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Veterans Health Administration

Title: BinaxNOW COVID-19 Ag Card Test Document No. POC 44 113 Rev. No. 1.1

POC 44 113 BinaxNOW COVID-19 Ag Card Test

Copy of version 1.1 (past periodic review date (1/28/2023))

Last Approval or Periodic Review Completed 1/28/2021
Next Periodic Review Needed On or Before 1/28/2023
Effective Date 1/21/2022

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Comments for version 1.0 (last major revision)

Initial version
 Corrected header- date, SOP #
 Format changes. Reviewed by A. Hankerson.

Comments for version 1.1 (this revision)

qc fail qc revision reviewed. Major revision for Test entry change from LRFAST/BYPASS to Manual Test Entry via RALS website. REVIEWED BY A. HANKERSON

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	1/28/2021	1.0	Eugene Pearlman	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.1	Past Periodic Review Date (1/28/2023)	Minor revision	11/3/2021	1/21/2022	Indefinite
1.0	Retired	Initial version	1/9/2021	1/28/2021	1/21/2022

1/21/2022



BINAX NOW COVID -19 Ag

POC 44 113

Memphis VA Medical Center
Memphis, TN 38104

Service Line(s):
Pathology and Laboratory Medicine
Service- Ancillary Testing & Nursing

Signatory Authority:
Chief, Pathology and Laboratory
Medicine Service

Effective Date:
January 15, 2021

Responsible Owner:
Kimberly Ballard, MHA, MT (ASCP)
Ancillary Testing Coordinator

Recertification Date:
January 31, 2026

1. PURPOSE AND AUTHORITY

- a. The purpose of this standard operating procedure (SOP) is to establish procedures on qualitative detection of the nucleocapsid protein antigen to SARS CoV-2 directly from nasal swab specimens collected from individuals suspected of COVID-19 within seven (7) days of the onset of symptoms. This SOP must be followed by nursing and laboratory staff members who have been initially trained and competency assessed.
- b. This SOP sets forth mandatory procedures and processes to ensure compliance with CLIA'88 Section 564(b)(1) of the Act, 21 U.S.C §360bbb-3(b)(1).

2. ASSIGNMENT OF RESPONSIBILITIES

- a. **Medical Lab Director.** Has the overall responsibility of ensuring that the provisions of this SOP are followed by all personnel in the use of the BinaxNOW COVID-19 Antigen Card Test in the Memphis VA Medical Center.
- b. **Ancillary Testing Coordinator.** Responsible for quality management and technical oversight functions regarding this test.
- c. **Ancillary Testing Specialist.** Provide technical assistance to testing personnel as needed, perform all proficiency testing, provide feedback to testing personnel on any specimen quality issues, and assist Ancillary Testing Coordinator in the performance of his/her duties.
- d. **Testing Operators** Responsible for the proper performance and documentation of all procedures as described in this SOP.

3. DEFINITIONS

- a. **Personal protective equipment.** Includes but not limited to gloves, gown, face shield, mask, and goggles to protect operator from potentially infectious diseases.



- b. **EUA.** Emergency Use Authorization supported by the Secretary of Health and Human Services declaration that circumstances exist to justify the emergency use of test platform without review from Food and Drug Administration (FDA).
- c. **CLIA'88** Clinical Laboratory Improvement Amendment of 1988, laboratory governing agency.

4. SPECIMEN INFORMATION

- a. Specimen Transport and Storage
 - (1) Only the swab provided in the kit is to be used for nasal swab collection.
 - (2) Test samples immediately after collection. Do not return the nasal swab to the original paper packaging.
 - (3) Testing is intended to be performed with a near patient workflow- no transport involved.
 - (4) It is stable for 1hour at room temperature (15-30°C).
 - (5) If greater than 1hour delay occurs, dispose of sample. A new sample must be collected.
- b. To collect sample:
 - (1) Carefully insert the swab into the nostril exhibiting the most visible drainage or congestion.
 - (2) Using gentle rotation, push the swab until resistance is met at the level of turbinate.
 - (3) Rotate swab five (5) times or more against the nasal wall then slowly remove.
 - (4) Using the same swab, repeat sample collection in the other nostril.

5. SPECIAL SAFETY PRECAUTIONS

- a. Wear appropriate personal protective equipment when running each test and handling patient samples. Change gloves when handling samples suspected of COVID-19.
- b. Do not use kit past the expiration date.
- c. Do not mix components of kits from different lots.
- d. Do not store samples in viral transport media for storage.
- e. Do not use swabs other than those supplied with use of this kit.



6. EQUIPMENT/FORMS

- a. BinaxNOW Training and Competency Assessment
- b. VISTA Lab access to include ^Bypass [LRFASST] function

7. REAGENTS

- a. Test card
- b. Extraction Reagent (one bottle containing 10mL of extraction reagent)
- c. Nasal Swab
- d. Positive Control Swab (Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried on swab)
- e. Negative Control Swab (Sterile patient swab)
- f. Timing device

8. QUALITY CONTROL

- a. External quality controls are to be performed once a month, on each new lot of kits, and on every untrained operator.
- b. Each card has an internal procedural control which is the pink/purple line at the “Control” position is the internal and must be documented on each test run.
- c. The clearing of the background color from the result window is a negative background control. It should be light pink to white and not hinder reading of the test after 15 minutes.
- d. Quality controls are indicated by either “PASS” or “FAIL”. Instruments or kits where quality controls have “PASSED” are satisfactory for patient use.
- e. Instruments or kits where quality controls have “FAILED” should be repeated using a new test strip/ cartridge and control solutions. Failed results could be an indicator of sampling air bubbles, expired reagents/ supplies, or underfilling test strips/ cartridges.
- f. Cease patient testing if failed quality controls persist by the third trial. Contact ATC for further troubleshooting instructions, to gain a replacement meter or kit, or other testing supplies.
- g. If ATC is unavailable, cease patient testing, remove meter or kit from service (attach a “Do Not Use” label or give to charge nurse on duty to arrange return to ATC) collect appropriate patient sample for analysis by the main lab.



9. EQUIPMENT CALIBRATION AND MAINTENANCE

a. n/a

10. PROCEDURES

a. Sample Test Procedure

- (1) Open the test card just prior to use. Lay it flat on a clean dry surface.
- (2) Label the outside of card with full patient identification, date, and time.
- (3) Open card. Hold the Extraction Reagent bottle vertically. Hovering ½ inch above the top hole, slowly add 6 drops to the top hole of the swab well. Do not touch the card to the dropper tip while dispensing.
- (4) Insert sample swab or control swab into the bottom hole and firmly push upwards so that the swab tip is visible in the top hole.
- (5) Rotate swab shaft 3 times clockwise (to the right). Do not remove swab.
- (6) Peel off adhesive liner from the right edge of the test card.
- (7) Close and securely seal the card by pressing along the right edge of the card.
- (8) Read result after setting a timing device for 15 minutes. Results should only be read after 15 minutes and not to exceed 30 minutes.
- (9) The attached patient swab/ card should be discarded in a biohazard container.

b. Method Limitations

- (1) This test has been authorized only for detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
 - (2) This test has not been FDA cleared or approved; it is authorized under FDA under an EUA for use by laboratories certified under CLIA'88
- c. False negative results can occur if the swab is not rotated prior to closing card, improper specimen collection, or tested beyond one hour of collection.
- d. Invalid results can occur when insufficient extraction reagent is delivered to the card.
- e. Negative results from patients with symptom onset beyond 7 days should be tested as presumptive and confirmed by molecular assay.



11. ENTRY OF RESULTS

a. A negative specimen will give a single pink/purple colored Control Line in the top half of the window.

(1) This Control Line means that the detection part of the test was performed correctly but no COVID-19 antigen was detected.

b. A positive specimen will give two pink/purple colored lines.

(1) This means that COVID-19 antigen was detected.

(2) Any visible pink/ purple colored line is positive.

c. Test should be ordered as:

(1) COVID-19 DIAG ANTIGEN BINAXNOW PANEL(AT)

(2) COVID-19 MONT ANTIGEN BINAXNOW PANEL(AT)

(3) COVID-19 SCR ANTIGEN BINAXNOW PANEL(AT)

d. Test Ordering Procedure

(1) Ensure that there is a “TEXT ORDER” placed in CPRS for the patient/employee.

(2) Under the RALS Manual Test Entry (MTE), enter all patient information. (Users must have access to the website <https://10.78.14.27/rals/#/login>.)

(3) Upon login to above web address, Click on the  located in lower left corner of screen, then select “RESULT”

(4) Enter/ select only the following:

(5) Location: MEM 1 West (Memphis VAMC)

(6) Manual Test: MEM COVID 19 (COVID-19).

(7) Sample Type: Patient. Click “NEXT”.

(8) Sample ID: Enter the patient FULL Social Security Number.

(9) Kit Lot: This is the lot number of the used for testing located on the posterior of the box.

(10) Collection Time: Time patient sample was collected.

(11) Result Time: Should be 15-30 minutes after collection time.



- (12) Specimen Type: Swab (COVID-19). Click “NEXT”.
- (13) Control Line: Acceptable (DO NOT enter patient order if UNACCEPTABLE.)
- (14) SARS-CoV-2 Ag: POSITIVE or NEGATIVE (This is your patient result.)
- (15) Test Kit: Select the current kit used for testing.
- (16) Skip down to “NEXT”
- (17) You may go back to entries if changes or errors were made. Go back through the prompts as described in this procedure to make changes.
- (18) Click on “ SAVE”. Once you have clicked on SAVE, you CAN NOT go back and make correction.

12. NOTIFICATION

- a. All results are to be notified to the provider upon conclusion of testing each patient sample.

13. REFERENCES

- a. BinaxNOW COVID-19 Ag Product Insert, IN95000 Rev.1 2020/08
- b. VHA Directive 11, Veterans Health Administration Coronavirus (COVID-19) Clinical Testing Guidance, dated December 17, 2020.

14. APPENDICES

NONE

15. REVIEW

This SOP will be reviewed at least every 2 years, when there are changes to the government document that need to be made and any regulatory requirement for frequent review.

16. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of January 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

17. SIGNATORY AUTHORITY

Dr. Eugene Pearlman



January 15, 2021

POC 44 113

Pathology and Laboratory Medicine Service, Chief

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This SOP is available in Media Lab at:
<https://www.medialab.com/dv/?e=1565da46f>