



MP Biomedicals Germany GmbH
Thüringer Straße 15
37269 Eschwege GERMANY
mpbio.com

Tel. +49-5651-921-0
Fax +49-5651-921-181

Performance Characteristics Nasopharyngeal and Nasal Specimens

To whom it may concern:

The clinical diagnosis ability and the in-use safety and effectiveness of the Rapid SARS-CoV-2 Antigen Test Card (07AG6020B) from MP Biomedicals Germany GmbH were evaluated based on comparison with the RT-PCR method.

The sensitivity, specificity, accuracy, and confidence intervals were calculated by comparing the detection results of the Rapid SARS-CoV-2 Antigen Test Card with RT-PCR.

Results as follows:

For Nasopharyngeal swab samples:

	RT-PCR Results		Total
	Positive (+)	Negative (-)	
Positive (+)	50	4	54
Negative (-)	2	200	202
Total	52	204	256
Sensitivity	96.15% (95% CI: 90.93% - 99.99%)		
Specificity	98.04% (95% CI: 96.14% - 99.94%)		
Accuracy	97.66% (95% CI: 95.80% - 99.51%)		

For Nasal swab samples:

	RT-PCR Results		Total
	Positive (+)	Negative (-)	
Positive (+)	30	1	31
Negative (-)	1	124	125
Total	31	125	156
Sensitivity	96.77% (95% CI: 90.55% - 99.99%)		
Specificity	99.20% (95% CI: 97.64% - 99.99%)		
Accuracy	98.72% (95% CI: 96.95% - 99.99%)		