Accelerated Stability Study Report

Edinburgh Genetics ActivXpress+ COVID-19 Antigen 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, we chose to examine the accelerated stability of the reagent stored at 56 °C after 1 week, 2 weeks, 3 weeks and 4 weeks.

I. Stability Testing Methods and Quality Standards

1. Appearance

Method: The appearance of the kit and the test cassette and the buffer 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.

Reference source

Positive reference material

SARS-CoV-2 recombinant antigen was created inhouse to an initial concentration of 1.1 mg/ml. The antigen was diluted with sample buffer to 200 ng/ml (P1), 100 ng/ml (P2), 50 ng/ml (P3), then stored at -20 ℃ for future use.

Negative reference

Five PCR negative nasopharyngeal swab samples were used (N1 - N5) and stored at -20 ℃.

Accelerated stability plan: 120 test cassettes from one batch are stored at 37°C in an incubator. They are used after 1 week, 2 weeks, 3 weeks, and 4 weeks.

3.2 Experimental investigation indicators and specific experimental process

The performance indicators for the accelerated stability study include negative coincidence rate, positive coincidence rate, sensitivity, repeatability, and batch-to-batch difference. The specific methods are as follows:

3.2.1 Negative coincidence rate

Use N1 - N5 as samples. Follow the instructions for use and record the results. The results should all be negative.

3.2.2 Positive coincidence rate

Use P1, P2 and P3 as samples. Follow the instructions for use and record the results. The results should all be positive.

3.2.3 Sensitivity

Take 20 ng/mL (S1) and 40 ng/mL (S2) corporate reference products, use them as samples, follow the steps in the instructions for testing and record the results. The results should be negative and positive.

3.2.4 Repeatability and inter-batch difference

Use P3 as a sample to test. Follow the instructions for use and record the result. The result should be positive and the colour development of each batch is equivalent.

3.4 Accelerated Stability Study

One batch (30C002012) of test kits was stored at 37°C in an incubator.

3.4.1 Negative Coincidence Rate

Test kits were tested with N1-N5. The test results are recorded in the table below.

Time / Sample	0 Day	Week 1	Week 2	Week 3	Week 4
N1	—	—	—	—	—
N2	—	—	—	—	—
N3	—	—	—	—	—
N4	—	—	—	—	—
N5	—	—	—	—	—

N1 - N5 all tested negative.

3.4.2 Positive coincidence rate

Test kits were tested with P1, P2 and P3. The test results are recorded in the table below.

Time / Sample	0 Day	Week 1	Week 2	Week 3	Week 4
P1	+++	+++	+++	+++	+++
P2	++	++	++	++	++
P3	+	+	+	+	+

P1 – P3 all tested negative.

3.4.3 Sensitivity

Use S1 and S2 as samples. Record the testing results in the table below.

Time / Sample	0 Day	Week 1	Week 2	Week 3	Week 4
S1	—	—	—	—	—
S2	+	+	+	+	+

S1 tested negative. S2 tested positive.

3.4.4 Repeatability

Use P3 as a sample. Record the testing results in the table below.

Time	0 Day	Week 1	Week 2	Week 3	Week 4
1	+	+	+	+	+
2	+	+	+	+	+
3	+	+	+	+	+
4	+	+	+	+	+

5	+	+	+	+	+
6	+	+	+	+	+
7	+	+	+	+	+
8	+	+	+	+	+
9	+	+	+	+	+
10	+	+	+	+	+

Results were all positive.

3.5 Room temperature exposure

Three batches of test kits were exposed to room temperature at 23.6℃ and relative humidity of 44%. S1 and S2 were used as samples and were tested every 10 minutes. The test results are recorded in the table below.

Time	Batch / Sample	30C002012	30C002013	30C002014
0 min	S1	—	—	—
	S2	+	+	+
10 min	S1	—	—	—
	S2	+	+	+
20 min	S1	—	—	—
	S2	+	+	+
30 min	S1	—	—	—
	S2	+	+	+
40 min	S1	—	—	—
	S2	+	+	+

50 min	S1	—	—	—
	S2	+	+	+
60 min	S1	—	—	—
	S2	+	+	+
70 min	S1	+	—	—
	S2	+	+	+
80 min	S1	—	—	+
	S2	+	+	+
90 min	S1	+	+	—
	S2	+	+	+

The test results show that after 0-60 minutes exposure, and the sensitivity test results met the sensitivity requirements. There were slight false positive results after 60 minutes. In order to ensure the validity and reliability of the tests, they should be used within 60 minutes after opening the package.

4. Summary

Under accelerated storage conditions, all indicators of the kits meet the requirements. The storage stability of the product can be at least 12 months by estimation through accelerated stability test.