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CERTIFICATE OF STABILITY

Accelerate Stability Study

Purpose: This report describes the methodology used to establish the shelf-life of Rapid 2019-nCoV IgG/IgM Combo Test.

Materials and Methods:

Test Devices: Three lots of Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) were manufactured to conduct this stability study. The devices were manufactured following Boson's current Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) Work Instruction Procedures, and stored at 40°C stress environment. Devices under heat stress were brought to room temperature before testing. Duplicate tests were performed at each control level, according to Boson's current Quality Control Procedures. Batch information is summarized in the following tables.

	LOT	LOT	LOT
Rapid 2019-nCoV IgG/IgM Combo Test P/N 1N38C2	20020110	20020111	20020112
Date of Manufacture	Feb. 01, 2020	Feb. 01, 2020	Feb. 01, 2020

Test site: Testing was conducted by R&D at Xiamen Boson Biotech Co., Ltd. Xiamen, China.

Control Panel:

Control Levels	Negative	Weak Positive	Positive
Control Lot#	Q20020101	Q20020102	Q20020103

Testing protocol:

1. Pouched test devices were stored at 40°C and tested on Week 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10, in duplicates.
2. Devices were tested in accordance with the product instructions for use with the controls described above.
3. Results were read visually at 15 minutes.

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Testing Results: Testing results were originally recorded manually and were in compliance with this report. The testing results are summarized below (As of 03/12/2020):

For IgG:

Product Name	Lot ID	Control	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	N / N	N / N	N / N	N / N	N / N	N / N	N / N	N / N	/	/	/
		Weak Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
		Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
	Lot 2	Negative	N / N	N / N	N / N	N / N	N / N	N / N	N / N	N / N	/	/	/
		Weak Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
		Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
	Lot 3	Negative	N / N	N / N	N / N	N / N	N / N	N / N	N / N	N / N	/	/	/
		Weak Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
		Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/

For IgM:

Product Name	Lot ID	Control	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	N / N	N / N	N / N	N / N	N / N	N / N	N / N	N / N	/	/	/
		Weak Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
		Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
	Lot 2	Negative	N / N	N / N	N / N	N / N	N / N	N / N	N / N	N / N	/	/	/
		Weak Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
		Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
	Lot 3	Negative	N / N	N / N	N / N	N / N	N / N	N / N	N / N	N / N	/	/	/
		Weak Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/
		Pos.	P/P	P/P	P/P	P/P	P/P	P/P	P/P	P/P	/	/	/

Note: Accelerated temperature stability is still going on and will be completed by 04/10/2020. Report was summarized based on current data.

Data Analysis and Conclusion:

Rapid 2019-nCoV IgG/IgM Combo Tests have met the QC acceptance criteria for the time period of ten weeks when stored at 40 °C stress environment. According to the established stability pattern of Boson's similar product lines, Rapid 2019-nCoV IgG/IgM Combo Test Devices will have at least 24 months of shelf life at room temperature. The products are thus proved to claim 18 months of shelf life at room temperature.

Approved by:

Liu Bin

Date: 2020-03-12

Liu Bin
Quality System Manager
Xiamen Boson Biotech Co., Ltd.

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CERTIFICATE OF STABILITY

Real-Time Stability Study

(Room Temperature 15–30ºC)

Purpose: This report describes the methodology used to establish the shelf-life of Rapid 2019-nCoV IgG/IgM Combo Test.

Materials and Methods:

Test Devices: Three lots of Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) were manufactured to conduct this stability study. The devices were manufactured following Boson's current Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) Work Instruction Procedures and stored at room temperature (15-30ºC). Duplicate tests were performed on each control level, according to Boson's current Quality Control Procedures. Batch information is summarized in the following tables.

	LOT	LOT	LOT
Rapid 2019-nCoV IgG/IgM Combo Test P/N 1N38C2	20020110	20020111	20020112
Date of Manufacture	Feb. 01, 2020	Feb. 01, 2020	Feb. 01, 2020

Test site: Testing was conducted by R&D at Xiamen Boson Biotech Co., Ltd. Xiamen, China.

Control Panel:

Control Levels	Negative	Weak Positive	Positive
Control Lot#	Q20020101	Q20020102	Q20020103

Testing protocol:

1. Pouched test devices were stored at room temperature (15-30ºC) and tested on Month 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 and 24, in duplicates.
2. Devices were tested in accordance with the product instructions for use with the controls described above.
3. Results were read visually at 15 minutes.

Testing Results: Testing results were originally recorded manually and were in compliance with this report. The testing results are summarized below (As of 03/12/2020):

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For IgG:

Product Name	Lot ID	Control	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	N / N	N / N	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
		Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
	Lot 2	Negative	N / N	N / N	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
		Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
	Lot 3	Negative	N / N	N / N	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
		Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/

Product Name	Lot ID	Control	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18	Month 19	Month 20	Month 21	Month 22	Month 23	Month 24
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	/	/	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	/	/	/	/	/	/	/	/	/	/	/	/
		Pos.	/	/	/	/	/	/	/	/	/	/	/	/
	Lot 2	Negative	/	/	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	/	/	/	/	/	/	/	/	/	/	/	/
		Pos.	/	/	/	/	/	/	/	/	/	/	/	/
	Lot 3	Negative	/	/	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	/	/	/	/	/	/	/	/	/	/	/	/
		Pos.	/	/	/	/	/	/	/	/	/	/	/	/

For IgM:

Product Name	Lot ID	Control	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	N / N	N / N	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
		Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
	Lot 2	Negative	N / N	N / N	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
		Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
	Lot 3	Negative	N / N	N / N	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/
		Pos.	P/P	P/P	/	/	/	/	/	/	/	/	/	/

Product Name	Lot ID	Control	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18	Month 19	Month 20	Month 21	Month 22	Month 23	Month 24
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	/	/	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	/	/	/	/	/	/	/	/	/	/	/	/
		Pos.	/	/	/	/	/	/	/	/	/	/	/	/
	Lot 2	Negative	/	/	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	/	/	/	/	/	/	/	/	/	/	/	/
		Pos.	/	/	/	/	/	/	/	/	/	/	/	/
	Lot 3	Negative	/	/	/	/	/	/	/	/	/	/	/	/
		Weak Pos.	/	/	/	/	/	/	/	/	/	/	/	/
		Pos.	/	/	/	/	/	/	/	/	/	/	/	/

Note: Room Temperature Stability is still going on and will be completed by 02/01/2022. Report was summarized by the current data.

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Data Analysis and Conclusion:

Room temperature stability study is still ongoing, and will be done by 02/01/2022. With current results, devices retained in room temperature are stable on performance with 100% agreement.

Approved by:

Liu Bin

Date：2020-03-12

Liu Bin

Quality System Manager

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CERTIFICATE OF STABILITY

Real-Time Stability Study

(Refrigerated Temperature 2-8ºC)

Purpose: This report describes the methodology used to establish the shelf-life of Rapid 2019-nCoV IgG/IgM Combo Test.

Materials and Methods:

Test Devices: Three lots of Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) were manufactured to conduct this stability study. The devices were manufactured following Boson's current Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) Work Instruction Procedures and stored at refrigerated temperature (2-8ºC). Duplicate tests were performed on each control level, according to Boson's current Quality Control Procedures. Batch information is summarized in the following tables.

	LOT	LOT	LOT
Rapid 2019-nCoV IgG/IgM Combo Test P/N 1N38C2	20020110	20020111	20020112
Date of Manufacture	Feb. 01, 2020	Feb. 01, 2020	Feb. 01, 2020

Test site: Testing was conducted by R&D at Xiamen Boson Biotech Co., Ltd. Xiamen, China.

Control Panel:

Control Levels	Negative	Weak Positive	Positive
Control Lot#	Q20020101	Q20020102	Q20020103

Testing protocol:

1. Pouched test devices were stored at refrigerated temperature (2-8ºC) and tested on Month 1, 6, 12, 18 and 24, in duplicates.

2. Devices were tested in accordance with the product instructions for use with the controls described above.

3. Results were read visually at 15 minutes.

Testing Results: Testing results were originally recorded manually and were in compliance with this report. The testing results are summarized below (As of 03/12/2020):

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For IgG:

Product Name	Lot ID	Control	Month 1	Month 6	Month 12	Month 18	Month 24
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	N / N	/	/	/	/
		Weak Pos.	P/P	/	/	/	/
		Pos.	P/P	/	/	/	/
	Lot 2	Negative	N / N	/	/	/	/
		Weak Pos.	P/P	/	/	/	/
		Pos.	P/P	/	/	/	/
	Lot 3	Negative	N / N	/	/	/	/
		Weak Pos.	P/P	/	/	/	/
		Pos.	P/P	/	/	/	/

For IgM:

Product Name	Lot ID	Control	Month 1	Month 6	Month 12	Month 18	Month 24
Rapid 2019-nCoV IgG/IgM Combo Test	Lot 1	Negative	N / N	/	/	/	/
		Weak Pos.	P/P	/	/	/	/
		Pos.	P/P	/	/	/	/
	Lot 2	Negative	N / N	/	/	/	/
		Weak Pos.	P/P	/	/	/	/
		Pos.	P/P	/	/	/	/
	Lot 3	Negative	N / N	/	/	/	/
		Weak Pos.	P/P	/	/	/	/
		Pos.	P/P	/	/	/	/

Note: Refrigerated Temperature Stability is still going on and will be completed by 02/01/2022. Report was summarized by the current data.

Data Analysis and Conclusion:

The first testing (month 6) of three lots stored in refrigerated temperature (2-8ºC) will be on 08/01/2020. No data available right now.

Approved by:

Liu Bin

Date: 2020-03-12

Liu Bin

Quality System Manager

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CERTIFICATE OF STABILITY

"In use" Real Time Un-pouched Stability Study

Purpose: This report describes the "In use" real time un-pouched stability of Rapid 2019-nCoV IgG/IgM Combo Test.

Materials and Methods:

Test Devices: One lot of Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) was manufactured to conduct this stability study. The devices were manufactured following Boson's current Rapid 2019-nCoV IgG/IgM Combo Test (REF 1N38C2) Work Instruction Procedures and stored at room temperature (15-30ºC). Duplicate tests were performed on each control level, according to Boson's current Quality Control Procedures. Batch information is summarized in the following tables.

	LOT	LOT	LOT
Rapid 2019-nCoV IgG/IgM Combo Test P/N 1N38C2	20020110	20020111	20020112
Date of Manufacture	Feb. 01, 2020	Feb. 01, 2020	Feb. 01, 2020

Test site: Testing was conducted by R&D at Xiamen Boson Biotech Co., Ltd. Xiamen, China.

Control Panel:

Control Levels	Negative	Weak Positive	Positive
Control Lot#	Q20020101	Q20020102	Q20020103

Testing protocol:

1. Devices were removed from pouches and exposed to ambient lab temperature and humidity for up to 24 hours.

2. Bring the controls to room temperature before each test.

3. Test 2 tests for each control according to the testing procedure and testing interval. Record the results at 15 minutes.

Testing Results: Testing results were originally recorded manually and were in compliance with this report. The testing results are summarized below:

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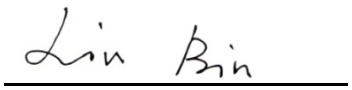
Interval		0 hour		2 hours		4 hours		8 hours		24 hours	
Control Level		Test 1	Test 2	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Neg	IgG	N	N	N	N	N	N	N	N	N	N
	IgM	N	N	N	N	N	N	N	N	N	N
Weak Pos.	IgG	P	P	P	P	P	P	P	P	P	P
	IgM	P	P	P	P	P	P	P	P	P	P
Pos.	IgG	P	P	P	P	P	P	P	P	P	P
	IgM	P	P	P	P	P	P	P	P	P	P

Data Analysis and Conclusion:

The ‘in use” Real time stability (un-pouched) results indicated that there were no significantly functional discrepancy between 2019-nCoV IgG/IgM combo test devices with pouch and without pouch, in the defined time range, twenty-four hours.

Approved by:



Date：2020-03-12

Liu Bin

Quality System Manager

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