

Experimental comparative statistical report

Statistics of the results of the assessment reagent and the nucleic acid test results

Table: 246samples test results

Assessment reagent	Nucleic acid test (RT-PCR)		Total
	Positive(+)	Negative(-)	
Positive (+)	103	0	103
Negative (-)	2	141	143
Total	105	141	246

① Positive and negative coincidence rate, total coincidence rate and Kappa value:

Clinical sensitivity (positive coincidence rate):

$$A/(A+C) \times 100\% = 103/(103+2) \times 100\% = 98.10\%$$

$$95\% \text{ confidence interval: } p \pm 1.96 \times [p(1-p)/n]^{1/2} = 0.9810 \pm 1.96 \times [0.9810 \times (1-0.9810)/105]^{1/2} \\ = [0.9549, 1.000]$$

Clinical specificity (negative coincidence rate):

$$D/(B+D) \times 100\% = 141/(0+141) \times 100\% = 100.00\%$$

$$95\% \text{ Confidence interval: } p \pm 1.96 \times [p(1-p)/n]^{1/2} = 1.0000 \pm 1.96 \times [1.0000 \times (1-1.0000)/141]^{1/2} \\ = [1.000, 1.000]$$

Overall coincidence rate:

$$(A+D)/(A+B+C+D) \times 100\% = (103+141)/(103+0+2+141) \times 100\% = 99.19\%$$

$$95\% \text{ Confidence interval: } p \pm 1.96 \times [p(1-p)/n]^{1/2} = 0.9919 \pm 1.96 \times [0.9919 \times (1-0.9919)/246]^{1/2} \\ = [0.9807, 1.000]$$

② Consistency coefficient Kappa value (K):

$$Kappa = (P_A - P_e) / (1 - P_e)$$

$$P_A = (A + D) / (A + B + C + D) = (103 + 141) / (103 + 0 + 2 + 141) = 0.9919$$

$$P_e = [(A + B)(A + C) + (C + D)(B + D)] / (A + B + C + D)^2 \\ = [(103 + 0)(103 + 2) + (2 + 141)(0 + 141)] / (103 + 0 + 2 + 141)^2 \\ = 0.5119$$

$$Kappa = (P_A - P_e) / (1 - P_e) = (0.9919 - 0.5119) / (1 - 0.5119) = 0.9834$$

Kappa=0.9834 (K>0.75), it can be considered that the strength of agreement between the assessment reagent result and the nucleic acid test result is extremely high. (K=0.9834>0.75)



Subject number	Gender	Assessment reagent test results	Nucleic acid test results
1	Male	+	+
2	Male	-	-
3	Female	-	-
4	Female	-	-
5	Female	+	+
6	Male	-	-
7	Female	-	-
8	Female	+	+
9	Male	-	-
10	Male	+	+
11	Male	-	-
12	Female	-	-
13	Female	+	+
14	Female	-	-
15	Female	+	+
16	Female	-	-
17	Female	-	-
18	Male	+	+
19	Male	-	-
20	Male	-	-
21	Male	+	+
22	Male	-	-
23	Female	-	-
24	Female	-	-
25	Male	+	+
26	Female	-	-
27	Male	-	-
28	Male	+	+
29	Male	-	-
30	Female	-	-
31	Female	-	-
32	Female	+	+
33	Male	-	-
34	Male	-	-
35	Female	-	-

36	Female	+	+
37	Female	-	-
38	Male	-	-
39	Male	-	-
40	Female	+	+
41	Female	-	-
42	Male	-	-
43	Male	-	-
44	Male	+	+
45	Male	-	-
46	Female	+	+
47	Female	-	-
48	Female	-	-
49	Female	-	-
50	Female	+	+
51	Male	+	+
52	Female	-	-
53	Male	-	-
54	Male	+	+
55	Male	+	+
56	Female	-	-
57	Male	-	-
58	Male	-	-
59	Female	+	+
60	Female	-	-
61	Male	+	+
62	Male	-	-
63	Female	-	-
64	Female	+	+
65	Male	-	+
66	Male	+	+
67	Male	-	-
68	Male	-	-
69	Male	+	+
70	Female	-	-
71	Female	-	-
72	Male	-	-
73	Female	+	+

74	Female	-	-
75	Male	+	+
76	Male	-	-
77	Female	+	+
78	Female	-	-
79	Male	-	-
80	Male	+	+
81	Male	-	-
82	Female	-	-
83	Male	+	+
84	Female	-	-
85	Female	+	+
86	Female	-	-
87	Male	-	-
88	Male	-	-
89	Male	+	+
90	Male	-	-
91	Male	-	-
92	Male	+	+
93	Female	-	-
94	Male	-	-
95	Female	-	-
96	Male	+	+
97	Male	-	-
98	Male	-	-
99	Female	+	+
100	Female	+	+
101	Male	-	-
102	Male	-	-
103	Female	-	-
104	Male	+	+
105	Male	-	-
106	Female	+	+
107	Male	+	+
108	Female	-	-
109	Male	-	-
110	Male	+	+
111	Female	-	-

112	Female	-	-
113	Female	+	+
114	Female	-	-
115	Male	-	-
116	Female	+	+
117	Female	-	-
118	Male	-	-
119	Male	+	+
120	Male	-	-
121	Female	+	+
122	Male	-	-
123	Female	+	+
124	Male	-	-
125	Male	+	+
126	Male	-	-
127	Male	-	-
128	Male	+	+
129	Female	-	-
130	Male	-	-
131	Male	+	+
132	Female	-	-
133	Female	+	+
134	Male	-	-
135	Male	+	+
136	Male	-	+
137	Female	+	+
138	Female	-	-
139	Female	+	+
140	Female	-	-
141	Female	-	-
142	Male	+	+
143	Female	+	+
144	Female	+	+
145	Female	-	-
146	Male	-	-
147	Male	+	+
148	Male	-	-
149	Female	-	-

150	Male	+	+
151	Male	-	-
152	Male	+	+
153	Male	-	-
154	Male	+	+
155	Female	+	+
156	Male	+	+
157	Female	-	-
158	Female	+	+
159	Male	+	+
160	Female	-	-
161	Male	-	-
162	Female	+	+
163	Female	-	-
164	Female	+	+
165	Male	+	+
166	Female	-	-
167	Male	-	-
168	Male	+	+
169	Female	-	-
170	Male	+	+
171	Male	-	-
172	Male	-	-
173	Male	+	+
174	Male	-	-
175	Female	+	+
176	Female	-	-
177	Male	+	+
178	Male	-	-
179	Male	-	-
180	Male	+	+
181	Male	-	-
182	Male	-	-
183	Male	-	-
184	Male	+	+
185	Male	+	+
186	Male	-	-
187	Female	-	-

188	Female	+	+
189	Female	-	-
190	Male	+	+
191	Male	-	-
192	Female	+	+
193	Female	-	-
194	Male	+	+
195	Female	+	+
196	Male	-	-
197	Male	-	-
198	Female	+	+
199	Female	+	+
200	Male	-	-
201	Male	-	-
202	Male	+	+
203	Female	+	+
204	Female	-	-
205	Female	+	+
206	Female	-	-
207	Female	-	-
208	Male	+	+
209	Male	-	-
210	Male	+	+
211	Male	+	+
212	Male	-	-
213	Male	-	-
214	Female	+	+
215	Male	-	-
216	Female	+	+
217	Male	-	-
218	Female	+	+
219	Male	-	-
220	Female	-	-
221	Male	+	+
222	Male	+	+
223	Female	-	-
224	Female	+	+
225	Male	-	-



226	Female	+	+
227	Male	-	-
228	Male	+	+
229	Male	-	-
230	Male	+	+
231	Male	-	-
232	Male	+	+
233	Female	-	-
234	Male	-	-
235	Male	+	+
236	Male	-	-
237	Male	+	+
238	Male	+	+
239	Male	-	-
240	Male	+	+
241	Male	+	+
242	Female	-	-
243	Male	+	+
244	Female	+	+
245	Female	-	-
246	Female	-	-