



Dynamiker SARS-CoV-2 Ag Rapid Test

Diagnostic sensitivity and specificity test report

1. Purpose

The Dynamiker SARS-CoV-2 Ag Rapid Test is used to detect different clinical samples. First, the homologous oropharyngeal swab and nasopharyngeal swab samples are verified for comparability, and then the results of the test reagents are compared with the clinical diagnosis results. Calculate the coincidence rate of the test results, and analyse the diagnostic sensitivity and specificity.

2. Reagents and materials

2.1 Dynamiker SARS-CoV-2 Ag Rapid Test: self-made, specification: 20 tests/kit, lot: 200401, 200402, 200403.

2.2 Clinical samples: from the Institute of Pathogen Biology, Chinese Academy of Medical Sciences (according to the "2019-nCoV Pneumonia Diagnosis and Treatment Plan" confirmed cases and excluded cases. Information of the detection reagents used: 2019-nCoV nucleic acid detection kit: from Shanghai Jienu Biotechnology Co., Ltd., registration number: National Machinery Note 20203400058).

2.3 Test device: timer.

3. Test method

3.1 Comparability verification of homologous samples

A total of 60 cases of two types of negative samples and different levels of positive samples (each sample includes an oropharyngeal swab and a nasopharyngeal swab sample from the same patient) were tested with 3 batches of kits. The specific detection method was operated in strict accordance with the instructions to verify the comparability of homologous oropharyngeal swab and nasopharyngeal swab samples.

3.2 Diagnostic sensitivity and diagnostic specificity analysis

Use the product to detect clinical serum samples, and compare the results of the test reagents with the clinical diagnosis results. Calculate the coincidence rate of the test results, and analyse the diagnostic sensitivity and specificity.



4. Test result

4.1 Comparability verification of homologous samples

The results of the three batches of reagents for testing two types of negative samples and different levels of positive samples are shown in the following table:

Table 1 Comparability verification results of homologous samples

Reagent	200401		200402		200403	
	Oropharyngeal swab	Nasopharyngeal swab	Oropharyngeal swab	Nasopharyngeal swab	Oropharyngeal swab	Nasopharyngeal swab
SN-1	-	-	-	-	-	-
SN-2	-	-	-	-	-	-
SN-3	-	-	-	-	-	-
SN-4	-	-	-	-	-	-
SN-5	-	-	-	-	-	-
SN-6	-	-	-	-	-	-
SN-7	-	-	-	-	-	-
SN-8	-	-	-	-	-	-
SN-9	-	-	-	-	-	-
SN-10	-	-	-	-	-	-
SN-11	-	-	-	-	-	-
SN-12	-	-	-	-	-	-
SN-13	-	-	-	-	-	-
SN-14	-	-	-	-	-	-
SN-15	-	-	-	-	-	-
SN-16	-	-	-	-	-	-
SN-17	-	-	-	-	-	-
SN-18	-	-	-	-	-	-
SN-19	-	-	-	-	-	-
SN-20	-	-	-	-	-	-
SN-21	-	-	-	-	-	-
SN-22	-	-	-	-	-	-
SN-23	-	-	-	-	-	-
SN-24	-	-	-	-	-	-
SN-25	-	-	-	-	-	-



Reagent	200401		200402		200403	
Sample	Oropharyngeal swab	Nasopharyngeal swab	Oropharyngeal swab	Nasopharyngeal swab	Oropharyngeal swab	Nasopharyngeal swab
SN-26	-	-	-	-	-	-
SN-27	-	-	-	-	-	-
SN-28	-	-	-	-	-	-
SN-29	-	-	-	-	-	-
SN-30	-	-	-	-	-	-
SP-1	+	+	+	+	+	+
SP-2	+	+	+	+	+	+
SP-3	+	+	+	+	+	+
SP-4	+	+	+	+	+	+
SP-5	+	+	+	+	+	+
SP-6	++	++	++	++	++	++
SP-7	++	++	++	++	++	++
SP-8	++	++	++	++	++	++
SP-9	++	++	++	++	++	++
SP-10	++	++	++	++	++	++
SP-11	+++	+++	+++	+++	+++	+++
SP-12	+++	+++	+++	+++	+++	+++
SP-13	+++	+++	+++	+++	+++	+++
SP-14	+++	+++	+++	+++	+++	+++
SP-15	+++	+++	+++	+++	+++	+++
SP-16	++++	++++	++++	++++	++++	++++
SP-17	++++	++++	++++	++++	++++	++++
SP-18	++++	++++	++++	++++	++++	++++
SP-19	++++	++++	++++	++++	++++	++++
SP-20	++++	++++	++++	++++	++++	++++
SP-21	++++	++++	++++	++++	++++	++++
SP-22	++++	++++	++++	++++	++++	++++
SP-23	++++	++++	++++	++++	++++	++++
SP-24	++++	++++	++++	++++	++++	++++
SP-25	++++	++++	++++	++++	++++	++++
SP-26	++++	++++	++++	++++	++++	++++
SP-27	++++	++++	++++	++++	++++	++++
SP-28	++++	++++	++++	++++	++++	++++



Reagent	200401		200402		200403	
Sample	Oropharyngeal swab	Nasopharyngeal swab	Oropharyngeal swab	Nasopharyngeal swab	Oropharyngeal swab	Nasopharyngeal swab
SP-29	++++	++++	++++	++++	++++	++++
SP-30	++++	++++	++++	++++	++++	++++

Remarks: "++++" and "+++" mean strong positive; "++" means medium positive; "+" means weak positive; "-" means negative.

It can be seen from the above results that the test results of the oropharyngeal swab and nasopharyngeal swab samples of the same patient are the same. It is believed that the test results of homologous oropharyngeal swabs and nasopharyngeal swab samples are comparable.

4.2 Analysis of diagnostic sensitivity and diagnostic specificity

4.2.1 Method

A total of 271 clinical samples were enrolled in this study, which included 60 PCR-positive samples and 211 PCR-negative samples for COVID-19.

4.2.2 Result

Table 2 Comparative analysis of antigen test results and clinical diagnosis results

Test reagent results	PCR diagnosis result		Total
	Confirmed	Exclude	
Positive	57 (A)	2 (B)	59 (A+B)
Negative	3 (C)	209 (D)	212 (C+D)
Total	60 (A+C)	211 (B+D)	271 (A+B+C+D)

Diagnostic sensitivity (positive coincidence rate) = $A/(A+C) \times 100\% = 95.0\%$

Diagnostic specificity (negative coincidence rate) = $D/(B+D) \times 100\% = 99.1\%$

Total coincidence rate = $(A+D)/(A+B+C+D) \times 100\% = 98.2\%$

By this test, the overall diagnostic sensitivity, specificity and total coincidence rate were 95.0%, 99.1% and 98.2%, respectively.

5. Test conclusion

The Dynamiker SARS-CoV-2 Ag Rapid Test is an important adjunction diagnostic of COVID-19. It can be used for the rapid screening of SARS-CoV-2 carriers, symptomatic or asymptomatic, in hospitals, clinics, and test laboratories.