

Statement of the Test Performance in Different Sampling Methods

To whom it may concern,

We, **New Gene (Hangzhou) Bioengineering Co., Ltd.** being the official designer and manufacturer of our proprietary **COVID-19 Antigen Detection Kit**, and having factories with address of Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou (310051), Zhejiang, P.R. China, do hereby state that:

The product performance (Sensitivity, Specificity & Total Accuracy) was evaluated with different sampling methods, which are **nasal swab** and **sputum**, are as follows, taking commercial RT-PCR kit as the gold standard.

Nasal Swab		RT-PCR		Total
		Positive	Negative	
COVID-19-NG08	Positive	168	2	170
	Negative	5	262	267
Total		173	264	437
		Sensitivity	Specificity	Total Accuracy
		97.1%	99.2%	98.4%
		95% CI: [93.4%-99.1%]	95% CI: [97.3%-99.9%]	95% CI: [96.7%-99.4%]
Sputum		RT-PCR		Total
		Positive	Negative	
COVID-19-NG08	Positive	109	1	110
	Negative	3	128	131
Total		112	129	241
		Sensitivity	Specificity	Total Accuracy
		97.3%	99.2%	98.3%
		95% CI: [92.4%-99.4%]	95% CI: [95.8%-100.0%]	95% CI: [95.8%-99.5%]

We also have conducted a clinical test with deep throat saliva in MDA, Malaysia. The operating procedure with deep throat saliva sample is the same with the one with sputum sample. The performance of **deep throat saliva** sample is as follows:

Sensitivity = 96%

Specificity = 100%.

Please refer to the attached report for detailed information.



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New Gene (Hangzhou) Bioengineering Co., Ltd. reserves all the right to the interpretation of this statement.

New Gene (Hangzhou) Bioengineering Co., Ltd.

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