

# **Performance Evaluation Report**

Revision

01

Form No.

# **COVID-19 IgM/IgG Antibody Test Performance** Evaluation Report

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## **Purpose**

To evaluate the sensitivity of Artron's COVID-19 IgM/IgG antibody (Ab) rapid diagnostic test device (RDT).

## **Materials**

- 1. Artron COVID-19 IgM/IgG Ab RDT
- 2. Company A and Company B COVID-19 Ab RDT
- 3. Provided buffers
- 4. Healthy human serum samples (COVID-19 Ab negative)
- 5. COVID-19 Ab positive human serum/plasma samples, confirmed by PCR and CT.

### **Method**

#### 1. Test Procedures

- 1.1. All test procedures were performed according to each manufacturer's inserts. Please refer to the manufacturers' inserts for further details.
- 1.2. Add 10 $\mu$ L of serum/plasma sample or 20 $\mu$ L of whole blood sample with 2 drops of provided loading buffer.
- 1.3. All positive results and pictures were recorded at 15 minutes after adding the sample; all negative results and pictures were recorded at 30 minutes after adding the sample.
- 1.4. Results were interpreted as directed by the each manufacturer's inserts.

#### **Test Results and Analysis**

1. A comparison of Artron's COVID-19 IgM/IgG Ab RDT against Company A and Company B's COVID-19 Ab RDTs with COVID-19 positive and negative serum.



Figure 1. Comparison between Artron, Company A, and Company B's COVID-19 Ab RDTs with positive COVID-19 IgM/IgG serums. Artron's T1 test line indicates an IgG test line while T2 indicates an IgM test line. Company A's test line represents IgG/IgM, and Company B separates the tests into two test strips with the left being IgM and right being IgG. The number at the bottom indicates the serum number.



Figure 2. Five additional tests were performed comparing positive serums between Artron, Company A and Company B's COVID-19 RDT. Artron T1 test line indicates an IgG test line while T2 indicates an IgM test line. Company A's test line is IgG/IgM, and Company B separates the test into two test strips with the left being IgM and right being IgG. The number at the bottom indicates the serum number.

From Figure 1, all three companies' COVID-19 Ab RDTs were able to detect both IgG and IgM with sample #7 and #45, but Artron was able to detect them with stronger signals. While Company A had comparable signal strength, it lacks the differential ability to detect IgM and IgG separately. Company B had weaker signals overall, especially in sample #45 for IgG, where the test line was not readily prevalent compared to the test line that is seen in the other two companies. Figure 2 shows additional five tests that were done to compare the test performance between the three companies. All five tests were done with COVID-19-positive serums but we were unable to confirm the immunoglobulin types such as IgM and IgG. Interestingly, while Artron's RDT could detect all the five tests for both IgM and IgG, Company A and Company B were both unable to detect IgM/IgG at #3, #4, and #5 serum samples. Furthermore, Company B could not detect IgM at #1 and #2 serum samples.

# 2. A comparison of Artron's COVID-19 IgM/IgG Ab RDT against COVID-19 antibodies chemiluminescent immunoassay (CLIA) with COVID-19positive and negative serum.

Sample #	Date of infection	Date of symptoms appearance	Date of specimen collection	Date of testing	RT- PCR results	COVID-19 antibodies chemiluminescent immunoassay results		Artron COVID-19 rapid test results	
						Serum	/Plasma	Serum/I	Plasma
						IgM	IgG	IgM	IgG
SX1		2020/1/29	2020/2/7	3/12/2020	+	3.30	16.74	+	+
SX2		2020/1/20	2020/2/7	3/12/2020	+	16.78	47.08	+	+
SX3	2020/1/22	2020/1/27	2020/2/7	3/12/2020	+	0.15	0.36	-	-
SX4		2020/1/25	2020/2/7	3/12/2020	+	3.64	15.41	+	+
SX5		2020/1/25	2020/2/7	3/12/2020	+	2.50	0.60	+	-
SX6		2020/1/21	2020/2/7	3/12/2020	+	13.56	117.26	+	+
SX7		2020/1/29	2020/2/7	3/12/2020	+	40.36	37.28	+	+
SX8		2020/1/22	2020/2/7	3/12/2020	+	12.87	11.82	+	+
SX9	2020/1/18	2020/1/25	2020/2/7	3/12/2020	+	1.43	6.19	-	+
SX10		2020/2/3	2020/2/7	3/12/2020	+	0.17	0.56	-	-
SX11	2020/1/22	2020/2/4	2020/2/7	3/12/2020	+	0.18	0.36	-	-
SX12		2020/1/31	2020/2/7	3/12/2020	+	7.95	141.48	+	+
SX13		2020/1/24	2020/2/7	3/12/2020	+	2.04	7.38	+	+
SX14		2020/1/24	2020/2/7	3/12/2020	+	2.17	35.90	+	+
SX15	2020/1/16	2020/1/19	2020/2/7	3/12/2020	+	20.20	3.42	+	+
SX16	2020/1/10	2020/1/24	2020/2/7	3/12/2020	+	0.84	1.06	-	+
SX17	2020/1/19	2020/1/24	2020/2/7	3/12/2020	+	10.03	0.61	+	-
SX18		2020/1/22	2020/2/7	3/12/2020	+	19.08	14.18	+	+
SX19	2020/1/18	2020/1/24	2020/2/7	3/12/2020	+	2.23	4.64	+	+
SX20		2020/1/30	2020/2/7	3/12/2020	+	4.81	0.66	+	+
SX21		2020/1/22	2020/2/7	3/12/2020	+	0.45	8.99	+	+
SX22		2020/1/25	2020/2/7	3/12/2020	+	7.91	6.79	+	+
SX23		2020/1/22	2020/2/7	3/12/2020	+	14.40	7.48	+	+
SX24		2020/1/26	2020/2/7	3/12/2020	+	5.05	27.98	+	+

SX25	2020/1/21	2020/1/21	2020/2/7	3/12/2020	+	2.22	14.24	+	+
SX26		2020/1/28	2020/2/7	3/12/2020	+	0.18	2.16	-	-
SX27	2020/1/15	2020/1/20	2020/2/7	3/12/2020	+	12.72	156.13	+	+
SX28		2020/1/17	2020/2/7	3/12/2020	+	21.52	29.65	+	+
SX29		2020/1/21	2020/2/7	3/12/2020	+	4.60	69.23	+	+
SX30	2020/1/11	2020/1/23	2020/2/7	3/12/2020	+	1.57	15.65	+	+
SX31		2020/2/1	2020/2/7	3/12/2020	+	0.24	0.44	-	-
SX32		2020/1/20	2020/2/7	3/12/2020	+	24.95	152.40	+	+
SX33	2020/1/19	2020/1/22	2020/2/7	3/12/2020	+	0.85	10.12	+	+
SX34		2020/1/23	2020/2/7	3/12/2020	+	11.27	39.92	+	+
SX35		2020/1/28	2020/2/7	3/12/2020	+	40.30	1.32	+	+
SX36		2020/1/25	2020/2/7	3/12/2020	+	5.35	17.81	+	+
SX37	2020/1/12	2020/2/2	2020/2/7	3/12/2020	+	7.29	8.17	+	+
SX38		2020/1/20	2020/2/7	3/12/2020	+	24.64	15.73	+	+
SX39	2020/1/20		2020/2/7	3/12/2020	+	5.44	33.39	+	+
SX40		2020/1/27	2020/2/7	3/12/2020	+	2.19	9.63	+	+
SX41		2020/1/24	2020/2/7	3/12/2020	+	27.81	232.04	+	+
SX42		2020/1/31	2020/2/7	3/12/2020	+	0.17	0.31	-	-
SX43	2020/1/22		2020/2/7	3/12/2020	+	0.19	13.72	-	+
SX44		2020/1/26	2020/2/7	3/12/2020	+	7.40	172.01	+	+
SX45	2020/1/19	2020/1/24	2020/2/7	3/12/2020	+	0.61	106.89	-	+
SX46		2020/1/26	2020/2/7	3/12/2020	+	6.08	7.69	-	+
SX47		2020/1/24	2020/2/7	3/12/2020	+	3.39	8.05	-	+
SX48		2020/1/23	2020/2/7	3/12/2020	+	3.06	3.27	+	+
SX49		2020/1/21	2020/2/7	3/12/2020	+	18.46	2.73	+	+
SX50		2020/1/24	2020/2/7	3/12/2020	+	17.68	1.63	+	+
SX51		2020/1/19	2020/2/7	3/12/2020	+	18.39	10.74	+	+
SX52		2020/1/30	2020/2/7	3/12/2020	+	0.94	0.92	-	-
SX53		2020/1/22	2020/2/7	3/12/2020	+	2.37	2.08	+	+
SX54		2020/1/21	2020/2/7	3/12/2020	+	33.01	17.63	+	+
SX55		2020/1/21	2020/2/7	3/12/2020	+	2.59	44.25	+	+
SX56		2020/1/26	2020/2/7	3/12/2020	+	4.13	18.47	-	+
SX57		2020/1/20	2020/2/7	3/12/2020	+	4.13	70.94	+	+
SX58	2020/1/17	2020/1/17	2020/2/7	3/12/2020	+	2.87	77.23	+	+
SX59	2020/1/21	2020/1/29	2020/2/7	3/12/2020	+	0.28	2.17	-	-
SX60	2020/1/18	2020/1/25	2020/2/7	3/12/2020	+	15.23	7.77	+	+
SX61		2020/1/17	2020/2/7	3/12/2020	+	6.39	141.65	+	+
SX62	2020/1/19		2020/2/7	3/12/2020	+	0.49	0.36	-	-
SX63		2020/1/26	2020/2/7	3/12/2020	+	20.63	27.51	+	+
SX64		2020/1/19	2020/2/7	3/12/2020	+	14.38	60.97	+	+
SX65		2020/1/21	2020/2/7	3/12/2020	+	0.73	12.76	-	+
SX66		2020/1/28	2020/2/7	3/12/2020	+	1.79	72.26	+	+
SX67	2020/1/18	2020/2/2	2020/2/7	3/12/2020	+	0.50	2.24	-	-
SX68		2020/2/4	2020/2/7	3/12/2020	+	0.22	0.37	-	-
SX69	2020/1/16	2020/1/27	2020/2/7	3/12/2020	+	13.67	1.02	-	-
SX70	2020/1/28	2020/1/29	2020/2/7	3/12/2020	+	10.07	2.94	+	+
SX71		2020/1/30	2020/2/7	3/12/2020	+	9.07	132.87	-	+

SX72		2020/1/22	2020/2/7	3/12/2020	+	2.50	7.01	+	+
SX73		2020/1/21	2020/2/7	3/12/2020	+	22.45	3.80	-	+
SX74	2020/1/22	2020/2/1	2020/2/7	3/12/2020	+	0.37	4.33	-	+
SX75		2020/2/4	2020/2/7	3/12/2020	+	2.06	2.99	+	+
SX76		2020/1/24	2020/2/7	3/12/2020	+	6.80	40.15	+	+

\* Note: samples were positive if the reading of the CLIA result was more than 1.

A total of 76 samples were evaluated for sensitivity and specificity. Chemiluminescent immunoassay (CLIA) was used as a reference method. The results showed that Artron COVID-19 IgM/IgG Antibody Test had a good correlation with CLIA.

#### 2. Positive samples

lgG	c E		C F	C -	с — 1	c	C -	C 12	C - 1 -	C - 1 2 -
IgM	2	2	20	2	2	2	20		20	- )
Sample No	#251	#252	#253	#254	#255	#256	#257	#258	#259	#260
Color IgG	9	3	5	0	0	0	4	7	6	0
Density IgM	4	0	3	4	6	6	0	6	5	6
lgG lgM	C 1 2	C 1 2	C 1 2	C 1 2	C 1 2	C - 1 2	C - ] 1 2	C - 1 2	C - 1 2	C 1 2
Sample No	#262	#263	#264	#265	#266	#267	#268	#269	#270	#272
Color IgG	7	3	0	4	0	0	0	0	0	5
Density IgM	0	1	4	4	3	4	4	3	4	4
lgG lgM	C	C 1 2	C 1 2	C 1 2	C 1 2	C 1 2	C	C	C - 1 2	C - 1 2
Sample No	#273	#274	#275	#276	#277	#278	#279	#281	#282	#283
Color IgG	0	0	0	8	0	0	0	0	0	0
Density IgM	6	5	0	0	0	4	5	3	0	4
lgG IgM	C 1 2	C 1 2	C 1 2	C 1 2	C 1 2	C 1 2	C 1 2	C 1 1 2	C	C 1 1 2
Sample No	#284	#285	#287	#288	#289	#290	#291	#292	#293	#294
Color IgG Density IgM	0	5	3	0	0	0	6	0	5	6 5
	т	0	Ŧ	U	т	т	5	5	J J	5
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14										

Figure 3. Artron COVID-19 IgM/IgG RDTs tested with 40 COVID-19 Ab positive serums. T1 line indicates an IgG test line while T2 indicates an IgM test line, and the number below each cassette indicates the serum number.

Forty COVID-19 positive serum samples were used to evaluate Artron's COVID-19 IgM/IgG RDT performance. Signal readings were determined by the reference card as shown above. Artron's COVID-19 IgM/IgG RDT can detect the IgM/IgG signal with 38 samples.

#### 3. Negative samples

In order to rule out the false-positive possibilities of Artron's COVID-19 IgM/IgG RDT, 33 tests were performed with healthy COVID-19 Ab negative serums as seen in Fig 4. Artron's RDT did not produce any false-positive signals in the tests performed.

C   1 2	C 1 2	C 1 2	C 1 2	C 1 2	C 1 2	C 1 2	C — 1 2	C 1 1 2	C 1 1 2	C1 2
93	94	95	96	97	98	99	100	101	102	103
C 1 2	C 1 2	C 1 2	C 1 2	C C 1 2	C F 1 2	C C 1 2	C C 1 2	C - 1 2	C - 1 2	C 1 1 2
107	108	109	110	111	112	113	114	115	116	117
C	C   1 2	C 1 2	C C 1 2	C - 1 2	C - 1 2	C 1 1 2	C 1 1 2	C - 1 2	C1 2	C1 2
121	122	123	124	125	126	127	128	129	130	131

Figure 4. Artron COVID-19 IgM/IgG RDTs tested with 33 COVID-19 Ab negative serums. The T1 test line indicates an IgG test line while T2 test line indicates an IgM test line, and the number below each cassette indicates the serum number.

#### 4. Summary

Besides the tests showed above, an additional 50 COVID-19 Ab positive serums, 10 COVID-19 Ab positive whole blood samples and 493 COVID-19 Ab negative serums were tested at different locations as shown in Table 1 below.

Table 1. Table showing the total tests performed on the Artron COVID-19 IgM/IgG RDT. A total of 709 tests were performed with 183 COVID-19 Ab positive samples and 526 COVID-19 Ab negative samples.

Diseas	e-State	Specimen Type	Test Positive	Test Negative	Total	Grouped Total	
COVID 10	A b Dogitivo	Serum	163	10	173	102	
COVID-19 Ab Positive		Whole Blood	8	2	10	183	
COVID-19 Ab Negative	Amoricos	Serum	3	127	130		
	Americas	Whole Blood	2	28	30	500	
		Serum	5	290	295	500	
	Ciilla	Whole Blood	2	43	45		

	HIV (+)	Serum	0	4	4	
	HBV (+)	Serum	0	4	4	
Other Disease- State, COVID-19	HCV (+)	Serum	0	4	4	
	HAV (+)	Serum	0	2	2	26
Ab Negative	HP (+)	Serum	0	4	4	
	TP (+)	Serum	0	4	4	
	TB (+)	Serum	0	4	4	
Total Result		/	183	526	70	)9

Table 2. Table showing the specificity and sensitivity of Artron COVID-19 IgM/IgG RDT.

COVID 10	Disease					
COVID-19	Disease (+)	Disease (-)				
Test (+)	171	12				
Test (-)	12	514				
Sensitivity	93.	4%				
Specificity	97.7%					

From Table 2. Artron COVID-19 IgM/IgG RDT presents 93.4% sensitivity and 97.7% specificity. As seen from the test results above, Artron COVID-19 IgM/IgG RDT is a readily deployable test with sufficient sensitivity and specificity to detect COVID-19 IgM/IgG during the current outbreak.