Abbott

FAST, EASY AND COST-EFFECTIVE COVID-19 TESTING

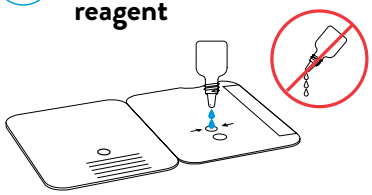
BinaxNOW™ COVID-19 Ag CARD

When it comes to testing for COVID-19, your patients are looking for answers — and you're looking for a fast, easy and cost-effective way to help. Abbott has designed the BinaxNOW™ COVID-19 Ag Card for decentralized testing, so you can test right at the point of care and get results for your patients quickly and easily.

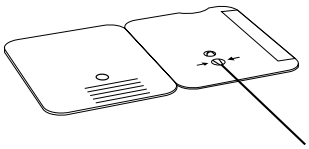
- Simple, CLIA-waived test procedure*
- Direct nasal swab
- No instrument necessary
- Visually read results in 15 minutes

FAST, EASY TEST PROCEDURE**

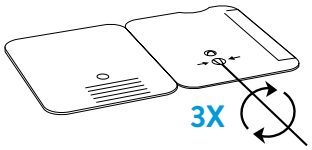
1 Add the extraction reagent



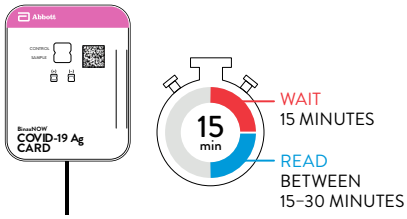
2 Insert the sample nasal swab



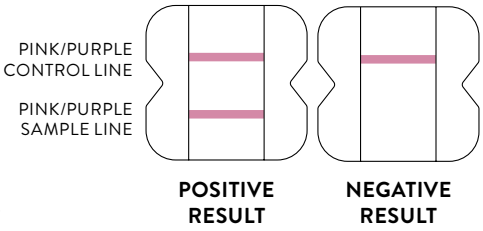
3 Rotate the nasal swab shaft three times



4 Close the test card; wait 15 minutes



5 Visually read the results



PERFORMANCE**

Direct nasal swabs taken from individuals suspected of COVID-19 by their healthcare provider within 7 days of symptom onset.

Sensitivity (PPA) **84.6%**

Specificity (NPA) **98.5%**

NPA = negative percent agreement
PPA = positive percent agreement

KIT CONTENTS

- 40 test cards
- 40 nasal swabs
- 1 positive control swab
- 1 reagent bottle
- 1 package insert
- 1 procedure card
- 40 patient COVID-19 fact sheets
- 1 healthcare provider COVID-19 fact sheet

ORDER INFORMATION

PRODUCT NAME	PRODUCT CODE
BinaxNOW™ COVID-19 Ag CARD 40 CT	195-000
BinaxNOW™ COVID-19 Ag CARD CONTROL KIT (10 POSITIVE)	195-080
COVID-19 SWAB TRANSPORT TUBE ACCESSORY PACK (24 CT)	190-010
BinaxNOW™ COVID-19 Ag CARD REAGENT ACCESSORY PACK (2 BOTTLES)	195-090

FOR MORE INFORMATION, CONTACT YOUR LOCAL ABBOTT REPRESENTATIVE OR VISIT **GLOBALPOINTOFCARE.ABBOTT**

*Before testing patients, federal regulations require testing sites to have a CLIA certificate issued by the Centers for Medicare & Medicaid Services. Sites performing only waived tests must obtain a Certificate of Waiver by applying for this certification for each location performing testing.

**Refer to the product package insert for full instructions and information on serial testing.

The BinaxNOW™ COVID-19 Ag Card has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization. It has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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