

Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit

Performance Evaluation and Stability Study Report

Edinburgh Genetics Limited

Directory

I. OVERVIEW	1
1. Test Purpose	1
2. Product name and batch number.....	1
3. Composition and Product Performance Index of Enterprise Reference	1
II. STABILITY STUDY OF THE KIT	2
1. Thermal stability	2
2. Transport & Real-time Stability.....	3
3. Stability of bottle opening of sample diluent.....	6
4. Test card opening stability	8
III. SAMPLE STABILITY STUDIES	9
1. Samples 2~8°C,-70 stability	9
2. Determination of number of freeze-thaw cycles.....	10

I. OVERVIEW

1. Test Purpose

Validity period of study kit, sample under different storage conditions.

2. Product name and batch number

Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit referred to as "this kit".

Lot No.20200801,20200802,20200803

Package specification :20 tests/Kit

3. Composition and Product Performance Index of Enterprise Reference

3.1 Composition of enterprise reference

Table 2 Composition of enterprise reference

Type of reference	Reference Number	Microbial category
Negative reference	QT01	Staphylococcus aureus
	QT02	Streptococcus pneumoniae
	QT03	Measles virus
	QT04	Mumps virus
	QT05	Adenovirus 3
	QT06	Mycoplasma pneumoniae
	QT07	Parainfluenza 2
	QT08	Partial pulmonary virus
	QT09	Coronary OC43
	QT10	Coronary 229 E
	QT11	Mycobacterium parabenae
	QT12	Influenza B virus (Victoria)
	QT13	Influenza B virus (Yamagata)
	QT14	Influenza A H1N1(2009) virus
	QT15	Influenza A H3N2 virus
	QT16	EB virus
	QT17	CA16 of enterovirus
	Positive reference	QY01
QY02		SARS-CoV-2
QY03		SARS-CoV-2
QY04		SARS-CoV-2
QY05		SARS-CoV-2
Repetitive reference	CV01	SARS-CoV-2 (Moderate Positive)
	CV02	SARS-CoV-2 (Weak positive)
Minimum limit of detection for Reference	S01	SARS-CoV-2

3.2 Performance indicators

3.2.1 Physical properties

3.2.1.1 Appearance

Visual examination of normal or corrected visual acuity under natural light:

The kit components should be complete, packaging should be clean and pollution-free.

Test card sealed preservation, no damage, no pollution. The sample diluent is colorless and homogeneous liquid without impurities or precipitates visible to the naked eye.

3.2.1.2 Width of membrane strips

The membrane strip in this kit should be randomly selected and measured with Vernier caliper. The width of the membrane strip should not be less than 2.5 mm.

3.2.1.3 Liquid migration speed

At random, 3 test cards were taken, placed horizontally, and the distance from the center of the sample hole to the distal end of the observation window was measured L (mm). A sample diluent is used as the sample to be tested, and the time required to move the liquid to the far end of the observation window is recorded with a stopwatch t (s). Calculate the L/t (mm/min), that is, the migration speed. Fluid migration speed should be no less than 10 mm/min.

3.2.2 Conformity rate of positive reference

The enterprise positive reference should be tested once per reference, and the results should be positive.

3.2.3 Conformity rate of negative reference

The enterprise negative reference should be tested once per reference, and the results should be negative.

3.2.4 Limit of detection (LOD)

Dilute the enterprise limit of detection reference product by 2 times, 4 times, 8 times, and 16 times into S1, S2, S3, and S4, and each sample is tested once. The results of S1 and S2 should be positive, and the results of S3 and S4 can be negative or positive.

3.2.5 Repeatability

Perform 10 tests on each enterprise's reproducible reference product, and the results should be positive, and the color rendering should be uniform.

II. STABILITY STUDY OF THE KIT

1. Thermal stability

One batch (batch 20200801) was used for the test. After the test kit is qualified, store it at 37°C and store it for 1, 7, 14, 21, and 22 days, and then take it out for physical properties, positive reference product compliance rate, negative reference product compliance rate, repeatability, and detection limit. The test results are shown in the table below. The results show that the kit can be stored for 21 days at 37°C.

Acceleration/detection time		1 day	7 days	14 days	21 days	22 days
Performance						
Appearance		Compliance requirements				
mm width of membrane strip		4.08	4.05	3.94	3.96	3.92
mm/min of migration speed		25.64, 25.11, 25.89	25.64, 25.91, 25.56	25.7, 25.3, 25.2	26.62, 26.37, 26.74	26.53, 26.11, 26.1
Positive reference coincidence rate		5/5 (+)	5/5 (+)	5/5 (+)	5/5 (+)	5/5 (+)
Conformity rate of negative reference		18/18 (-)	18/18 (-)	18/18 (-)	18/18 (-)	18/18 (-)
CV01 of repeatability		10/10 (+)	10/10 (+)	10/10 (+)	10/10 (+)	10/10 (+)
CV02 of repeatability		10/10 (+)	10/10 (+)	10/10 (+)	10/10 (+)	10/10 (+)
limit of detections	S 1	+	+	+	+	+
	S2	+	+	+	+	+
	S3	+	-	-	+	+
	S4	-	-	-	-	-

Note : "+" indicates positive results ; "-" indicates negative results. "The m/n" indicates that n reference is tested, m of which is positive or negative, or one is repeated and m is positive or negative.

2. Transport & Real-time Stability

Take 3 consecutive batches of kits (batch numbers: 20200801, 20200802, 20200803) for testing. Place the kit directly in the packing box, and place the packaged kit in a transport vehicle for 7 days in Guangzhou. After the transportation is completed, test the kits. After passing the test, each batch of kits is divided into 2 parts, one part is stored at 2~8°C, and the other part is stored at 30°C for real-time stability study. Each batch of kits were stored for 1, 2, 3, 6, 12, 18, 20 months and then taken out for physical shape, positive reference product compliance rate, negative reference product compliance rate, detection limit, and repeatability testing. Real-time stability is still in progress.

Note: in the following table, "+" means positive ; "-" means negative ; " m/n" means testing n reference, with m positive or negative, or each reference tested once, with m times positive or negative.

Test results after transportation

Batch Number	20200801	20200802	20200803
Appearance	Compliance requirements	Compliance requirements	Compliance requirements
mm width of membrane strip	3.93	3.97	4.02
mm/min of migration speed	26.53, 26.88, 25.75	25.25, 26.96, 26.08	26.54, 26.15, 26.42
Positive reference coincidence rate	5/5 (+)	5/5 (+)	5/5 (+)
Conformity rate of negative reference	18/18 (-)	18/18 (-)	18/18 (-)
CV01 of repeatability	10/10 (+)	10/10 (+)	10/10 (+)

CV02 of repeatability		10/10 (+)	10/10 (+)	10/10 (+)
limit of detection	S 1	+	+	+
	S 2	+	+	+
	S 3	+	+	-
	S4	-	-	-

Test results of this kit stored at 2~8°C

Batch Number	Time (date)		1 month	2 months	3 months	6 month	12 month	18 month	20 month
	Performance								
20200801	Appearance		Compliance requirements	Compliance requirements	Compliance requirements	Ongoing			
	mm width of membrane strip		4.08	4.05	3.99				
	mm/min of migration speed		25.97	26.65	26.95				
			26.27	26.06	25.52				
			25.82	25.91	25.71				
	Positive reference coincidence rate		5/5 (+)	5/5 (+)	5/5 (+)				
	Conformity rate of negative reference		18/18 (-)	18/18 (-)	18/18 (-)				
	Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
		CV02	10/10 (+)	10/10 (+)	10/10 (+)				
	limit of detection	S1	+	+	+				
S2		+	+	+					
S3		+	-	+					
S4		-	-	-					
20200802	Appearance		Compliance requirements	Compliance requirements	Compliance requirements	Ongoing			
	mm width of membrane strip		3.96	4.01	3.93				
	mm/min of migration speed		25.19	26.9	25.56				
			26.61	25.09	25.14				
			26.94	26.55	25.07				
	Positive reference coincidence rate		5/5 (+)	5/5 (+)	5/5 (+)				
	Conformity rate of negative reference		18/18 (-)	18/18 (-)	18/18 (-)				
	Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
		CV02	10/10 (+)	10/10 (+)	10/10 (+)				
	limit of detection	S1	+	+	+				
S2		+	+	+					
S3		-	+	-					
S4		-	-	-					
20200803	Appearance		Compliance requirements	Compliance requirements	Compliance requirements	Ongoing			

	mm width of membrane strip	3.9	4.08	3.98					
	mm/min of migration speed	25.31	25.24	25.75					
		25.88	25.64	25.57					
		25.43	26.91	26.07					
	Positive reference coincidence rate	5/5 (+)	5/5 (+)	5/5 (+)					
	Conformity rate of negative reference	18/18 (-)	18/18 (-)	18/18 (-)					
	Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
		CV02	10/10 (+)	10/10 (+)	10/10 (+)				
	limit of detection	S1	+	+	+				
		S2	+	+	+				
S3		-	+	+					
S4		-	-	-					

The test results of this kit stored at 30°C

Batch Number	Time (date) Performance	1 month	2 month	3 month	6 month	12 month	18 month	20 month	
		20200801	Appearance	Compliance requirements	Compliance requirements	Compliance requirements	Ongoing		
	mm width of membrane strip	4.01	4.02	4.01					
		25.65	26.19	26.29					
		26.64	26.06	25.6					
	mm/min of migration speed	26.91	26.9	25.64					
		Positive reference coincidence rate	5/5 (+)	5/5 (+)	5/5 (+)				
		Conformity rate of negative reference	18/18 (-)	18/18 (-)	18/18 (-)				
	Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
		CV02	10/10 (+)	10/10 (+)	10/10 (+)				
	limit of detection	S1	+	+	+				
		S2	+	+	+				
		S3	+	-	+				
		S4	-	-	-				
20200802	Appearance	Compliance requirements	Compliance requirements	Compliance requirements	Ongoing				
	mm width of membrane strip	4.01	3.95	3.99					
		25.49	25.64	25.31					
		26.61	26.52	25.87					
	mm/min of migration speed	25.36	25.13	26.81					

	Positive reference coincidence rate	5/5 (+)	5/5 (+)	5/5 (+)					
	Conformity rate of negative reference	18/18 (-)	18/18 (-)	18/18 (-)					
	Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
		CV02	10/10 (+)	10/10 (+)	10/10 (+)				
	limit of detection	S1	+	+	+				
		S2	+	+	+				
		S3	-	+	-				
S4		-	-	-					
20200803	Appearance	Compliance requirements	Compliance requirements	Compliance requirements	Ongoing				
	mm width of membrane strip	4.08	4.01	3.92					
	mm/min of migration speed	26.87	25.57	25.97					
		26.81	26.05	26.99					
		25.12	25.97	26.13					
	Positive reference coincidence rate	5/5 (+)	5/5 (+)	5/5 (+)					
	Conformity rate of negative reference	18/18 (-)	18/18 (-)	18/18 (-)					
	Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
		CV02	10/10 (+)	10/10 (+)	10/10 (+)				
	limit of detection	S1	+	+	+				
		S2	+	+	+				
		S3	-	+	+				
		S4	-	-	-				

3. Stability of bottle opening of sample diluent

The test was carried out using the kit with batch number 20200801. Take several kits of reagents and use them for the first time (the sample processing solution is opened, the physical properties of the test kit, the positive reference product compliance rate, the negative reference product compliance rate, repeatability, and the lowest detection limit) are divided into A and B Part, the remaining test cards are stored at room temperature (not higher than 30°C); and after the sample diluent is opened and used, it should be capped immediately, part A will be kept at 2~8°C, and part B will be kept at 30°C. Save it for 1, 2, 3, 6, 12, 18, and 20 months and then take it out for use. After storing for 1, 2, 3, 6, 12, 18, and 20 months after opening the bottle, squeeze out 10 drops vertically and discard according to the operation in the manual, and observe its appearance (whether it

is a colorless, clear and uniform liquid, No visible impurities or precipitation); in the bottle opening test after storage for 1, 2, 3, 6, 12, 18, and 20 months, in addition to the appearance, the kit's positive reference product compliance rate and negative reference product compliance rate, repeatability, detection limit detection. The test is still in progress.

Test results for first use

Appearance	mm/min of migration speed	Positive reference coincidence rate	Conformity rate of negative reference	Repeatability		Limit of detection				
Compliance requirements	25.79, 25.19, 26.21	5/5 (+)	18/18 (-)							

Sample diluent Results

Temperature	2~8°C							
Time	1 month	2 months	3 months	6 months	12 months	18 months	20 months	
Appearance	Compliance requirements	Compliance requirements	Compliance requirements	Ongoing				
Temperature	30°C							
Time	1 month	2 months	3 months	6 months	12 months	18 months	20 months	
Appearance	Compliance requirements	Compliance requirements	Compliance requirements	Ongoing				

Coincidence rate, repeatability and LOD of positive/negative reference kit

Temperature	2~8°C							
Performance	Time (date)	1 month	2 months	3 months	6 months	12 months	18 months	20 months
		Positive reference coincidence rate	5/5 (+)	5/5 (+)	5/5 (+)			
	Conformity rate of negative reference	18/18 (-)	18/18 (-)	18/18 (-)				
Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
	CV02	10/10 (+)	10/10 (+)	10/10 (+)				
limit of	S1	+	+	+				

detection	S2	+	+	+				
	S3	-	+	+				
	S4	-	-	-				
Temperature	30°C							
Performance	Time (date)	1 month	2 months	3 months	6 months	12 months	18 months	20 months
	Positive reference coincidence rate	5/5 (+)	5/5 (+)	5/5 (+)				
	Conformity rate of negative reference	18/18 (-)	18/18 (-)	18/18 (-)				
Repeatability	CV01	10/10 (+)	10/10 (+)	10/10 (+)				
	CV02	10/10 (+)	10/10 (+)	10/10 (+)				
limit of detection	S1	+	+	+				
	S2	+	+	+				
	S3	-	+	-				
	S4	-	-	-				

4. Test card opening stability

One batch (Lot 20200801) was used for the test. The test card was taken out of the aluminum foil bag, and placed flat on a table at room temperature (the temperature was within the range of 25-30°C during the test, and the humidity was about 72%). The sample diluent is stored at 2-8°C. After the test card is left for 20 minutes, 40 minutes, and 60 minutes, physical properties, positive reference product compliance rate, negative reference product compliance rate, detection limit, and repeatability testing were performed. The test results are shown in the table below.

Performance	Time	20 minutes	40 minutes	60 minutes
Appearance	Compliance requirements	Compliance requirements	Compliance requirements	Compliance requirements
mm width of membrane strip		3.97	4.09	3.91
mm/min of migration speed		25.04, 26.81, 25.78	25.25, 26.25, 26.64	26.48, 26.74, 25.35
Positive reference coincidence rate		5/5 (+)	5/5 (+)	5/5 (+)
Conformity rate of negative reference		18/18 (-)	18/18 (-)	18/18 (-)
CV01 of repeatability		10/10 (+)	10/10 (+)	10/10 (+)
CV02 of repeatability		10/10 (+)	10/10 (+)	10/10 (+)
limit of detection	S1	+	+	+
	S2	+	+	+
	S3	+	-	+
	S4	-	-	-

Analysis and conclusion: the results of the above table show that the performance of the test card remains stable within 60 minutes after opening. Therefore, the test card should be used as soon as possible within 1 hour after opening, more than 1 hour effect is not verified.

III. SAMPLE STABILITY STUDIES

1. Samples 2~8°C, -70 stability

A negative human nasopharyngeal swab sample (collected from a population with no associated clinical symptoms and tested negative for COVID-19 by this kit), was combined with a sample diluent. The virus culture inactivated with β -propiolactone was diluted into three gradients of high, medium, and low to become the test sample. After testing with this kit (preserved for 0h), each sample was divided into two parts, then stored at 2~8°C and -70°C respectively, and then they were taken out of storage at different time points. The test used was from batch number 20200801, each sample was tested once. The test is still in progress but the results so far are shown in the table below.

Sample for testing

Sample number	Pathogens and subtypes	Type	Test concentration
1	novel coronavirus (nCoV)	Strong positive	2×10^4 pfu/ml
2	novel coronavirus (nCoV)	Moderate positive	5×10^3 pfu/ml
3	novel coronavirus (nCoV)	Weak positive	2×10^3 pfu/ml

Storage time settings at each temperature

Temperature	2~8°C	-70°C
Time interval	0h, 3h, 6h, 24h, 48h, 72h, 96h	0h, 2 months, 3 months, 4 months, 5 months, 6 months and 8 months

2~8°C Test results

Sample number	0h	3h	6h	12h	24 h	48 h	72 h	96 h
1	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	-

Note : "+" means positive ; "-" means negative.

-70°C Test results

Sample number	0h	1 month	2 months	3 months	4 months	5 months	6 months	8 months
1	+	+	+	+	Ongoing			
2	+	+	+	+	Ongoing			
3	+	+	+	+	Ongoing			

Analysis and conclusion: The above results show that each sample can be accurately detected by this kit when stored at 2~8°C and -70°C for a certain time interval. Weakly positive samples are negative after being stored at 2~8°C for 96h. Therefore, samples can be stored for 72h at 2~8°C. According to current experimental results, it can be stored for at least 3 months at -70°C.

2. Determination of number of freeze-thaw cycles

The sample storage stability was studied. The samples were tested by the kit and stored under the condition of -70°C . After the samples were completely frozen, the samples were extracted and thawed for detection, and then put back to -70°C for preservation. Each sample was tested by 5 repeated freeze-thaw tests, and each thawing was detected by this kit with batch number 20200801. The results are shown in the table below.

Sample number	0h	1 time	2 times	3 times	4 times	5 times	6 times
1	+	+	+	+	+	+	+
2	+	+	+	+	+	+	-
3	+	+	+	+	+	+	-

Note : "+" means positive ; "-" means negative.

Analysis and conclusion: the results show that each sample can still be accurately detected by this kit after repeated freezing and thawing for 5 times. After 6 freeze-thaw times, the sample test results were negative. Therefore, the number of freeze-thaw times of the sample should not exceed 5 times.