

Test Report for (COVID-19) IgM/IgG Test Kit

Name:	(COVID-19) IgM/IgG Test Kit (Dry Fluorescence Immunoassay)	Sample Quantity:	200T
Storage Condition:	Room temperature	Validity:	18 months
Sample Date:	2020.02.21	Test Date:	2020.02.23
Test Item:	COVID-19 IgM Antibody; COVID-19 IgG Antibody		
Test Basis:	Lansionbio (COVID-19) IgM/IgG Test Kit (Dry Fluorescence Immunoassay) User Manual		

1. Test Result

No.	Sample Information		COVID-19 IgM (AU/mL)			COVID-19 IgG (AU/mL)		
	*Interval Days	Test result of COVID-19	Result 1	Result 2	Interpretation of results	Result 1	Result 2	Interpretation of results
1	5	Positive	0.09	0.08	Positive	0.04	0.04	Positive
2	2	Positive	0.05	0.04	Positive	0.02	0.02	Negative
3	2	Positive	0.04	0.04	Positive	0.03	0.03	Negative
4	3	Positive	0.05	0.06	Positive	0.01	0.01	Negative
5	5	Positive	0.14	0.14	Positive	0.01	0.01	Negative
6	1	Positive	0.07	0.09	Positive	0.01	0.01	Negative
7	2	Positive	0.12	0.12	Positive	0.03	0.03	Negative
8	2	Positive	0.06	0.06	Positive	0.01	0.01	Negative
9	3	Positive	0.10	0.09	Positive	0.02	0.02	Negative
10	6	Positive	0.08	0.09	Positive	0.01	0.01	Negative
11	1	Positive	0.09	0.09	Positive	0.04	0.04	Positive
12	3	Positive	0.09	0.10	Positive	0.01	0.01	Negative
13	2	Positive	0.06	0.06	Positive	0.03	0.03	Negative
14	3	Positive	0.08	0.08	Positive	0.01	0.02	Negative
15	6	Positive	0.11	0.13	Positive	0.02	0.02	Negative
16	2	Positive	0.03	0.02	Negative	0.01	0.01	Negative
17	2	Positive	0.04	0.04	Positive	0.01	0.01	Negative
18	3	Positive	0.04	0.05	Positive	0.01	0.01	Negative
19	4	Positive	0.08	0.07	Positive	0.01	0.01	Negative

20	5	Positive	0.11	0.14	Positive	0.02	0.02	Negative
21	5	Positive	0.06	0.07	Positive	0.01	0.01	Negative
22	2	Positive	0.10	0.11	Positive	0.02	0.02	Negative
23	2	Positive	0.13	0.14	Positive	0.01	0.01	Negative
24	4	Positive	0.06	0.07	Positive	0.01	0.01	Negative
25	3	Positive	0.10	0.13	Positive	0.02	0.02	Negative
26	0	Positive	0.05	0.04	Positive	0.02	0.02	Negative
27	2	Positive	0.08	0.06	Positive	0.01	0.01	Negative
28	1	Positive	0.05	0.07	Positive	0.02	0.03	Negative
29	6	Positive	0.06	0.07	Positive	0.02	0.02	Negative
30	2	Positive	0.67	0.68	Positive	0.33	0.33	Positive
31	0	Positive	0.14	0.15	Positive	0.01	0.01	Negative
32	2	Positive	0.46	0.48	Positive	0.01	0.01	Negative
33	1	Positive	0.04	0.06	Positive	0.03	0.03	Negative
34	2	Positive	0.35	0.36	Positive	0.01	0.01	Negative
35	2	Positive	0.05	0.07	Positive	0.01	0.01	Negative
36	4	Positive	0.06	0.07	Positive	0.02	0.02	Negative
37	4	Positive	0.02	0.02	Negative	0.02	0.02	Negative
38	1	Positive	0.05	0.06	Positive	0.05	0.05	Positive
39	4	Positive	0.07	0.06	Positive	0.01	0.01	Negative
40	4	Positive	0.11	0.11	Positive	0.02	0.02	Negative
41	3	Positive	0.05	0.05	Positive	0.01	0.01	Negative
42	2	Positive	0.11	0.12	Positive	0.02	0.02	Negative
43	2	Positive	0.04	0.05	Positive	0.02	0.02	Negative
44	2	Positive	0.10	0.10	Positive	0.02	0.02	Negative
45	5	Positive	0.09	0.09	Positive	0.01	0.02	Negative
46	3	Positive	0.07	0.08	Positive	0.01	0.01	Negative
47	0	Positive	0.05	0.06	Positive	0.01	0.01	Negative
48	4	Positive	0.06	0.07	Positive	0.04	0.04	Positive
49	6	Positive	0.12	0.12	Positive	0.01	0.01	Negative
50	6	Positive	0.13	0.13	Positive	0.04	0.04	Positive
51	2	Positive	0.07	0.07	Positive	0.02	0.02	Negative
52	2	Positive	0.06	0.08	Positive	0.01	0.01	Negative

53	3	Positive	0.08	0.09	Positive	0.03	0.03	Negative
54	4	Positive	0.05	0.06	Positive	0.01	0.01	Negative
55	2	Positive	0.05	0.04	Positive	0.05	0.05	Positive
56	3	Positive	0.02	0.01	Negative	0.01	0.01	Negative
57	5	Positive	0.04	0.05	Positive	0.01	0.01	Negative
58	4	Positive	0.06	0.07	Positive	0.03	0.03	Negative
59	4	Positive	0.09	0.08	Positive	0.01	0.02	Negative
60	5	Positive	0.05	0.04	Positive	0.02	0.02	Negative
61	2	Positive	0.05	0.06	Positive	0.01	0.01	Negative
62	2	Positive	0.06	0.07	Positive	0.02	0.02	Negative
63	1	Positive	0.10	0.12	Positive	0.01	0.01	Negative
64	3	Positive	0.06	0.07	Positive	0.03	0.03	Negative
65	4	Positive	0.05	0.06	Positive	0.01	0.01	Negative
66	1	Positive	0.22	0.24	Positive	0.01	0.01	Negative
67	3	Positive	0.14	0.11	Positive	0.02	0.02	Negative
68	5	Positive	0.04	0.05	Positive	0.05	0.05	Positive
69	6	Positive	0.05	0.06	Positive	0.02	0.03	Negative
70	2	Positive	0.14	0.15	Positive	0.01	0.01	Negative
71	0	Positive	0.07	0.08	Positive	0.15	0.15	Positive
72	4	Positive	0.09	0.08	Positive	0.03	0.03	Negative
73	1	Positive	0.09	0.10	Positive	0.01	0.01	Negative
74	2	Positive	0.07	0.08	Positive	0.02	0.02	Negative
75	5	Positive	0.06	0.07	Positive	0.01	0.01	Negative
76	4	Positive	0.05	0.06	Positive	0.01	0.01	Negative
77	45	Positive	0.45	0.46	Positive	0.01	0.01	Negative
78	4	Positive	0.25	0.26	Positive	0.01	0.01	Negative
79	5	Positive	0.05	0.05	Positive	0.02	0.02	Negative
80	2	Positive	0.06	0.07	Positive	0.05	0.05	Positive
101	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
102	/	Negative	0.02	0.03	Negative	0.02	0.01	Negative
103	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
104	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
105	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative

106	/	Negative	0.03	0.03	Negative	0.02	0.02	Negative
107	/	Negative	0.01	0.01	Negative	0.02	0.03	Negative
108	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
109	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
110	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
111	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
112	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
113	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
114	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
115	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
116	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
117	/	Negative	0.03	0.02	Negative	0.01	0.01	Negative
118	/	Negative	0.01	0.02	Negative	0.02	0.02	Negative
119	/	Negative	0.03	0.02	Negative	0.01	0.01	Negative
120	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
121	/	Negative	0.03	0.02	Negative	0.01	0.01	Negative
122	/	Negative	0.01	0.02	Negative	0.02	0.01	Negative
123	/	Negative	0.02	0.01	Negative	0.01	0.01	Negative
124	/	Negative	0.02	0.03	Negative	0.02	0.02	Negative
125	/	Negative	0.01	0.02	Negative	0.02	0.02	Negative
126	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
127	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
128	/	Negative	0.03	0.02	Negative	0.01	0.01	Negative
129	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
130	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
131	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
132	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
133	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
134	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
135	/	Negative	0.02	0.03	Negative	0.01	0.01	Negative
136	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
137	/	Negative	0.03	0.02	Negative	0.01	0.011	Negative
138	/	Negative	0.01	0.02	Negative	0.02	0.02	Negative

139	/	Negative	0.03	0.02	Negative	0.01	0.01	Negative
140	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
141	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
142	/	Negative	0.02	0.02	Negative	0.02	0.01	Negative
143	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
144	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
145	/	Negative	0.03	0.02	Negative	0.02	0.02	Negative
146	/	Negative	0.02	0.01	Negative	0.02	0.01	Negative
147	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
148	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
149	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
150	/	Negative	0.01	0.01	Negative	0.01	0.02	Negative
151	/	Negative	0.03	0.01	Negative	0.02	0.02	Negative
152	/	Negative	0.01	0.02	Negative	0.03	0.03	Negative
153	/	Negative	0.01	0.01	Negative	0.01	0.02	Negative
154	/	Negative	0.01	0.01	Negative	0.01	0.02	Negative
155	/	Negative	0.01	0.01	Negative	0.01	0.02	Negative
156	/	Negative	0.02	0.01	Negative	0.01	0.01	Negative
157	/	Negative	0.02	0.01	Negative	0.01	0.01	Negative
158	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
159	/	Negative	0.02	0.01	Negative	0.01	0.01	Negative
160	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
161	/	Negative	0.02	0.03	Negative	0.01	0.01	Negative
162	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
163	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
164	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
165	/	Negative	0.01	0.01	Negative	0.01	0.02	Negative
166	/	Negative	0.03	0.03	Negative	0.01	0.01	Negative
167	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
168	/	Negative	0.01	0.02	Negative	0.01	0.03	Negative
169	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
170	/	Negative	0.02	0.03	Negative	0.02	0.02	Negative
171	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative

172	/	Negative	0.02	0.01	Negative	0.02	0.02	Negative
173	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
174	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
175	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
176	/	Negative	0.01	0.01	Negative	0.02	0.02	Negative
177	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
178	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
179	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
180	/	Negative	0.01	0.01	Negative	0.02	0.01	Negative
181	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
182	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
183	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
184	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
185	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
186	/	Negative	0.02	0.02	Negative	0.02	0.01	Negative
187	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
188	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
189	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
190	/	Negative	0.01	0.01	Negative	0.02	0.01	Negative
191	/	Negative	0.01	0.02	Negative	0.02	0.02	Negative
192	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
193	/	Negative	0.02	0.02	Negative	0.02	0.02	Negative
194	/	Negative	0.02	0.02	Negative	0.01	0.01	Negative
195	/	Negative	0.01	0.01	Negative	0.02	0.01	Negative
196	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
197	/	Negative	0.02	0.02	Negative	0.01	0.02	Negative
198	/	Negative	0.01	0.01	Negative	0.01	0.01	Negative
199	/	Negative	0.01	0.02	Negative	0.01	0.01	Negative
200	/	Negative	0.02	0.01	Negative	0.01	0.01	Negative

*: It indicates Interval Days between the date of onset of disease and sampling date.

Negative: Test result < 0.04; Positive: Test result ≥ 0.04.

2. Conclusion

Lansionbio (COVID-19) IgM/IgG Test Kit (Dry Fluorescence Immunoassay) (Lot: 0612001) meets the requirements of the test kit User Manual. The positive test rate of (COVID-19) IgM/IgG for 80 confirmed cases (Interval Days from 0 to 6 days) is (77/80) 96.25%. The negative coincidence rate of (COVID-19) IgM/IgG for 120 negative samples (Interval Days from 0 to 6 days) is (120/120) 100%.