

Storage Stability Studies

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

File No.	RR1N40005
Date	2020.06.15-2021.01.20
Drafted by / Date	Mengjuan Wu 2021.01.21
Reviewed by / Date	Zhijuan Jia 2021.01.22
Approved by / Date	Haolong Shen 2021.01.22

Xiamen Boson Biotech Co., Ltd.

Table of Contents

1. Purpose	1
2. References	1
3. Personnel and Responsibility	1
4. Materials	1
4.1 Evaluated Reagent	1
4.2 Equipment	1
4.3 Corporate Controls	1
5. Methods	2
5.1 Test Kit Storage	2
5.2 Testing	2
5.3 Standard Requirements	2
6. Results	2
6.1 Storage Stability Test Results for Three Batches of Products at 2-8°C	2
6.2 Storage Stability Test Results for Three Batches of Products at 15-30°C	3
7. Conclusion	4

1. Purpose

To perform a comprehensive evaluation of the storage stability of the Rapid SARS-CoV-2 Antigen Test Card under refrigerated (2-8°C) and room temperature (15-30°C) conditions in order to provide basis for establishing product shelf-life.

2. References

	Document No.	Document
1	BS EN ISO 23640:2015	In vitro diagnostic medical devices Evaluation of stability of in vitro diagnostic reagents.
2	EP25-A	Evaluation of stability of in vitro diagnostic reagents; Approved Guideline

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. Materials

4.1 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.

4.2 Equipment

	Equipment	Model (No.)	Manufacturer
1	2-8°C cold storage warehouse	/	Xiamen Boson Biotech Co., Ltd.
2	Room temperature warehouse	/	Xiamen Boson Biotech Co., Ltd.

4.3 Corporate Controls

	Name	Lot No. (Catalog No.)	Notes
1	Limit of detection controls	Q20061902	Xiamen Boson Biotech Co., Ltd.
2	Positive controls	Q20061903	Xiamen Boson Biotech Co., Ltd.
3	Negative controls	Q20061904	Xiamen Boson Biotech Co., Ltd.

4	Repeatability controls	Q20061905	Xiamen Boson Biotech Co., Ltd.
---	------------------------	-----------	--------------------------------

5. Methods

5.1 Test Kit Storage

Take three batches of products, and store separately in 2-8°C and room temperature warehouses for 20 months.

5.2 Testing

Take out the products from the cold storage and room temperature warehouses at month 0, 3, 6, 9, 12, 14, 16, 18 and 20. Testing the limit of detection, positive agreement, negative agreement, repeatability of products with limit of detection controls, positive controls, negative controls and repeatability controls.

5.3 Standard Requirements

5.3.1 Negative Agreement

Testing 20 negative controls (N1-N20) and the agreement rate for negative controls should be 20/20.

5.3.2 Positive Agreement

Testing 8 positive controls (P1-P8) and the agreement rate for positive controls should be 8/8.

5.3.3 Limit of Detection

Testing the limit of detection controls and the results should be consistent: S1 to S4 are positive, S5 and S6 are positive or negative.

5.3.4 Repeatability

Testing repeatability control J1 and each control were tested 10 times in parallel and the results were consistent and positive.

Testing repeatability control J2 and each control were tested 10 times in parallel and the results were consistent and positive.

6. Results

6.1 Storage Stability Test Results for Three Batches of Products at 2-8°C

Table 1. Storage stability test results for batch H20061502 (2-8°C)

Placing time	Limit of Detection						Positive Agreement (+/-)	Negative Agreement (-/-)	Repeatability J1	Repeatability J2
	S1	S2	S3	S4	S5	S6				
Month 0	+	+	+	+	-	-	8/8	20/20	+	+
Month 3	+	+	+	+	-	-	8/8	20/20	+	+
Month 6	+	+	+	+	-	-	8/8	20/20	+	+

Notes: This stability experiment has not yet been completed and is still ongoing and will be concluded on 2022.02.15.

The results of the tests show that the products have been placed in an environment of 2-8°C for 6 months and that the results are in accordance with the proposed quality standards; the stability over

a longer period of time needs to be further investigated.

Table 2. Storage stability test results for batch H20061601 (2-8°C)

Placing time	Limit of Detection						Positive Agreement (+/+)	Negative Agreement (-/-)	Repeatability J1	Repeatability J2
	S1	S2	S3	S4	S5	S6				
Month 0	+	+	+	+	-	-	8/8	20/20	+	+
Month 3	+	+	+	+	-	-	8/8	20/20	+	+
Month 6	+	+	+	+	-	-	8/8	20/20	+	+

Notes: This stability experiment has not yet been completed and is still ongoing and will be concluded on 2022.02.16.

The results of the tests show that the products have been placed in an environment of 2-8°C for 6 months and that the results are in accordance with the proposed quality standards; the stability over a longer period of time needs to be further investigated.

Table 3. Storage stability test results for batch H20061701 (2-8°C)

Placing time	Limit of Detection						Positive Agreement (+/+)	Negative Agreement (-/-)	Repeatability J1	Repeatability J2
	S1	S2	S3	S4	S5	S6				
Month 0	+	+	+	+	-	-	8/8	20/20	+	+
Month 3	+	+	+	+	-	-	8/8	20/20	+	+
Month 6	+	+	+	+	-	-	8/8	20/20	+	+

Notes: This stability experiment has not yet been completed and is still ongoing and will be concluded on 2022.02.17.

The results of the tests show that the products have been placed in an environment of 2-8°C for 6 months and that the results are in accordance with the proposed quality standards; the stability over a longer period of time needs to be further investigated.

6.2 Storage Stability Test Results for Three Batches of Products at 15-30°C

Table 4. Storage stability test results for batch H20061502 (15-30°C)

Placing time	Limit of Detection						Positive Agreement (+/+)	Negative Agreement (-/-)	Repeatability J1	Repeatability J2
	S1	S2	S3	S4	S5	S6				
Month 0	+	+	+	+	-	-	8/8	20/20	+	+
Month 3	+	+	+	+	-	-	8/8	20/20	+	+
Month 6	+	+	+	+	-	-	8/8	20/20	+	+

Notes: This stability experiment has not yet been completed and is still ongoing and will be concluded on 2022.02.15.

The results of the tests show that the products have been placed in an environment of 15-30°C for 6

months and that the results are in accordance with the proposed quality standards; the stability over a longer period of time needs to be further investigated.

Table 5. Storage stability test results for batch H20061601 (15-30°C)

Placing time	Limit of Detection						Positive Agreement (+/+)	Negative Agreement (-/-)	Repeatability J1	Repeatability J2
	S1	S2	S3	S4	S5	S6				
Month 0	+	+	+	+	-	-	8/8	20/20	+	+
Month 3	+	+	+	+	-	-	8/8	20/20	+	+
Month 6	+	+	+	+	-	-	8/8	20/20	+	+

Notes: This stability experiment has not yet been completed and is still ongoing and will be concluded on 2022.02.16.

The results of the tests show that the products have been placed in an environment of 15-30°C for 6 months and that the results are in accordance with the proposed quality standards; the stability over a longer period of time needs to be further investigated.

Table 6. Storage stability test results for batch H20061701 (15-30°C)

Placing time	Limit of Detection						Positive Agreement (+/+)	Negative Agreement (-/-)	Repeatability J1	Repeatability J2
	S1	S2	S3	S4	S5	S6				
Month 0	+	+	+	+	-	-	8/8	20/20	+	+
Month 3	+	+	+	+	-	-	8/8	20/20	+	+
Month 6	+	+	+	+	-	-	8/8	20/20	+	+

Notes: This stability experiment has not yet been completed and is still ongoing and will be concluded on 2022.02.17.

The results of the tests show that the products have been placed in an environment of 15-30°C for 6 months and that the results are in accordance with the proposed quality standards; the stability over a longer period of time needs to be further investigated.

7. Conclusion

The results of the refrigerated stability test of three batches of Rapid SARS-CoV-2 Antigen Test Card showed that the test results met the proposed quality standards when placed under refrigerated conditions (2~8°C) for 6 months, and the stability for a longer period of time needs to be further investigated.

The results of the room temperature stability test of three batches of Rapid SARS-CoV-2 Antigen Test Card showed that the test results met the proposed quality standards when placed under refrigerated conditions (15~30°C) for 6 months, and the stability for a longer period of time needs to be further investigated.