

Accelerated Stability Study Report

Edinburgh Genetics ActivXpress+ COVID-19 IgG/IgM Immunoassay Complete Testing Kit

This stability study inspects the change of the quality of the kit with the change of the storage conditions under the specified storage conditions.

The test is designed to be stored in a sealed environment with a temperature of 2- 30 °C. In order to understand the storage stability of the product more quickly and directly, we chose to examine the accelerated stability of the reagent stored at 56 °C after 1 day, 5 days, 10 days, 20 days, 30 days, 40 days and 45 days.

I. Stability Testing Methods and Quality Standards

1. Appearance

Method: The appearance of the kit and the test cassette and the diluent were visually tested in bright natural light by visual inspection.

Standard: The kit should be clean and tidy in appearance, with clear signs and symbols, no damage to the package and complete contents. The appearance of the test cassette should meet the following requirements: smooth appearance, uniform colour, no burrs on the edge, and no patches or stains; the diluent should be clear and transparent without precipitation.

2. Physical test

Method: The width of test strip and the volume of sample diluent were tested by measuring method.

Standard: The width of test strip should not be less than 2.5 mm; The volume of sample diluent should not be less than 60µl/bottle.

3. Liquid migration speed test

Method: Three test cassettes were randomly selected under the condition of complete kit appearance and no damage. After the sample was added, the timer was used for timing immediately. When the sample completely passed through the observation window, the timing was stopped and the time (t, in seconds) was recorded. Measure the distance (S)mm from the centre of the sample addition area to the upper edge of the observation window. Calculate the migration speed (V)=S/(t/60) (mm/min).

Standard: During sample addition, the sample cannot overflow from the sample addition area to the NC membrane, and the migration speed of the sample on the test cassette should not be less than 10mm/min.

4. Coincidence rate of negative reference

Method: 10 negative reference materials were tested with the reagents of the same batch, and each reference material was tested once.

Standard: The test results of negative reference materials should be negative.

5. Coincidence rate of positive reference

Method: 10 positive reference materials were tested with the reagents of the same batch, and each reference material was tested once.

Standard: The test results of positive reference materials should be positive.

6. Detection limit

Method: The detection limit reference materials were tested with the reagents of the same batch, and repeated for ten times.

Standard: The positive detection rate of the detection limit reference materials should not be less than 90%.

7. Within-run variance

Method: The repetitive reference materials were tested with the reagents of the same batch for ten times. Standard: The test results should be consistent after testing the repetitive reference materials for 10 times.

Method: The repetitive reference materials were tested with three reagents of different batches, each repeated for 10 times.

Standard: The test results should be consistent after testing the repetitive reference materials for 10 and 30 times, respectively.

8. Interference test

Method: Take the prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum and add bilirubin, hemoglobin, triglyceride, rheumatoid factor HAMA serum into the reference material P1 in the same batch according to the ratio of interferent to matrix sample of 1:9, so that the final concentration of the interferent is 250mg/L bilirubin, 2.5g/L hemoglobin, 5.0g/L triglyceride, 400IU/ml rheumatoid factor and 20ng/ml HAMA serum. The reference material and each interference sample were tested with the reagents of the same batch in parallel for 3 times respectively.

Standard: The parallel test results should be consistent.

II. Process and Results

Table 1 Stability Results of Batch No. 20200202 Kit under Accelerated Conditions

1 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60 μ L/ bottle.	60 μ L		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	19.52	Passed
		Cassette2(mm/min)	17.85	
		Cassette3(mm/min)	18.19	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance		COVID-19 IgM	100%	Passed

	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
5 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
Cassette 3		2.95mm		
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	19.42	Passed
		Cassette2(mm/min)	18.45	
		Cassette3(mm/min)	17.83	
Coincidence rate of negative reference	The test results should be negative after	COVID-19 IgM	100%	Passed

	testing 10 negative reference materials	COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
10 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test		Cassette 1	2.95mm	Passed

	The width of the test strip should not be less than 2.5 mm.	Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	19.06	Passed
		Cassette2(mm/min)	18.28	
		Cassette3(mm/min)	17.80	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
20 Day Acceleration	Standard Requirements	Test Results		Conclusion

Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60 μ L/ bottle.	60 μ L		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.70	Passed
		Cassette2(mm/min)	18.32	
		Cassette3(mm/min)	17.56	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml	COVID-19 IgM	100%	Passed

	HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgG	100%	
Conclusion - PASSED				
30 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60 μ L/ bottle.	60 μ L		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.88	Passed
		Cassette2(mm/min)	18.68	
		Cassette3(mm/min)	17.67	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less	COVID-19 IgM	90%	Passed

	than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
40 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
		Cassette1(mm/min)	19.02	Passed

Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette2(mm/min)	18.42	
		Cassette3(mm/min)	17.62	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
45 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the	Requirements Met		Passed

	edge, and no patch or stain.			
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.73	Passed
		Cassette2(mm/min)	18.67	
		Cassette3(mm/min)	18.15	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	

Conclusion - PASSED

Table 2 Stability Results of Batch No. 20200204 Kit under Accelerated Conditions

1 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.12	Passed
		Cassette2(mm/min)	18.05	
		Cassette3(mm/min)	19.61	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance		COVID-19 IgM	100%	Passed

	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
5 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
Cassette 3		2.95mm		
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	17.46	Passed
		Cassette2(mm/min)	18.61	
		Cassette3(mm/min)	19.28	
Coincidence rate of negative reference	The test results should be negative after	COVID-19 IgM	100%	Passed

	testing 10 negative reference materials	COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
10 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test		Cassette 1	2.95mm	Passed

	The width of the test strip should not be less than 2.5 mm.	Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	17.72	Passed
		Cassette2(mm/min)	18.98	
		Cassette3(mm/min)	18.67	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
20 Day Acceleration	Standard Requirements	Test Results		Conclusion

Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60 μ L/ bottle.	60 μ L		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	17.16	Passed
		Cassette2(mm/min)	18.57	
		Cassette3(mm/min)	18.93	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml	COVID-19 IgM	100%	Passed

	HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgG	100%	
Conclusion - PASSED				
30 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	17.33	Passed
		Cassette2(mm/min)	18.11	
		Cassette3(mm/min)	19.22	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less	COVID-19 IgM	90%	Passed

	than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
40 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
		Cassette1(mm/min)	18.07	Passed

Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette2(mm/min)	18.07	
		Cassette3(mm/min)	19.04	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
45 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the	Requirements Met		Passed

	edge, and no patch or stain.			
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	17.73	Passed
		Cassette2(mm/min)	18.18	
		Cassette3(mm/min)	19.14	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	

Conclusion - PASSED

Table 3 Stability Results of Batch No. 20200206 Kit under Accelerated Conditions

1 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60 μ L/ bottle.	60 μ L		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.98	Passed
		Cassette2(mm/min)	18.59	
		Cassette3(mm/min)	17.69	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance		COVID-19 IgM	100%	Passed

	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
5 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
Cassette 3		2.95mm		
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.97	Passed
		Cassette2(mm/min)	19.83	
		Cassette3(mm/min)	17.57	
Coincidence rate of negative reference	The test results should be negative after	COVID-19 IgM	100%	Passed

	testing 10 negative reference materials	COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
10 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test		Cassette 1	2.95mm	Passed

	The width of the test strip should not be less than 2.5 mm.	Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.52	Passed
		Cassette2(mm/min)	18.79	
		Cassette3(mm/min)	19.27	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
20 Day Acceleration	Standard Requirements	Test Results		Conclusion

Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60 μ L/ bottle.	60 μ L		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.64	Passed
		Cassette2(mm/min)	18.87	
		Cassette3(mm/min)	18.78	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml	COVID-19 IgM	100%	Passed

	HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgG	100%	
Conclusion - PASSED				
30 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60 μ L/ bottle.	60 μ L		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	18.64	Passed
		Cassette2(mm/min)	19.04	
		Cassette3(mm/min)	17.37	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less	COVID-19 IgM	90%	Passed

	than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	

Conclusion - PASSED

40 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the edge, and no patch or stain.	Requirements Met		Passed
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
		Cassette1(mm/min)	19.35	Passed

Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette2(mm/min)	18.05	
		Cassette3(mm/min)	17.09	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Conclusion - PASSED				
45 Day Acceleration	Standard Requirements	Test Results		Conclusion
Appearance	1.The kit has a neat appearance, clear characters and symbols, no damage to the package and complete contents.	Requirements Met		Passed
	2.The test cassette has a smooth appearance, uniform colour and luster, no burr on the	Requirements Met		Passed

	edge, and no patch or stain.			
	3.The diluent should be clear and transparent without precipitation.	Requirements Met		Passed
Physical Test	The width of the test strip should not be less than 2.5 mm.	Cassette 1	2.95mm	Passed
		Cassette 2	2.95mm	
		Cassette 3	2.95mm	
	The volume of sample diluent should not be less than 60µL/ bottle.	60µL		Passed
Liquid Migration Speed	Liquid migration speed should not be less than 10.0mm/min.	Cassette1(mm/min)	19.31	Passed
		Cassette2(mm/min)	19.74	
		Cassette3(mm/min)	16.94	
Coincidence rate of negative reference	The test results should be negative after testing 10 negative reference materials	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Coincidence rate of positive reference	The test results should be positive after testing 10 positive reference materials.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Detection Limit	The positive detection rate should not be less than 90% after testing the detection limit reference materials for 10 times repeatedly.	COVID-19 IgM	90%	Passed
		COVID-19 IgG	100%	
Within-Run Variance	The test results should be consistent after testing the repetitive reference materials for 10 times.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	
Interference Test	The prepared 2500mg/L bilirubin, 25g/L hemoglobin, 50g/L triglyceride, 4000IU/ml rheumatoid factor and 200ng/ml HAMA serum are taken, and the reference materials and interference samples are respectively measured in parallel for 3 times with the reagents.	COVID-19 IgM	100%	Passed
		COVID-19 IgG	100%	

Conclusion - PASSED

III. Analysis of Stability Assessment Results

Under accelerated storage conditions, all indicators of the kits meet the requirements. The storage stability of the product can be at least 18 months by estimation through accelerated stability test.