



Sofia[®]
SARS Antigen FIA



Objective SARS-CoV-2 Results at Your Fingertips



Accurate, objective and automated
results in **15 minutes**



Integrated data management
automatically stores test and user history



Excellent performance compared to
molecular methods



User and patient ID captured
with **onboard barcode scanner**

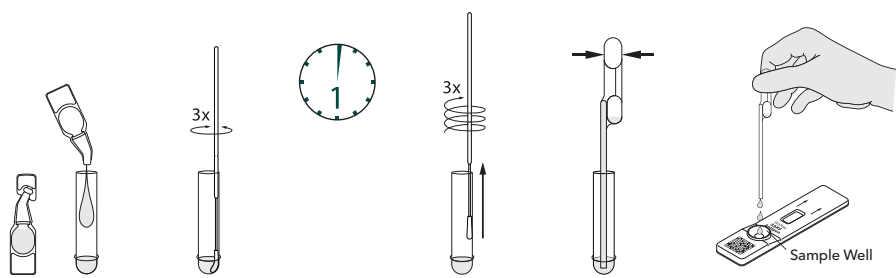


Flexible, dual mode testing for high
throughput in variety of laboratory
environments



Sofia SARS Antigen FIA – Procedure

Nasal/Nasopharyngeal Swab Procedure



Sofia Development Modes



Sofia SARS Antigen FIA

- Nasal and nasopharyngeal specimens
- Accurate detection with direct samples
- Results in 15 minutes
- Kit includes 25 sterile nasal swabs and a set of positive and negative control swabs
- Room temperature storage

| | Reference Extracted RT-PCR assay | | | | | 95% CI | | |
|---------------------------------|-------------------------------------|-----|-----|-------|-------------|--------|-------|--------|
| | | POS | NEG | Total | PPA | 96.7% | 83.3% | 99.4% |
| Sofia SARS Antigen FIA Assay | POS | 29 | 0 | 29 | NPA | 100.0% | 97.9% | 100.0% |
| | NEG | 1 | 179 | 180 | PPV | 100.0% | 88.3% | 100.0% |
| | Total | 30 | 179 | 209 | NPV | 99.4% | 96.9% | 99.9% |
| | | | | | Prevalence | 14.4% | 7.4% | 14.3% |
| | | | | | % agreement | 99.5% | | |

*Refer to the Package Insert.

