

Reagent and Materials

▶ Materials Provided:

- ▶ 40 Test Cards
- ▶ Extraction Reagent
- ▶ Patient Collection Nasal Swabs
- ▶ Positive Control Swab
- ▶ Blank Nasal Swab for Negative Control
- ▶ Product Insert
- ▶ Procedure Card
- ▶ Healthcare Provider & Patient COVID-19 Fact Sheets

▶ Materials Required but not Provided:

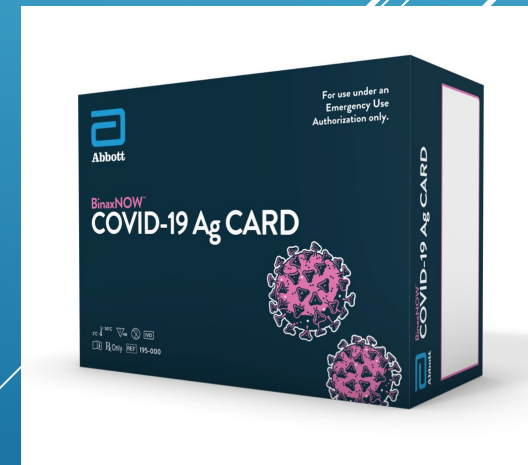
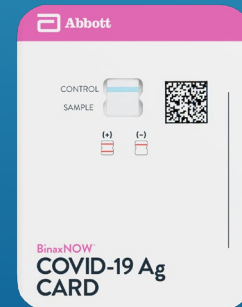
- ▶ Clock, timer or stopwatch

▶ Optional Materials:

- ▶ Plastic Transport Tube

▶ Storage & Stability:

- ▶ Store kit at 2-30°C
- ▶ Ensure all test components are at room temperature before use
- ▶ Stable until the expiration date marked on the outer packaging



Quality Control

BinaxNOW™ COVID-19 Ag Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run.

► Procedural Controls:

- In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position, which is an internal procedural control.
- In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working.
- The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes.
- Background color should not hinder reading of the test.



Note: If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.

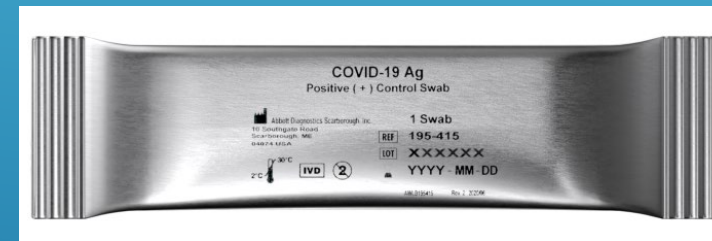
Quality Control

► External Positive & Negative Controls:

- Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed
- BinaxNOW™ COVID-19 Ag Card kits contain a positive control swab and sterile swabs that can be used as a negative control
- These swabs will monitor the entire assay

Required Frequency:

- New shipments received
- Untrained operators
- Conforming with local, state, and/or federal regulations, accrediting groups, or lab's standard QC procedures.



If correct results are not obtained, contact Technical Services before testing patient specimens.