Abbott

BinaxNOW™ COVID-19 ANTIGEN SELF TEST

Healthcare Provider Instructions for Use

For Use Under an Emergency Use Authorization (EUA) Only
For use with anterior nasal swab specimens

For ***in vitro*** Diagnostic Use Only

INTENDED USE

The BinaxNOW™ COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older.

The BinaxNOW COVID-19 Antigen Self Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the BinaxNOW COVID-19 Antigen Self Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory *In Vitro* Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The BinaxNOW COVID-19 Antigen Self Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The BinaxNOW COVID-19 Antigen Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY and EXPLANATION of the TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States.

The BinaxNOW COVID-19 Antigen Self Test is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from anterior nasal swabs, without viral transport media. The BinaxNOW COVID-19 Antigen Self Test kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLES of the PROCEDURE

The BinaxNOW COVID-19 Antigen Self Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from direct anterior nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

To perform the test, an anterior nasal swab specimen is collected by the patient, then 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.

REAGENTS and MATERIALS

Materials Provided

Test Cards (2): A cardboard, book-shaped hinged test card containing the test strip
Extraction Reagent (2): Bottle containing <1 mL of extraction reagent
Nasal Swabs (2): Sterile swab for use with BinaxNOW COVID-19 Antigen Self Test
Patient Instructions for Use (1)
Individual Fact Sheet (1)

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This test has not been FDA cleared or approved but has been authorized by FDA under an EUA.
3. Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
4. Use of gloves is recommended when conducting testing.
5. Keep testing kit and kit components out of the reach of children and pets before and after use.
6. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
7. The emergency use of this product 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.
8. Proper sample collection and handling are essential for correct results.
9. Do not use a kit that has been opened and/or tampered with.
10. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
11. Do not dip the swab into the liquid reagent or other liquid before inserting the swab into the nose.
12. Do not touch swab tip when handling the swab sample.
13. Do not use kit past its expiration date.
14. Do not mix components from different kit lots.
15. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card or swab.
16. Dispose of kit components and patient samples in household trash.
17. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold bottle vertically, 1/2 inch above the swab well, and add drops slowly.
18. The Reagent Solution contains a harmful chemical (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

Chemical Name/CAS	GHS Code for each Ingredient	Concentration
Sodium Azide/26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.0125%

STORAGE and STABILITY

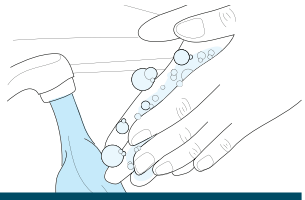
Store kit between 35.6-86°F (2-30°C). Ensure all test components are at room temperature before use. The BinaxNOW COVID-19 Antigen Self Test is stable until the expiration date marked on the outer packaging and containers.

INSTRUCCIONES - EMPIEZA AQUÍ

Lea atentamente las instrucciones antes de iniciar la prueba. Se recomienda utilizar tambien guantes (no suministrados) durante las pruebas.

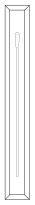
ANTES DE EMPEZAR

1. Lávese o desinféctese las manos. Asegúrese de que están secas antes de empezar.



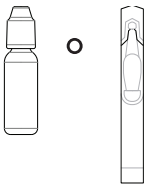
A. PREPARARSE PARA LA PRUEBA

1 hisopo



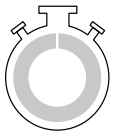
1 tarjeta de prueba en bolsa

1 frasco gotero



o

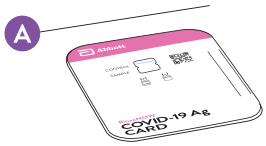
Dispositivo para medir el tiempo (no incluido)



! **NO toque ninguna parte del interior de la tarjeta. Manipule la tarjeta agarrándola solo por los bordes.**

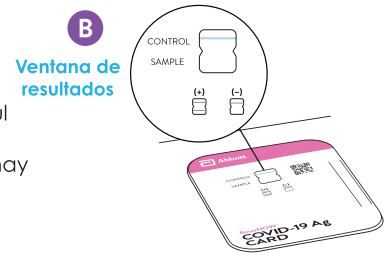
! **La tarjeta debe permanecer PLANA en la mesa durante todo el examen.**

2. Saque la tarjeta de prueba de la bolsa y coloquela en posición plana sobre la mesa.

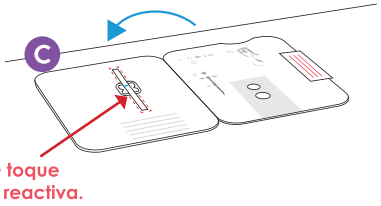


La tarjeta debe quedar en posición plana sobre la superficie de la mesa durante toda la prueba.

Asegúrese de que la linea azul de control esté presente en la ventana de resultados. Si no hay una linea azul, no utilice esta tarjeta.



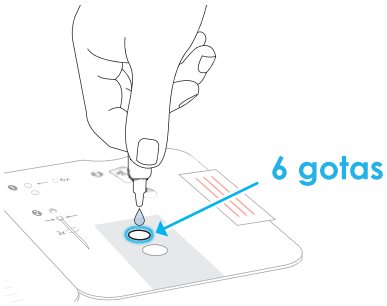
Abra la tarjeta plana sobre la mesa. Doble la columna en la dirección opuesta para ayudar a que la tarjeta permanezca plana.



3. Retire el tapon del frasco gotero.

Sujete el frasco gotero directamente sobre el **orificio superior**, sin formar un ángulo.

Eche 6 gotas en el orificio superior.
No toque la tarjeta con la punta.

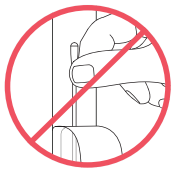


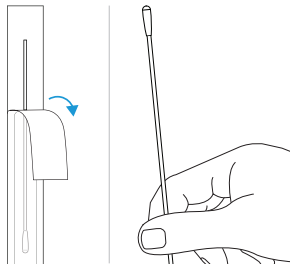
Nota: Se pueden producir resultados falsos negativos si se echan menos de 6 gotas de liquido en el orificio.

B. TOMAR LA MUESTRA NASAL

! **Mantenga los dedos alejados de la punta del hisopo.**

4. Abra el envase del hisopo por el extremo del baston. Extraiga el hisopo.

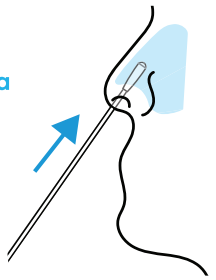




5. **Frote ambas fosas nasales con cuidado como se muestra.**
Introduzca la totalidad de la punta absorbente del hisopo en una fosa nasal (habitualmente, de 1/2 a 3/4 de pulgada).

No es necesario ir mas profundo.

A **Hasta 3/4 de pulgada**

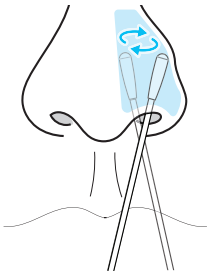


Utilizando una presion media, frote el hisopo contra todas las paredes interiores de la fosa nasal.

Haga al menos **5 circulos grandes.**
No se limite a girar el hisopo.

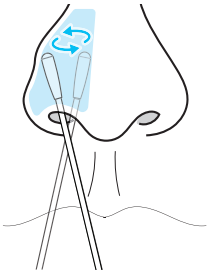
Hay que frotar cada fosa nasal durante unos **15 segundos**.

B **Al menos 5 circulos grandes**



Con el mismo hisopo, repita el paso 5 en la otra fosa nasal.

C **Al menos 5 circulos grandes**



ALTO

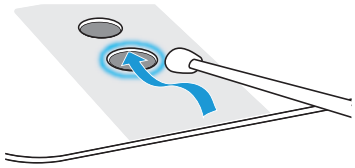
Comprobaciones:
¿Ha frotado el hisopo en AMBAS fosas nasales?

Nota: Se pueden producir resultados falsos negativos si la muestra nasal no se toma correctamente con el hisopo.

C. REALIZA LA PRUEBA

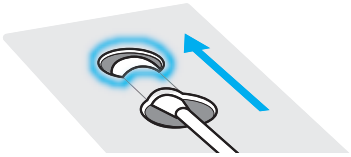
! **Mantenga la tarjeta de FORMA HORIZONTAL O PLANA sobre la mesa.**

6. Introduzca el hisopo en el orificio inferior.



Empuje firmemente la punta del hisopo desde el orificio inferior hasta que se vea en el orificio superior.

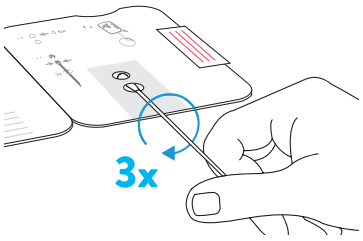
No retire el hisopo de la tarjeta.



7. Gire el hisopo hacia la derecha tres veces para mezclar el hisopo con las gotas.

No se salte este paso.

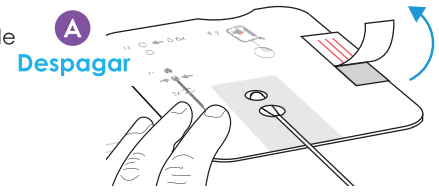
Deje el hisopo en la tarjeta durante el resto de la prueba.



Nota: Se pueden producir resultados falsos negativos si se echan menos de 6 gotas de liquido en el orificio.

! **NO retire el hisopo.**

8. Despegue la cubierta del adhesivo. Tenga cuidado de no tocar otras partes de la tarjeta.



Cierre el lado izquierdo de la tarjeta sobre el hisopo. Presione firmemente sobre las dos líneas del borde derecho de la tarjeta para sellarla.

Mantenga la tarjeta sobre la mesa mirando hacia arriba.

! **NO retire el hisopo.**

9. **Espere 15 minutos.**

Lea el resultado a los 15 minutos.

No lea el resultado antes de 15 minutos ni después de 30 minutos.

Mantenga la tarjeta sobre la mesa mirando hacia arriba.

Nota: Se pueden producir resultados falsos negativos si se echan menos de 6 gotas de líquido en el orificio.

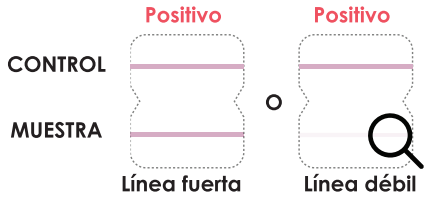
Nota: Los resultados no se deben leer luego de transcurrido 30 minutos.

D. INTERPRETA LOS RESULTADOS

A. Comprobación de un resultado positivo de COVID-19

Localice la ventana de resultados y busque detenidamente si aparece, dos líneas rosas/moradas.

Resultado positivo: Si ve dos líneas rosas/moradas (una en la mitad superior y otra en la inferior), significa que se ha detectado COVID-19.



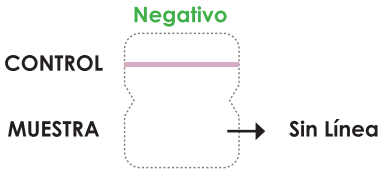
'Mire muy detenidamenta' La línea inferior puede ser muy debil. Cualquier línea de color rosa/morado que apresca aqui indica un resultado positivo

Estas fotografías son de pruebas positivas reales. A la derecha, observe lo débil que puede ser la línea inferior.

B. Comprobación de un resultado negativo de COVID-19

Localice la ventana de resultados y busque una unica línea de color rosa/morada en la ventana.

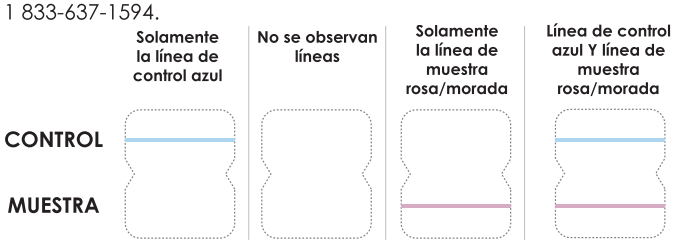
Resultado negativo: Si solo ve una línea rosa/morada en la mitad superior, donde dice "Control", significa que no se detectó COVID-19.



C. Comprobar resultado inválido

Si observa cualquiera de estas combinaciones, la prueba es inválida. Un resultado inválido significa que esta prueba no pudo determinar si usted tiene COVID-19 o no. Se necesita una nueva prueba para obtener un resultado válido.

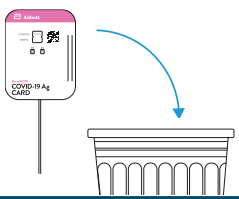
Pongase en contacto con Servicio Técnico llamando al + 1 833-637-1594.



Nota: Consulte el dorso para leer sobre lo que significan los resultados.

E. DESECHAR EL KIT DE PRUEBA

Tire a la basura todos los componentes usados del kit de pruebas.



F. INFORMAR SUS RESULTADOS

Por favor, comparta el resultado de su prueba con su proveedor de atención médica.