

CareStart™ COVID-19 Antigen

The CareStart™ COVID-19 Antigen test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal or anterior nasal swab samples collected by a healthcare provider from individuals who are suspected of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

 **US FDA**
Emergency
Use Authorized



- For use under Emergency Use Authorization (EUA) only
- For *in vitro* diagnostic use only
- For professional use only / For prescription use only

- ✓ Fast and easy to use in Point-of-Care setting
- ✓ CE-marked
- ✓ Use for anterior nasal or nasopharyngeal swab specimen
- ✓ Test results obtained in 10 minutes
- ✓ No special equipment or training required
- ✓ Identify individual's current infection status to COVID-19
- ✓ Clinical Performance (Nasal Swab) 87.18% PPA and 100.00% NPA