

Clinical Performance

1 Sensitivity and Specificity

The Medomics COVID-19 Ag test was evaluated with clinical samples whose status was confirmed by RT-PCR. The results are shown in the following table:

Medomics COVID-19 Ag test	RT-PCR		Total
	Positive	Negative	
Positive	115	2	117
Negative	4	219	223
Total	119	221	340

Sensitivity: 96.64% (91.62%–99.08%)

Specificity: 99.10% (96.77%–99.89%)

Positive Predictive Value: 98.29% (93.96%–99.79%)

Negative Predictive Value: 98.21% (95.47%–99.51%)

General match: 98.24% (96.20%–99.35%)

2 Limit of Detection (LoD) Study Results

Concentration TCID ₅₀ /mL	Number Positive/Total	% Detected
10	20/20	100%