LUMOS DIAGNOSTICS

Convenient COVID Ag Testing at the Point of Need

CoviDx™

Introducing the CoviDx™ SARS CoV-2 Rapid Antigen Test

FOR PROFESSIONAL USE ONLY*

RAPID RESULTS: facilitate immediate patient isolation and prioritization of confirmatory testing

FLEXIBLE WORKFLOW: pre-filled extraction vials and individually wrapped reagents enable multiple independent workstations for increased test distribution

EASY-TO-USE: instrument-free, user-friendly test procedure for non-lab settings

CONVENIENT: all materials included in the kit for hassle-free logistics

ACCURATE: 100% PPA with PCR for samples with Ct values ≤ 30[1]

Point-of-Care TEST RESULTS within **20 MINUTES**

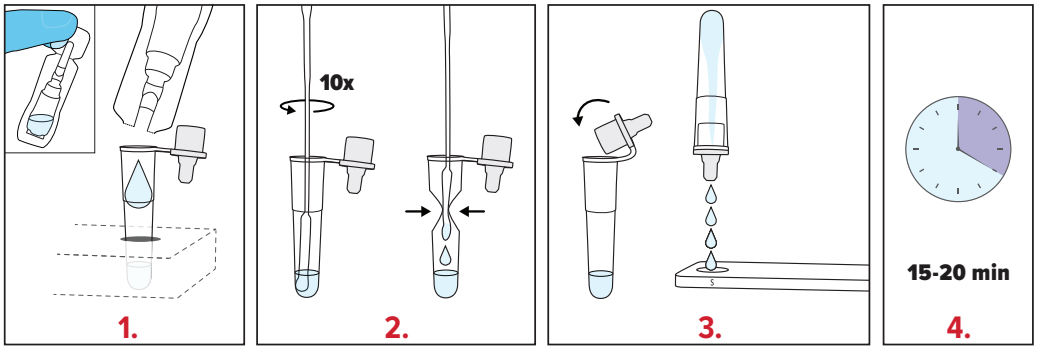
*For use under Health Canada Interim Order Authorization only

lumosdiagnostics.com

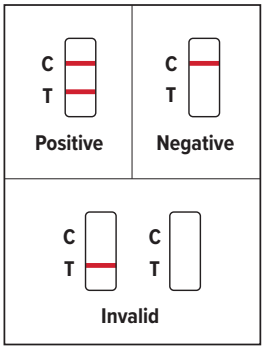
FOR PROFESSIONAL USE ONLY

CoviDx

SIMPLE PROCEDURE

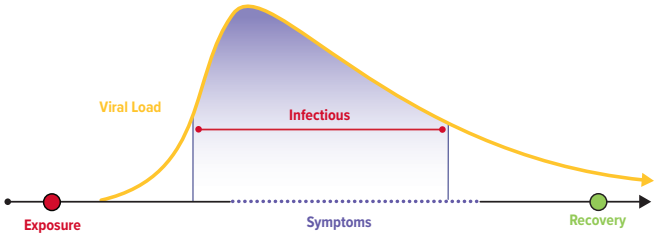


SIMPLE RESULT INTERPRETATION



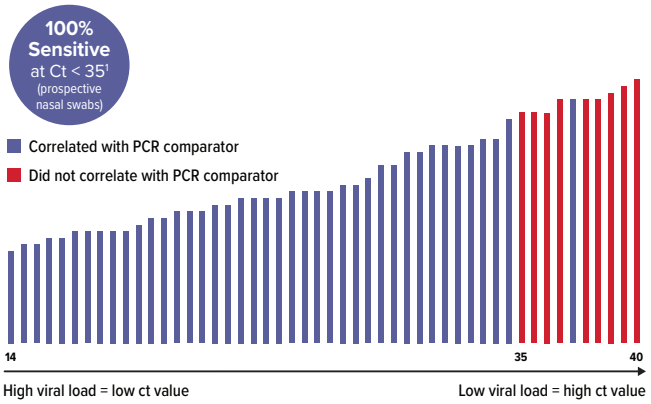
SARS-CoV-2 Viral Load Over Course of Infection[2]

Frequent testing with antigen tests can identify people when their infection is most likely to be transmissible.[3]



CoviDx Detection Compared to PCR Ct Values[1]

Increased cycle threshold (Ct) indicates decreasing sample viral concentration.



CLINICAL PERFORMANCE

Prospective Data (Nasal Swabs)[1]

	PCR test					
	Ct ≤ 30			All		
CoviDx SARS-CoV-2 Rapid Antigen Test	Positive	Negative	Total	Positive	Negative	Total
Positive	31	5	36	41	5	46
Negative	0	96	96	9	96	105
Total	31	101	132	50	101	151
Positive Percent Agreement (PPA) Sensitivity	**100.0%** (95% CI: 89.0% - 100.0%)			**82.0%** (95% CI: 69.2% - 90.2%)		
Negative Percent Agreement (NPA)	**95.0%** (95% CI: 88.9% - 97.9%)			**95.0%** (95% CI: 88.9% - 97.9%)		

Retrospective Data (Nasopharyngeal Swabs)[1]

	PCR test					
	Ct ≤ 30			All		
CoviDx SARS-CoV-2 Rapid Antigen Test	Positive	Negative	Total	Positive	Negative	Total
Positive	33	0	33	33	0	33
Negative	0	29	29	4	29	33
Total	33	29	62	37	29	66
Positive Percent Agreement (PPA)	**100.0%** (95% CI: 89.6% - 100.0%)			**89.2%** (95% CI: 75.3% - 95.7%)		
Negative Percent Agreement (NPA)	**100.0%** (95% CI: 83.3% - 100.0%)			**100.0%** (95% CI: 83.3% - 100.0%)		

1. CoviDx [package insert] PM-128.0. Sarasota, FL: Lumos Diagnostics; 2021. 2. Adapted from Crozier A. Put to the test: Use of rapid testing technologies for Covid-19. BMJ. 2021;372:n208. 3. Mina MJ, Parker R, Larremore DB. Rethinking Covid-19 test sensitivity - A strategy for containment. N Engl J Med. 2020;383:e120.

For use under Health Canada Interim Order Authorization only

-Refer to package insert for full performance, warnings, and limitations
-PCR is the gold standard for diagnosing COVID-19
-Testing should follow provincial or territorial guidance and be administered regularly to employees in accordance with the interim guidance on the use of rapid antigen detection tests for identifying SARS-CoV-2 infection

Lumos Diagnostics: 7040 Professional Parkway, Suite B, Sarasota, FL 34240
P +1 941 556 1850 **E** info@lumosdiagnostics.com **W** lumosdiagnostics.com

LUMOS DIAGNOSTICS