



Gardian T3 COVID-19-SARS-CoV-2 Antigen Saliva Self Test Research Report on Detection Limit of Wild Type, Delta, and Omicron Viruses.

The report is aimed to identify and verify the minimum detection limit of Gardian T3 COVID-19-SARS-CoV-2 Antigen Saliva Self Test. Viruses in 4 batches were diluted to 1000, 200, 100, 50, 10, and 5 TCID₅₀/ml. Each test dilutant was tested in replicates up to 20 for the low limit of detection which is determined at the positive detection rate of over 95% across 3 batches of Gardian T3.

Information on PCR Reagents for detection:

Manufacturer	Sansure Biotech Inc.
Product name	Reagent kit for detecting RNA of coronaviruses 2019-nCoV by real-time PCR
Packaging specification	24 tests/Kit
Storage temperature	-20 ± °C5
Shelf-life	12 months
Country of manufacture	China
RNA extraction	Automated nucleic acid extraction system NATCH CS
Amplifier	Amplifier for quantitative real-time PCR MA-6000
Negative control	FAM, ROX channel and internal standard (HEX) channel have no Ct value or Ct>40.
Positive control	Ct≤35 for FAM, ROX and internal standard (HEX) channels.



Samples used for Study

Sample number	Note	CT value	RNA Load (copies/mL)	TCID ₅₀ /mL	Source
Positive sample (1#)	Wildtype	16.26	5.4×10 ⁸	3.2×10 ⁵	JPCDCP
Positive sample (2#)	Wildtype	16.52	4.5×10 ⁸	2.8×10 ⁵	JPCDCP
Positive sample (3#)	Wildtype	16.66	4.0×10 ⁸	2.3×10 ⁵	JPCDCP
Positive sample (4#)	Wildtype	15.74	7.8×10 ⁸	4.7×10 ⁵	JPCDCP
Positive sample (5#)	Delta variant	18.00	1.6×10 ⁸	8.5×10 ⁴	JPCDCP
Positive sample (6#)	Delta variant	18.02	1.5×10 ⁸	8.7×10 ⁴	JPCDCP
Positive sample (7#)	Delta variant	16.55	4.2×10 ⁸	2.6×10 ⁵	JPCDCP
Positive sample (8#)	Delta variant	20.71	2.1×10 ⁷	1.3×10 ⁴	JPCDCP
Positive sample (9#)	Omicron variant (B.1.1.529)	19.00	1.5×10 ⁸	8.3×10 ⁴	JPCDCP
Positive sample (9#)	Omicron variant (B.1.1.529)	18.02	1.5×10 ⁸	8.7×10 ⁴	JPCDCP
Positive sample (10#)	Omicron variant (B.1.1.529)	16.55	4.2×10 ⁸	2.6×10 ⁵	JPCDCP
Positive sample (11#)	Omicron variant (B.1.1.529)	20.71	2.1×10 ⁷	1.3×10 ⁴	JPCDCP
Positive sample (12#)	Omicron variant (BA.2)	19.20	1.5×10 ⁸	8.2×10 ⁴	JPCDCP
Positive sample (13#)	Omicron variant (BA.2)	18.00	1.5×10 ⁸	8.6×10 ⁴	JPCDCP
Positive sample (14#)	Omicron variant (BA.2)	16.42	4.3×10 ⁸	2.6×10 ⁵	JPCDCP
Positive sample (15#)	Omicron variant (BA.2)	21.90	2.0×10 ⁷	1.2×10 ⁴	JPCDCP



Identification of the minimum detection of Limit

Dilution levels were as follows:

Wild Type

Virus Sample Level (TCID ₅₀ /ml)	1000	100	10
CT Value	24.35	27.57	30.8
RNA Load (Copies/ml)	1.67x10 ⁶	1.64x10 ⁵	1.68x10 ⁴

Delta

Virus Sample Level (TCID ₅₀ /ml)	1000	100	10
CT Value	24.30	27.55	30.9
RNA Load (Copies/ml)	1.70x10 ⁶	1.68x10 ⁵	1.64x10 ⁴

Omicron B.1.1.529

Virus Sample Level (TCID ₅₀ /ml)	1000	100	10
CT Value	24.40	27.50	30.91
RNA Load (Copies/ml)	1.60x10 ⁶	1.60x10 ⁵	1.62x10 ⁴

Omicron BA.2

Virus Sample Level (TCID ₅₀ /ml)	1000	100	10
CT Value	25.40	27.52	30.20
RNA Load (Copies/ml)	1.5x10 ⁶	1.58x10 ⁵	1.61x10 ⁴

Results for 10 TCID₅₀/ml for viruses

Positive Virus	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11	#12	#13	#14	#15
Result %	100	99	100	100	99	100	100	100	100	99	100	99	99	100	99

Conclusion:

Gardian T3 Can detect Covid-19 at a limit of detection of 10 TCID₅₀/ml.