

Clinical Performance of COVISTIX™

COVISTIX™ is a highly sensitive and accurate lateral flow immunoassay for rapid SARS-CoV-2 antigen detection. COVISTIX™ is a precise assay that detects single SARS-CoV-2 virus antigens directly from a nasal swab sample in 15 minutes. COVISTIX™ only requires mixing the sample with a buffer and applying the sample to the COVISTIX™ test. Simple capillary action will drive the sample through the cassette and displays an obvious black line if the viral antigen is detected.

The test uses a proprietary platinum nano-catalyst core (PtNC) which yields up to 100-fold increases in sensitivity over conventional lateral flow colloidal gold assays. As viral antigen passes over the labeled antibody, the sample encounters the PtNC particles targeted specifically to the virus nucleocapsid (N) or matrix (M) antigens. The antigen is then captured in a strong biotin-avidin complex, producing a conspicuous black line on the membrane stick, indicating a positive result.

COVISTIX™ has been tested for cross-reactivity and is specific for detection of SARS-CoV-2 and viruses in the same family. As a platform technology, the PtNC lateral flow also has the potential to be developed as a multiplex system to detect other respiratory pathogens leveraging the same assay, processes, and training.

In the tables below, Sensitivity is Positive Percent Agreement (PPA), or true positive (true positive + false negative). Specificity is Negative Percent Agreement, or true negative (true negative + false positive).

Sensitivity (PPA) and Specificity (NPA) Days 0–7

Table 1 Summary of Positive and Negative Agreement with Real Patient Specimen Type

Test Result	PCR Confirmed Samples		
	Positive	Negative	Total
Positive	50	1	51
Negative	0	50	50
PPA	98.04% (95% CI 89.70% to 99.65%)		
NPA	100% (95% CI 92.87% to 100.00%)		

Abbreviations: CI = confidence intervals; PCR = polymerase chain reaction.

Days 0–14

Table 2 Summary of Positive and Negative Agreement with Real Patient Specimen Type

Test Result	PCR Confirmed Samples		
	Positive	Negative	Total
Positive	53	2	55
Negative	0	50	50
PPA	96.36% (95% CI 87.68% to 99.00%)		
NPA	100% (95% CI 92.87% to 100.00%)		

Abbreviations: CI = confidence intervals; PCR = polymerase chain reaction.