



Clinical Evaluation Report of

Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test

1. Purpose

The purpose of this report is to provide information regarding the clinical performance of the “Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test”, compared to the already well-established PCR system, present on world market.

2. Introduction

2.1 Description of qSARS-CoV-2 IgG/IgM Cassette Rapid Test

Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a product for in-vitro analysis of whole blood, serum and plasma, designed to deliver qualitative results for a panel of tests. The resulting complex overflows a nitrocellulose membrane where the specific antigens against IgG or IgM antibodies are immobilized on the test zone and forms the pink to purple line at the “G” or “M” position of the window. The unreacted colloidal gold-labeled antigens react with the antibodies on the control zone and forms the pink to purple line at the “C” position of the window. The intensity and speed at which the color develops depends on the concentration of 2019-nCoV IgG/IgM antibodies in the specimen. The user can get the qualitative result by observing the G/M-line.

Result Interpretation

- ♦ In addition to the presence of C band, if only G line is developed, the test result indicates the presence of IgG anti- SARS-CoV-2 virus; the result is IgG positive or reactive, suggesting late stage primary, early secondary or previous infection.
- ♦ In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-SARS-CoV-2 virus. The result is IgM positive or reactive, suggesting a primary SARS-CoV-2 virus infection.
- ♦ In addition to the presence of C line, both G and M lines are developed, the test indicates for the presence of IgG and IgM anti-SARS-CoV-2 virus. The result is IgG and IgM positive or reactive, suggesting current primary or early secondary SARS-CoV-2 virus infection.
- ♦ If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti-SARS-CoV-2 virus antibodies are detected. The result is negative or non-reactive. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2 virus infection. A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limits of the assay, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.



Product	Lot #	Manufacturer
qSARS-CoV-2 IgG/IgM Cassette Rapid Test	20200131	Cellex Inc.

2.2 Intended Use

The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow immunoassay for the qualitative detection of 2019-nCoV IgM/IgG antibodies in serum, plasma or whole blood specimens. It is intended to be used as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).

3. Clinical Methods

3.1 Performance evaluation of an IVD medical device

Comparative method of Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is done according to the established and standardized guideline NCCLS Evaluation Protocol.

3.2 Clinical Evaluation

Ninety-eight (98) positive serum or plasma samples collected from individuals who were tested positive with an RT-PCR method for SARS-CoV-2 infection and were quarantined in a makeshift hospital were used in this study. These patients, at the time of sample collected, exhibited mild or no clinical symptoms. These samples, along with 180 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test.

Another 30 samples were collected from hospitalized individuals who were clinically confirmed positive and exhibited severe symptoms. These samples, along with 70 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test.

A total of 378 samples were collected for this clinical evaluation test, of which 128 confirmed positive samples and 250 negative samples

Using the NCCLS Evaluation Protocol as a guideline, the following table provides the suggested distribution of sample concentrations:

Sample will be used throughout the study period. The positive and negative coincidence rate will be analysis as following.

	Test Method	Total



		+	-	
Reference Method	+	a	b	a+b
	-	c	d	c+d
Total		a+c	b+d	a+b+c+d

Positive coincidence rate =a/(a+b)*100%

Negative coincidence rate =d/(c+d)*100%

Total coincidence rate =(a+d)/(a+b+c+d)*100%

3.3 Clinical Performance

The conclusion is as below. A very good coincidence rate was found between the two methods. Of the 128 positive samples, one hundred twenty (120) were tested positive with IgG or IgM or both lines. Of the 250 negative samples, two hundred forty one (241) were tested negative.

Taken together, the qSARS-CoV-2 IgG/IgM Rapid Test had a sensitivity and specificity of 93.75% (95% CI: 88.06-97.26%) and 96.40% (95% CI: 92.26-97.78%), respectively.

		qSARS-CoV-2 IgG/IgM Rapid Test				Sub
		IgG+ IgM+	IgG- IgM+	IgG+ IgM-	IgG- IgM-	
PCR & Clinical Status	Pos.	65	46	9	8	128
	Neg.	0	5	4	241	250
Subtotal		65	51	13	249	378

Positive coincidence rate =93.75%

Negative coincidence rate =96.40%

Total coincidence rate =95.50%

4. Conclusion

Method comparison shows good agreement between Cellex and comparative method. Positive coincidence rate is 93.75%, Negative coincidence rate is 96.40%, and Total coincidence rate is 95.50%.

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.



APPENDIX A: TEST DATA OF CLINICAL EVALUATION

No.	qSARS-CoV-2 IgG/IgM Cassette Rapid Test		PCR & Clinical Status	No.	qSARS-CoV-2 IgG/IgM Cassette Rapid Test		PCR & Clinical Status
	IgG	IgM			IgG	IgM	
	1	+			+	+	
3	+	+	+	4	-	-	-
5	-	-	-	6	-	-	-
7	+	-	+	8	-	-	-
9	-	-	-	10	-	-	-
11	-	-	-	12	-	-	-
13	-	-	-	14	-	-	-
15	-	-	-	16	-	-	-
17	+	+	+	18	+	+	+
19	-	+	+	20	+	+	+
21	-	-	-	22	-	-	-
23	-	+	+	24	+	-	+
25	+	-	-	26	-	-	-
27	-	-	-	28	-	-	-
29	+	+	+	30	+	+	+
31	-	-	-	32	-	-	-
33	+	+	+	34	+	+	+
35	-	-	-	36	-	-	-
37	-	-	-	38	-	-	-
39	-	-	-	40	-	-	-
41	-	-	-	42	-	-	-
43	-	-	-	44	-	-	-
45	+	-	+	46	+	+	+
47	-	-	-	48	-	-	-
49	+	+	+	50	-	-	+
51	-	-	-	52	-	-	-
53	-	-	-	54	-	-	-
55	-	-	+	56	+	+	+
57	+	+	+	58	+	+	+
59	-	-	-	60	-	-	-
61	-	+	+	62	-	+	+
63	-	-	-	64	+	-	-
65	-	-	-	66	-	-	-
67	+	+	+	68	+	+	+
69	-	-	-	70	-	-	-
71	-	+	+	72	-	+	+



73	-	-	-	74	-	-	-
75	-	+	-	76	-	-	-
77	-	-	-	78	-	-	-
79	-	-	-	80	-	-	-
81	-	-	-	82	-	-	-
83	-	+	+	84	+	+	+
85	-	-	-	86	-	-	-
87	+	+	+	88	+	+	+
89	-	-	-	90	-	-	-
91	-	-	-	92	-	-	-
93	-	+	+	94	+	-	+
95	-	-	-	96	-	-	-
97	-	-	-	98	-	-	-
99	+	+	+	100	+	+	+
101	-	-	-	102	-	-	-
103	-	-	-	104	-	-	-
105	+	+	+	106	+	+	+
107	-	-	-	108	-	-	-
109	+	+	+	110	+	+	+
111	-	-	-	112	-	-	-
113	+	-	+	114	+	+	+
115	-	-	-	116	-	-	-
117	-	-	-	118	-	-	-
119	-	-	-	120	-	-	-
121	+	+	+	122	-	-	+
123	-	+	-	124	-	-	-
125	-	+	+	126	+	+	+
127	-	-	-	128	-	-	-
129	-	-	-	130	-	-	-
131	-	-	-	132	-	-	-
133	-	-	-	134	-	-	-
135	-	-	-	136	-	-	-
137	-	+	+	138	+	+	+
139	-	-	-	140	-	-	-
141	+	+	+	142	-	+	+
143	-	-	-	144	+	-	-
145	-	-	-	146	-	-	-
147	+	+	+	148	-	+	+
149	-	-	-	150	-	-	-
151	-	-	-	152	-	-	-
153	-	-	+	154	+	+	+
155	-	-	-	156	-	-	-
157	-	-	-	158	-	-	-



159	+	+	+	160	-	+	+
161	-	-	-	162	-	-	-
163	+	+	+	164	-	+	+
165	-	+	-	166	-	-	-
167	-	-	-	168	-	-	-
169	-	-	-	170	-	-	-
171	-	-	-	172	-	-	-
173	-	-	-	174	-	-	-
175	-	+	+	176	+	+	+
177	-	-	-	178	-	-	-
179	+	+	+	180	-	+	+
181	-	-	-	182	-	-	-
183	-	-	-	184	-	-	-
185	-	+	+	186	+	-	+
187	-	-	-	188	-	-	-
189	-	+	+	190	+	+	+
191	+	+	+	192	-	+	+
193	-	-	-	194	-	-	-
195	-	-	-	196	-	-	-
197	-	-	-	198	-	-	-
199	-	-	-	200	-	-	-
201	+	+	+	202	-	-	+
203	-	-	-	204	-	+	-
205	-	+	+	206	+	+	+
207	-	-	-	208	-	-	-
209	-	-	-	210	-	-	-
211	-	-	-	212	-	-	-
213	-	-	-	214	-	-	-
215	-	-	-	216	-	-	-
217	-	+	+	218	+	+	+
219	-	-	-	220	-	-	-
221	+	+	+	222	-	+	+
223	-	+	+	224	+	+	+
225	-	-	-	226	-	-	-
227	-	-	-	228	-	-	-
229	-	-	-	230	-	-	-
231	-	-	-	232	-	-	-
233	-	-	-	234	-	-	-
235	-	-	-	236	-	-	-
237	-	+	+	238	-	+	+
239	+	+	+	240	+	+	+
241	-	-	-	242	-	-	-
243	+	+	+	244	-	+	+



245	-	-	-	246	-	-	-
247	-	-	-	248	+	-	-
249	-	-	-	250	-	-	-
251	-	-	-	252	-	-	-
253	-	-	-	254	-	-	-
255	-	-	+	256	+	+	+
257	-	-	-	258	-	-	-
259	-	-	-	260	-	-	-
261	-	-	-	262	-	-	-
263	-	-	-	264	-	-	-
265	-	-	-	266	-	-	-
267	+	+	+	268	-	-	+
269	-	-	-	270	-	-	-
271	-	+	+	272	-	-	+
273	-	+	-	274	-	-	-
275	-	-	-	276	-	-	-
277	-	-	-	278	-	-	-
279	-	-	-	280	-	-	-
281	-	+	+	282	+	+	+
283	-	+	+	284	+	+	+
285	-	-	-	286	-	-	-
287	+	+	+	288	-	+	+
289	-	-	-	290	-	-	-
291	-	-	-	292	-	-	-
293	+	+	+	294	-	+	+
295	-	-	-	296	-	-	-
297	-	+	+	298	+	+	+
299	-	-	-	300	-	-	-
301	-	-	-	302	-	-	-
303	-	-	-	304	-	-	-
305	-	-	-	306	-	-	-
307	-	-	-	308	-	-	-
309	-	+	+	310	-	+	+
311	-	-	-	312	-	-	-
313	-	+	+	314	-	+	+
315	-	-	-	316	-	-	-
317	-	-	-	318	-	-	-
319	+	+	+	320	+	+	+
321	-	-	-	322	-	-	-
323	-	-	-	324	-	-	-
325	-	+	+	326	+	+	+
327	-	-	-	328	-	-	-
329	-	-	-	330	-	-	-



331	+	+	+	332	+	-	+
333	-	-	-	334	-	-	-
335	-	+	+	336	+	-	+
337	-	-	-	338	-	-	-
339	-	-	-	340	-	-	-
341	-	-	-	342	-	-	-
343	-	-	-	344	-	-	-
345	-	-	-	346	-	-	-
347	+	+	+	348	-	+	+
349	-	-	-	350	-	-	-
351	+	+	+	352	-	+	+
353	-	-	-	354	-	-	-
355	-	-	-	356	-	-	-
357	-	+	+	358	+	+	+
359	-	-	-	360	-	-	-
361	-	+	+	362	+	-	+
363	-	+	+	364	+	+	+
365	-	-	-	366	-	-	-
367	+	+	+	368	-	+	+
369	-	-	-	370	-	-	-
371	-	+	+	372	-	+	+
373	+	+	+	374	+	+	+
375	-	-	-	376	-	-	-
377	-	-	-	378	-	-	-