

Clinical Accuracy

SARS-CoV-2

Method		RT-PCR		Total Results
fluorecare [®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	342	0	342
	Negative	26	450	476
Total Results		368	450	818

Positive correct rate (Clinical sensitivity)at Ct<38=92.93%(95%CI:89.82%~95.33%)

Negative correct rate (Clinical specificity) = 100% (95%CI:99.18% ~100%)

Method		RT-PCR		Total Results
By Lay Person	Results	Positive	Negative	
	Positive	30	0	30
	Negative	2	87	89
Total Results		32	87	119

Clinical Accuracy

Influenza A

Method		Reference Product		Total Results
fluorecare [®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	104	0	104
	Negative	9	555	564
Total Results		113	555	668

Clinical sensitivity = 92.04% (95%CI:85.42% ~96.29%)

Clinical specificity = 100.00% (95%CI:99.34%~100.00%)

Method		Reference Product Professional Test		Total Results
Self-Test	Results	Positive	Negative	
	Positive	17	0	17
	Negative	0	102	102
Total Results		17	102	119

Clinical Accuracy

Influenza B

Method		Reference Product		Total Results
fluorecare [®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	80	0	80
	Negative	8	580	588
Total Results		88	580	668

Clinical sensitivity = 90.91% (95%CI:82.87% ~95.99%)

Clinical specificity = 100.00% (95%CI:99.37%~100.00%)

Method		Reference Product Professional Test		Total Results
Self-Test	Results	Positive	Negative	
	Positive	11	0	11
	Negative	1	107	108
Total Results		12	107	119

Clinical Accuracy

RSV

Method		Reference Product		Total Results
fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	63	0	63
	Negative	3	602	605
Total Results		66	602	668

Clinical sensitivity = 95.45% (95%CI:87.45% ~99.05%)

Clinical specificity = 100.00% (95%CI:99.39%~100.00%)

Method		Reference Product Professional Test		Total Results
Self-Test	Results	Positive	Negative	
	Positive	31	0	31
	Negative	1	87	88
Total Results		32	87	119