Diagnostics

ZiP-CoVx-P2 Test (SARS-CoV-2)

Key features:

- Molecular point-of-care test
- Direct detection of SARS-CoV-2 virus
- Two gene targets for test result confirmation
- Combined throat and nasal swab sampling
- Results within 7-30 minutes
- Sensitivity comparable to PCR
- Transport and storage at room temperature

Use with the ZiP-P2 Instrument

- Deployable at point-of-care settings
- Decentralised diagnosis
- Integrated sample preparation
- Screen-guided easy-to-use workflow with automated results and reporting

Product Specifications

Intended Use

The ZiP-CoVx-P2 test detects SARS-CoV-2 virus nucleic acids in combined throat and nasal swab samples to aid diagnosis of COVID-19 disease in symptomatic individuals, or to screen for SARS-CoV-2 infection in asymptomatic individuals. The test is intended for use in dedicated test spaces by healthcare professionals, or in pathology settings by laboratory-trained professionals. The ZiP-CoVx-P2 test is performed using the ZiP-P2 instrument.

Sample Types

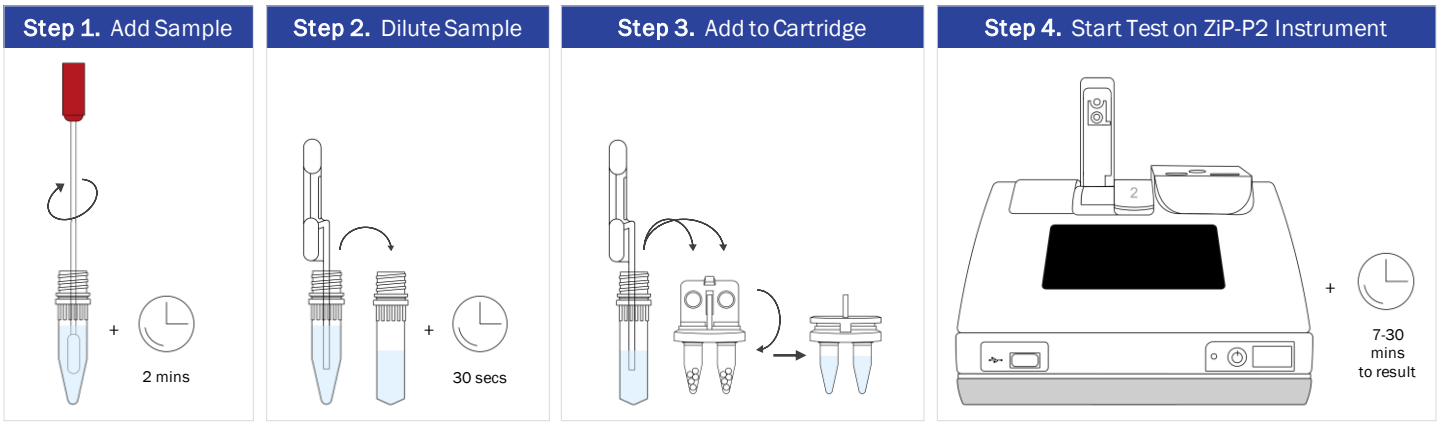
A combined oropharyngeal (throat) and bilateral mid-turbinate (nasal) sample, collected on a synthetic flocked swab. Dry swab samples must be used because swabs in liquid transport media may interfere with test performance.

Targets and Strains Detected

SARS-CoV-2; dual gene targets for *M* and *ORF1ab* genes. Detects at minimum, all variants of concern including: Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), and Omicron (BA.2, BA.4, BA.2.75, and XBB).
Endogenous control; human *RNaseP* gene. This is used to confirm sample adequacy and to ensure no test inhibition.

Test Workflow

Simple 4 step process, guided by on-screen instructions. Minimal training required.



Analytical and Clinical Performance

The overall analytical limit of detection (LoD) of the ZiP-CoVx-P2 test is 2,000 copies/swab (*M* gene 2,000 copies/swab, *ORF1ab* gene 4,000 copies/swab).
The overall clinical performance of the ZiP-CoVx-P2 test is 98.3% sensitivity (114/116) and 99.0% specificity (589/595) when compared to lab-based RT-PCR testing.

Interpretation of Results

Results are interpreted automatically by the ZiP-P2 instrument and shown on-screen.
Results are reported as POSITIVE++ (both SARS-CoV-2 gene targets are detected), POSITIVE + (one SARS-CoV-2 gene target is detected), NEGATIVE or INVALID.
This is a qualitative test and does not provide the quantitative value of the detected organism.

Storage and Stability

The ZiP-CoVx-P2 test is stable until its expiry date if stored between 2°C to 25°C.
Avoid direct light. Do not freeze.

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THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC
THIS PRODUCT IS NOT COMMERCIALLY AVAILABLE IN ALL MARKETS
ALWAYS FOLLOW THE DIRECTIONS FOR USE

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