

Clinical Data for Sample Correlation Study

(COVID-19 Antigen Rapid Test Cassette(Oral Fluid))

Product:

COV-2C25B: COVG2007001-T, Exp:2022-07 COVG2007002-T, Exp:2022-07

COVG2007003-T, Exp:2022-07

Sample:

The COVID-19 Antigen Rapid Test Cassette has been evaluated with specimens obtained from the patients. PCR is used as the reference method for the COVID-19 Antigen Rapid Test Cassette(Oral Fluid). Specimens were considered positive if PCR indicated a positive result.

Method:

The assay was performed according to the package insert. Specimens were rated as either positive or negative at 10 minutes. Do not interpret the results after 20 minutes.

Results were presented in table below

Results:

Lot# COVG2007001-T

Method	PCR		Total	
COVID-19 Antigen Rapid Test Cassette(Oral Fluid)	Results	Positive	Negative	Results
	Positive	38	0	38
	Negative	2	324	326
Total Results	40	324	364	

Relative Sensitivity: 95.0% (81.8%-99.1%)* Relative Specificity: 100% (98.53%-100.0%)* Relative accuracy: 99.5% (97.8%-99.9%)* * 95% Confidence Interval

Lot# COVG2007002-T

Method	PCR		Total	
COVID-19 Antigen Rapid Test Cassette(Oral Fluid)	Results	Positive	Negative	Results
	Positive	38	0	38
	Negative	2	324	326
Total Results	40	324	364	

Relative Sensitivity: 95.0% (81.8%-99.1%)* Relative Specificity: 100% (98.53%-100.0%)* Relative accuracy: 99.5% (97.8%-99.9%)*

* 95% Confidence Interval

Lot# COVG2007003-T



570 Hood Road, Unit 23, Markham, ON T: 905-944-9565 F: 905-944-0406

Clinical Study Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) COV-2C25B

Method	PCR	Total		
COVID-19 Antigen Rapid Test Cassette(Oral Fluid)	Results	Positive	Negative	Results
	Positive	38	0	38
	Negative	2	324	326
Total Results	40	324	364	

Relative Sensitivity: 95.0% (81.8%-99.1%)* Relative Specificity: 100% (98.53%-100.0%)* Relative accuracy: 99.5% (97.8%-99.9%)*

* 95% Confidence Interval

Conclusion:

The COVID-19 Antigen Rapid Test Cassette have been calibrated against specimens that have been collected from individuals found to be either PCR positive or negative. The results were showed as blow:

Relative Sensitivity: 95.0% (81.8%-99.1%)*

Relative Specificity: 100% (98.53%-100.0%)*

Relative accuracy: 99.5% (97.8%-99.9%)*

* 95% Confidence Interval

Prepared by: <u>Carrie Lin</u> Date: <u>2020.09.30</u> Review by: <u>Luna Hou</u> Date: <u>2020.09.30</u>



570 Hood Road, Unit 23, Markham, ON T: 905-944-9565 F: 905-944-0406

Clinical Study Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) COV-2C25B

Attachment1: the clinical data showed below that the clinical specimens were evaluated.

					COVID-19 Antigen Rapid
	Specimen	Gender	Age	PCR	Test Cassette(Oral Fluid)
1	Oral fluid	Male	45	Negative	Negative
2	Oral fluid	Male	57	Negative	Negative
3	Oral fluid	Female	69	Negative	Negative
4	Oral fluid	Female	64	Negative	Negative
5	Oral fluid	Female	42	Negative	Negative
6	Oral fluid	Male	52	Negative	Negative
7	Oral fluid	Female	50	Positive	Positive
8	Oral fluid	Male	56	Negative	Negative
9	Oral fluid	Female	64	Negative	Negative
10	Oral fluid	Male	42	Positive	Positive
11	Oral fluid	Male	35	Negative	Negative
12	Oral fluid	Male	65	Negative	Negative
13	Oral fluid	Male	67	Negative	Negative
14	Oral fluid	Male	50	Negative	Negative
15	Oral fluid	Male	36	Negative	Negative
16	Oral fluid	Male	43	Negative	Negative
17	Oral fluid	Male	61	Negative	Negative
18	Oral fluid	Female	56	Negative	Negative
19	Oral fluid	Female	55	Negative	Negative
20	Oral fluid	Female	37	Negative	Negative
21	Oral fluid	Male	63	Negative	Negative
22	Oral fluid	Male	49	Negative	Negative
23	Oral fluid	Male	56	Negative	Negative
24	Oral fluid	Female	20	Positive	Positive
25	Oral fluid	Female	61	Negative	Negative
26	Oral fluid	Male	54	Negative	Negative
27	Oral fluid	Female	56	Negative	Negative
28	Oral fluid	Male	38	Positive	Positive
29	Oral fluid	Female	50	Negative	Negative
30	Oral fluid	Male	52	Negative	Negative
31	Oral fluid	Female	39	Positive	Positive
32	Oral fluid	Male	71	Negative	Negative
33	Oral fluid	Female	72	Negative	Negative
34	Oral fluid	Male	58	Negative	Negative
35	Oral fluid	Male	71	Negative	Negative



r r					
36	Oral fluid	Male	68	Negative	Negative
37	Oral fluid	Female	34	Positive	Positive
38	Oral fluid	Male	54	Negative	Negative
39	Oral fluid	Female	72	Negative	Negative
40	Oral fluid	Female	45	Negative	Negative
41	Oral fluid	Male	63	Negative	Negative
42	Oral fluid	Male	65	Negative	Negative
43	Oral fluid	Male	64	Negative	Negative
44	Oral fluid	Female	68	Negative	Negative
45	Oral fluid	Female	51	Positive	Positive
46	Oral fluid	Male	61	Negative	Negative
47	Oral fluid	Male	40	Negative	Negative
48	Oral fluid	Male	49	Negative	Negative
49	Oral fluid	Male	64	Negative	Negative
50	Oral fluid	Female	59	Negative	Negative
51	Oral fluid	Female	49	Negative	Negative
52	Oral fluid	Female	41	Negative	Negative
53	Oral fluid	Female	36	Negative	Negative
54	Oral fluid	Female	63	Negative	Negative
55	Oral fluid	Male	67	Negative	Negative
56	Oral fluid	Female	71	Negative	Negative
57	Oral fluid	Male	38	Negative	Negative
58	Oral fluid	Female	67	Positive	Positive
59	Oral fluid	Female	69	Negative	Negative
60	Oral fluid	Female	50	Negative	Negative
61	Oral fluid	Male	64	Negative	Negative
62	Oral fluid	Female	37	Negative	Negative
63	Oral fluid	Female	69	Negative	Negative
64	Oral fluid	Female	56	Negative	Negative
65	Oral fluid	Male	43	Negative	Negative
66	Oral fluid	Female	71	Negative	Negative
67	Oral fluid	Female	49	Negative	Negative
68	Oral fluid	Male	37	Negative	Negative
69	Oral fluid	Male	45	Negative	Negative
70	Oral fluid	Male	44	Negative	Negative
71	Oral fluid	Female	56	Negative	Negative
72	Oral fluid	Female	43	Negative	Negative
73	Oral fluid	Male	42	Negative	Negative



		1			
74	Oral fluid	Male	64	Negative	Negative
75	Oral fluid	Female	59	Negative	Negative
76	Oral fluid	Male	56	Negative	Positive
77	Oral fluid	Male	70	Positive	Positive
78	Oral fluid	Male	57	Negative	Negative
79	Oral fluid	Male	39	Negative	Negative
80	Oral fluid	Male	44	Negative	Negative
81	Oral fluid	Female	35	Negative	Negative
82	Oral fluid	Male	68	Negative	Negative
83	Oral fluid	Male	50	Negative	Negative
84	Oral fluid	Female	27	Positive	Positive
85	Oral fluid	Female	63	Negative	Negative
86	Oral fluid	Male	37	Negative	Negative
87	Oral fluid	Male	68	Negative	Negative
88	Oral fluid	Female	59	Negative	Negative
89	Oral fluid	Female	65	Negative	Negative
90	Oral fluid	Male	72	Negative	Negative
91	Oral fluid	Male	53	Negative	Negative
92	Oral fluid	Male	45	Negative	Negative
93	Oral fluid	Male	45	Negative	Negative
94	Oral fluid	Female	49	Negative	Negative
95	Oral fluid	Male	54	Positive	Positive
96	Oral fluid	Male	46	Negative	Negative
97	Oral fluid	Male	35	Negative	Negative
98	Oral fluid	Male	45	Negative	Negative
99	Oral fluid	Female	66	Negative	Negative
100	Oral fluid	Male	40	Negative	Negative
101	Oral fluid	Female	68	Negative	Negative
102	Oral fluid	Female	42	Negative	Negative
103	Oral fluid	Male	53	Negative	Negative
104	Oral fluid	Female	35	Negative	Negative
105	Oral fluid	Female	67	Negative	Negative
106	Oral fluid	Female	70	Negative	Negative
107	Oral fluid	Male	51	Negative	Negative
108	Oral fluid	Female	72	Negative	Negative
109	Oral fluid	Female	58	Negative	Negative
110	Oral fluid	Male	62	Negative	Negative
111	Oral fluid	Female	53	Negative	Negative



r		-		т т	
112	Oral fluid	Female	38	Negative	Negative
113	Oral fluid	Female	41	Negative	Negative
114	Oral fluid	Female	46	Negative	Negative
115	Oral fluid	Female	66	Negative	Negative
116	Oral fluid	Female	47	Negative	Negative
117	Oral fluid	Female	67	Negative	Negative
118	Oral fluid	Male	68	Negative	Negative
119	Oral fluid	Male	43	Negative	Negative
120	Oral fluid	Female	50	Negative	Negative
121	Oral fluid	Male	38	Negative	Negative
122	Oral fluid	Female	37	Negative	Negative
123	Oral fluid	Male	38	Negative	Negative
124	Oral fluid	Female	66	Negative	Negative
125	Oral fluid	Male	35	Negative	Negative
126	Oral fluid	Male	42	Negative	Negative
127	Oral fluid	Male	54	Negative	Negative
128	Oral fluid	Female	22	Positive	Positive
129	Oral fluid	Male	70	Negative	Negative
130	Oral fluid	Male	57	Negative	Negative
131	Oral fluid	Female	37	Negative	Negative
132	Oral fluid	Female	36	Negative	Negative
133	Oral fluid	Male	54	Negative	Negative
134	Oral fluid	Male	56	Negative	Negative
135	Oral fluid	Male	56	Negative	Negative
136	Oral fluid	Female	71	Negative	Negative
137	Oral fluid	Female	52	Negative	Negative
138	Oral fluid	Male	69	Negative	Negative
139	Oral fluid	Male	41	Negative	Negative
140	Oral fluid	Male	36	Negative	Negative
141	Oral fluid	Female	70	Negative	Negative
142	Oral fluid	Male	69	Negative	Negative
143	Oral fluid	Male	49	Negative	Negative
144	Oral fluid	Female	68	Negative	Negative
145	Oral fluid	Male	35	Negative	Negative
146	Oral fluid	Female	69	Negative	Negative
147	Oral fluid	Female	41	Negative	Negative
148	Oral fluid	Female	49	Negative	Negative
149	Oral fluid	Male	37	Negative	Negative



				I I I	
150	Oral fluid	Female	61	Negative	Negative
151	Oral fluid	Male	60	Negative	Negative
152	Oral fluid	Female	56	Negative	Negative
153	Oral fluid	Male	49	Negative	Negative
154	Oral fluid	Female	36	Negative	Negative
155	Oral fluid	Female	36	Positive	Positive
156	Oral fluid	Female	64	Negative	Negative
157	Oral fluid	Male	58	Negative	Negative
158	Oral fluid	Male	67	Negative	Negative
159	Oral fluid	Male	50	Negative	Negative
160	Oral fluid	Male	54	Negative	Negative
161	Oral fluid	Female	35	Negative	Negative
162	Oral fluid	Male	47	Negative	Negative
163	Oral fluid	Male	51	Negative	Negative
164	Oral fluid	Female	58	Negative	Negative
165	Oral fluid	Male	41	Negative	Negative
166	Oral fluid	Male	38	Negative	Negative
167	Oral fluid	Male	41	Negative	Negative
168	Oral fluid	Male	39	Negative	Negative
169	Oral fluid	Male	44	Negative	Negative
170	Oral fluid	Male	49	Negative	Negative
171	Oral fluid	Male	42	Negative	Negative
172	Oral fluid	Female	44	Negative	Negative
173	Oral fluid	Male	35	Negative	Negative
174	Oral fluid	Female	41	Negative	Negative
175	Oral fluid	Female	44	Negative	Negative
176	Oral fluid	Male	56	Negative	Negative
177	Oral fluid	Male	55	Negative	Negative
178	Oral fluid	Female	39	Negative	Negative
179	Oral fluid	Male	49	Negative	Negative
180	Oral fluid	Female	39	Negative	Negative
181	Oral fluid	Female	44	Negative	Negative
182	Oral fluid	Male	59	Negative	Negative
183	Oral fluid	Female	56	Negative	Negative
184	Oral fluid	Male	44	Negative	Negative
185	Oral fluid	Male	50	Negative	Negative
186	Oral fluid	Male	36	Negative	Negative
187	Oral fluid	Male	47	Negative	Negative



188	Oral fluid	Male	38	Negative	Negative
189	Oral fluid	Female	52	Negative	Negative
190	Oral fluid	Male	36	Negative	Negative
191	Oral fluid	Female	43	Negative	Negative
192	Oral fluid	Female	59	Negative	Negative
193	Oral fluid	Male	68	Negative	Negative
194	Oral fluid	Male	60	Negative	Negative
195	Oral fluid	Female	47	Positive	Positive
196	Oral fluid	Male	57	Negative	Negative
197	Oral fluid	Male	45	Negative	Negative
198	Oral fluid	Female	70	Negative	Negative
199	Oral fluid	Female	69	Negative	Negative
200	Oral fluid	Male	62	Positive	Positive
201	Oral fluid	Male	72	Negative	Negative
202	Oral fluid	Female	72	Negative	Negative
203	Oral fluid	Female	41	Negative	Negative
204	Oral fluid	Female	61	Negative	Negative
205	Oral fluid	Female	52	Positive	Positive
206	Oral fluid	Male	54	Negative	Negative
207	Oral fluid	Female	53	Negative	Negative
208	Oral fluid	Female	71	Negative	Negative
209	Oral fluid	Male	39	Negative	Negative
210	Oral fluid	Female	65	Negative	Negative
211	Oral fluid	Male	40	Negative	Negative
212	Oral fluid	Male	41	Positive	Positive
213	Oral fluid	Female	46	Negative	Negative
214	Oral fluid	Female	70	Negative	Negative
215	Oral fluid	Male	52	Negative	Negative
216	Oral fluid	Male	57	Negative	Negative
217	Oral fluid	Male	54	Negative	Negative
218	Oral fluid	Female	41	Negative	Negative
219	Oral fluid	Male	49	Positive	Positive
220	Oral fluid	Female	56	Negative	Negative
221	Oral fluid	Male	57	Negative	Negative
222	Oral fluid	Female	50	Positive	Positive
223	Oral fluid	Male	71	Negative	Negative
224	Oral fluid	Female	45	Negative	Negative
225	Oral fluid	Female	57	Negative	Negative



				Г Г Г	
226	Oral fluid	Female	35	Negative	Negative
227	Oral fluid	Female	58	Negative	Negative
228	Oral fluid	Female	67	Negative	Negative
229	Oral fluid	Male	35	Negative	Negative
230	Oral fluid	Male	42	Negative	Positive
231	Oral fluid	Male	36	Negative	Negative
232	Oral fluid	Female	60	Negative	Negative
233	Oral fluid	Female	68	Negative	Negative
234	Oral fluid	Male	66	Negative	Negative
235	Oral fluid	Male	49	Negative	Negative
236	Oral fluid	Female	56	Negative	Negative
237	Oral fluid	Female	36	Negative	Negative
238	Oral fluid	Female	35	Negative	Negative
239	Oral fluid	Female	72	Negative	Negative
240	Oral fluid	Female	39	Negative	Negative
241	Oral fluid	Female	50	Negative	Negative
242	Oral fluid	Male	72	Negative	Negative
243	Oral fluid	Male	64	Negative	Negative
244	Oral fluid	Female	43	Negative	Negative
245	Oral fluid	Male	60	Negative	Negative
246	Oral fluid	Male	68	Negative	Negative
247	Oral fluid	Male	67	Negative	Negative
248	Oral fluid	Female	63	Negative	Negative
249	Oral fluid	Female	53	Negative	Negative
250	Oral fluid	Female	54	Negative	Negative
251	Oral fluid	Female	53	Negative	Negative
252	Oral fluid	Female	39	Negative	Negative
253	Oral fluid	Male	59	Negative	Negative
254	Oral fluid	Male	48	Negative	Negative
255	Oral fluid	Female	44	Negative	Negative
256	Oral fluid	Male	70	Negative	Negative
257	Oral fluid	Female	52	Negative	Negative
258	Oral fluid	Female	54	Negative	Negative
259	Oral fluid	Male	67	Negative	Negative
260	Oral fluid	Male	36	Negative	Negative
261	Oral fluid	Male	46	Positive	Negative
262	Oral fluid	Male	35	Negative	Negative
263	Oral fluid	Female	36	Negative	Negative



264	Oral fluid	Male	63	Positive	Positive
265	Oral fluid	Male	16	Positive	Positive
266	Oral fluid	Male	65	Negative	Negative
267	Oral fluid	Male	52	Negative	Negative
268	Oral fluid	Male	44	Negative	Negative
269	Oral fluid	Female	44		-
	Oral fluid			Negative	Negative
270		Female	64	Negative	Negative
271	Oral fluid	Female	52	Negative	Negative
272	Oral fluid	Female	69	Positive	Positive
273	Oral fluid	Female	68	Negative	Negative
274	Oral fluid	Male	48	Negative	Negative
275	Oral fluid	Female	55	Positive	Positive
276	Oral fluid	Female	58	Negative	Negative
277	Oral fluid	Female	40	Negative	Negative
278	Oral fluid	Female	63	Negative	Negative
279	Oral fluid	Male	71	Negative	Negative
280	Oral fluid	Male	61	Negative	Negative
281	Oral fluid	Male	54	Negative	Negative
282	Oral fluid	Male	70	Negative	Negative
283	Oral fluid	Male	71	Negative	Negative
284	Oral fluid	Male	47	Negative	Negative
285	Oral fluid	Male	66	Negative	Negative
286	Oral fluid	Female	36	Negative	Negative
287	Oral fluid	Male	60	Negative	Negative
288	Oral fluid	Male	47	Negative	Negative
289	Oral fluid	Male	53	Negative	Negative
290	Oral fluid	Female	56	Negative	Negative
291	Oral fluid	Female	67	Negative	Negative
292	Oral fluid	Male	71	Negative	Negative
293	Oral fluid	Female	61	Negative	Negative
294	Oral fluid	Male	71	Negative	Negative
295	Oral fluid	Female	61	Negative	Negative
296	Oral fluid	Female	49	Negative	Negative
297	Oral fluid	Female	64	Negative	Negative
298	Oral fluid	Male	55	Negative	Negative
299	Oral fluid	Female	50	Negative	Negative
300	Oral fluid	Female	71	Negative	Negative
301	Oral fluid	Male	70	Negative	Negative



302	Oral fluid	Female	53	Negative	Negative
303	Oral fluid	Male	61	Negative	Negative
304	Oral fluid	Female	42	Negative	Negative
305	Oral fluid	Male	58	Negative	Negative
306	Oral fluid	Female	46	Negative	Negative
307	Oral fluid	Male	44	Negative	Negative
308	Oral fluid	Female	34	Positive	Positive
309	Oral fluid	Male	41	Negative	Negative
310	Oral fluid	Male	54	Negative	Negative
311	Oral fluid	Female	51	Negative	Negative
312	Oral fluid	Male	53	Negative	Negative
313	Oral fluid	Male	54	Negative	Negative
314	Oral fluid	Male	36	Negative	Negative
315	Oral fluid	Female	61	Negative	Negative
316	Oral fluid	Female	44	Negative	Negative
317	Oral fluid	Male	52	Negative	Negative
318	Oral fluid	Female	53	Negative	Negative
319	Oral fluid	Female	35	Negative	Negative
320	Oral fluid	Female	44	Negative	Negative
321	Oral fluid	Female	56	Negative	Negative
322	Oral fluid	Female	57	Negative	Negative
323	Oral fluid	Female	52	Negative	Negative
324	Oral fluid	Male	36	Negative	Negative
325	Oral fluid	Female	69	Negative	Negative
326	Oral fluid	Male	37	Negative	Negative
327	Oral fluid	Male	54	Negative	Negative
328	Oral fluid	Female	59	Negative	Negative
329	Oral fluid	Male	70	Negative	Negative
330	Oral fluid	Female	28	Positive	Positive
331	Oral fluid	Male	36	Positive	Positive
332	Oral fluid	Female	72	Negative	Negative
333	Oral fluid	Male	63	Negative	Negative
334	Oral fluid	Male	71	Negative	Negative
335	Oral fluid	Female	70	Positive	Positive
336	Oral fluid	Female	61	Negative	Negative
337	Oral fluid	Female	35	Negative	Negative
338	Oral fluid	Male	63	Negative	Negative
339	Oral fluid	Male	59	Negative	Negative



			-	-	
340	Oral fluid	Female	57	Negative	Negative
341	Oral fluid	Female	66	Negative	Negative
342	Oral fluid	Female	51	Negative	Negative
343	Oral fluid	Female	54	Negative	Negative
344	Oral fluid	Male	64	Negative	Negative
345	Oral fluid	Female	59	Negative	Negative
346	Oral fluid	Female	45	Negative	Negative
347	Oral fluid	Male	46	Negative	Negative
348	Oral fluid	Female	57	Negative	Negative
349	Oral fluid	Male	50	Negative	Negative
350	Oral fluid	Female	62	Positive	Positive
351	Oral fluid	Female	52	Negative	Negative
352	Oral fluid	Male	69	Negative	Negative
353	Oral fluid	Male	66	Negative	Negative
354	Oral fluid	Female	69	Positive	Negative
355	Oral fluid	Female	13	Positive	Positive
356	Oral fluid	Male	58	Positive	Positive
357	Oral fluid	Female	35	Positive	Positive
358	Oral fluid	Female	41	Positive	Positive
359	Oral fluid	Male	38	Positive	Positive
360	Oral fluid	Female	42	Positive	Positive
361	Oral fluid	Female	53	Positive	Positive
362	Oral fluid	Male	62	Positive	Positive
363	Oral fluid	Male	29	Positive	Positive
364	Oral fluid	Male	33	Positive	Positive