

Sienna™ COVID-19 IgG/IgM Rapid Test Cassette and Clarity COVIBLOCK™ COVID-19 IgG/IgM Antibody Test Negative Agreement Study Results (Pre-Pandemic)

Method:

The specificity of the **Sienna™ COVID-19 IgG/IgM Rapid Test Cassette** and **Clarity COVIBLOCK™ COVID-19 IgG/IgM Antibody Test** was evaluated using a total of 220 plasma/ serum samples collected from individuals, before the COVID-19 outbreak.

In the first study, 80 presumed negative plasma samples collected within the US, before October 2019 were tested; 30 presumed negative plasma samples collected within Cote d-Ivoire, in 2016 were tested; 58 presumed negative plasma samples collected within Uganda, in 1995 were tested. Testing were performed at the Washington University School of Medicine.

In the second study, 52 presumed negative serum sample collected within France, between October and November 2019, were tested. Within the 58 negative samples, there were 18 *CMV* positive, 2 *229E* positive, 6 *NL63* positive, 4 *OC43*, and 1 *MPV* positive samples.

Testing were performed as per the instructions provided in the product insert(s).

Results:

Table 1

Origin	Matrix	No. of Samples	IgM (-)	IgG (-)	IgM and IgG (-)
United States	Plasma	80	79 (79/80= 98.75%)	80 (80/80= 100%)	79 (79/80= 98.75%)
Cote d-Ivoire	Plasma	30	29 (29/30= 96.67%)	30 (30/30= 100%)	29 (29/30= 96.67%)
Uganda	Plasma	58	52 (52/58= 89.66%)	58 (58/58= 100%)	52 (52/58= 89.66%)
France	Serum	52	51 (51/52= 98.08%)	52 (52/52= 100%)	51 (51/52= 98.08%)
Total:		220	211	220	211
Negative Agreement:			95.91%	100%	95.91%

COVID-19 IgG/IgM Antibody Test Negative Agreement Result Summary (Pre-Pandemic Samples)

Conclusion

Based on the study results, it was determined that the Sienna™ COVID-19 IgG/IgM Rapid Test Cassette and Clarity COVIBLOCK™ COVID-19 IgG/IgM Antibody Test demonstrated:

- IgM negative agreement, of 95.91% for pre-pandemic samples.
- IgG negative agreement, of 100% for pre-pandemic samples.

Within the 18 *CMV* positive, 2 *229E* positive, 6 *NL63* positive, 4 *OC43*, and 1 *MPV* positive samples, none displayed a positive result with the COVID-19 IgG/IgM Antibody Test.

Raw Data:

Table 2

Item No.	Sample ID	Sample type	Expected IgM Test Result	IgM Test Result	Expected IgG Test Result	IgG Test Result	Origin	Date of Sample Collection	Notes
1	WAb013	Plasma	-	-	-	-	United States	Before Oct 2019	
2	WAb021	Plasma	-	-	-	-	United States	Before Oct 2019	
3	WAb023	Plasma	-	-	-	-	United States	Before Oct 2019	
4	WAb024	Plasma	-	-	-	-	United States	Before Oct 2019	
5	WAb026	Plasma	-	-	-	-	United States	Before Oct 2019	
6	WAb037	Plasma	-	-	-	-	United States	Before Oct 2019	
7	WAb046	Plasma	-	-	-	-	United States	Before Oct 2019	
8	WAb049	Plasma	-	-	-	-	United States	Before Oct 2019	
9	WAb050	Plasma	-	-	-	-	United States	Before Oct 2019	
10	WAb066	Plasma	-	+	-	-	United States	Before Oct 2019	
11	WAb075	Plasma	-	-	-	-	United States	Before Oct 2019	
12	WAb082	Plasma	-	-	-	-	United States	Before Oct 2019	
13	WAb084	Plasma	-	-	-	-	United States	Before Oct 2019	
14	WAb088	Plasma	-	-	-	-	United States	Before Oct 2019	
15	WAb108	Plasma	-	-	-	-	United States	Before Oct 2019	
16	WAb121	Plasma	-	-	-	-	United States	Before Oct 2019	
17	WAb124	Plasma	-	-	-	-	United States	Before Oct 2019	
18	WAb127	Plasma	-	-	-	-	United States	Before Oct 2019	
19	WAb134	Plasma	-	-	-	-	United States	Before Oct 2019	
20	WAb136	Plasma	-	-	-	-	United States	Before Oct 2019	
21	WAb137	Plasma	-	-	-	-	United States	Before Oct 2019	
22	WAb138	Plasma	-	-	-	-	United States	Before Oct 2019	
23	WAb152	Plasma	-	-	-	-	United States	Before Oct 2019	
24	WAb168	Plasma	-	-	-	-	United States	Before Oct 2019	
25	WAb193	Plasma	-	-	-	-	United States	Before Oct 2019	
26	WAb197	Plasma	-	-	-	-	United States	Before Oct 2019	
27	WAb216	Plasma	-	-	-	-	United States	Before Oct 2019	
28	WAb227	Plasma	-	-	-	-	United States	Before Oct 2019	
29	WAb231	Plasma	-	-	-	-	United States	Before Oct 2019	
30	WAb234	Plasma	-	-	-	-	United States	Before Oct 2019	
31	WAb235	Plasma	-	-	-	-	United States	Before Oct 2019	
32	WAb255	Plasma	-	-	-	-	United States	Before Oct 2019	

Item No.	Sample ID	Sample type	Expected IgM Test Result	IgM Test Result	Expected IgG Test Result	IgG Test Result	Origin	Date of Sample Collection	Notes
33	WAb256	Plasma	-	-	-	-	United States	Before Oct 2019	
34	WAb270	Plasma	-	-	-	-	United States	Before Oct 2019	
35	WAb272	Plasma	-	-	-	-	United States	Before Oct 2019	
36	WAb274	Plasma	-	-	-	-	United States	Before Oct 2019	
37	WAb293	Plasma	-	-	-	-	United States	Before Oct 2019	
38	WAb301	Plasma	-	-	-	-	United States	Before Oct 2019	
39	WAb304	Plasma	-	-	-	-	United States	Before Oct 2019	
40	WAb320	Plasma	-	-	-	-	United States	Before Oct 2019	
41	WAb325	Plasma	-	-	-	-	United States	Before Oct 2019	
42	WAb336	Plasma	-	-	-	-	United States	Before Oct 2019	
43	WAb337	Plasma	-	-	-	-	United States	Before Oct 2019	
44	WAb340	Plasma	-	-	-	-	United States	Before Oct 2019	
45	WAb341	Plasma	-	-	-	-	United States	Before Oct 2019	
46	WAb350	Plasma	-	-	-	-	United States	Before Oct 2019	
47	WAb355	Plasma	-	-	-	-	United States	Before Oct 2019	
48	WAb357	Plasma	-	-	-	-	United States	Before Oct 2019	
49	WAb360	Plasma	-	-	-	-	United States	Before Oct 2019	
50	WAb368	Plasma	-	-	-	-	United States	Before Oct 2019	
51	WAb370	Plasma	-	-	-	-	United States	Before Oct 2019	
52	WAb374	Plasma	-	-	-	-	United States	Before Oct 2019	
53	WAb377	Plasma	-	-	-	-	United States	Before Oct 2019	
54	WAb390	Plasma	-	-	-	-	United States	Before Oct 2019	
55	WAb395	Plasma	-	-	-	-	United States	Before Oct 2019	
56	WAb396	Plasma	-	-	-	-	United States	Before Oct 2019	
57	WAb404	Plasma	-	-	-	-	United States	Before Oct 2019	
58	WAb412	Plasma	-	-	-	-	United States	Before Oct 2019	
59	WAb004	Plasma	-	-	-	-	United States	Before Oct 2019	
60	WAb032	Plasma	-	-	-	-	United States	Before Oct 2019	
61	WAb033	Plasma	-	-	-	-	United States	Before Oct 2019	
62	WAb039	Plasma	-	-	-	-	United States	Before Oct 2019	
63	WAb057	Plasma	-	-	-	-	United States	Before Oct 2019	
64	WAb058	Plasma	-	-	-	-	United States	Before Oct 2019	
65	WAb104	Plasma	-	-	-	-	United States	Before Oct 2019	
66	WAb109	Plasma	-	-	-	-	United States	Before Oct 2019	
67	WAb122	Plasma	-	-	-	-	United States	Before Oct 2019	

Item No.	Sample ID	Sample type	Expected IgM Test Result	IgM Test Result	Expected IgG Test Result	IgG Test Result	Origin	Date of Sample Collection	Notes
68	WAb126	Plasma	-	-	-	-	United States	Before Oct 2019	
69	WAb153	Plasma	-	-	-	-	United States	Before Oct 2019	
70	WAb154	Plasma	-	-	-	-	United States	Before Oct 2019	
71	WAb161	Plasma	-	-	-	-	United States	Before Oct 2019	
72	WAb171	Plasma	-	-	-	-	United States	Before Oct 2019	
73	WAb177	Plasma	-	-	-	-	United States	Before Oct 2019	
74	WAb187	Plasma	-	-	-	-	United States	Before Oct 2019	
75	WAb218	Plasma	-	-	-	-	United States	Before Oct 2019	
76	WAb305	Plasma	-	-	-	-	United States	Before Oct 2019	
77	WAb344	Plasma	-	-	-	-	United States	Before Oct 2019	
78	WAb351	Plasma	-	-	-	-	United States	Before Oct 2019	
79	WAb375	Plasma	-	-	-	-	United States	Before Oct 2019	
80	WAb416	Plasma	-	-	-	-	United States	Before Oct 2019	
81	WAb002	Plasma	-	-	-	-	Cote d-Ivoire	2016	
82	WAb005	Plasma	-	-	-	-	Cote d-Ivoire	2016	
83	WAb036	Plasma	-	-	-	-	Cote d-Ivoire	2016	
84	WAb043	Plasma	-	-	-	-	Cote d-Ivoire	2016	
85	WAb051	Plasma	-	-	-	-	Cote d-Ivoire	2016	
86	WAb063	Plasma	-	-	-	-	Cote d-Ivoire	2016	
87	WAb068	Plasma	-	+	-	-	Cote d-Ivoire	2016	
88	WAb074	Plasma	-	-	-	-	Cote d-Ivoire	2016	
89	WAb081	Plasma	-	-	-	-	Cote d-Ivoire	2016	
90	WAb087	Plasma	-	-	-	-	Cote d-Ivoire	2016	
91	WAb132	Plasma	-	-	-	-	Cote d-Ivoire	2016	
92	WAb143	Plasma	-	-	-	-	Cote d-Ivoire	2016	
93	WAb180	Plasma	-	-	-	-	Cote d-Ivoire	2016	
94	WAb182	Plasma	-	-	-	-	Cote d-Ivoire	2016	
95	WAb189	Plasma	-	-	-	-	Cote d-Ivoire	2016	
96	WAb209	Plasma	-	-	-	-	Cote d-Ivoire	2016	
97	WAb219	Plasma	-	-	-	-	Cote d-Ivoire	2016	
98	WAb220	Plasma	-	-	-	-	Cote d-Ivoire	2016	
99	WAb226	Plasma	-	-	-	-	Cote d-Ivoire	2016	
100	WAb240	Plasma	-	-	-	-	Cote d-Ivoire	2016	
101	WAb242	Plasma	-	-	-	-	Cote d-Ivoire	2016	
102	WAb245	Plasma	-	-	-	-	Cote d-Ivoire	2016	

Item No.	Sample ID	Sample type	Expected IgM Test Result	IgM Test Result	Expected IgG Test Result	IgG Test Result	Origin	Date of Sample Collection	Notes
103	WAb262	Plasma	-	-	-	-	Cote d-Ivoire	2016	
104	WAb308	Plasma	-	-	-	-	Cote d-Ivoire	2016	
105	WAb327	Plasma	-	-	-	-	Cote d-Ivoire	2016	
106	WAb381	Plasma	-	-	-	-	Cote d-Ivoire	2016	
107	WAb384	Plasma	-	-	-	-	Cote d-Ivoire	2016	
108	WAb385	Plasma	-	-	-	-	Cote d-Ivoire	2016	
109	WAb398	Plasma	-	-	-	-	Cote d-Ivoire	2016	
110	WAb414	Plasma	-	-	-	-	Cote d-Ivoire	2016	
111	WAb003	Plasma	-	-	-	-	Uganda	1995	
112	WAb014	Plasma	-	+	-	-	Uganda	1995	
113	WAb027	Plasma	-	-	-	-	Uganda	1995	
114	WAb035	Plasma	-	-	-	-	Uganda	1995	
115	WAb042	Plasma	-	-	-	-	Uganda	1995	
116	WAb053	Plasma	-	+	-	-	Uganda	1995	
117	WAb054	Plasma	-	-	-	-	Uganda	1995	
118	WAb062	Plasma	-	+	-	-	Uganda	1995	
119	WAb070	Plasma	-	-	-	-	Uganda	1995	
120	WAb072	Plasma	-	-	-	-	Uganda	1995	
121	WAb079	Plasma	-	-	-	-	Uganda	1995	
122	WAb090	Plasma	-	-	-	-	Uganda	1995	
123	WAb091	Plasma	-	-	-	-	Uganda	1995	
124	WAb092	Plasma	-	-	-	-	Uganda	1995	
125	WAb094	Plasma	-	-	-	-	Uganda	1995	
126	WAb096	Plasma	-	+	-	-	Uganda	1995	
127	WAb101	Plasma	-	-	-	-	Uganda	1995	
128	WAb131	Plasma	-	-	-	-	Uganda	1995	
129	WAb140	Plasma	-	-	-	-	Uganda	1995	
130	WAb148	Plasma	-	-	-	-	Uganda	1995	
131	WAb166	Plasma	-	-	-	-	Uganda	1995	
132	WAb170	Plasma	-	-	-	-	Uganda	1995	
133	WAb200	Plasma	-	-	-	-	Uganda	1995	
134	WAb207	Plasma	-	-	-	-	Uganda	1995	
135	WAb213	Plasma	-	-	-	-	Uganda	1995	
136	WAb230	Plasma	-	-	-	-	Uganda	1995	
137	WAb243	Plasma	-	-	-	-	Uganda	1995	

Item No.	Sample ID	Sample type	Expected IgM Test Result	IgM Test Result	Expected IgG Test Result	IgG Test Result	Origin	Date of Sample Collection	Notes
138	WAb247	Plasma	-	-	-	-	Uganda	1995	
139	WAb250	Plasma	-	-	-	-	Uganda	1995	
140	WAb259	Plasma	-	-	-	-	Uganda	1995	
141	WAb266	Plasma	-	-	-	-	Uganda	1995	
142	WAb275	Plasma	-	-	-	-	Uganda	1995	
143	WAb282	Plasma	-	-	-	-	Uganda	1995	
144	WAb283	Plasma	-	-	-	-	Uganda	1995	
145	WAb284	Plasma	-	-	-	-	Uganda	1995	
146	WAb286	Plasma	-	-	-	-	Uganda	1995	
147	WAb294	Plasma	-	-	-	-	Uganda	1995	
148	WAb302	Plasma	-	-	-	-	Uganda	1995	
149	WAb306	Plasma	-	-	-	-	Uganda	1995	
150	WAb307	Plasma	-	-	-	-	Uganda	1995	
151	WAb328	Plasma	-	-	-	-	Uganda	1995	
152	WAb330	Plasma	-	+	-	-	Uganda	1995	
153	WAb331	Plasma	-	-	-	-	Uganda	1995	
154	WAb339	Plasma	-	-	-	-	Uganda	1995	
155	WAb358	Plasma	-	-	-	-	Uganda	1995	
156	WAb364	Plasma	-	-	-	-	Uganda	1995	
157	WAb365	Plasma	-	+	-	-	Uganda	1995	
158	WAb372	Plasma	-	-	-	-	Uganda	1995	
159	WAb379	Plasma	-	-	-	-	Uganda	1995	
160	WAb388	Plasma	-	-	-	-	Uganda	1995	
161	WAb389	Plasma	-	-	-	-	Uganda	1995	
162	WAb391	Plasma	-	-	-	-	Uganda	1995	
163	WAb392	Plasma	-	-	-	-	Uganda	1995	
164	WAb406	Plasma	-	-	-	-	Uganda	1995	
165	WAb408	Plasma	-	-	-	-	Uganda	1995	
166	WAb418	Plasma	-	-	-	-	Uganda	1995	
167	WAb435	Plasma	-	-	-	-	Uganda	1995	
168	WAb436	Plasma	-	-	-	-	Uganda	1995	
169	FRN001	Serum	-	-	-	-	France	Oct to Nov 2019	229E Positive
170	FRN002	Serum	-	-	-	-	France	Oct to Nov 2019	OC43 Positive
171	FRN003	Serum	-	-	-	-	France	Oct to Nov 2019	
172	FRN004	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive

Item No.	Sample ID	Sample type	Expected IgM Test Result	IgM Test Result	Expected IgG Test Result	IgG Test Result	Origin	Date of Sample Collection	Notes
173	FRN005	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
174	FRN006	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
175	FRN007	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
176	FRN008	Serum	-	-	-	-	France	Oct to Nov 2019	NL63 Positive
177	FRN009	Serum	-	-	-	-	France	Oct to Nov 2019	
178	FRN010	Serum	-	-	-	-	France	Oct to Nov 2019	
179	FRN011	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
180	FRN012	Serum	-	-	-	-	France	Oct to Nov 2019	OC43 Positive
181	FRN013	Serum	-	-	-	-	France	Oct to Nov 2019	
182	FRN014	Serum	-	-	-	-	France	Oct to Nov 2019	NL63 Positive
183	FRN015	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
184	FRN016	Serum	-	-	-	-	France	Oct to Nov 2019	
185	FRN017	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
186	FRN018	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
187	FRN019	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
188	FRN020	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
189	FRN021	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
190	FRN022	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
191	FRN023	Serum	-	-	-	-	France	Oct to Nov 2019	NL63 Positive
192	FRN024	Serum	-	-	-	-	France	Oct to Nov 2019	NL63 Positive
193	FRN025	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
194	FRN026	Serum	-	-	-	-	France	Oct to Nov 2019	OC43/ MPV Positive
195	FRN027	Serum	-	-	-	-	France	Oct to Nov 2019	OC43 Positive
196	FRN028	Serum	-	-	-	-	France	Oct to Nov 2019	229E Positive
197	FRN029	Serum	-	-	-	-	France	Oct to Nov 2019	NL63 Positive
198	FRN030	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
199	FRN031	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
200	FRN032	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
201	FRN033	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
202	FRN034	Serum	-	-	-	-	France	Oct to Nov 2019	NL63 Positive
203	FRN035	Serum	-	-	-	-	France	Oct to Nov 2019	CMV Positive
204	FRN036	Serum	-	-	-	-	France	Oct to Nov 2019	
205	FRN037	Serum	-	-	-	-	France	Oct to Nov 2019	
206	FRN038	Serum	-	-	-	-	France	Oct to Nov 2019	
207	FRN039	Serum	-	-	-	-	France	Oct to Nov 2019	

Item No.	Sample ID	Sample type	Expected IgM Test Result	IgM Test Result	Expected IgG Test Result	IgG Test Result	Origin	Date of Sample Collection	Notes
208	FRN040	Serum	-	-	-	-	France	Oct to Nov 2019	
209	FRN041	Serum	-	-	-	-	France	Oct to Nov 2019	
210	FRN042	Serum	-	-	-	-	France	Oct to Nov 2019	
211	FRN043	Serum	-	-	-	-	France	Oct to Nov 2019	
212	FRN044	Serum	-	-	-	-	France	Oct to Nov 2019	
213	FRN045	Serum	-	-	-	-	France	Oct to Nov 2019	
214	FRN046	Serum	-	-	-	-	France	Oct to Nov 2019	
215	FRN047	Serum	-	-	-	-	France	Oct to Nov 2019	
216	FRN048	Serum	-	-	-	-	France	Oct to Nov 2019	
217	FRN049	Serum	-	-	-	-	France	Oct to Nov 2019	
218	FRN050	Serum	-	-	-	-	France	Oct to Nov 2019	
219	FRN051	Serum	-	-	-	-	France	Oct to Nov 2019	
220	FRN052	Serum	-	+	-	-	France	Oct to Nov 2019	

Study results of the COVID-19 IgG/IgM Antibody Test, when tested with 220 presumed negative plasma/ serum samples collected before the COVID-19 outbreak in the United States, Uganda, Cote d-Ivoire, and France. All samples were presumed negative samples, hence, all expected results are negative for SARS-CoV-2 IgG and IgM Antibody.