

Clinical Validation Result

Validated Product: COVID-19 antigen test (LFA) from SHENZHEN SEKBIO Co., LTD.

Benchmark product: COVID-19 RT-PCR

Experiment 1: (Oropharyngeal swab eluted with matched sample extraction solution)

Number of samples	RT-PCR Results		SEKBIO COVID-19 antigen test result	
	CT values	Result	Result	Consistency
57	≤30	57 positives	57 positives	100%
82	≤33	82 positives	82 positives	100%
91	≤34	91 positives	90 positives	98.90%
149	≤36	149 positives	136 positives	91.28%
45	≥40	45 negatives	44 negatives	97.78%

Experiment 2 : (Nasopharyngeal swab/Oropharyngeal swab kept in UTM)

Number of samples	RT-PCR Results		SEKBIO COVID-19 antigen test result	
	CT values	Result	Result	Consistency
52	≤25.1	52 positives	52 positives	100%
82	≤34.8	82 positives	77 positives	93.9%
45	>40	45 negatives	45 negatives	100%