

**Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)**  
**Guangzhou Wondfo Biotech Co., Ltd.**  
**Clinical Evaluation Report**

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## Content

1. Introduction and description of the assay .....	3
2. Evaluation method .....	3
3. Clinical samples .....	4
4. Clinical trial period .....	4
5. Results and Analysis .....	4
6. Conclusion.....	5
Annex I Clinical Verification Data List.....	6

## **1. Introduction and description of the assay**

### **Introduction**

Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen extracted from the nasopharyngeal swab or oropharyngeal swab specimen.

### **Description of the assay (principle):**

Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) is based on the principle of Immunochromatography sandwich for determination of SARS-CoV-2 antigen extracted from the nasopharyngeal swab or oropharyngeal swab specimen. When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antibody-dye conjugate and flows across the pre-coated membrane.

When the SARS-CoV-2 antigen level in the specimen is at or above the target cutoff (the detection limit of the test), the antigen bound to the antibody-dye conjugate are combined by SARS-CoV-2 antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antigen level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result. To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

## **2. Evaluation method**

In this trial, based on the comparison of PCR diagnosis results of the patients, clinical application study of Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) was conducted and thus verified the safety and effectiveness of such reagents manufactured by Guangzhou Wondfo Biotech Co., Ltd.

### 3. Clinical samples

A total of 859 clinical oropharyngeal swab samples were included in this trial.

### 4. Clinical trial period

October 12 to October 20, 2020

### 5. Results and Analysis

#### 5.1 Test procedure

Throughout the evaluation, all samples should be tested with the Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method) according to the 'Test procedure' described in the Instruction for Use supplied with the reagent.

#### 5.2 Comparative Analysis of Trial Results

##### Trial Completion

A total of 497 PCR positive cases and 362 PCR negative cases were included in this trial of 2 clinical sites.

##### Major Effectiveness Statistical Methods

Compared with PCR results, calculate the sensitivity, specificity, overall consistency and the 95% confidence interval (CI) of test reagents. Sensitivity, specificity, overall consistency: range from 0%~100%, the closer the value is to 100%, the higher the degree of compliance with clinical diagnosis.

#### 5.3 Result Analysis

Test results are shown as Table 1, and clinical trial results are detailed in Annex I Clinical verification data list.

Table 1: 2 × 2 Contingency Table Analysis of PCR Results and Evaluation Reagent Test

Evaluation Reagents	Results		Total
	PCR Positive	PCR Negative	
SARS-CoV-2 Antigen positive	478	1	479
SARS-CoV-2 Antigen Negative	19	361	380

Total	497	362	859
Sensitivity	96.18%	95%CI:	96.43%~98.49%
Specificity	99.72%	95%CI:	98.45%~99.95%
Total conformity rate	97.67%	95%CI:	94.11%~97.54%

There were 478 positive samples and 361 negative samples whose SARS-CoV-2 antigen detection results were consistent with PCR results. 19 cases were confirmed PCR positive and meanwhile tested negative by Wondfo SARS-CoV-2 Antigen Test (Lateral flow method) and 1 case was confirmed PCR negative and meanwhile tested positive by Wondfo SARS-CoV-2 Antigen Test (Lateral flow method).

## 6. Conclusion

From the results of 859 clinical samples, it is conducted that Wondfo SARS-CoV-2 Antigen Test (Lateral flow method) developed by Guangzhou Wondfo Biotech Co., Ltd. can meet the requirement of clinical intended use.

**Annex I Clinical Verification Data List**

Results of negative samples:

Sample	Clinical site	Date of testing	Wondfo result	PCR result	Coincidence
1	Site 1	12-Oct-20	N	N	Yes
2	Site 1	12-Oct-20	N	N	Yes
3	Site 1	12-Oct-20	N	N	Yes
4	Site 1	12-Oct-20	N	N	Yes
5	Site 1	12-Oct-20	N	N	Yes
6	Site 1	12-Oct-20	N	N	Yes
7	Site 1	12-Oct-20	N	N	Yes
8	Site 1	12-Oct-20	N	N	Yes
9	Site 1	12-Oct-20	N	N	Yes
10	Site 1	12-Oct-20	N	N	Yes
11	Site 1	12-Oct-20	N	N	Yes
12	Site 1	12-Oct-20	N	N	Yes
13	Site 1	12-Oct-20	N	N	Yes
14	Site 1	12-Oct-20	N	N	Yes
15	Site 1	12-Oct-20	N	N	Yes
16	Site 1	12-Oct-20	N	N	Yes
17	Site 1	12-Oct-20	N	N	Yes
18	Site 1	12-Oct-20	N	N	Yes
19	Site 1	12-Oct-20	N	N	Yes
20	Site 1	12-Oct-20	N	N	Yes
21	Site 1	12-Oct-20	N	N	Yes
22	Site 1	12-Oct-20	N	N	Yes
23	Site 1	13-Oct-20	N	N	Yes
24	Site 1	13-Oct-20	N	N	Yes
25	Site 1	13-Oct-20	N	N	Yes
26	Site 1	13-Oct-20	N	N	Yes
27	Site 1	13-Oct-20	N	N	Yes
28	Site 1	13-Oct-20	N	N	Yes
29	Site 1	13-Oct-20	N	N	Yes
30	Site 1	13-Oct-20	N	N	Yes
31	Site 1	13-Oct-20	N	N	Yes
32	Site 1	13-Oct-20	N	N	Yes
33	Site 1	13-Oct-20	N	N	Yes
34	Site 1	13-Oct-20	N	N	Yes
35	Site 1	13-Oct-20	N	N	Yes
36	Site 1	13-Oct-20	N	N	Yes
37	Site 1	13-Oct-20	N	N	Yes
38	Site 1	13-Oct-20	N	N	Yes
39	Site 1	13-Oct-20	N	N	Yes

40	Site 1	13-Oct-20	N	N	Yes
41	Site 1	13-Oct-20	N	N	Yes
42	Site 1	13-Oct-20	N	N	Yes
43	Site 1	13-Oct-20	N	N	Yes
44	Site 1	14-Oct-20	N	N	Yes
45	Site 1	14-Oct-20	N	N	Yes
46	Site 1	14-Oct-20	N	N	Yes
47	Site 1	14-Oct-20	N	N	Yes
48	Site 1	14-Oct-20	N	N	Yes
49	Site 1	14-Oct-20	N	N	Yes
50	Site 1	14-Oct-20	N	N	Yes
51	Site 1	14-Oct-20	N	N	Yes
52	Site 1	14-Oct-20	N	N	Yes
53	Site 1	14-Oct-20	N	N	Yes
54	Site 1	14-Oct-20	N	N	Yes
55	Site 1	14-Oct-20	P	N	No
56	Site 1	14-Oct-20	N	N	Yes
57	Site 1	14-Oct-20	N	N	Yes
58	Site 1	14-Oct-20	N	N	Yes
59	Site 1	14-Oct-20	N	N	Yes
60	Site 1	14-Oct-20	N	N	Yes
61	Site 1	14-Oct-20	N	N	Yes
62	Site 1	14-Oct-20	N	N	Yes
63	Site 1	14-Oct-20	N	N	Yes
64	Site 1	14-Oct-20	N	N	Yes
65	Site 1	14-Oct-20	N	N	Yes
66	Site 1	14-Oct-20	N	N	Yes
67	Site 1	14-Oct-20	N	N	Yes
68	Site 1	14-Oct-20	N	N	Yes
69	Site 1	14-Oct-20	N	N	Yes
70	Site 1	14-Oct-20	N	N	Yes
71	Site 1	14-Oct-20	N	N	Yes
72	Site 1	14-Oct-20	N	N	Yes
73	Site 1	14-Oct-20	N	N	Yes
74	Site 1	14-Oct-20	N	N	Yes
75	Site 1	14-Oct-20	N	N	Yes
76	Site 1	14-Oct-20	N	N	Yes
77	Site 1	14-Oct-20	N	N	Yes
78	Site 1	14-Oct-20	N	N	Yes
79	Site 1	14-Oct-20	N	N	Yes
80	Site 1	14-Oct-20	N	N	Yes
81	Site 1	14-Oct-20	N	N	Yes
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83	Site 1	14-Oct-20	N	N	Yes
84	Site 1	14-Oct-20	N	N	Yes
85	Site 1	14-Oct-20	N	N	Yes
86	Site 1	14-Oct-20	N	N	Yes
87	Site 1	14-Oct-20	N	N	Yes
88	Site 1	14-Oct-20	N	N	Yes
89	Site 1	14-Oct-20	N	N	Yes
90	Site 1	14-Oct-20	N	N	Yes
91	Site 1	14-Oct-20	N	N	Yes
92	Site 1	15-Oct-20	N	N	Yes
93	Site 1	15-Oct-20	N	N	Yes
94	Site 1	15-Oct-20	N	N	Yes
95	Site 1	15-Oct-20	N	N	Yes
96	Site 1	15-Oct-20	N	N	Yes
97	Site 1	15-Oct-20	N	N	Yes
98	Site 1	15-Oct-20	N	N	Yes
99	Site 1	15-Oct-20	N	N	Yes
100	Site 1	15-Oct-20	N	N	Yes
101	Site 1	15-Oct-20	N	N	Yes
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109	Site 1	15-Oct-20	N	N	Yes
110	Site 1	15-Oct-20	N	N	Yes
111	Site 1	15-Oct-20	N	N	Yes
112	Site 1	15-Oct-20	N	N	Yes
113	Site 1	15-Oct-20	N	N	Yes
114	Site 1	15-Oct-20	N	N	Yes
115	Site 1	15-Oct-20	N	N	Yes
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123	Site 1	15-Oct-20	N	N	Yes
124	Site 1	15-Oct-20	N	N	Yes
125	Site 1	15-Oct-20	N	N	Yes



126	Site 1	15-Oct-20	N	N	Yes
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128	Site 1	15-Oct-20	N	N	Yes
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132	Site 1	15-Oct-20	N	N	Yes
133	Site 1	16-Oct-20	N	N	Yes
134	Site 1	16-Oct-20	N	N	Yes
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246	Site 1	20-Oct-20	N	N	Yes
247	Site 1	20-Oct-20	N	N	Yes
248	Site 1	20-Oct-20	N	N	Yes
249	Site 2	12-Oct-20	N	N	Yes
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251	Site 2	12-Oct-20	N	N	Yes
252	Site 2	12-Oct-20	N	N	Yes
253	Site 2	12-Oct-20	N	N	Yes
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271	Site 2	13-Oct-20	N	N	Yes
272	Site 2	13-Oct-20	N	N	Yes
273	Site 2	13-Oct-20	N	N	Yes
274	Site 2	13-Oct-20	N	N	Yes
275	Site 2	13-Oct-20	N	N	Yes
276	Site 2	13-Oct-20	N	N	Yes
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280	Site 2	14-Oct-20	N	N	Yes
281	Site 2	14-Oct-20	N	N	Yes
282	Site 2	14-Oct-20	N	N	Yes
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285	Site 2	14-Oct-20	N	N	Yes
286	Site 2	14-Oct-20	N	N	Yes
287	Site 2	14-Oct-20	N	N	Yes
288	Site 2	14-Oct-20	N	N	Yes
289	Site 2	14-Oct-20	N	N	Yes
290	Site 2	14-Oct-20	N	N	Yes
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293	Site 2	14-Oct-20	N	N	Yes
294	Site 2	14-Oct-20	N	N	Yes
295	Site 2	14-Oct-20	N	N	Yes
296	Site 2	14-Oct-20	N	N	Yes
297	Site 2	15-Oct-20	N	N	Yes

298	Site 2	15-Oct-20	N	N	Yes
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301	Site 2	15-Oct-20	N	N	Yes
302	Site 2	15-Oct-20	N	N	Yes
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305	Site 2	15-Oct-20	N	N	Yes
306	Site 2	15-Oct-20	N	N	Yes
307	Site 2	15-Oct-20	N	N	Yes
308	Site 2	15-Oct-20	N	N	Yes
309	Site 2	15-Oct-20	N	N	Yes
310	Site 2	16-Oct-20	N	N	Yes
311	Site 2	16-Oct-20	N	N	Yes
312	Site 2	16-Oct-20	N	N	Yes
313	Site 2	16-Oct-20	N	N	Yes
314	Site 2	16-Oct-20	N	N	Yes
315	Site 2	16-Oct-20	N	N	Yes
316	Site 2	16-Oct-20	N	N	Yes
317	Site 2	16-Oct-20	N	N	Yes
318	Site 2	16-Oct-20	N	N	Yes
319	Site 2	16-Oct-20	N	N	Yes
320	Site 2	16-Oct-20	N	N	Yes
321	Site 2	16-Oct-20	N	N	Yes
322	Site 2	19-Oct-20	N	N	Yes
323	Site 2	19-Oct-20	N	N	Yes
324	Site 2	19-Oct-20	N	N	Yes
325	Site 2	19-Oct-20	N	N	Yes
326	Site 2	19-Oct-20	N	N	Yes
327	Site 2	19-Oct-20	N	N	Yes
328	Site 2	19-Oct-20	N	N	Yes
329	Site 2	19-Oct-20	N	N	Yes
330	Site 2	19-Oct-20	N	N	Yes
331	Site 2	19-Oct-20	N	N	Yes
332	Site 2	19-Oct-20	N	N	Yes
333	Site 2	19-Oct-20	N	N	Yes
334	Site 2	19-Oct-20	N	N	Yes
335	Site 2	19-Oct-20	N	N	Yes
336	Site 2	19-Oct-20	N	N	Yes
337	Site 2	19-Oct-20	N	N	Yes
338	Site 2	19-Oct-20	N	N	Yes
339	Site 2	19-Oct-20	N	N	Yes
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341	Site 2	19-Oct-20	N	N	Yes
342	Site 2	19-Oct-20	N	N	Yes
343	Site 2	20-Oct-20	N	N	Yes
344	Site 2	20-Oct-20	N	N	Yes
345	Site 2	20-Oct-20	N	N	Yes
346	Site 2	20-Oct-20	N	N	Yes
347	Site 2	20-Oct-20	N	N	Yes
348	Site 2	20-Oct-20	N	N	Yes
349	Site 2	20-Oct-20	N	N	Yes
350	Site 2	20-Oct-20	N	N	Yes
351	Site 2	20-Oct-20	N	N	Yes
352	Site 2	20-Oct-20	N	N	Yes
353	Site 2	20-Oct-20	N	N	Yes
354	Site 2	20-Oct-20	N	N	Yes
355	Site 2	20-Oct-20	N	N	Yes
356	Site 2	20-Oct-20	N	N	Yes
357	Site 2	20-Oct-20	N	N	Yes
358	Site 2	20-Oct-20	N	N	Yes
359	Site 2	20-Oct-20	N	N	Yes
360	Site 2	20-Oct-20	N	N	Yes
361	Site 2	20-Oct-20	N	N	Yes
362	Site 2	20-Oct-20	N	N	Yes

Note: N=Negative, P=Positive

Results of positive samples:

Sample	Clinical site	Date of testing	Wondfo result	PCR result	Coincidence
1	Site 1	12-Oct-20	P	P	Yes
2	Site 1	12-Oct-20	P	P	Yes
3	Site 1	12-Oct-20	P	P	Yes
4	Site 1	12-Oct-20	P	P	Yes
5	Site 1	12-Oct-20	P	P	Yes
6	Site 1	12-Oct-20	P	P	Yes
7	Site 1	12-Oct-20	P	P	Yes
8	Site 1	12-Oct-20	P	P	Yes
9	Site 1	12-Oct-20	N	P	No
10	Site 1	12-Oct-20	P	P	Yes
11	Site 1	12-Oct-20	P	P	Yes
12	Site 1	12-Oct-20	P	P	Yes
13	Site 1	12-Oct-20	P	P	Yes
14	Site 1	12-Oct-20	P	P	Yes
15	Site 1	12-Oct-20	P	P	Yes
16	Site 1	12-Oct-20	P	P	Yes
17	Site 1	12-Oct-20	P	P	Yes

18	Site 1	12-Oct-20	P	P	Yes
19	Site 1	12-Oct-20	P	P	Yes
20	Site 1	12-Oct-20	P	P	Yes
21	Site 1	12-Oct-20	P	P	Yes
22	Site 1	12-Oct-20	P	P	Yes
23	Site 1	12-Oct-20	P	P	Yes
24	Site 1	12-Oct-20	P	P	Yes
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476	Site 2	20-Oct-20	P	P	Yes
477	Site 2	20-Oct-20	P	P	Yes
478	Site 2	20-Oct-20	P	P	Yes
479	Site 2	20-Oct-20	P	P	Yes
480	Site 2	20-Oct-20	P	P	Yes
481	Site 2	20-Oct-20	P	P	Yes
482	Site 2	20-Oct-20	P	P	Yes
483	Site 2	20-Oct-20	P	P	Yes
484	Site 2	20-Oct-20	P	P	Yes
485	Site 2	20-Oct-20	P	P	Yes
486	Site 2	20-Oct-20	P	P	Yes
487	Site 2	20-Oct-20	P	P	Yes
488	Site 2	20-Oct-20	P	P	Yes
489	Site 2	20-Oct-20	P	P	Yes
490	Site 2	20-Oct-20	P	P	Yes

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491	Site 2	20-Oct-20	P	P	Yes
492	Site 2	20-Oct-20	N	P	No
493	Site 2	20-Oct-20	P	P	Yes
494	Site 2	20-Oct-20	P	P	Yes
495	Site 2	20-Oct-20	P	P	Yes
496	Site 2	20-Oct-20	P	P	Yes
497	Site 2	20-Oct-20	P	P	Yes

Note: N=Negative, P=Positive