



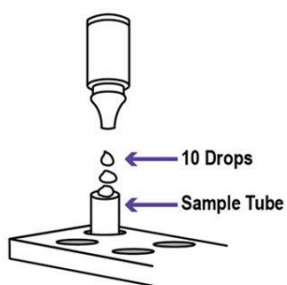
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COVISTIX™ (Antigen Test for the Detection of SARS-CoV-2 Virus in Nasal Swab)

COVI-STIX™ has been developed by Sorrento as a highly sensitive and accurate lateral flow immunoassay for rapid SARS-CoV-2 antigen detection. COVI-STIX is a highly sensitive assay that detects single SARS-CoV-2 virus antigens directly from a shallow nasal swab (nasal, not nasopharyngeal) sample in 15 – 20 minutes. COVI-STIX uses a simple one-step protocol that only requires mixing the sample with a buffer and applying the sample to the COVI-STIX test well. Simple capillary action will drive the sample through the cassette and displays an obvious black line if the viral antigen is detected. This technology is ideally suited (when cleared for use) for rapid laboratory, point-of-care testing or at-home use.

Set Up

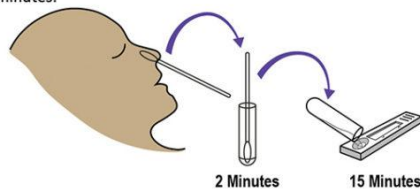
Add 10 drops of Lysis Buffer to the sample tube.



Specimen Collection

Insert the swab into the nose (not more than ¼ of an inch or 1.5 cm) and slowly rotate at least 6 times against nostril wall and repeat it in the other nostril.

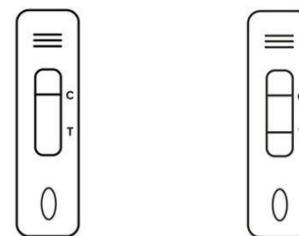
Transfer the swab to the sample tube containing the Lysis Buffer and leave it for 2 minutes.



Results

Negative:
If only C line is visible, COVID-19 VIRUS antigen is **not detected**.

Positive:
If the C line and T line appear, COVID-19 VIRUS 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.

Initial validation of COVISTIX has demonstrated a sensitivity of 98%, a specificity of 100%, and an LOD of 6.25 TCID₅₀/swab (exact values to be confirmed by the FDA). 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. A request for EUA of this technology has been submitted in December of 2020. We are also evaluating the potential for COVISTIX using a saliva sample as well. Development plans include multiplexing this platform to enable a patient to tell if they have COVID-19 or Flu A/Flu B.



COVISTIX

COVITRACK

COVIGUARD

COVI-AMG

COVIDROPS

COVISHIELD

COVIDTRAP

ABIVERTINIB

SALICYN-30

COVI-MSA