

Flow*flex*[™] SARS-CoV-2 Antigen Rapid Test

Provides an aid in identifying individuals suspected of an active COVID-19 infection by their healthcare provider within the first seven (7) days of the onset of symptoms





Flowflex SARS-CoV-2 Antigen Rapid Test

The Flowflex SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of an active COVID-19 infection by their healthcare provider within the first seven days of the onset of symptoms.

- · Nasal swab specimens
- Results in 15 minutes
- Excellent performance compared to molecular methods
- Room temperature storage

Clinical Performance

The performance of Flowflex SARS-CoV-2 Antigen Rapid Test was established with 304 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The performance of the Flowflex SARS-CoV-2 Antigen Rapid Test was compared to a RT-PCR method.

Clinical Performance of SARS-CoV-2 Antigen Rapid Test

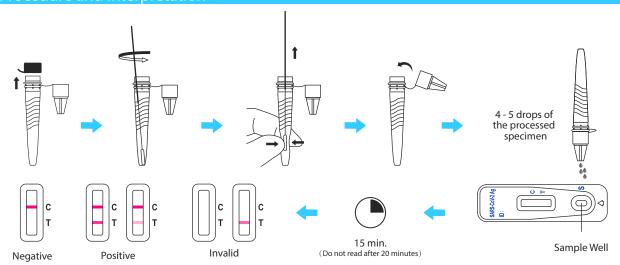
| Method | | RT-PCR | | Total Results |
|--------------------------------|----------------------------|-----------------------------|----------|---------------|
| SARS-CoV-2 Antigen Rapid Test | Results | Negative | Positive | Total nesults |
| | Negative | 269 | 1 | 270 |
| | Positive | 1 | 33 | 34 |
| Total Results | | 270 | 34 | 304 |
| PPA: 97.1% (83.8% - 99.9%)* NI | PA: 99.6% (97.7% - 99.9%)* | OPA: 99.3% (97.5% - 99.9%)* | | |

PPA- Positive Percent Agreement; NPA – Negative Percent Agreement; OPA – Overall Percent Agreement, *95% Confidence Intervals

Materials Provided

- Test Cassettes
- Extraction Buffer
- Quick Reference Instructions
- Extraction Buffer Tubes
- Negative Control SwabPositive Control Swab
- Nasal Swabs
- · Package Insert

Test Procedure and Interpretation



Ordering Information

| Product Name | Catalog No. | Format | Specimen | Package |
|--|-------------|----------|-------------|--------------|
| Flowflex SARS-CoV-2 Antigen Rapid Test | L031-11815 | Cassette | Nasal swabs | 25 Tests/Kit |





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