

Clinical Performance Report

DIAQUICK COVID-19 Ag Cassette

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1. Diagnostic Accuracy / Comparison Test

Study objective:

The aim of this study was the evaluation of the performance of the DIAQUICK COVID-19 Ag Cassette (Swab) for testing clinical samples.

Study design:

- Materials:
 - o DIAQUICK COVID-19 Ag Cassette (Swab):
 - Lot: 20200313 / Exp: 2022-02-28
 - o Commercial PCR assay:
 - DAAN GENE, 2019 Novel Coronavirus (2019-nCoV) RNA detection kit (PCR Fluorescence probing)

- Study design:

203 patients exhibiting pneumonia or respiratory symptoms were sequentially enrolled and nasopharyngeal (NP) swab samples for testing were collected. From each person two swab samples were taken at the same time, one swab sample for DIAQUICK COVID-19 Ag Cassette testing, the other swab sample for commercial PCR assay testing. The swab samples were tested in single with DIAQUICK COVID-19 Ag Cassette, the results were compared to the PCR assay results.

- Test site:

A total of two investigational sites participated in the study.

- Test procedure:

Followed the package insert.

Results:

Table 1: DIAQUICK COVID-19 Ag Cassette vs. PCR

Method		PCR		Total Results
DIAQUICK COVID-19 Ag Cassette	Results	Positive	Negative	
	Positive	71	0	71
	Negative	2	130	132
Total Results		73	130	203

Relative Sensitivity: 97.3% (71/73)

Relative Specificity: 100% (130/130)

Accuracy: 99.0% (201/203)

Table 2: Positive results broken down by days since symptom onset

Days since Symptom Onset	Cumulative PCR Positive (+)	Cumulative DIAQUICK COVID-19 Ag Cassette Positive (+)	PPA
1	7	7	100%
2	18	18	100%
3	30	30	100%
4	44	44	100%
5	59	58	98.3%
6	62	60	96.8%
7	70	68	97.1%

8	71	69	97.2%
9	72	70	97.2%
10	73	71	97.3%

Table 3: DIAQUICK COVID-19 Ag Cassette Performance against the comparison method – by Cycle Threshold Counts

DIAQUICK COVID-19 Ag Cassette	PCR Results (Ct) of nucleoprotein(N) gene	
	Positive (Ct <30)	Positive (Ct ≥30)
Positive	62	9
Negative	0	2
Total	62	11

DIAQUICK COVID-19 Ag Cassette	PCR Results (Ct) of open reading frame (ORF) gene	
	Positive (Ct <30)	Positive (Ct ≥30)
Positive	40	31
Negative	0	2
Total	40	33

Conclusion:

The above results showed that:

The Relative Sensitivity of DIAQUICK COVID-19 Ag Cassette (Swab) is 97.3% (71/73), Relative Specificity is 100% (130/130) compared to PCR.

Discussion:

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.