

MS-TRA-SD-5 Covid-19 Rapid Antigen Self-Test

Compliant With Health Canada

Medsup COVID-19 Rapid Antigen Test (Self-Testing) is a lateral flow chromatographic immunoassay assembled in Canada for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.



Clinical Performance

Performance of the COVID-19 Antigen Rapid Test (Self-Testing) was established with 419 nasal swabs self-tested or tested by another study participant from 167 individual symptomatic patients (within 7 days of onset) and 252 asymptomatic patients. The study was conducted in a simulated home setting environment. The COVID-19 Antigen Rapid Test (Self-Testing) results were compared to RT-PCR to determine test performance in the tables below:

Medsup COVID-19 Antigen Rapid Test (Self-Testing)	Reference Method (RT-PCR)		
	Positive	Negative	Total
Positive	160	1	161
Negative	10	248	258
Total	170	249	419
Sensitivity Positive Percent Agreement (PPA)	94.12% (95% CI: 89.39%-96.90%)		
Specificity Negative Percent Agreement (NPA)	99.60% (95% CI: 97.53%-99.99%)		

Cumulative PPA results by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive Results	Medsup COVID-19 Antigen Rapid Test (Self-Testing) Positive Results	PPA
0-3 days	66	65	98.5%
4-7 days	89	83	93.3%

Result Time	15 to 30 minutes
Patient Type	Symptomatic and asymptomatic
Conservation	Keep at 2°C - 30°C, keep dry
Shelf Life	24 months after manufacturing
Limit of Detection (LOD)	1.6*10 ² TCID ₅₀ /mL
Language	Bilingual (English – French)
Certifications	Compliant with Health Canada, & established the quality management system in according with ISO 13485 standards

Box Content	<ul style="list-style-type: none"> • 5 Test Cassettes • 5 Extraction Buffer Tubes • 5 Disposable Nasal Swabs • 1 Packaging Insert
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