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IVD AND POCT PRODUCTS MANUFACTURER

SARS-CoV-2 antigen IVD kit SALIVA Performance Evaluation Report

1 . Mainly Analyze Performance Indicators And Basis For Determination

The SARS-CoV-2 antigen IVD kit SALIVA produced by Shenzhen Reagent Technology Co.,Ltd., according to the classification of the State Food and Drug Administration of China, belongs to the third Class in vitro diagnostic reagents, classified according to the CE risk level of EU products, belong to the IVDD Others category, based on "Administrative Measures for the Registration of In Vitro Diagnostic Reagents" and the European Union In Vitro Diagnostic Medical Devices (98/79/EC), refer to the "Guiding Principles of In Vitro Diagnostic Reagent Analytical Performance Evaluation Series" and "Key Points for Technical Review of Registration of SARS-CoV-2 Antigen/Antibody Detection Reagents in 2019" .This report mainly focuses on the SARS-CoV-2 antigen IVD kit appearance, liquid moving speed, accuracy (negative/positive sample compliance), minimum detection. The main analytical performance indicators such as limit (sensitivity), precision, specificity, etc. were studied, and the specific contents are

as follows under.

2. Testing Materials And Equipment

2.1 SARS-CoV-2 antigen IVD kit SALIVA

Three batches of SARS-CoV-2 antigen IVD kit SALIVA for performance evaluation. The batch numbers are 20201025, 20201102, 20201113.

The kit packaging specification is 20 T/ box.

2.2 Reference Products

2.2.1 Positive reference

This product uses the SARS-CoV-2 N protein, Antibodies NP-33, NP-19 produced by Optin Biotechnology (Shenzhen) Co., Ltd.

The reference product adopts the eukaryotic N protein of Beijing Bepsis, and the sample extract is used to dissolve it

De-dilution is used as an internal reference in the kit. See Table 1 for the composition of internal reference products.

Table 1 SARS-CoV-2 Positive Reference Product Information Sheet

Raw Material Name	N protein	Concentration (μ g/ml)	100
Reference Product Name	Dilution Factor		Preparation batch
S1	1:10000		20201011
S2	1:20000		
S3	1:40000		
S4	1: 80000		
S5	1:160000		
S6	1:320000		
S7	1:640000		
S8	1:1280000		
S9	1:2560000		
S10	1:5120000		
R1	1:10000		
R2	1:40000		

2.2.2 Negative Reference

No hemolysis, no jaundice, no bacterial contamination collected from the hospital, confirmed by the SARS-CoV-2 20 cases of antigen-negative, IgM and IgG antibody-negative sera, respectively numbered as negative reference. N1~Negative reference product N20, aliquoted after heating in a water bath for inactivation, for use.

2.3 Personnel, Equipment, Date And Site of Experiment

2.3.1 **Personnel:** This performance evaluation experiment was conducted by the R&D department and quality of Shenzhen Reagent Technology Co.,Ltd. The department is jointly completed in the inspection room. All the above personnel have undergone long-term , strict biological experiment training , training, and have a background in science, medicine, and biology.

Experimenter	Zeng Xiangfu
Reviewer	Chen Huan
Approved personnel	Lin Jinchang

2.3.2 Equipment

Pipettes, vernier calipers, timers, the above instruments are all measured and calibrated.

2.3.3 Date of Experiment

Experiment start date: November 19, 2020

Experiment end date: November 20, 2020

2.3.4 Site

R7777,Hangcheng Wisdom Science Park, Hangcheng street,Bao'an District Shenzhen ,China

2.4 Matters needing attention

2.4.1 SARS-CoV-2 antigen IVD kit SALIVA is suitable for trained clinical laboratories personnel, especially clinical practice trained in in vitro diagnostic procedures and appropriate infection control procedure techniques laboratory personnel, and individuals who have received similar training at the point of care.

2.4.2 All samples should be considered as biological hazards capable of spreading disease. According to biosafety level 2 or higher guidelines for collecting, processing, storing and disposing of patient samples and used kit contents take appropriate precautions.

2.4.3 When handling the items in this toolbox, please wear appropriate personal protective equipment (such as gowns, gloves, Goggles).

2.4.4 Discard the test card after use. This test cannot be used multiple times.

2.4.5 Do not touch the reaction area of the test strip.

2.4.6 Testing should be carried out by professionally trained staff in a certified laboratory or clinic. These tests Samples from the room or clinic are collected by qualified medical personnel.

2.4.7 Test results should be interpreted by doctors or trained medical professionals, and should be compared with clinical results and the laboratory test results are explained together.

2.4.8 All samples and used kits should be regarded as biomedical waste containing potentially infectious substances deal with. The handling process of used diagnostic kits and sample materials must comply with local infectious disease handling laws or laboratory regulations.

3. Analytical Performance Evaluation Methods And Judgment Standards

3.1 Appearance

Method: Under natural light, check visually with normal eyesight.

Standard: The appearance of the kit should be clean and tidy, the text and symbols should be clearly marked, the package should not be damaged, and the contents should be complete.The test card should have a smooth appearance, uniform color, no burrs on the edges, and no stains or stains. Diluent should be clear transparent, no precipitation.

3.2 Physical Inspection

Method: Use a vernier caliper to measure the width of the test strip in the test card, and use a universal instrument that has passed the measurement.Measure the net content of the sample diluent.

Standard: The width of the test strip should be ≥2.5mm; the volume of the sample extract should be ≥8.0mL/bottle.

3.3 Liquid Moving Speed

Method: randomly select 3 test cards, after adding samples, use a timer to time the samples immediately

Stop timing when completely passing the observation window and record the elapsed time (t)s. Measure the center of the sample area to the observation window,the distance of the edge (S) mm. Calculate the traveling speed (V) = S/(t/60) (mm/min).

Standard: When adding samples, the sample should not overflow from the sample area to the NC membrane. The sample is in the

test card.The moving speed on the top should be ≥10mm/min.

3.4 Compliance Rate Of Negative Reference

Method: Use the same batch of reagents to measure 20 negative reference samples, and each reference sample is measured 1 times.

Standard: The test results are all negative.

3.5 Positive Peference And Detection Limit (Sensitivity)

Method: Use the same batch number of reagents and the detection sensitivity reference products S1-S10. Each reference is measured 1times.

Standard: S1-S7 should be detected as positive.

3.6 Precision

Method: Test repeatable reference products (R1, R2) 10 times each.

Standard: The test results should be consistent.

3.7 Specificity

Method: Take the prepared 2.5mg/mL bilirubin, 25g/L hemoglobin, 50g/L triglycerides, 4000 IU/ml rheumatoid factor and 200ng/ml HAMA serum, according to the ratio of interfering substance: matrix sample=1:9,Add the above bilirubin and blood red to the negative sample N1, the positive reference product S1, and the positive reference product S3.Protein, triglycerides, rheumatoid factor and HAMA serum, so that the final concentration of the interfering substance is: bilirubin 250mg/L, hemoglobin 2.5g/L, triglyceride 5.0g/L, rheumatoid factor 400IU/ml, HAMA serum 20ng/ml. Use the same batch of reagents to measure the reference product and each interference sample 3 times.

Standard: The results obtained should be consistent.

4. Analysis of Test Results

4.1 Appearance Evaluation Results

Table 2 Appearance test results of three batches of kits

Reagent Lot Number	Acceptance Criteria	Results	Test Conclusion
20201025	①The appearance of the kit is neat and tidy, with characters,the number is clearly marked, the package is not damaged, and the content complete. ②The appearance and color of the test card are flat uniform, no burrs on the edges, no stains or stains. ③The diluent should be clear and transparent, without precipitation.	Meet the requirements	Pass
20201102		Meet the requirements	Pass
20201113		Meet the requirements	Pass

4.2 Physical Inspection Evaluation Results

Table 3 Appearance test results of three batches of kits

Reagent Lot Number	Acceptance Criteria	Results				Test Conclusion
20201025	The width of the test strip should be ≥2.5mm; sample diluent filling volume should be ≥8.0mL/bottle.	Card 1	Card 1	Card 1	Diluent	Pass
		2.96mm	2.96mm	2.96mm	8.1mL	Pass
20201102		Card 1	Card 1	Card 1	Diluent	Pass
		2.98mm	2.98mm	2.98mm	8.1mL	Pass
20201113		Card 1	Card 1	Card 1	Diluent	Pass
		2.98mm	2.98mm	2.98mm	8.1mL	Pass

4.3 Liquid Moving Speed Test Results

Table 4 Physical test results of three batches of kits

Reagent Lot Number	Acceptance Criteria	Results				Test Conclusion
		Serial Number	Distance (mm)	Time (s)	Speed(mm/min)	
20201025	The phenomenon that the sample overflows from the sample area to the NC membrane should not occur, and the sample migration speed on the test card should be ≥10mm/min.	1	31.5	138	14.921	Pass
		2	31.5	115		
		3	31.5	127		
		Average value	31.5	126.7		
20201102		1	31.5	115	16.628	Pass
		2	31.5	121		
		3	31.5	105		
		Average value	31.5	113.7		
20201113		1	31.5	120	15.794	Pass
		2	31.5	126		
		3	31.5	113		
		Average value	31.5	119.7		

4.4 Evaluation Results of Negative Reference

Table 5 Accuracy test results of three batches of kits

Reagent Lot Number	Acceptance Criteria		Results										Test Conclusion
20201025	The results of the reference were all negative.	Reference	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		Results	_	_	_	_	_	_	_	_	_	_	
		Reference	N11	N12	N13	N14	N15	N16	N17	N18	N19	N20	
		Results	_	_	_	_	_	_	_	_	_	_	
20201102		Reference	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		Results	_	_	_	_	_	_	_	_	_	_	
		Reference	N11	N12	N13	N14	N15	N16	N17	N18	N19	N20	
		Results	_	_	_	_	_	_	_	_	_	_	
20201113		Reference	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		Results	_	_	_	_	_	_	_	_	_	_	
		Reference	N11	N12	N13	N14	N15	N16	N17	N18	N19	N20	
		Results	_	_	_	_	_	_	_	_	_	_	

Note:“-”means negative

4.5 Positive Reference And Detection Limit (sensitivity) Evaluation Result

Table 6 Test results of recovery test of three batches of kits

Reagent Lot Number	Acceptance Criteria	Results											Test Conclusion
		Reference	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	
20201025	The results of the reference were all	Results	+	+	+	+	+	+	+	+	+	+	Pass
20201102		Results	+	+	+	+	+	+	+	+	+	+	Pass

20201113	positive	Results	+	+	+	+	+	+	+	+	+	+	Pass

Note: “+”means positive

4.6 Precision Evaluation Test Results

Table 7 Precision evaluation results of three batches of kits

Reagent Lot Numbe	**Acceptance Criteria**	**Results**								**Test Conclusion**
		R1				R2				
		Frequency	Results	Frequency	Results	Frequency	Results	Frequency	Results	
20201025	Test the repeatability reference 10 times, and the test results should be consistent.	1	+	6	+	1	+	6	+	Pass
		2	+	7	+	2	+	7	+	
		3	+	8	+	3	+	8	+	
		4	+	9	+	4	+	9	+	
		5	+	10	+	5	+	10	+	
20201102		1	+	6	+	1	+	6	+	Pass
		2	+	7	+	2	+	7	+	
		3	+	8	+	3	+	8	+	
		4	+	9	+	4	+	9	+	
		5	+	10	+	5	+	10	+	
20201113		1	+	6	+	1	+	6	+	Pass
		2	+	7	+	2	+	7	+	
		3	+	8	+	3	+	8	+	
		4	+	9	+	4	+	9	+	
		5	+	10	+	5	+	10	+	

Note: “+”means positive

4.7 Analysis of Specific Test Evaluation Results

Table 10 Evaluation results of interference test of 20201025 batch

Acceptance	**Reference**	**Interfering**	**1**	**2**	**3**	**Test**

Criteria	Name	Substances				Conclusion
The test results of each sample should be consistent.	N1	No	_	_	_	Pass
		Hemoglobin	_	_	_	
		Triglycerides	_	_	_	
		Bilirubin	_	_	_	
		Rheumatoid factor	_	_	_	
		HAMA serum	_	_	_	
	S1	No	+	+	+	Pass
		Hemoglobin	+	+	+	
		Triglycerides	+	+	+	
		Bilirubin	+	+	+	
		Rheumatoid factor	+	+	+	
		HAMA serum	+	+	+	
	S3	No	+	+	+	Pass
		Hemoglobin	+	+	+	
		Triglycerides	+	+	+	
		Bilirubin	+	+	+	
		Rheumatoid factor	+	+	+	
		HAMA serum	+	+	+	

Table 11 Evaluation results of interference test of 20201102 batch

Acceptance Criteria	Reference Name	Interfering Substances	1	2	3	Test Conclusion
The test results	N1	No	_	_	_	Pass
		Hemoglobin	_	_	_	
		Triglycerides	_	_	_	
		Bilirubin	_	_	_	
		Rheumatoid factor	_	_	_	

of each sample should be consistent.		HAMA serum	–	–	–	
	S1	No	+	+	+	Pass
		Hemoglobin	+	+	+	
		Triglycerides	+	+	+	
		Bilirubin	+	+	+	
		Rheumatoid factor	+	+	+	
		HAMA serum	+	+	+	
	S3	No	+	+	+	Pass
		Hemoglobin	+	+	+	
		Triglycerides	+	+	+	
		Bilirubin	+	+	+	
		Rheumatoid factor	+	+	+	
		HAMA serum	+	+	+	

Table 12 Evaluation results of interference test of 20201113 batch

Acceptance Criteria	**Reference Name**	**Interfering Substances**	**1**	**2**	**3**	**Test Conclusion**
The test results of each sample should be consistent.	**N1**	No	–	–	–	Pass
		Hemoglobin	–	–	–	
		Triglycerides	–	–	–	
		Bilirubin	–	–	–	
		Rheumatoid factor	–	–	–	
		HAMA serum	–	–	–	
	S1	No	+	+	+	Pass
		Hemoglobin	+	+	+	
		Triglycerides	+	+	+	
		Bilirubin	+	+	+	
		Rheumatoid factor	+	+	+	

		HAMA serum	+	+	+	
	S3	No	+	+	+	Pass
		Hemoglobin	+	+	+	
		Triglycerides	+	+	+	
		Bilirubin	+	+	+	
		Rheumatoid factor	+	+	+	
		HAMA serum	+	+	+	

Note: “＋”means positive，“-”means negative.

5. Conclusion

The SARS-CoV-2 antigen IVD kit SALIVA of Shenzhen Reagent Technology Co.,Ltd. , the results of the analysis of performance evaluation show that all the verification results of the physical examination, liquid moving speed, accuracy (negative / positive sample coincidence), detection limit (sensitivity), precision and specificity were all up to the design requirements. It can meet the clinical needs.