	$1.83\times10^{6}TCID_{50}/mL$

Influenza B/Yamagata		
乙型流行性感冒 B/Voctoria Influenza B/Voctoria	BV/江西修水/32/2000 BV/Jiangxixiushui/32/2000	2.07×10^{6} $TCID_{50}$/mL
甲型流行性感冒 H1N1 Influenza A H1N1	A/布里斯班/5/2007 A/Brisbane/5/2007	1.00×10^{6} $TCID_{50}$/mL
甲型流行性感冒 H3N2 Influenza A H3N2	A/布里斯班/10/2007 A/Brisbane/10/2007	1.15×10^{6} $TCID_{50}$/mL
甲型流行性感冒 H5N1 Influenza A H5N1	/	1.32×10^{6} $TCID_{50}$/mL
H7N9 型禽流感 H7N9 Avian Influenza	/	1.60×10^{6} $TCID_{50}$/mL
SARS 冠状病毒 SARS Coronavirus	/	2.14×10^{6} $TCID_{50}$/mL
腺病毒 1 型 Adenovirus 1	/	1.39×10^{6} $TCID_{50}$/mL
腺病毒 3 型 Adenovirus 3	VR-3	1.24×10^{6} $TCID_{50}$/mL
腺病毒 7 型 Adenovirus 7	VR-7	1.87×10^{6} $TCID_{50}$/mL
人冠状病毒 229E 型 Human coronavirus 229E	VR-740	1.00×10^{6} $TCID_{50}$/mL
人冠状病毒 OC43 型 Human coronavirus OC43	/	2.34×10^{6} $TCID_{50}$/mL
人冠状病毒 NL63 型 Human coronavirus NL63	/	2.00×10^{6} $TCID_{50}$/mL
人冠状病毒 HKU1 型 Human coronavirus HKU1	/	2.00×10^{6} $TCID_{50}$/mL
MERS 冠状病毒 MERS-coronavirus	/	1.00×10^{6} $TCID_{50}$/mL
巨细胞病毒 Cytomegalovirus	VR-538	1.00×10^{6} $TCID_{50}$/mL
肠道病毒 71 型 Enterovirus 71	VR-1775	2.55×10^{6} $TCID_{50}$/mL
人副流行性感冒病毒 1 型 Human parainfluenza virus 1	VR-94	1.35×10^{6} $TCID_{50}$/mL
人副流行性感冒病毒 2 型 Human parainfluenza virus 2	VR-92	6.31×10^{6} $TCID_{50}$/mL
人副流行性感冒病毒 3 型 Human parainfluenza virus 3	VR-93	3.25×10^{6} $TCID_{50}$/mL
人副流行性感冒病毒 4 型 Human parainfluenza virus 4	/	3.31×10^{6} $TCID_{50}$/mL
麻疹病毒 Measles virus	VR-24	6.31×10^{5} $TCID_{50}$/mL
流行性腮腺炎病毒 Mumps virus	VR-106	6.31×10^{6} $TCID_{50}$/mL
呼吸道合胞病毒 Respiratory syncytial virus	VR-2542	2.00×10^{5} $TCID_{50}$/mL
鼻病毒 1A 型 Rhinovirus 1A	VR-1559	1.26×10^{6} $TCID_{50}$/mL
诺如病毒 Norovirus	/	1.30×10^{6} $TCID_{50}$/mL
EB 病毒 Epstein Barr Virus	/	2.18×10^{6} $TCID_{50}$/mL
水痘—带状疱疹病毒 Varicella zoster virus	/	1.00×10^{6} $TCID_{50}$/mL
百日咳杆菌 Bacillus pertussis	BAA-589	1.30×10^{6} CFU/mL
肺炎衣原体 Chlamydophila pneumoniae	VR-2282	1.00×10^{6} CFU/mL
埃希氏大肠杆菌 Escherichia coli	25922	1.00×10^{6} CFU/mL
流感嗜血杆菌 Haemophilus influenzae	10211	1.20×10^{6} CFU/mL
结合分枝杆菌	25177	1.00×10^{6} CFU/mL

Mycobacterium binding		
肺炎支原体 Mycoplasma Pneumoniae	39505	1.00×10^6 CFU/mL
白色念珠菌 Candida Albicans	10231	1.00×10^6 CFU/mL
奈瑟氏脑膜炎球菌 Neisseria meningococcus	13077	1.00×10^6 CFU/mL
奈瑟氏淋球菌 Neisseria gonorrhoeae	19424	1.00×10^6 CFU/mL
铜绿假单胞菌 Pseudomonas aeruginosa	9721	3.70×10^6 CFU/mL
金黄色葡萄球菌 Staphylococcus aureus	12598	2.20×10^6 CFU/mL
肺炎链球菌 Streptococcus pneumoniae	55143	1.00×10^6 CFU/mL
化脓链球菌 Streptococcus pyogenes	21060	1.28×10^6 CFU/mL
唾液链球菌 Streptococcus salivarius	14485	1.00×10^6 CFU/mL
嗜肺军团菌 Iegionella Pneumophila	/	1.58×10^6 CFU/mL

（2）采用试剂盒样本提取液（磷酸盐缓冲液：pH7.4±0.2）对以上培养物进行稀释，稀释至以下浓度梯度，具体如下：

Use the Extraction solution of the reagent kit (Phosphate Buffer Solution: pH7.4±0.2) to dilute the above culture to the following concentration gradient, as follows:

名称（微生物） Name (microorganism)	毒株编号 Preservation code	浓度 1 Concentration 1	浓度 2 Concentration 2	浓度 3 Concentration 3
乙型流行性感冒 B/Yamagata Influenza B/Yamagata	BY055	1.83×10^6 $TCID_{50}$/mL	1.83×10^4 $TCID_{50}$/mL	1.83×10^3 $TCID_{50}$/mL
乙型流行性感冒 B/Voctoria Influenza B/Voctoria	BV/江西修水/32/2000 BV/Jiangxixiushui/32/2000	2.07×10^6 $TCID_{50}$/mL	2.07×10^4 $TCID_{50}$/mL	2.07×10^3 $TCID_{50}$/mL
甲型流行性感冒 H1N1 Influenza A H1N1	A/布里斯班/5/2007 A/Brisbane/5/2007	1.00×10^6 $TCID_{50}$/mL	1.00×10^4 $TCID_{50}$/mL	1.00×10^3 $TCID_{50}$/mL
甲型流行性感冒 H3N2 Influenza A H3N2	A/布里斯班/10/2007 A/Brisbane/10/2007	1.15×10^6 $TCID_{50}$/mL	1.15×10^4 $TCID_{50}$/mL	1.15×10^3 $TCID_{50}$/mL
甲型流行性感冒 H5N1 Influenza A H5N1	/	1.32×10^6 $TCID_{50}$/mL	1.32×10^4 $TCID_{50}$/mL	1.32×10^3 $TCID_{50}$/mL
H7N9 型禽流感 H7N9 Avian Influenza	/	1.60×10^6 $TCID_{50}$/mL	1.60×10^4 $TCID_{50}$/mL	1.60×10^3 $TCID_{50}$/mL
SARS 冠状病毒 SARS Coronavirus	/	2.14×10^6 $TCID_{50}$/mL	2.14×10^4 $TCID_{50}$/mL	2.14×10^3 $TCID_{50}$/mL
腺病毒 1 型 Adenovirus 1	/	1.39×10^6 $TCID_{50}$/mL	1.39×10^4 $TCID_{50}$/mL	1.39×10^3 $TCID_{50}$/mL
腺病毒 3 型 Adenovirus 3	VR-3	1.24×10^6 $TCID_{50}$/mL	1.24×10^4 $TCID_{50}$/mL	1.24×10^3 $TCID_{50}$/mL
腺病毒 7 型 Adenovirus 7	VR-7	1.87×10^6 $TCID_{50}$/mL	1.87×10^4 $TCID_{50}$/mL	1.87×10^3 $TCID_{50}$/mL
人冠状病毒 229E 型 Human coronavirus 229E	VR-740	2.00×10^6 $TCID_{50}$/mL	2.00×10^4 $TCID_{50}$/mL	2.00×10^3 $TCID_{50}$/mL

人冠状病毒 OC43 型 Human coronavirus OC43	/	2.34×10^{6} $TCID_{50}$/mL	2.34×10^{4} $TCID_{50}$/mL	2.34×10^{3} $TCID_{50}$/mL
人冠状病毒 NL63 型 Human coronavirus NL63	/	2.00×10^{6} $TCID_{50}$/mL	2.00×10^{4} $TCID_{50}$/mL	2.00×10^{3} $TCID_{50}$/mL
人冠状病毒 HKU1 型 Human coronavirus HKU1	/	2.00×10^{6} $TCID_{50}$/mL	2.00×10^{4} $TCID_{50}$/mL	2.00×10^{3} $TCID_{50}$/mL
MERS 冠状病毒 MERS-coronavirus	/	1.00×10^{6} $TCID_{50}$/mL	1.00×10^{4} $TCID_{50}$/mL	1.00×10^{3} $TCID_{50}$/mL
巨细胞病毒 Cytomegalovirus	VR-538	1.00×10^{6} $TCID_{50}$/mL	1.00×10^{4} $TCID_{50}$/mL	1.00×10^{3} $TCID_{50}$/mL
肠道病毒 71 型 Enterovirus 71	VR-1775	2.55×10^{6} $TCID_{50}$/mL	2.55×10^{4} $TCID_{50}$/mL	2.55×10^{3} $TCID_{50}$/mL
人副流行性感冒病毒 1 型 Human parainfluenza virus 1	VR-94	1.35×10^{6} $TCID_{50}$/mL	1.35×10^{4} $TCID_{50}$/mL	1.35×10^{3} $TCID_{50}$/mL
人副流行性感冒病毒 2 型 Human parainfluenza virus 2	VR-92	6.31×10^{6} $TCID_{50}$/mL	6.31×10^{4} $TCID_{50}$/mL	6.31×10^{3} $TCID_{50}$/mL
人副流行性感冒病毒 3 型 Human parainfluenza virus 3	VR-93	3.25×10^{6} $TCID_{50}$/mL	3.25×10^{4} $TCID_{50}$/mL	3.25×10^{3} $TCID_{50}$/mL
人副流行性感冒病毒 4 型 Human parainfluenza virus 4	/	3.31×10^{6} $TCID_{50}$/mL	3.31×10^{4} $TCID_{50}$/mL	3.31×10^{3} $TCID_{50}$/mL
麻疹病毒 Measles virus	VR-24	6.31×10^{6} $TCID_{50}$/mL	6.31×10^{4} $TCID_{50}$/mL	6.31×10^{3} $TCID_{50}$/mL
流行性腮腺炎病毒 Mumps virus	VR-106	6.31×10^{6} $TCID_{50}$/mL	6.31×10^{4} $TCID_{50}$/mL	6.31×10^{3} $TCID_{50}$/mL
呼吸道合胞病毒 Respiratory syncytial virus	VR-2542	2.00×10^{6} $TCID_{50}$/mL	2.00×10^{4} $TCID_{50}$/mL	2.00×10^{3} $TCID_{50}$/mL
鼻病毒 1A 型 Rhinovirus 1A	VR-1559	1.26×10^{6} $TCID_{50}$/mL	1.26×10^{4} $TCID_{50}$/mL	1.26×10^{3} $TCID_{50}$/mL
诺如病毒 Norovirus	/	1.30×10^{6} $TCID_{50}$/mL	1.30×10^{4} $TCID_{50}$/mL	1.30×10^{3} $TCID_{50}$/mL
EB 病毒 Epstein Barr Virus	/	2.18×10^{6} $TCID_{50}$/mL	2.18×10^{4} $TCID_{50}$/mL	2.18×10^{3} $TCID_{50}$/mL
水痘-带状疱疹病毒 Varicella zoster virus	/	1.00×10^{6} $TCID_{50}$/mL	1.00×10^{4} $TCID_{50}$/mL	1.00×10^{3} $TCID_{50}$/mL
百日咳杆菌 Bacillus pertussis	BAA-589	1.30×10^{6} CFU/mL	1.30×10^{4} CFU/mL	1.30×10^{3} CFU/mL
肺炎衣原体 Chlamydophila pneumoniae	VR-2282	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
埃希氏大肠杆菌 Escherichia coli	25922	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
流感嗜血杆菌 Haemophilus influenzae	10211	1.20×10^{6} CFU/mL	1.20×10^{4} CFU/mL	1.20×10^{3} CFU/mL
结合分枝杆菌 Mycobacterium binding	25177	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL

肺炎支原体 Mycoplasma Pneumoniae	39505	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
白色念珠菌 Candida Albicans	10231	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
奈瑟氏脑膜炎球菌 Neisseria meningococcus	13077	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
奈瑟氏淋球菌 Neisseria gonorrhoeae	19424	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
铜绿假单胞菌 Pseudomonas aeruginosa	9721	3.70×10^{6} CFU/mL	3.70×10^{4} CFU/mL	3.70×10^{3} CFU/mL
金黄色葡萄球菌 Staphylococcus aureus	12598	2.20×10^{6} CFU/mL	2.20×10^{4} CFU/mL	2.20×10^{3} CFU/mL
肺炎链球菌 Streptococcus pneumoniae	55143	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
化脓链球菌 Streptococcus pyogenes	21060	1.28×10^{6} CFU/mL	1.28×10^{4} CFU/mL	1.28×10^{3} CFU/mL
唾液链球菌 Streptococcus salivarius	14485	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
嗜肺军团菌 legionella Pneumophila	/	1.58×10^{6} CFU/mL	1.58×10^{4} CFU/mL	1.58×10^{3} CFU/mL

（3）稀释后的样本溶液取 50μL 至一次性取样棒（每个稀释梯度制备一份），待稀释液被一次性取样棒吸收后，按照样本处理方法将一次性取样棒进行处理，处理后的样本根据检测卡说明书的检测方法进行检测。

Take 50μL of the diluted sample solution to the Disposable sampling rod(Prepare one for each dilution gradient). After the diluent is absorbed by the Disposable sampling rod, the Disposable sampling rod is treated according to the sample processing method, and the treated sample is tested according to the test method of reagent.

5 检验标准
Inspection standards

不同种类、不同类型的微生物在不同浓度条件下检测应均为阴性反应。

Different types of microorganisms should be negative when tested under different concentration.

6 研究结果
Research results

表 1 交叉反应研究结果

Tab.1 Cross-reactivity study results

名称（微生物） Name (microorganism)	毒株编号 Preservation code	检测结果		
		浓度 1 Concentration 1	浓度 2 Concentration 2	浓度 3 Concentration 3

乙型流行性感冒 B/Yamagata Influenza B/Y amagata	BY055	1.83×10^{6} $TCID_{50}$/mL	1.83×10^{4} $TCID_{50}$/mL	1.83×10^{3} $TCID_{50}$/mL
		—	—	—
乙型流行性感冒 B/Voctoria Influenza B/Voctoria	BV/江西修水/32/2000 BV/Jiangxixiushui/32/2000	2.07×10^{6} $TCID_{50}$/mL	2.07×10^{4} $TCID_{50}$/mL	2.07×10^{3} $TCID_{50}$/mL
		—	—	—
甲型流行性感冒 H1N1 Influenza A H1N1	A/布里斯班/5/2007 A/Brisbane/5/2007	1.00×10^{6} $TCID_{50}$/mL	1.00×10^{4} $TCID_{50}$/mL	1.00×10^{3} $TCID_{50}$/mL
		—	—	—
甲型流行性感冒 H3N2 Influenza A H3N2	A/布里斯班/10/2007 A/Brisbane/10/2007	1.15×10^{6} $TCID_{50}$/mL	1.15×10^{4} $TCID_{50}$/mL	1.15×10^{3} $TCID_{50}$/mL
		—	—	—
甲型流行性感冒 H5N1 Influenza A H5N1	/	1.32×10^{6} $TCID_{50}$/mL	1.32×10^{4} $TCID_{50}$/mL	1.32×10^{3} $TCID_{50}$/mL
		—	—	—
H7N9 型禽流感 H7N9 Avian Influenza	/	1.60×10^{6} $TCID_{50}$/mL	1.60×10^{4} $TCID_{50}$/mL	1.60×10^{3} $TCID_{50}$/mL
		—	—	—
SARS 冠状病毒 SARS Coronavirus	/	2.14×10^{6} $TCID_{50}$/mL	2.14×10^{4} $TCID_{50}$/mL	2.14×10^{3} $TCID_{50}$/mL
		—	—	—
腺病毒 1 型 Adenovirus 1	/	1.39×10^{6} $TCID_{50}$/mL	1.39×10^{4} $TCID_{50}$/mL	1.39×10^{3} $TCID_{50}$/mL
		—	—	—
腺病毒 3 型 Adenovirus 3	VR-3	1.24×10^{6} $TCID_{50}$/mL	1.24×10^{4} $TCID_{50}$/mL	1.24×10^{3} $TCID_{50}$/mL
		—	—	—
腺病毒 7 型 Adenovirus 7	VR-7	1.87×10^{6} $TCID_{50}$/mL	1.87×10^{4} $TCID_{50}$/mL	1.87×10^{3} $TCID_{50}$/mL
		—	—	—
人冠状病毒 229E 型 Human coronavirus 229E	VR-740	2.00×10^{6} $TCID_{50}$/mL	2.00×10^{4} $TCID_{50}$/mL	2.00×10^{3} $TCID_{50}$/mL
		—	—	—
人冠状病毒 OC43 型 Human coronavirus OC43	/	2.34×10^{6} $TCID_{50}$/mL	2.34×10^{4} $TCID_{50}$/mL	2.34×10^{3} $TCID_{50}$/mL
		—	—	—
人冠状病毒 NL63 型 Human coronavirus NL63	/	2.00×10^{6} $TCID_{50}$/mL	2.00×10^{4} $TCID_{50}$/mL	2.00×10^{3} $TCID_{50}$/mL
		—	—	—
人冠状病毒 HKU1 型 Human coronavirus HKU1	/	2.00×10^{6} $TCID_{50}$/mL	2.00×10^{4} $TCID_{50}$/mL	2.00×10^{3} $TCID_{50}$/mL
		—	—	—
MERS 冠状病毒 MERS-coronavirus	/	1.00×10^{6} $TCID_{50}$/mL	1.00×10^{4} $TCID_{50}$/mL	1.00×10^{3} $TCID_{50}$/mL
		—	—	—
巨细胞病毒 Cytomegalovirus	VR-538	1.00×10^{6} $TCID_{50}$/mL	1.00×10^{4} $TCID_{50}$/mL	1.00×10^{3} $TCID_{50}$/mL
		—	—	—
肠道病毒 71 型 Enterovirus 71	VR-1775	2.55×10^{6} $TCID_{50}$/mL	2.55×10^{4} $TCID_{50}$/mL	2.55×10^{3} $TCID_{50}$/mL
		—	—	—

人副流行性感冒病毒 1 型 Human parainfluenza virus 1	VR-94	1.35×10^{6} $TCID_{50}$/mL	1.35×10^{4} $TCID_{50}$/mL	1.35×10^{3} $TCID_{50}$/mL
		—	—	—
人副流行性感冒病毒 2 型 Human parainfluenza virus 2	VR-92	6.31×10^{6} $TCID_{50}$/mL	6.31×10^{4} $TCID_{50}$/mL	6.31×10^{3} $TCID_{50}$/mL
		—	—	—
人副流行性感冒病毒 3 型 Human parainfluenza virus 3	VR-93	3.25×10^{6} $TCID_{50}$/mL	3.25×10^{4} $TCID_{50}$/mL	3.25×10^{3} $TCID_{50}$/mL
		—	—	—
人副流行性感冒病毒 4 型 Human parainfluenza virus 4	/	3.31×10^{6} $TCID_{50}$/mL	3.31×10^{4} $TCID_{50}$/mL	3.31×10^{3} $TCID_{50}$/mL
		—	—	—
麻疹病毒 Measles virus	VR-24	6.31×10^{6} $TCID_{50}$/mL	6.31×10^{4} $TCID_{50}$/mL	6.31×10^{3} $TCID_{50}$/mL
		—	—	—
流行性腮腺炎病毒 Mumps virus	VR-106	6.31×10^{6} $TCID_{50}$/mL	6.31×10^{4} $TCID_{50}$/mL	6.31×10^{3} $TCID_{50}$/mL
		—	—	—
呼吸道合胞病毒 Respiratory syncytial virus	VR-2542	2.00×10^{6} $TCID_{50}$/mL	2.00×10^{4} $TCID_{50}$/mL	2.00×10^{3} $TCID_{50}$/mL
		—	—	—
鼻病毒 1A 型 Rhinovirus 1A	VR-1559	1.26×10^{6} $TCID_{50}$/mL	1.26×10^{4} $TCID_{50}$/mL	1.26×10^{3} $TCID_{50}$/mL
		—	—	—
诺如病毒 Norovirus	/	1.30×10^{6} $TCID_{50}$/mL	1.30×10^{4} $TCID_{50}$/mL	1.30×10^{3} $TCID_{50}$/mL
		—	—	—
EB 病毒 Epstein Barr Virus	/	2.18×10^{6} $TCID_{50}$/mL	2.18×10^{4} $TCID_{50}$/mL	2.18×10^{3} $TCID_{50}$/mL
		—	—	—
水痘-带状疱疹病毒 Varicella zoster virus	/	1.00×10^{6} $TCID_{50}$/mL	1.00×10^{4} $TCID_{50}$/mL	1.00×10^{3} $TCID_{50}$/mL
		—	—	—
百日咳杆菌 Bacillus pertussis	BAA-589	1.30×10^{6} CFU/mL	1.30×10^{4} CFU/mL	1.30×10^{3} CFU/mL
		—	—	—
肺炎衣原体 Chlamydophila pneumoniae	VR-2282	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
		—	—	—
埃希氏大肠杆菌 Escherichia coli	25922	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
		—	—	—
流感嗜血杆菌 Haemophilus influenzae	10211	1.20×10^{6} CFU/mL	1.20×10^{4} CFU/mL	1.20×10^{3} CFU/mL
		—	—	—
结合分枝杆菌 Mycobacterium binding	25177	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
		—	—	—
肺炎支原体 Mycoplasma Pneumoniae	39505	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL
		—	—	—
白色念珠菌	10231	1.00×10^{6} CFU/mL	1.00×10^{4} CFU/mL	1.00×10^{3} CFU/mL

Candida Albicans		—	—	—
奈瑟氏脑膜炎球菌 Neisseria meningococcus	13077	1.00×10^6 CFU/mL	1.00×10^4 CFU/mL	1.00×10^3 CFU/mL
		—	—	—
奈瑟氏淋球菌 Neisseria gonorrhoeae	19424	1.00×10^6 CFU/mL	1.00×10^4 CFU/mL	1.00×10^3 CFU/mL
		—	—	—
铜绿假单胞菌 Pseudomonas aeruginosa	9721	3.70×10^6 CFU/mL	3.70×10^4 CFU/mL	3.70×10^3 CFU/mL
		—	—	—
金黄色葡萄球菌 Staphylococcus aureus	12598	2.20×10^6 CFU/mL	2.20×10^4 CFU/mL	2.20×10^3 CFU/mL
		—	—	—
肺炎链球菌 Streptococcus pneumoniae	55143	1.00×10^6 CFU/mL	1.00×10^4 CFU/mL	1.00×10^3 CFU/mL
		—	—	—
化脓链球菌 Streptococcus pyogenes	21060	1.28×10^6 CFU/mL	1.28×10^4 CFU/mL	1.28×10^3 CFU/mL
		—	—	—
唾液链球菌 Streptococcus salivarius	14485	1.00×10^6 CFU/mL	1.00×10^4 CFU/mL	1.00×10^3 CFU/mL
		—	—	—
嗜肺军团菌 legionella Pneumophila	/	1.58×10^6 CFU/mL	1.58×10^4 CFU/mL	1.58×10^3 CFU/mL
		—	—	—

研究结果表明，新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）与以上所列病毒、细菌等微生物在一定浓度范围内均不存在交叉反应。

Research results show that SARS-CoV-2 Antigen Rapid Test (Saliva) has no cross-react with the above-listed viruses, bacteria and other microorganisms within certain concentration range.

7 研究结论
Research conclusion

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）与呼吸道病毒、常见口腔细菌等微生物在研究范围内未见交叉反应。

The SARS-CoV-2 Antigen Rapid Test (Saliva) has no cross-react with microorganisms such as respiratory viruses and common oral bacteria within the scope of the study concentration.

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）
不同区域感染者及感染者不同感染期研究资料
SARS-CoV-2 Antigen Rapid Test (Saliva)
Research documentation on samples of infected persons in different regions and samples of infected persons in different infection periods

1 研究依据
Research basis

依据中国国家药品监督管理局医疗器械技术审评中心发布的《2019 新型冠状病毒抗原/抗体检测试剂注册技术审评要点（试行）》中关于不同区域病毒样本包容性内容进行研究。

According to the research on the inclusive content of virus samples in different regions in the《The Technical Key Points for Coronavirus (COVID-19) Antigen-antibody Detection Reagent Registration Review (Trial)》formulated by The Center For Medical Device Evaluation Of The National Medical Products Administration (NMPA).

2 研究目的
Research purposes

（1）评估不同区域病毒检测能力是否存在差异，明确试剂检测能力；

Evaluate whether there are differences in the detection capabilities of the reagents in different regions, so as to clarify the detection capabilities of the reagents.

（2）评估不同患者在不同感染期试剂的检测能力。

Evaluate the reagent's ability to detect different patients in different infection stages.

3 研究材料
Research materials

3.1 试剂盒
Reagent

名称 Name	批号 Batch code	生产厂家 Manufacturer	备注 Remarks
新型冠状病毒抗原（唾液）检测试剂盒（胶体金法） SARS-CoV-2 Antigen Rapid Test (Saliva)	Lot 01: 2020030405	厦门为正生物科技股份有限公司 Xiamen WIZ Biotech Co., LTD.	规格：25 人份/盒 Specification: 25tests/Kit

3.2 临床样本

Clinical sample

（1）通过不同区域的临床单位收集相应的唾液样本（已通过临床诊断及核酸确诊的病例），详细样本类型如下：

Collect corresponding Saliva samples from medical institutions in different regions (these samples have been clinically diagnosed and confirmed by nucleic acid). The specific types of samples collected are as follows:

样本编号 Sample number	区域 region	样本类型 samples type	发病时间（天） Onset time (days)	备注 Remarks
TT003	区域 1 Area-1	唾液样本 Saliva samples	3	
TT120	区域 1 Area-1	唾液样本 Saliva samples	2	
TT205	区域 1 Area-1	唾液样本 Saliva samples	8	
XH211	区域 1 Area-1	唾液样本 Saliva samples	12	
XH104	区域 1 Area-1	唾液样本 Saliva samples	5	
XH186	区域 1 Area-1	唾液样本 Saliva samples	32	
S1182	区域 2 Area-2	唾液样本 Saliva samples	6	
S0097	区域 2 Area-2	唾液样本 Saliva samples	2	
S2187	区域 2 Area-2	唾液样本 Saliva samples	5	
S1002	区域 2 Area-2	唾液样本 Saliva samples	2	
W1008	区域 3 Area-3	唾液样本 Saliva samples	1	
W1129	区域 3 Area-3	唾液样本 Saliva samples	4	
W1082	区域 3 Area-3	唾液样本 Saliva samples	2	
W1218	区域 3 Area-3	唾液样本 Saliva samples	18	
W1002	区域 3 Area-3	唾液样本 Saliva samples	5	

注：发病时间为出现症状后开始计算，即出现症状当天记为 0 天。

Note: The onset time is calculated after the onset of symptoms, which means that the day of the onset of symptoms is counted as 0 days.

（2）通过临床收集不同的疾病感染期采集的咽拭子样本（已通过临床诊断及核酸确诊的病例），详细资料如下：

Collect Oropharyngeal swab samples (these samples have been clinically diagnosed and confirmed by nucleic acid) from different infection periods of the disease through medical institutions. The detailed information is as follows:

患者编号 Patient code	发病时间（天） Onset time (days)	样本类型 samples type	核酸检测情况 Nucleic acid test results	备注 Remarks
W001	3	唾液样本 Saliva samples	阳性 Positive	
	6	唾液样本 Saliva samples	阳性 Positive	
	9	唾液样本 Saliva samples	阳性 Positive	
	12	唾液样本 Saliva samples	阳性 Positive	
	16	唾液样本 Saliva samples	阴性 Negative	
W002	0	唾液样本 Saliva samples	阳性 Positive	
	3	唾液样本 Saliva samples	阳性 Positive	
	6	唾液样本 Saliva samples	阳性 Positive	
	9	唾液样本 Saliva samples	阴性 Negative	
W003	1	唾液样本 Saliva samples	阳性 Positive	
	4	唾液样本 Saliva samples	阳性 Positive	
	7	唾液样本 Saliva samples	阳性 Positive	
	10	唾液样本 Saliva samples	阳性 Positive	
	13	唾液样本 Saliva samples	阳性 Positive	
	16	唾液样本 Saliva samples	阳性 Positive	
	19	唾液样本 Saliva samples	阴性 Negative	
	22	唾液样本 Saliva samples	阴性 Negative	
	25	唾液样本 Saliva samples	阴性 Negative	

W004	5	唾液样本 Saliva samples	阳性 Positive	
	8	唾液样本 Saliva samples	阳性 Positive	
	11	唾液样本 Saliva samples	阳性 Positive	
W005	2	唾液样本 Saliva samples	阳性 Positive	
	5	唾液样本 Saliva samples	阳性 Positive	
	8	唾液样本 Saliva samples	阳性 Positive	
	11	唾液样本 Saliva samples	阳性 Positive	
	14	唾液样本 Saliva samples	阳性 Positive	
	17	唾液样本 Saliva samples	阳性 Positive	
	20	唾液样本 Saliva samples	阴性 Negative	

注：发病时间为出现症状后开始计算，即出现症状当天记为 0 天。

Note: The onset time is calculated after the onset of symptoms, which means that the day of the onset of symptoms is counted as 0 days.

4 研究方法
Research method

（1）通过临床单位收集不同区域和同一个病人的不同阶段唾液样本，同时要求采用核酸试剂平行检测（核酸检测结果引用临床单位检测结果），样本收集类型详见上述的样本列表中；

Collect oropharyngeal swab samples from different areas and different stages of saliva samples from the same patient through medical institutions. At the same time, the samples are required to be tested in parallel with nucleic acid reagents (nucleic acid test results refer to the test results of medical institutions), and the type of sample collection See the above sample list.

（2）收集完成后采用新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）试剂进行检测，检测结果记录于原始记录中。

After the sample collection is completed, use the SARS-CoV-2 Antigen Rapid Test (Saliva) for testing, and record the test results.

5 检验标准
Inspection standards

（1）不同区域采集的样本检测结果与核酸保持相一致，表明试剂盒检测不受区域病毒的影响；

The test results of samples collected in different regions are consistent with the nucleic acid test results, indicating that the reagent test is not affected by the regions of the virus.

（2）感染者不同感染期检测结果与核酸保持相一致，表明试剂盒具有较好的临床检验能力。

The test results of infected persons at different infection stages are consistent with the nucleic acid test results, indicating that the reagent has good clinical testing capabilities.

6 研究结果
Research results

表 1 不同区域感染者样本研究结果

Tab.1 Research results of different regions infected persons

样本编号 Sample number	区域 Region	样本类型 Sample type	发病时间（天） Onset time (days)	检测结果 Test results	备注 Remarks
TT003	区域 1 Area-1	唾液样本 Saliva samples	3	+	
TT120	区域 1 Area-1	唾液样本 Saliva samples	2	+	
TT205	区域 1 Area-1	唾液样本 Saliva samples	8	+	
XH211	区域 1 Area-1	唾液样本 Saliva samples	12	+	
XH104	区域 1 Area-1	唾液样本 Saliva samples	5	+	
XH186	区域 1 Area-1	唾液样本 Saliva samples	32	+	
S1182	区域 2 Area-2	唾液样本 Saliva samples	6	+	
S0097	区域 2 Area-2	唾液样本 Saliva samples	2	+	
S2187	区域 2 Area-2	唾液样本 Saliva samples	5	+	
S1002	区域 2 Area-2	唾液样本 Saliva samples	2	+	
W1008	区域 3 Area-3	唾液样本 Saliva samples	1	+	
W1129	区域 3 Area-3	唾液样本 Saliva samples	4	+	
W1082	区域 3 Area-3	唾液样本 Saliva samples	2	+	

W1218	区域 3 Area-3	唾液样本 Saliva samples	18	+	
W1002	区域 3 Area-3	唾液样本 Saliva samples	5	+	

表 2 感染者不同感染期样本研究结果

Tab.2 Research results of samples from infected persons at different stages of infection

患者编号 Patient code	发病时间（天） Onset time (days)	样本类型 samples type	核酸检测情况 Nucleic acid test results	检测结果 Test results	备注 Remarks
W001	3	唾液样本 Saliva samples	阳性 Positive	+	
	6	唾液样本 Saliva samples	阳性 Positive	+	
	9	唾液样本 Saliva samples	阳性 Positive	+	
	12	唾液样本 Saliva samples	阳性 Positive	+	
	16	唾液样本 Saliva samples	阴性 Negative	—	
W002	0	唾液样本 Saliva samples	阳性 Positive	+	
	3	唾液样本 Saliva samples	阳性 Positive	+	
	6	唾液样本 Saliva samples	阳性 Positive	+	
	9	唾液样本 Saliva samples	阴性 Negative	—	
W003	1	唾液样本 Saliva samples	阳性 Positive	+	
	4	唾液样本 Saliva samples	阳性 Positive	+	
	7	唾液样本 Saliva samples	阳性 Positive	+	
	10	唾液样本 Saliva samples	阳性 Positive	+	
	13	唾液样本 Saliva samples	阳性 Positive	+	
	16	唾液样本 Saliva samples	阳性 Positive	+	
	19	唾液样本 Saliva samples	阴性 Negative	—	
	22	唾液样本 Saliva samples	阴性 Negative	—	

	25	唾液样本 Saliva samples	阴性 Negative	—	
W004	5	唾液样本 Saliva samples	阳性 Positive	+	
	8	唾液样本 Saliva samples	阳性 Positive	+	
	11	唾液样本 Saliva samples	阳性 Positive	+	
W005	2	唾液样本 Saliva samples	阳性 Positive	+	
	5	唾液样本 Saliva samples	阳性 Positive	+	
	8	唾液样本 Saliva samples	阳性 Positive	+	
	11	唾液样本 Saliva samples	阳性 Positive	+	
	14	唾液样本 Saliva samples	阳性 Positive	+	
	17	唾液样本 Saliva samples	阳性 Positive	+	
	20	唾液样本 Saliva samples	阴性 Negative	—	

7 研究结论
Research conclusions

（1）新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）对于区域样本检测不存在差异；

There is no difference in SARS-CoV-2 Antigen Rapid Test (Saliva) testing sample from difference regions.

（2）新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）对于感染者在不同的感染期的检测不存在差异。

There is no difference in the test results of the SARS-CoV-2 Antigen Rapid Test (Saliva) testing samples of infected persons in different infection stages.

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）
干扰物质研究资料
SARS-CoV-2 Antigen Rapid Test (Saliva)
Research documentation of Interfering substances

1 研究依据
Research basis

依据中国国家药品监督管理局医疗器械技术审评中心发布的《2019 新型冠状病毒抗原/抗体检测试剂注册技术审评要点（试行）》中关于干扰物质的研究。

According to the research on the Interfering substances in the《The Technical Key Points for Coronavirus (COVID-19) Antigen-antibody Detection Reagent Registration Review (Trial)》formulated by The Center For Medical Device Evaluation Of The National Medical Products Administration (NMPA).

2 研究目的
Research purpose

评估样本中常见物质或可能存在物质或患者可能服用的相关药物对项目检测是否存在影响。

Evaluate whether common or possible substances in the sample or related drugs that the patient may take have an impact on the testing of this item.

3 研究材料
Research materials

3.1 试剂盒

Reagent

名称 Name	批号 Batch code	生产厂家 Manufacturer	备注 Remarks
新型冠状病毒抗原（唾液）检测试剂盒（胶体金法） SARS-CoV-2 Antigen Rapid Test (Saliva)	Lot 01: 2020030405	厦门为正生物科技股份有限公司 Xiamen WIZ Biotech Co., LTD.	规格：25 人份/盒 Specification: 25tests/Kit

3.2 干扰样本

Interference sample

活性物质 Active ingredient	评价浓度 Concentration	原药浓度/质量 Original drug concentration/quality	药物名称或原材料名称 Drug name Or raw material name	注册证号 registration number（China）	药物厂家/原材料供应商 Drug manufacturer / Suppliers of raw materials	备注 Remarks

扎那米韦 Zanamivir	500ng/mL	5mg	扎那米韦吸入粉雾剂 Zanamivir Powder for Inhalation	国药准字 H20103037 National yao zhun zi H20103037	南京先声东元制药有限公司 Nanjing Simeere Dongyuan Pharmaceutical Co., Ltd.	
利巴韦林 Ribavirin	20μg/mL	0.1g	利巴韦林片 Ribavirin Tablets	国药准字 H10940014 National yao zhun zi H10940014	浙江浙北药业有限公司 Zhejiang Zhebei Pharmaceutical Co., Ltd.	
奥司他韦 Oseltamivir	5μg/mL	75mg	磷酸奥司他韦胶囊 Oseltamivir Phosphate Capsules	国药准字 H20065415 National yao zhun zi H20065415	宜昌东阳光长江药业股份有限公司 Yichang HEC Changjiang Pharmaceutical Co., Ltd.	
洛匹那韦 Lopinavir	8 mg/mL	100mg	洛匹那韦利托那韦片 Lopinavir and Ritonavir Tablets	国药准字 H20181115 National yao zhun zi H20181115	AbbVie Deutschland GmbH & Co. KG	
利托那韦 Ritonavir	530μg/mL	25mg	洛匹那韦利托那韦片 Lopinavir and Ritonavir Tablets	国药准字 H20181115 National yao zhun zi H20181115	AbbVie Deutschland GmbH & Co. KG	
阿比多尔 Umifenovir	4μg/mL	0.1g	盐酸阿比多尔分散片 Arbidol Dispersible Tablets	国药准字 H20060993 National yao zhun zi H20060993	海南先声药业有限公司 Hainan Simeere Co., Ltd.	
左氧氟沙星 Levofloxacin	30μg/mL	0.1g	盐酸左氧氟沙星胶囊 Levofloxacin hydrochloride capsules	国药准字 H20056031 National yao zhun zi H20056031	石药集团欧意药业有限公司 Shijiazhuang Pharmaceutical Group Ouyi Co., Ltd.	
阿奇霉素 Azithromycin	4.5μg/mL	0.25g	阿奇霉素分散片 Azithromycin Dispersible Tablets	国药准字 H20045804 National yao zhun zi H20045804	石家庄四药有限公司 Shijiazhuang No.4 Pharmaceutical Co.,Ltd	
头孢曲松 Ceftriaxone	0.8 mg/mL	1g	头孢曲松钠 Ceftriaxone Sodium	国药准字 H20013185 National yao zhun zi H20013185	瑞阳制药有限公司 Reyoung Pharmaceutical Co., Ltd.	
美罗培南 Meropenem	1.1mg/ml	0.5g	注射用美罗培南 Meropenem for Injection	国药准字 H20093466 National yao zhun zi H20093466	上海上药新亚药业有限公司 Shanghai Pharma New Asia Pharmaceutical Co., Ltd	
α-干扰素 α-interferon	50 万 U/mL 5 hundred thousand U/mL	1000 万 IU/1mL 10 million IU/1mL	重组人干扰素 α2b 注射液 Recombinant human α-interferon 2b injection	国药准字 S20113008 National yao zhun zi S20113008	长春海伯尔生物技术有限责任公司 Changchun heber biological technology CO.,LTD	
帕拉米韦 Peramivir	0.2mg/mL	0.3g/100mL	帕拉米韦氯化钠注射液 Peramivir and Sodium Chloride Injection	国药准字 H20130029 National yao zhun zi H20130029	广州南新制药有限公司 Guangzhou Nanxin Pharmaceutical Co., Ltd.	
妥布霉素 Tobramycin	4ng/mL	80mg/100mL	硫酸妥布霉素氯化钠注射液 Tobramycin Sulfate and Sodium Chloride Injection	国药准字 H20010825 National yao zhun zi H20010825	华仁药业股份有限公司 Huaren Pharmaceutical Co.,Ltd.	
苯福林 Phenylephrine	20μg/mL	1mg/mL	盐酸肾上腺素注射液 Epinephrine hydrochloride injection	国药准字 H31021062 National yao zhun zi H31021062	上海禾丰制药有限公司 Shanghai Harvest Pharmaceutical Co., Ltd.	
羟甲唑啉 Oxymetazoline	0.1 mg/mL	0.5mg/mL	盐酸羟甲唑啉滴鼻液 Oxymetazoline Hydrochloride Nasal Drops	国药准字 H20093702 National yao zhun zi H20093702	南京天朗制药有限公司 Nanjing Tianlang Pharmaceutical Co., Ltd.	
倍氯美松 Beclomethasone	0.1mg/mL	10ug/mL	丙酸倍氯米松气雾剂 Beclometasone Dipropionate Aerosol	国药准字 H20059867 National yao zhun zi H20059867	山东京卫制药有限公司 Jewim Pharmaceutical (Shandong) Co., Ltd.	
地塞米松 Dexamethasone	2 mg/mL	5mg/mL	醋酸地塞米松注射液 Dexamethasone Acetate Injection	国药准字 H51020514 National yao zhun zi H51020514	成都天台山制药有限公司 Chengdu Tiantaishan pharmaceutical Co., Ltd.	
氟尼缩松 Flunisolide	0.1 mg/mL	0.5mg/mL	丙酸氟替卡松吸入气雾剂 Fluticasone Propionate Inhalation Aerosol	国药准字 H20130189 National yao zhun zi H20130189	Glaxo Wellcome SA	

曲安奈德 Triamcinolone acetonide	10.5ng/mL	0.1%（1g 含有 1mg）30g/支 0.1% (1g contains 1mg) 30g/branch	曲安奈德益康唑乳膏 Triamcinolone acetonide cream	国药准字 H20067497 National yao zhun zi H20067497	浙江得恩德制药股份有限公司 Zhejiang DND PHARMACEUTICAL Co., Ltd.	
布地奈德 Budesonide	2.75ng/mL	0.64mg/mL	布地奈德鼻喷雾剂 Budesonide Spray	国药准字 J20180024 National yao zhun zi J20180024	上海强生制药有限公司 Shanghai Johnson Pharmaceutical Co., Ltd.	
莫米松 Mometasone	10ng/mL	0.1%,10mg/10g	糠酸莫米松乳膏 Mometasone furoate cream	国药准字 H20183221 National yao zhun zi H20183221	湖北科田药业有限公司 Hubei Ketian Pharmaceutical Co., Ltd.	
氟替卡松 Fluticasone	55μg/mL	275μg/mL	糠酸氟替卡松鼻用喷雾剂 Fluticasone Furoate Nasal Spray	国药准字 H20170104 National yao zhun zi H20170104	GlaxoSmithKline (Ireland) Limited	
盐酸组胺 Histamine Hydrochloride	10ng/mL	5mg	二盐酸组胺化学物质 Histamine Hydrochloride Chemical material	—	—	
氯化钠 Sodium chloride	5%	—	氯化钠 Sodium chloride	—	—	
黏蛋白 Mucin	5%	2g	黏蛋白 Mucin	—	—	
全血 Whole blood	5%	—	全血样本 Whole blood sample	—	临床单位 Medical institutions	

4 研究方法
Research method

（1）片剂、膏剂和纯物质的配制方法

Preparation methods of tablets, ointments and pure substances

①阴性样本：采用样本提取液分别将以下药物溶解至所需的浓度；

Negative sample: Using the Extraction solution to dissolve the following drugs to the required concentration.

②阳性样本：采用含有 $3.4\times10^{3}TCID_{50}$/mL 的阳性样本分别将以下药物溶解至所需的浓度。

Positive sample: Using the positive samples with concentration $3.4\times10^{3}TCID_{50}$/mL to dissolve the following drugs to the required concentration.

活性物质 Active ingredient	评价浓度 Concentration	原药浓度/质量 Original drug concentration/quality	药物名称或原材料名称 Drug name Or raw material name
扎那米韦 Zanamivir	500ng/mL	5mg	扎那米韦吸入粉雾剂 Zanamivir Powder for Inhalation
利巴韦林 Ribavirin	20μg/mL	0.1g	利巴韦林片 Ribavirin Tablets
奥司他韦 Oseltamivir	5μg/mL	75mg	磷酸奥司他韦胶囊 Oseltamivir Phosphate Capsules
洛匹那韦 Lopinavir	8mg/mL	100mg	洛匹那韦利托那韦片 Lopinavir and Ritonavir Tablets
利托那韦 Ritonavir	530μg/mL	25mg	洛匹那韦利托那韦片 Lopinavir and Ritonavir Tablets
阿比多尔 Umifenovir	4μg/mL	0.1g	盐酸阿比多尔分散片 Arbidol Dispersible Tablets
左氧氟沙星 Levofloxacin	30μg/mL	0.1g	盐酸左氧氟沙星胶囊 Levofloxacin hydrochloride capsules
阿奇霉素 Azithromycin	4.5μg/mL	0.25g	阿奇霉素分散片 Azithromycin Dispersible Tablets
头孢曲松 Ceftriaxone	0.8 mg/mL	1g	头孢曲松钠 Ceftriaxone Sodium
芙罗培南	1.1mg/ml	0.5g	注射用芙罗培南

Meropenem			Meropenem for Injection
氯化钠 Sodium chloride	5%（5g/100mL）	-	氯化钠 Sodium chloride
黏蛋白 Mucin	5%（5g/100mL）	2g	黏蛋白 Mucin

（2）液体药物

Liquid medicine

①阴性样本：采用样本提取液分别将以下药物稀释至药物活性物质的评价浓度；

Negative sample: Using the Extraction solution to dilute the following drugs to the estimated concentration of the active substance.

②阳性样本：采用样本提取液、含有 3.4×10^5TCID$_{50}$/mL 的阳性样本将以下药物稀释至药物活性物质的评价浓度且阳性样本病毒浓度为 3.4×10^3TCID$_{50}$/mL。

Positive sample: Using the Extraction solution, and the positive sample with concentration of 3.4×10^5TCID$_{50}$/mL, the following drugs were diluted to the evaluated concentration of the pharmaceutically active substance, and the diluted sample virus concentration was 3.4×10^3TCID$_{50}$/mL.

活性物质 Active ingredient	评价浓度 Concentration	原药浓度/质量 Original drug concentration/quality	药物名称或原材料名称 Drug name Or raw material name
α-干扰素 α-interferon	50 万 U/mL 5 hundred thousand U/mL	1000 万 IU/1mL 10 million IU/1mL	重组人干扰素 α2b 注射液 Recombinant human α-interferon 2b injection
帕拉米韦 Peramivir	0.2mg/mL	0.3g/100mL	帕拉米韦氯化钠注射液 Peramivir and Sodium Chloride Injection
妥布霉素 Tobramycin	4ng/mL	80mg/100mL	硫酸妥布霉素氯化钠注射液 Tobramycin Sulfate and Sodium Chloride Injection
苯福林 Phenylephrine	20μg/mL	1mg/mL	盐酸肾上腺素注射液 Epinephrine hydrochloride injection
羟甲唑啉 Oxymetazoline	0.1 mg/mL	0.5mg/mL	盐酸羟甲唑啉滴鼻液 Oxymetazoline Hydrochloride Nasal Drops
倍氯美松 Beclomethasone	0.1mg/mL	10ug/mL	丙酸倍氯米松气雾剂 Beclometasone Dipropionate Aerosol
地塞米松 Dexamethasone	2 mg/mL	5mg/mL	醋酸地塞米松注射液 Dexamethasone Acetate Injection
氟尼缩松 Flunisolide	0.1 mg/mL	0.5mg/mL	丙酸氟替卡松吸入气雾剂 Fluticasone Propionate Inhalation Aerosol
曲安奈德 Triamcinolone acetonide	10.5ng/mL	0.1%（1g 含有 1mg）30g/支 0.1% (1g contains 1mg) 30g/ branch	曲安奈德益康唑乳膏 Triamcinolone acetonide cream
布地奈德 Budesonide	2.75ng/mL	0.64mg/mL	布地奈德鼻喷雾剂 Budesonide Spray
莫米松 Mometasone	10ng/mL	0.1%,10mg/10g	糠酸莫米松乳膏 Mometasone furoate cream
氟替卡松 Fluticasone	55μg/mL	275ug/mL	糠酸氟替卡松鼻用喷雾剂 Fluticasone Furoate Nasal Spray

盐酸组胺 Histamine Hydrochloride	10ng/mL	5mg	二盐酸组胺化学物质 Histamine Hydrochloride Chemical material
全血 Whole blood	5%(红细胞压积) 5%(hematocrit value)	—	全血样本（破碎溶血） Whole blood sample(Fragment hemolysis)

（3）将处理好含有干扰物质的阴性样本和阳性样本按照产品说明书直接加样，观察评估结果。

After the treated negative and positive samples containing interfering substances are directly tested accordance with the requirements of the product Instructions for Use, observe the evaluation results.

5 检验标准
Inspections standards

（1）阴性样本（样本提取液）组所有检测结果应均为阴性；

All test results of the negative sample (Extraction solution) group should be negative.

（2）阳性样本（病毒浓度为 $3.4\times10^{3}TCID_{50}/mL$）组所有检测结果应均为阳性。

All test results of the positive sample (virus concentration $3.4\times10^{3}TCID_{50}/mL$) group should be positive.

6 研究结果
Research results

表 1 干扰物质研究结果

Tab.1 Research results of interfering substances

活性物质 Active ingredient	评价终浓度 Concentration to Evaluate	检测结果 Test results		备注 Remarks
		阴性样本（样本提取液） Negative sample (Extraction solution)	阳性样本 （终浓度 $3.4\times10^{3}TCID_{50}/mL$） positive sample (virus concentration $3.4\times10^{3}TCID_{50}/mL$)	
扎那米韦 Zanamivir	500ng/mL	—	+	
利巴韦林 Ribavirin	20μg/mL	—	+	
奥司他韦 Oseltamivir	5μg/mL	—	+	
洛匹那韦 Lopinavir	8 mg/mL	—	+	
利托那韦 Ritonavir	530μg/mL	—	+	
阿比多尔 Umifenovir	4μg/mL	—	+	
左氧氟沙星 Levofloxacin	30μg/mL	—	+	
阿奇霉素 Azithromycin	4.5μg/mL	—	+	
头孢曲松 Ceftriaxone	0.8 mg/mL	—	+	
美罗培南 Meropenem	1.1mg/ml	—	+	

氯化钠 Sodium chloride	5%（5g/100mL）	—	+	
黏蛋白 Mucin	5%（5g/100mL）	—	+	
α-干扰素 α-interferon	50 万 U/ mL 5 hundred thousand U/mL	—	+	
帕拉米韦 Peramivir	0.2mg/mL	—	+	
妥布霉素 Tobramycin	4ng/mL	—	+	
苯福林 Phenylephrine	20μg/mL	—	+	
羟甲唑啉 Oxymetazoline	0.1 mg/mL	—	+	
倍氯美松 Beclomethasone	0.1mg/mL	—	+	
地塞米松 Dexamethasone	2 mg/mL	—	+	
氟尼缩松 Flunisolide	0.1 mg/mL	—	+	
曲安奈德 Triamcinolone acetonide	10.5ng/mL	—	+	
布地奈德 Budesonide	2.75ng/mL	—	+	
莫米松 Mometasone	10ng/mL	—	+	
氟替卡松 Fluticasone	55μg/mL	—	+	
盐酸组胺 Histamine Hydrochloride	10ng/mL	—	+	
全血 Whole blood	5%(红细胞压积) 5%(hematocrit value)	—	+	

根据试验结果显示，列表中所列干扰物质在相应浓度对试剂盒阳性和阴性反应不产生干扰。

According to the experimental results, the interfering substances with corresponding concentrations in the above list do not interfere with the detection of reagents.

7 研究结论
Research conclusions

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）在相应常见物质、药物的浓度范围对检测结果不影响。

Within the concentration range of the corresponding common substances and drugs, the detection SARS-CoV-2 Antigen Rapid Test (Saliva) will not be affected.

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）
最低检出限研究资料
SARS-CoV-2 Antigen Rapid Test (Saliva)
The limit of detection research documentation

1 研究依据
Research basis

依据中国国家药品监督管理局医疗器械技术审评中心发布的《2019 新型冠状病毒抗原/抗体检测试剂注册技术审评要点（试行）》和 CLSI 发布的 EP-A12《User protocol for evaluation of qualitative test performance; approved guideline 》进行最低检出限确定及评估。

According to《The Technical Key Points for Coronavirus (COVID-19) Antigen-antibody Detection Reagent Registration Review (Trial)》formulated by The Center For Medical Device Evaluation Of The National Medical Products Administration（NMPA）and EP-A12《User protocol for evaluation of qualitative test performance; approved guideline》formulated by CLSI, the limit of detection is determined and evaluated.

2 研究目的
Research purpose

通过最低检出限的研究明确本产品的灵敏度，同时通过培养物稀释进行验证，明确确定的灵敏度的可靠性。

The sensitivity of this product is clarified by studying the limit of detection, and the reliability of the obtained sensitivity is clarified by verifying the culture dilution.

3 研究材料
Research materials

3.1 试剂盒

Reagent

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法），厦门为正生物科技股份有限公司。

SARS-CoV-2 Antigen Rapid Test (Saliva), Xiamen WIZ Biotech Co., LTD.

3.2 新冠病毒培养物

SARS-CoV-2 culture

通过热灭活的新型冠状病毒培养物，浓度 3.4×10^5 $TCID_{50}$/mL。

The heat-inactivated SARS-CoV-2 culture with concentration of 3.4×10^5 $TCID_{50}$/mL.

3.3 稀释溶液

Dilution solution

试剂盒的样本提取液，磷酸盐缓冲液（pH7.4±0.2）。

Extraction solution of the reagent kit, Phosphate Buffer Solution (pH7.4±0.2)

4 研究方法
Research method

（1）临界值的初筛

Initial screening of cutoff value

将热灭活的新型冠状病毒培养物（浓度：3.4×10^5 $TCID_{50}$/mL）按照 10 倍倍比进行稀释，每份稀释样本吸取 50μL 至一次性取样棒（每个稀释梯度制备三份），待稀释液被一次性取样棒吸收后，按照样本处理方法将一次性取样棒进行处理，处理后的样本根据检测卡检测方法进行检测，通过此检测方法来初步确定试剂盒的临界值；

Dilute the heat-inactivated SARS-CoV-2 culture (concentration: 3.4×10^5 $TCID_{50}$/mL) at 10-fold ratio, and draw 50μL from each diluted sample to Disposable sampling rod (Prepare three for each dilution gradient). After the diluent is absorbed by the Disposable sampling rod, the Disposable sampling rod is treated according to the sample processing method, and the treated sample is tested according to the test method of reagent. The cutoff value of the reagent is preliminarily determined by this test method.

（2）临界值的确定

Determination of cutoff value

根据确定的初始临界值范围，采用样本提取液对临界值附近浓度进一步细化稀释（2 倍倍比稀释），每份稀释样本吸取 50μL 至一次性取样棒（每个稀释梯度制备三份），待稀释液被一次性取样棒吸收后，按照样本处理方法将一次性取样棒进行处理，处理后的样本根据检测卡检测方法进行检测，通过此检测方法来确定试剂盒的临界值；

According to the determined initial cutoff value range, the sample extraction solution is used to further dilute the concentration near the cutoff value (2 times dilution), and draw 50μL from each diluted sample to Disposable sampling rod (Prepare three for each dilution gradient). After the diluent is absorbed by the Disposable sampling rod, the Disposable sampling rod is treated according to the sample processing method, and the treated sample is tested according to the test method of reagent. The cutoff value of the reagent is determined by this test method.

（3）临界值的验证

Verification of cutoff value

根据步骤（2）中确定的临界值，将热灭活的新型冠状病毒培养物（浓度：3.4×10^5 $TCID_{50}$/mL）分别平行配制三次，配制后均稀释至确定的临界值，每份稀释样本吸取 50μL 至一次性取样棒（每个稀释

梯度制备 20 份），待稀释液被一次性取样棒吸收后，按照样本处理方法将一次性取样棒进行处理，处理后的样本根据检测卡检测方法进行检测，通过此检测方法来验证试剂盒临界值的准确性。

According to the cutoff value determined in step (2), the heat-inactivated SARS-CoV-2 culture (concentration: 3.4×10^5 $TCID_{50}$/mL) was prepared three times in parallel, and all diluted to the determined cutoff value after preparation. and draw 50μL from each diluted sample to Disposable sampling rod(Prepare twenty for each dilution gradient). After the diluent is absorbed by the Disposable sampling rod, the Disposable sampling rod is treated according to the sample processing method, and the treated sample is tested according to the test method of reagent. The cutoff value of the reagent is verified by this test method.

5 检验标准
Inspection standards

（1）临界值的初筛、临界值的确定采用临界阳性作为判定标准，即阳性后下一个稀释梯度为阴性。

The initial screening of the cutoff value and the determination of the cutoff value adopt the critical positive as the criterion, which means that the next dilution gradient after the positive is negative.

（2）临界值的验证采用的是 95%的阳性率，即 20 次检测时不低于 19 次阳性。

The cut-off value verification uses 95% positive rate, which means that there are no less than 19 positives out of 20 tests.

6 研究结果
Research results

6.1 临界值的初筛

Initial screening of cutoff value

表 1 临界值的初筛研究结果

Tab.1 Initial screening research results of cutoff value

浓度/序号 Concentration/No.	1	2	3
3.4×10^5 $TCID_{50}$/mL	+	+	+
3.4×10^4 $TCID_{50}$/mL	+	+	+
3.4×10^3 $TCID_{50}$/mL	+	+	+
3.4×10^2 $TCID_{50}$/mL	+	+	+
3.4×10^1 $TCID_{50}$/mL	—	—	—
3.4×10^0 $TCID_{50}$/mL	—	—	—

6.2 临界值的确定

Determination of cutoff value

表 2 临界值的确定研究结果

Tab.2 Determination research results of cutoff value

浓度/序号 Concentration/No.	1	2	3
1.36×10^{3} $TCID_{50}$/mL	+	+	+
6.8×10^{2} $TCID_{50}$/mL	+	+	+
3.4×10^{2} $TCID_{50}$/mL	+	+	+
1.7×10^{2} $TCID_{50}$/mL	+	+	+
0.85×10^{2} $TCID_{50}$/mL	±	—	—
0.43×10^{2} $TCID_{50}$/mL	—	—	—

6.3 临界值的验证

Verification of cutoff value

表 3 临界值的验证研究结果

Tab.3 Verification research results of cutoff value

浓度/序号 Concentration/No.	1.7×10^{2} $TCID_{50}$/mL			0.85×10^{2} $TCID_{50}$/mL		
	1	2	3	1	2	3
1	+	+	+	—	—	—
2	+	+	+	—	—	±
3	+	+	+	—	±	—
4	+	+	+	±	—	—
5	+	+	+	—	—	—
6	+	+	+	—	—	—
7	+	+	+	—	±	±
8	+	+	+	—	—	—
9	+	+	+	±	—	—
10	+	+	+	—	—	±
11	+	+	+	—	—	—
12	+	+	+	—	±	—
13	+	+	+	—	—	—
14	+	+	+	—	—	—

15	+	+	+	±	—	—
16	+	+	+	—	—	±
17	+	+	+	—	—	—
18	+	+	+	±	±	—
19	+	+	+	—	—	±
20	+	+	+	±	—	—
符合率	20/20	20/20	20/20	5/20	4/20	5/20

根据以上研究结果，本试剂盒的最低检出限浓度最终确定为 1.7×10^2 $TCID_{50}$/mL。

Based on the above research results, the limit of detection concentration of this kit was finally determined to be 1.7×10^2 $TCID_{50}$/mL.

7 研究结论
Research conclusions

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）最低检出限浓度为 1.7×10^2 $TCID_{50}$/mL，经过相关研究和验证结果可靠。

The limit of detection on the SARS-CoV-2 Antigen Rapid Test (Saliva) Test is 1.7×10^2 $TCID_{50}$/mL, and the results are reliable after relevant research and verification.

第四节　性能评估结论
Section 4　Performance Evaluation Conclusion

新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）满足以下性能：
The Performance of SARS-CoV-2 Antigen Rapid Test (Saliva) meets the following requirements:

1 按照技术要求进行三批产品的全性能评估，产品能够满足相关要求：
According to the technical requirements, the whole performance evaluation of three batches of products can meet the relevant requirements:

（1）物理性能：
Physical properties

外观检测：外观应平整，标识应清晰，各组分应牢固附着，内容应齐全，液体无渗漏。
Appearance inspection: The appearance should be flat, the identification should be clear, the components should be firmly attached, the content should be complete, and no liquid leakage.

液体移行速度：液体移行速度应不低于 10mm/min。
The moving speed of liquid: The moving speed of liquid should not be less than 10mm/min.

膜条宽度：膜条宽度应不小于 2.5mm。
Width of strip: The width of the strip should not be less than 2.5mm.

（2）阴性符合率：阴性参考品 N1～N10 的检测结果应均为阴性，阴性符合率 10/10。
Coincidence rate of negative reference: The test results of negative reference N1～N10 should all be negative, and the negative coincidence rate is 10/10.

（3）阳性符合率：阳性参考品 P1～P4 的检测结果应均为阳性，阳性符合率 4/4。
Coincidence rate of positive reference: The test results of positive reference product P1～P4 should all be positive, and the positive coincidence rate is 4/4.

（4）最低检测限：最低检测限 DL1、DL2 的检测结果应均为阳性，DL3 的检测结果可为阳性或阴性。
The limit of detection: DL1 and DL2 enterprise references should all be positive, and DL3 enterprise reference can be positive or negative.

（5）重复性：重复性参考品 CV1 和 CV2 的 10 次检测结果应均为阳性，且显色强度均一无色差。
Repeatability: The 10 test results of the repeatability reference CV1 and CV2 should all be positive, and the color intensity is uniform without color difference.

2 HOOK 效应：新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）在病毒浓度为 3.40×10^5 $TCID_{50}$/mL 范围内未产生 HOOK 效应。
HOOK effect: There is no HOOK effect when SARS-CoV-2 Antigen Rapid Test (Saliva) tests sample below the virus concentration of 3.40×10^5 $TCID_{50}$/mL.

3 交叉反应：新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）与呼吸道病毒、常见口腔细菌等微生物在研究范围内未见交叉反应。
Cross-reaction: The SARS-CoV-2 Antigen Rapid Test (Saliva) has no cross-react with microorganisms such as respiratory viruses and common oral bacteria within the scope of the study concentration.

4 不同区域感染者及感染者不同感染期研究：
Study on infected persons in different regions and samples of infected persons in different infection periods:

（1）新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）对于区域样本检测不存在差异；
There is no difference in SARS-CoV-2 Antigen Rapid Test (Saliva) testing sample from difference regions.

（2）新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）对于感染者在不同的感染期的检测不存在差异。
There is no difference in the test results of the SARS-CoV-2 Antigen Rapid Test (Saliva) testing samples of infected persons in different infection stages.

5 干扰反应：新型冠状病毒抗原（唾液）检测试剂盒（胶体金法）在相应常见物质、药物的浓度范围对检测结果不影响。
Interfering substances: Within the concentration range of the corresponding common substances and drugs, the detection SARS-CoV-2 Antigen Rapid Test (Saliva) will not be affected.