

COVID-19 Saliva Antigen At-Home Test Data

- 1) **Limit of Detection (LoD) (Analytical Sensitivity):** 20 of 20 samples of heat inactivated Isolate USA-WA1/2020 were successfully detected at **1.6×10^3 TCID₅₀ per mL** (Table 1). The study used SARS-Related Coronavirus 2, Isolate USA-WA1/2020, heat Inactivated (BEI Resources, NR-52286, Lot: 70037779). The viral isolate was spiked into **saliva specimen** (Lee Biosolutions, Maryland Heights, MO). The saliva specimens were confirmed by PCR to be Covid-19 negative. Dilutions were carried out from 1.6×10^4 to 2×10^2 TCID₅₀ per mL.

Table 1. *COVID-19 Saliva Antigen At-Home Test* Limit of Detection Data.

(SARS-CoV-2), isolate USA-WA1/2020, 1.6×10^5 TCID₅₀ per mL					
Dilution	1/10	1/100	1/200	1/400	1/800
Conc.	1.6×10^4	1.6×10^3	8×10^2	4×10^2	2×10^2
5 replicates	100% (5/5)	100% (5/5)	60% (3/5)	0% (0/5)	NA
20 replicates	100% (20/20)	100% (20/20)	50% (10/20)	0% (0/20)	NA

- 2) **Cross-reactivity (Analytical Specificity):** 19 of 19 related pathogens tested negative using the *COVID-19 Saliva Antigen At-Home Test* (Table 2). Cross-reactivity studies were performed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The organisms in the table below were measured **in pooled saliva**.

Table 2. *COVID-19 Saliva Antigen At-Home Test* Cross-Reactivity Data.

Virus/Bacteria	Source	Concentration	Result
Adenovirus	BEI, cell preparation	2.5×10^7 TCID ₅₀ /ml	Negative
Respiratory syncytial virus	ATCC	4×10^5 TCID ₅₀ /ml	Negative
Haemophilus influenzae	Hardy Diagnostics	3×10^6 TCID ₅₀ /ml	Negative
Human Metapneumovirus	BEI, Inactive cell lysate	5×10^5 TCID ₅₀ /ml	Negative
Enterovirus	BEI, cell preparation	2.4×10^5 TCID ₅₀ /ml	Negative
Rhinovirus	BEI, Inactive cell lysate	2×10^6 TCID ₅₀ /ml	Negative
Influenza A	BEI, Inactive cell lysate	6×10^5 CEID ₅₀ /ml	Negative
Influenza B	BEI, Inactive cell lysate	5.3×10^4 CEID ₅₀ /ml	Negative
Human coronavirus 229E	ZeptoMetrix	1×10^5 TCID ₅₀ /ml	Negative
Human coronavirus OC43	ZeptoMetrix	1×10^5 TCID ₅₀ /ml	Negative
Human coronavirus NL63	ZeptoMetrix	1×10^5 TCID ₅₀ /ml	Negative
MERS	BEI, Inactive cell lysate	8.9×10^5 TCID ₅₀ /ml	Negative
<i>Streptococcus pneumoniae</i>	ATCC	5×10^6 cells/ml	Negative
<i>Streptococcus pyogenes</i>	ATCC	8×10^5 cells/ml	Negative
<i>Mycoplasma pneumoniae</i>	ATCC	3.2×10^6 cells/ml	Negative
<i>Chlamydia pneumoniae</i>	ATCC	7.5×10^7 cells/ml	Negative
<i>Legionella pneumophila</i>	ATCC	5×10^5 cells/ml	Negative
<i>Mycobacterium tuberculosis</i>	Univ. Rhode Island	6.3×10^6 cells/ml	Negative
<i>Candida albicans</i>	ATCC	4×10^6 cells/ml	Negative



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- 3) **Clinical Evaluation:** 30 of 30 (100%) volunteers that had PCR tests performed by Connecticut labs the same day, self-administered the test and correctly obtained Negative results. 17 of 23 (73.91%) Positive saliva samples with Ct values, obtained from Boca Biolistics and Lee Biosolutions tested positive. All positive samples were tested 3 times by RTA lab personnel. 17 of 17 samples that had Ct values from 13 to 30 correctly tested Positive using the RTA kit. All 6 samples that incorrectly tested negative had Ct values from 31-33 (Tables 3 and 4).

Table 3. *COVID-19 Saliva Antigen At-Home Test* Sensitivity, Specificity, Predicted Positive, and Predicted Negative percents are provided for Ct 13-33 values and Ct 13-30 values.

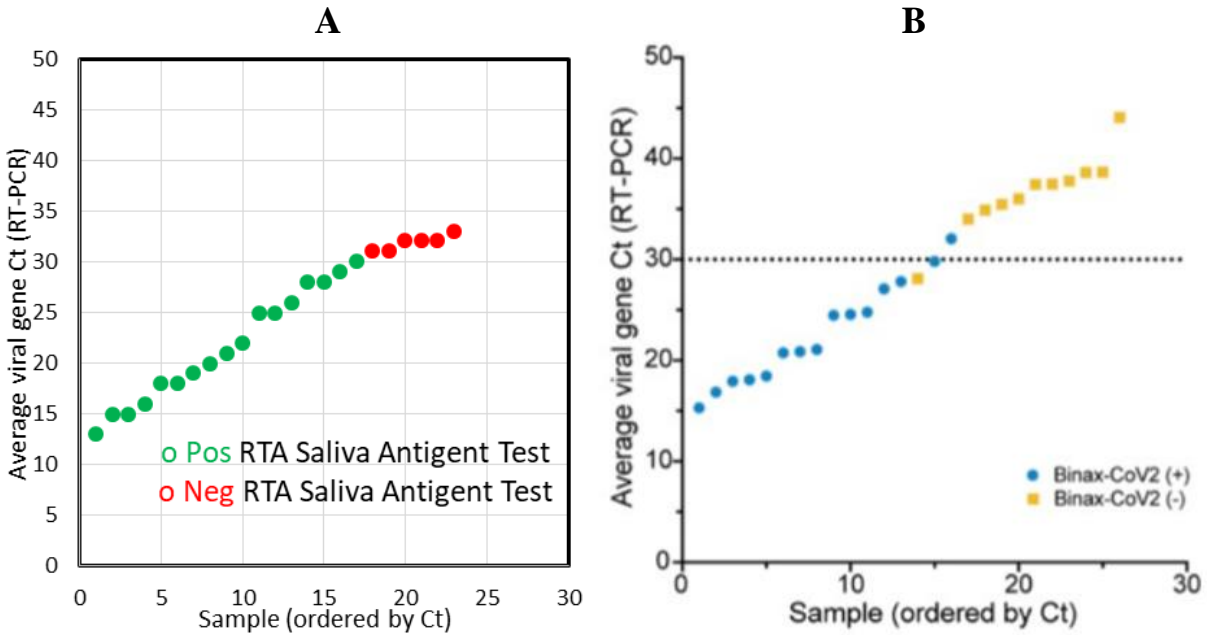
LFA Statistics	Sensitivity	Specificity	Predicted Pos.	Predicted Neg.
Total True Positive = a, Total False Positive = b, Total False Negative = c, Total True Negative = d				
	$a/(a+c)$	$d/(b+d)$	$a/(a+b)$	$d/(d+c)$
	17/(17+6)	30/(30+0)	17/(17+0)	30/(30+6)
For Ct 13-33	73.91%	100.00%	100.00%	83.33%
	17/(17+0)	30/(30+0)	17/(17+0)	30/(30+0)
For Ct 13-30	100.00%	100.00%	100.00%	100.00%

Table 4. *COVID-19 Saliva Antigen At-Home Test* compared to PCR for all positive samples.

Positive Samples #	PCR Ct Value	LFA Test	True Positives (Ct = 13 to 33)	True Positives (Ct ≤ 30)
1	28	Positive	1	1
2	25	Positive	1	1
3	13	Positive	1	1
4	21	Positive	1	1
5	32	Negative		
6	15	Positive	1	1
7	32	Negative		
8	20	Positive	1	1
9	25	Positive	1	1
10	22	Positive	1	1
11	31	Negative		
12	18	Positive	1	1
13	19	Positive	1	1
14	15	Positive	1	1
15	18	Positive	1	1
16	31	Negative		
17	26	Positive	1	1
18	28	Positive	1	1
19	30	Positive	1	1
20	33	Negative		
21	29	Positive	1	1
22	32	Negative		
23	16	Positive	1	1
Total True LFA Pos. Tests			17	17
Total True PCR Pos. Tests			23	17

While RTA is still in the process of performing the Clinical Validation, the results as shown in Tables 3 and 4 for their saliva swab test are very favorable compared to Abbott's Binax-CoV2 nasopharyngeal swab test (Graph 1). A number of studies suggest that the ideal antigen test can detect the virus 100% of the time at 30 Ct and below. It is at these concentrations that people are most likely to infect others. This is an ~ 9 day window from days 3 to day 12 of the infection (Graph 2).

Graph 1. Comparison of A) RTA's *COVID-19 Saliva Antigen At-Home Test* to B) Abbott's Binax-CoV2 test for the detection of infected patients. RTA's Table 4 data.



Graph 2. Graph of Log10 RNA copies/mL as a function of days since infection. The peak infection at day five is 2.1×10^8 (210 million) RNA copies/mL of nasal mucus.

