Analytical Sensitivity Studies – Nasal Sample Validation Report

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

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Xiamen Boson Biotech Co., Ltd.

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Overview

The limit of detection for the Rapid SARS-CoV-2 Antigen Test Card has been evaluated for nasopharyngeal samples. For this study, the validation of the limit of detection for the Rapid SARS-CoV-2 Antigen Test Card for nasal samples has been added to assess the suitability for nasal sample types.

1. Purpose

To evaluate the limit of detection of nasal samples for the Rapid SARS-CoV-2 Antigen Test Card.

2. References

	Document No.	Document
1	EP17-A	Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline
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
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. Standard Requirements

The positive detection rate should be ≥95% for samples at the limit of detection concentration.

5. Materials

5.1 Evaluated Reagent

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.

5.2 Other Materials

	Name	Lot No. (Catalog No.)	Notes
1	SARS-CoV-2 recombinant antigens (N-protein)	R20050718	Shanghai Novoprotein Technology Co., Ltd.
2	SARS-CoV-2 viral culture 1#	NR-52284 (Italy-INMI1)	ZeptoMetrix Corporation
3	SARS-CoV-2 viral culture 2#	NR-52282 (Hong Kong/VM2000106/2020)	ZeptoMetrix Corporation
4	SARS-CoV-2 viral culture 3#	NR-52281 (USA-WA1/2020)	ZeptoMetrix

			Corporation

6. Verification of the Limit of Detection for SARS-CoV-2 Recombinant Antigen

6.1 Sample Preparation

1) Negative Samples

Collect the nasal samples with the nasal swabs from healthy individuals, add into the extraction tubes with sample extraction buffer, mix well and use as the SARS-CoV-2 antigen negative samples.

2) SARS-CoV-2 Recombinant Antigen Samples

Test samples were prepared by diluting SARS-CoV-2 recombinant antigen at a concentration of 1 μg/mL with negative samples at the limit of detection concentration level of 1 ng/mL.

6.2 Sample Testing

Use the Rapid SARS-CoV-2 Antigen Test Card to separately test the sample at the limit of detection. Repeat 20 tests for the sample.

Carry out the test according to the instructions for use. Read and record results 15-20 min after sample addition.

6.3 Verification Results

Table 1. Test results for SARS-CoV-2 recombinant antigen for the verification of the limit of detection

No.	Concentration	H20061502	H20061601	H20061701	Total Agreement
1	1 ng/mL	20/20	20/20	20/20	60/60 (100%)

6.4 Analysis of Results

The positive agreement was 100% for SARS-CoV-2 recombinant antigen sample at the limit of detection.

6.5 Conclusion

The limit of detection for SARS-CoV-2 recombinant antigen was verified by collecting nasal samples. The total agreement was 100%.

7. Verification of the Limit of Detection for SARS-CoV-2 Viral Cultures

7.1 Sample Preparation

1) Negative Samples

Collect the nasal samples with the nasal swabs from healthy individuals, add into the extraction tubes with sample extraction buffer, mix well and use as the SARS-CoV-2 antigen negative samples.

2) SARS-CoV-2 Recombinant Antigen Samples

Add three different strains of SARS-CoV-2 viral cultures into the negative sample, and separately prepare test samples at the limit of detection (1.3×10^2 $TCID_{50}$/mL).

7.2 Sample Testing

Use the Rapid SARS-CoV-2 Antigen Test Card to separately test the three samples at the limit of detection. Repeat 20 tests for each sample.

Carry out the test according to the instructions for use. Read and record results 15-20 min after

sample addition.

7.3 Verification Results

Table 2. Test results for SARS-CoV-2 viral cultures for the verification of the limit of detection

No.	Concentration ($TCID_{50}$/mL)	H20061502	H20061601	H20061701	Total Agreement
1#	1.3×10^2	20/20	20/20	20/20	60/60 (100%)
2#	1.3×10^2	20/20	20/20	20/20	60/60 (100%)
3#	1.3×10^2	20/20	20/20	20/20	60/60 (100%)

7.4 Analysis of Results

Three strains of SARS-CoV-2 viral cultures at the limit of detection were tested, with 20 tests repeated for each sample. Based on the verification, the positive detection rate for the Rapid SARS-CoV-2 Antigen Test Card was 100%.

7.5 Conclusion

The limit of detection for SARS-CoV-2 viral cultures was verified by collecting nasal samples. The total agreement was 100%.

8. Summary

The limit of detection was verified for both SARS-CoV-2 recombinant antigens and viral cultures for nasal samples. The total agreement was 100%. Therefore, nasal samples are suitable samples for the Rapid SARS-CoV-2 Antigen Test Card.