



## REDCELL Covid 19 Clinical Performance Study

**Product name:** Covid 19 Antigen Test    **Product No:** RCCOVAG

**Kit lot number and expiry date:** Lot No: COVAG1121    **Production date:** 04.10.2020  
**Expiry date:** 04.11.2021

**Performed by;** Ali İhsan Manav, Dr Mete Ataç

**Test Method:** Covid 19 Clinical Performance Study

**Responsible person:** Dr Erdal Ataç

**Issue Date:** 20.12.2020

The specimens were collected via nasopharyngeal and throat swabs and placed in VTM or rNAT Transfer Tubes. Total 380 specimens were analyzed, including 122 positive cases and 258 negative cases. All samples were collected during the epidemic of the new coronavirus SARS-CoV-2 and a blind control test was used during this study.

The age range of 380 samples was 18-79. Gender distribution; 221 men (58.2), 159 women (41.8%)

Test samples were obtained from the following units.

Istanbul Sabiha Gokcen Airport Pre-Flight Test Center and Saglik Bilimleri University Technopol Campus.

REDCELL Direct SARS-CoV-2 RT-qPCR Test Kit Test was selected as the reference reagent on the same clinical samples of the nasopharyngeal and throat swabs. Clinical equivalence between the test reagents was investigated.

With the samples, RED CELL Biyoteknoloji A.Ş. REDCELL Covid 19 Antigen Test was used in the laboratory of the company headquarters.

Samples taken with nasopharyngeal swab and put in Viral Transport Medium for PCR test were used as test material. Samples obtained from relevant institutions were stored at -20 ° C.

Frozen samples were thawed and included in the study for Covid 19 Antigen test.

Samples with a reaction intensity of +1 and above were considered positive.

Covid 19 Antigen Test evaluation criteria are defined below.

<i>Negative</i>	<i>No visible reaction on the Test line .</i>
<i>+1</i>	<i>Barely noticeable reaction on the test line.</i>
<i>+2</i>	<i>Visible but not intense reaction on the test line</i>
<i>+3</i>	<i>Significant and intense reaction in the test line.</i>
<i>+4</i>	<i>Completely color-saturated reaction on the test line</i>

It was found positive by 122 qPCR tests out of 380 samples. Of the samples that gave positive results with the PCR test, 116 were detected as positive by the Covid 19 antigen test.

Although 258 samples were detected as negative by the PCR test, 264 samples were detected as negative with the Covid 19 antigen test.

REDCELL Covid-19 Antigen Test	Direct SARS-CoV-2 RT-qPCR Test	
	Positive	Negative
Positive	116	3
Negative	6	255
Total	122	258

As a result of the study, REDCELL Covid 19 Antigen test sensitivity; 95.08%, specificity was reported as 98.8%.

The data of the study are presented in the table below.

Sample ID	Direct SARS-CoV-2 RT-qPCR	REDCELL Covid 19 Antigen
	CT Value	Results
1. 0040097	26.54	Positive
2. 0104857	29.82	Positive
3. 0107982	23.19	Positive
4. 0050137	28.67	Positive
5. 0037827	30.89	Positive
6. 0026044	29.35	Positive
7. 0026282	30.14	Positive
8. 0074658	28.70	Positive
9. 0051007	25.92	Positive
10. 0051276	29.53	Positive
11. 0081273	31.75	Positive
12. 0042620	30.40	Positive
13. 0073317	26.46	Positive
14. 0030756	31.49	Positive
15. 0028601	31.20	Positive
16. 0087254	28.32	Positive

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17. 0039571	23.9	Positive
18. 0085638	34.58	Positive
19. 0008847	28.16	Positive
20. 0073659	33.92	Negative
21. 0068392	29.90	Positive
22. 0069478	34.44	Negative
23. 0946491	32.27	Positive
24. 0091449	26.87	Positive
25. 0080903	29.75	Positive
26. 0014535	31.27	Positive
27. 0051403	30.67	Positive
28. 0096261	27.25	Positive
29. 0089048	29.84	Positive
30. 0047353	26.37	Positive
31. 00106195	29.32	Positive
32. 0097144	31.79	Positive
33. 0015623	28.29	Positive
34. 00104955	22.23	Positive
35. 0046401	26.48	Positive
36. 0062486	34.25	Negative
37. 0086711	31.34	Positive
38. 0015350	30.4	Positive
39. 0069245	29.48	Positive
40. 0056870	31.20	Positive
41. 0039816	21.86	Positive
42. 0072269	29.58	Positive
43. 0074782	28.75	Positive

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44. 0036379	31.92	Positive
45. 0037934	30.33	Positive
46. 0092980	28.54	Positive
47. 0092460	29.86	Positive
48. 0068916	28.63	Positive
49. 00108609	19.41	Positive
50. 00101096	27.96	Positive
51. 0032686	25.11	Positive
52. 0079511	29.92	Positive
53. 0108000	25.62	Positive
54. 0034393	30.34	Positive
55. 0063387	29.14	Positive
56. 0020636	26.47	Positive
57. 0109941	32.21	Positive
58. 0077617	29.99	Positive
59. 0011570	35.13	Negative
60. 0067518	29.24	Positive
61. 0020005	28.34	Positive
62. 0020302	27.54	Positive
63. 0089888	30.92	Positive
64. 0038448	27.53	Positive
65. 0014564	29.40	Positive
66. 0039577	31.84	Positive
67. 0048201	30.82	Positive
68. 0068335	30.67	Positive
69. 0018071	28.72	Positive
70. 0055797	27.99	Positive

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71. 00100572	29.33	Positive
72. 0036136	26.49	Positive
73. 0088521	28.41	Positive
74. 0047890	30.69	Positive
75. 0038966	27.17	Positive
76. 00101937	32.42	Positive
77. 0073174	29.54	Positive
78. 0072764	28.81	Positive
79. 0052845	29.54	Positive
80. 0019797	34.42	Negative
81. 0066104	30.50	Positive
82. 0079448	29.22	Positive
83. 00101371	33.61	Negative
84. 0093481	27.48	Positive
85. 0012262	30.68	Positive
86. 0064336	22.88	Positive
87. 00101616	31.37	Positive
88. 0053026	27.30	Positive
89. 0077794	25.29	Positive
90. 0060245	31.15	Positive
91. 0061373	29.52	Positive
92. 0056298	30.22	Positive
93. 0045347	28.58	Positive
94. 0050483	30.36	Positive
95. 0036973	27.87	Positive
96. 0015559	26.47	Positive
97. 0034384	29.19	Positive

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98.	00107907	29.68	Positive
99.	0016091	28.74	Positive
100.	0049029	29.61	Positive
101.	0046499	28.78	Positive
102.	0058989	27.16	Positive
103.	0025566	27.80	Positive
104.	0057445	25.20	Positive
105.	0035726	31.95	Positive
106.	0072875	30.6	Positive
107.	0064207	30.6	Positive
108.	0025630	28.79	Positive
109.	00103854	25.37	Positive
110.	0075449	30.46	Positive
111.	0060608	28.11	Positive
112.	0049047	29.11	Positive
113.	0020737	27.17	Positive
114.	0088399	27.4	Positive
115.	0055964	28.71	Positive
116.	0085368	28.53	Positive
117.	0069609	28.56	Positive
118.	0093273	27.21	Positive
119.	0011875	27.46	Positive
120.	0031036	29.74	Positive
121.	0017395	28.75	Positive
122.	0020545	30.39	Positive

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**Total 122 Samples**

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Sample ID	Direct SARS-CoV-2 RT-qPCR	REDCELL Covid 19 Antigen
	Results	Results
1. 0073457	(-)	(-)
2. 0081302	(-)	(-)
3. 0011568	(-)	(-)
4. 0053114	(-)	(-)
5. 0050198	(-)	(-)
6. 0090258	(-)	(-)
7. 0079610	(-)	(-)
8. 0051759	(-)	(-)
9. 0083448	(-)	(-)
10. 0045658	(-)	(-)
11. 0053345	(-)	(-)
12. 0104497	(-)	(-)
13. 0022154	(-)	(-)
14. 0074595	(-)	(-)
15. 0044783	(-)	(-)
16. 0020443	(-)	(-)
17. 0028540	(-)	(-)
18. 0017768	(-)	(-)
19. 0053275	(-)	(-)
20. 0105927	(-)	(-)
21. 0064202	(-)	(-)
22. 0059437	(-)	(-)
23. 0107296	(-)	(-)

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24. 0031779	(-)	(-)
25. 0047899	(-)	(-)
26. 0049584	(-)	(-)
27. 0038150	(-)	(-)
28. 0060337	(-)	(-)
29. 0023873	(-)	(-)
30. 0061725	(-)	(-)
31. 0106536	(-)	(-)
32. 0065750	(-)	(-)
33. 0100920	(-)	(-)
34. 0075725	(-)	(-)
35. 0054111	(-)	(-)
36. 0079299	(-)	(-)
37. 0016449	(-)	(-)
38. 0085609	(-)	(-)
39. 0080051	(-)	(-)
40. 0059707	(-)	(-)
41. 0025543	(-)	(-)
42. 0032373	(-)	(-)
43. 0042614	(-)	(-)
44. 0088448	(-)	(-)
45. 0015026	(-)	(-)
46. 0061801	(-)	(-)
47. 0085702	(-)	(-)
48. 0090066	(-)	(-)
49. 0042520	(-)	(-)
50. 0107272	(-)	(+)

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51. 0090426	(-)	(-)
52. 0077482	(-)	(-)
53. 0100512	(-)	(-)
54. 0097577	(-)	(-)
55. 0051664	(-)	(-)
56. 0022308	(-)	(-)
57. 0105415	(-)	(-)
58. 0089729	(-)	(-)
59. 0079628	(-)	(-)
60. 0050160	(-)	(-)
61. 0011629	(-)	(-)
62. 0026776	(-)	(-)
63. 0026423	(-)	(-)
64. 0020613	(-)	(-)
65. 0050606	(-)	(-)
66. 0074304	(-)	(-)
67. 0094909	(-)	(-)
68. 0059796	(-)	(+)
69. 0028777	(-)	(-)
70. 0099661	(-)	(-)
71. 0047281	(-)	(-)
72. 0042355	(-)	(-)
73. 0087083	(-)	(-)
74. 0031800	(-)	(-)
75. 0054699	(-)	(-)
76. 0033602	(-)	(-)
77. 0097838	(-)	(-)

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78.	0071043	(-)	(-)
79.	0047443	(-)	(-)
80.	0048950	(-)	(-)
81.	0096058	(-)	(-)
82.	0050486	(-)	(-)
83.	0084178	(-)	(-)
84.	0053766	(-)	(-)
85.	0017798	(-)	(-)
86.	0051063	(-)	(-)
87.	0043937	(-)	(-)
88.	0081055	(-)	(-)
89.	0041228	(-)	(-)
90.	0089877	(-)	(-)
91.	0025175	(-)	(-)
92.	0069299	(-)	(-)
93.	0105623	(-)	(-)
94.	0034314	(-)	(-)
95.	0103997	(-)	(-)
96.	0021433	(-)	(-)
97.	0108425	(-)	(-)
98.	0073297	(-)	(-)
99.	0069885	(-)	(-)
100.	0100256	(-)	(-)
101.	0067486	(-)	(-)
102.	0034517	(-)	(-)
103.	0096016	(-)	(-)
104.	0017495	(-)	(-)

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105.	0053882	(-)	(-)
106.	0085997	(-)	(-)
107.	0034567	(-)	(-)
108.	0047860	(-)	(-)
109.	0049724	(-)	(-)
110.	0062657	(-)	(-)
111.	0037035	(-)	(-)
112.	0068117	(-)	(-)
113.	0030969	(-)	(-)
114.	0017870	(-)	(-)
115.	0099544	(-)	(-)
116.	0021143	(-)	(-)
117.	0075237	(-)	(-)
118.	0100033	(-)	(-)
119.	0033159	(-)	(+)
120.	0104990	(-)	(-)
121.	0094618	(-)	(-)
122.	0054121	(-)	(-)
123.	0059200	(-)	(-)
124.	0086950	(-)	(-)
125.	0093489	(-)	(-)
126.	0048256	(-)	(-)
127.	0029553	(-)	(-)
128.	0042615	(-)	(-)
129.	0051323	(-)	(-)
130.	0025267	(-)	(-)
131.	0071983	(-)	(-)

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132.	0103155	(-)	(-)
133.	0079251	(-)	(-)
134.	0060445	(-)	(-)
135.	0028307	(-)	(-)
136.	0109140	(-)	(-)
137.	0057139	(-)	(-)
138.	0010401	(-)	(-)
139.	0052584	(-)	(-)
140.	0038871	(-)	(-)
141.	0085254	(-)	(-)
142.	0099127	(-)	(-)
143.	0092193	(-)	(-)
144.	0027688	(-)	(-)
145.	0020878	(-)	(-)
146.	0011029	(-)	(-)
147.	0025165	(-)	(-)
148.	0047740	(-)	(-)
149.	0028813	(-)	(-)
150.	0107953	(-)	(-)
151.	0097211	(-)	(-)
152.	0068150	(-)	(-)
153.	0082941	(-)	(-)
154.	0024500	(-)	(-)
155.	0035778	(-)	(-)
156.	0012824	(-)	(-)
157.	0092789	(-)	(-)
158.	0088337	(-)	(-)

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159.	0089115	(-)	(-)
160.	0043269	(-)	(-)
161.	0055094	(-)	(-)
162.	0065511	(-)	(-)
163.	0090333	(-)	(-)
164.	0066398	(-)	(-)
165.	0030358	(-)	(-)
166.	0030759	(-)	(-)
167.	0046468	(-)	(-)
168.	0067351	(-)	(-)
169.	0044418	(-)	(-)
170.	0062822	(-)	(-)
171.	0067301	(-)	(-)
172.	0015004	(-)	(-)
173.	0064759	(-)	(-)
174.	0030648	(-)	(-)
175.	0106267	(-)	(-)
176.	00103305	(-)	(-)
177.	0109257	(-)	(-)
178.	0093958	(-)	(-)
179.	0050932	(-)	(-)
180.	0090527	(-)	(-)
181.	0108942	(-)	(-)
182.	0035844	(-)	(-)
183.	0027448	(-)	(-)
184.	0079460	(-)	(-)
185.	0011698	(-)	(-)

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186.	0043909	(-)	(-)
187.	0079254	(-)	(-)
188.	0021038	(-)	(-)
189.	0049887	(-)	(-)
190.	0065902	(-)	(-)
191.	0041095	(-)	(-)
192.	0039558	(-)	(-)
193.	0090794	(-)	(-)
194.	0040961	(-)	(-)
195.	0047581	(-)	(-)
196.	0050103	(-)	(-)
197.	0094142	(-)	(-)
198.	0050959	(-)	(-)
199.	0082455	(-)	(-)
200.	0075876	(-)	(-)
201.	0050638	(-)	(-)
202.	0105033	(-)	(-)
203.	0074557	(-)	(-)
204.	0061608	(-)	(-)
205.	0032332	(-)	(-)
206.	0068275	(-)	(-)
207.	0084853	(-)	(-)
208.	0055647	(-)	(-)
209.	0100437	(-)	(-)
210.	0038301	(-)	(-)
211.	0076753	(-)	(-)
212.	0099012	(-)	(-)

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213.	0038138	(-)	(-)
214.	0046805	(-)	(-)
215.	0011422	(-)	(-)
216.	0039465	(-)	(-)
217.	0108404	(-)	(-)
218.	0086128	(-)	(-)
219.	0068087	(-)	(-)
220.	0070567	(-)	(-)
221.	0036804	(-)	(-)
222.	0060816	(-)	(-)
223.	0089359	(-)	(-)
224.	0095741	(-)	(-)
225.	0019315	(-)	(-)
226.	0064187	(-)	(-)
227.	0051537	(-)	(-)
228.	0017337	(-)	(-)
229.	0055137	(-)	(-)
230.	0079889	(-)	(-)
231.	0059925	(-)	(-)
232.	0050693	(-)	(-)
233.	0104507	(-)	(-)
234.	0108464	(-)	(-)
235.	0069144	(-)	(-)
236.	0063198	(-)	(-)
237.	0071507	(-)	(-)
238.	0018915	(-)	(-)
239.	0028442	(-)	(-)

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240.	0038355	(-)	(-)
241.	0011880	(-)	(-)
242.	0025259	(-)	(-)
243.	0052011	(-)	(-)
244.	0064842	(-)	(-)
245.	0065844	(-)	(-)
246.	0088100	(-)	(-)
247.	0014294	(-)	(-)
248.	0050574	(-)	(-)
249.	0015899	(-)	(-)
250.	0041183	(-)	(-)
251.	0070304	(-)	(-)
252.	0061769	(-)	(-)
253.	0069643	(-)	(-)
254.	0042962	(-)	(-)
255.	0100929	(-)	(-)
256.	0087007	(-)	(-)
257.	0067587	(-)	(-)
258.	0053160	(-)	(-)

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258 Negative Samples

3 False Positives

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