



## Healgen Rapid COVID-19 Antigen Test

Clinical Performance of the Rapid COVID-19 Antigen Test (swab) was evaluated by being involved in 7 sites within the US where patients were enrolled and tested. Testing was performed by 24 Healthcare Workers that were not familiar with the testing procedure. A total of 865 fresh nasopharyngeal swab samples was collected and tested, which includes 120 positive samples and 745 negative samples. The Rapid COVID-19 Antigen Test (Swab) results were compared to USFDA Emergency Use Authorized RT-PCR assays for SARS-CoV-2 in nasopharyngeal swab specimens.

Overall study results are shown in Table 1.

**Table 1: Summary Results**

Method		PCR		Total Results
Rapid COVID-19 Antigen Test	Results	Positive	Negative	
	Positive	117	3	120
	Negative	2	743	745
<b>Total</b>		119	746	865

Relative Sensitivity: 98.32% (95% CI\* 94.06% to 99.80%)

Relative Specificity: 99.60% (95% CI\* 98.83.03% to 99.92%)

Accuracy: 99.42% (95%CI\* 98.66% to 99.81%)

*Additional data is still being collected as part of this study and the data above will not be the final study results.*