Precision Studies

Product Name: Rapid SARS-CoV-2 Antigen Test Card
Catalog No.: 1N40C5

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Overview

Precision refers to the degree of agreement between mutually independent test results under specified conditions, Precision evaluation includes both repeatability and reproducibility. Repeatability measures the variation in measurements for the same sample taken under the same testing conditions (e.g., the same operator or laboratory), and reproducibility measures the variation in measurements for the same sample taken under different testing conditions (e.g., different operators or laboratories).

1. Purpose

To evaluate the precision of the Rapid SARS-CoV-2 Antigen Test Card.

2. References

	Document No.	Document
1	EP12-A2	User Protocol for Evaluation of Qualitative Test Performance
2	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
Liting Chen	R&D Engineer	B.S.	Study implementation, recording, and analysis of results
Yangyang Gao	R&D Engineer	B.S.	Study implementation, recording, and analysis of results
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. Statistical Analysis Methods

The test results should be negative for negative samples, and positive for weak positive and positive samples. Calculate the positive and negative agreements for the three batches of test kits.

5. Standard Requirements

The negative agreement for negative samples should be 100%. The positive agreement for weak positive samples should be 100%. The positive agreement for positive samples should be 100%.

6. Materials

6.1. Evaluated Reagents

Rapid SARS-CoV-2 Antigen Test Card (1N40C5)		
	Lot Number	Manufacturer
1	H20061502	Xiamen Boson Biotech Co., Ltd.
2	H20061601	Xiamen Boson Biotech Co., Ltd.
3	H20061701	Xiamen Boson Biotech Co., Ltd.

6.2. Other Materials

	Name	Lot No. (Catalog No.)	Notes
1	SARS-CoV-2 viral culture	NR-52281 (USA-WA1/2020)	ZeptoMetrix Corporation

7. Methods

7.1. Sample Preparation

1) Negative Samples

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 SARS-CoV-2 antigen negative samples.

2) Weak Positive Samples

Add SARS-CoV-2 viral cultures into the negative samples and prepare SARS-CoV-2 antigen weak positive samples with viral concentration of 3.9×10^2 $TCID_{50}$/mL (about 3×LoD).

3) Positive Samples

Add SARS-CoV-2 viral cultures into the negative samples and prepare SARS-CoV-2 antigen positive samples with viral concentration of 6.5×10^2 $TCID_{50}$/mL (about 5×LoD).

7.2. Sample Testing

Three lots of the Rapid SARS-CoV-2 Antigen Test Card were used to test SARS-CoV-2 antigen positive, weak positive, and negative samples.

Samples were tested by 3 different operators at different locations for 5 consecutive days. There was one test session per day, with 20 tests for each sample.

The test procedures were carried out according to the instructions for use. Test results were interpreted and recorded 15-20 min after sample addition.

8. Results

Table 1 Test Results by Operator A

Sample Type	Lot No.	Day 1	Day 2	Day 3	Day 4	Day 5
Negative	H20061502	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
	H20061601	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
	H20061701	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
Weak Positive	H20061502	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061601	+,20/20	+,20/20	+, 20/20	+,20/20	+,20/20

	H20061701	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
Positive	H20061502	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061601	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061701	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20

Table 2 Test Results by Operator B

Sample Type	Lot No.	Day 1	Day 2	Day 3	Day 4	Day 5
Negative	H20061502	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
	H20061601	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
	H20061701	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
Weak Positive	H20061502	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061601	+,20/20	+,20/20	+, 20/20	+,20/20	+,20/20
	H20061701	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
Positive	H20061502	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061601	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061701	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20

Table 3 Test Results by Operator C

Sample Type	Lot No.	Day 1	Day 2	Day 3	Day 4	Day 5
Negative	H20061502	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
	H20061601	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
	H20061701	-,20/20	-,20/20	-,20/20	-,20/20	-,20/20
Weak Positive	H20061502	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061601	+,20/20	+,20/20	+, 20/20	+,20/20	+,20/20
	H20061701	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
Positive	H20061502	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061601	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20
	H20061701	+,20/20	+,20/20	+,20/20	+,20/20	+,20/20

Notes: "-" = negative result; "+" = positive result.

9. Analysis of Results

Table 4 Summary of test results of 3 batches of test kits by 3 operators

Lot No.	H20061502	H20061601	H20061701
Negative Samples Tested	300	300	300
Weak Positive Samples Tested	300	300	300
Positive Samples Tested	300	300	300
Positive Agreement	100%	100%	100%
Negative Agreement	100%	100%	100%

Three batches of test kits were used to test SARS-CoV-2 antigen negative, weak positive, and positive samples. Samples were tested by 3 different operators at different locations for 5 consecutive days, with one test session per day and 20 tests per sample per session. The

test results for SARS-CoV-2 antigen negative samples were consistent and all negative. The test results for SARS-CoV-2 antigen positive samples were consistent and all positive.

10. Conclusion

Three lots of the Rapid SARS-CoV-2 Antigen Test Card were used to test SARS-CoV-2 antigen positive, weak positive, and negative samples. Samples were tested by 3 different operators at different locations for 5 consecutive days, with one test session per day and 20 tests per sample per session. Tests results were all consistent with the proposed quality standards, with 100% agreement rates. Therefore, the reagent has good precision.