Objectives

• Provide instructions for employees who are performing COVID-19 tests
• Learn about the type of test FSIS will be using for testing
• Learn procedures for COVID-19 testing and how to understand test results

These interim considerations on SARS-CoV-2 testing strategies for non-healthcare workplaces during the COVID-19 pandemic are based on what is currently known about the transmission and severity of COVID-19 and is subject to change as additional information becomes available.

COVID-19 Voluntary Use of COVID-19 Self Test Kits

These instructions are for employees who:

1. Become symptomatic while at the workplace
   • Can perform the test at the same time symptoms develop
2. Employees who have been exposed to persons with COVID-19 at the physical worksite or in the performance of their official duties can perform testing
   • An employee who has no symptoms and has been exposed should perform the test at least five days after the employee last had close contact with someone with COVID-19
   • An employee who has developed symptoms should perform the test at the same time symptoms develop
COVID-19 Voluntary Use of COVID-19 Self Test Kits

Additional reasons for self-tests include:

3. Testing prior to, and immediately following, travel in accordance with CDC guidance
4. Testing of employees attending large scale meetings prior to the start of the meeting, daily for the full duration of the meeting, and after the conclusion of the meeting

Quarantine and Isolation, Updated March 30, 2022
Self-Testing | CDC, Updated March 9, 2022
Stay Up to Date with Your Vaccines | COVID-19 | CDC, Updated April 21, 2022
Safer Federal Workforce, Accessed May 2022
Domestic Travel During COVID-19, Updated May 3, 2022
COVID-19 Voluntary Use of COVID-19 Self Test Kits

Additional reasons for self-tests include:

5. Testing by employees at the physical worksite who are not fully vaccinated and who have no symptoms according to CDC guidance
   • If an employee is not fully vaccinated and would like to voluntarily be tested, the employee can perform testing on a weekly basis when COVID-19 Community Levels are MEDIUM or HIGH.

6. Any other work-related reason where an employee requests a COVID test. No justification or documentation is required
   • Employees can request test kits from their supervisor, and no proof of worksite exposure is needed

Quarantine and Isolation, Updated March 30, 2022
Self-Testing | CDC, Updated March 9, 2022
Stay Up to Date with Your Vaccines | COVID-19 | CDC, Updated April 21, 2022
Safer Federal Workforce, Accessed May 2022
Employee Responsibilities: Positive Test Results

- FSIS employees who test positive for COVID-19 may not physically report to a USDA worksite until they complete CDC recommended isolation, even if they are asymptomatic, and regardless of vaccination status, and regardless of whether they perform mission critical duties.

- If an employee has received a FSIS provided COVID-19 test and receives a positive result, they must immediately notify their supervisor or appropriate FSIS-designated supervisory point of contact, and the supervisor is expected to follow the USDA COVID-19 Workplace Safety Plan guidance.
COVID-19 Quarantine and Testing Guidance After Exposure

- Up to date on vaccines means a person has received all recommended COVID-19 vaccines, including any booster dose(s) when eligible
- Employees who are persons exposed to COVID-19 and not up to date on COVID-19 vaccines should quarantine for at least five days
- Employees up to date on COVID-19 vaccines or had confirmed COVID-19 within the last 90 days and have completed isolation do not need to quarantine
- If an employee has no symptoms, perform test at least five days after the employee last had close contact with someone with COVID-19
  - If the employee who was exposed develops symptoms consistent with COVID-19 during the workday prior to five days, the employee must immediately isolate, wear a mask, notify their supervisor, and promptly leave the workplace
  - The employee can perform testing the same day symptoms develop
  - This applies both to employees who were exposed to COVID-19 at the physical worksite who are not up to date on their vaccinations, as well as employees who are up to date on their vaccinations

USDA COVID-19 Workplace Safety Plan, Updated January 14, 2022
Quarantine and Isolation, Updated January 9, 2022
Stay Up to Date with Your Vaccines, January 16, 2022
COVID-19 Screening Testing Guidance for USDA Employees, Accessed May 2022
CareStart™ COVID-19 Antigen Home Test

Device: CareStart COVID-19 Antigen Home Test
EUA¹ Number: EUA210314
Company: Access Bio, Inc.

Product Details:
- Non-prescription
- Lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2

EUA = Emergency Use Authorization, On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives.

Source: CareStart COVID-19 Antigen Home Test - Letter of Authorization [fda.gov], Updated November 22, 2021
Indications: Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with:

• Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19.
• Self-collected anterior nasal swab sample from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.
Test Type: Rapid Antigen Serial Self-Test

- Antigen tests detect proteins from the virus
- Molecular tests detect genetic material from the virus
- Antibody tests look for antibodies that are made by the immune system
Test Type at FSIS: Rapid Antigen Serial Self-Test

- **Rapid**: results are available in **10 minutes**
- **Antigen**: detect specific **proteins** on the surface of virus
- **Self-test**: Employee will collect their own sample

Source: USDA COVID-19 Workplace Safety Plan, Updated March 31, 2022
COVID-19 Tests and Collection Kits Authorized by the FDA: Infographic | FDA Updated September 2021
CareStart COVID-19 Antigen Home Test - Letter of Authorization (fda.gov), Updated November 22, 2021
Safer Federal WorkForce, Accessed May 2022
COVID-19 Screening Testing Guidance for USDA Employees, Accessed May 2022
Potential Risks and Benefits

SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. The test is used to detect this protein antigen.

Potential risks include:
- Possible discomfort or other complications that can happen during sample collection
- Possible incorrect test result

Potential benefits include:
- The results of this test may help limit the spread of COVID-19 to your family, your colleagues, and others in your community
- The results, along with other information, can help your healthcare provider make informed recommendations about your care

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated 2021
CareStart COVID-19 Antigen Home Test Video in Spanish: (see attached/linked video)
How to Perform Testing

• Follow the test instructions:
  – “CareStart™ COVID-19 Antigen Home Test User Instructions” provided as a hard copy with the kit
• Review the fact sheet
• The test should be observed by the supervisor or by the supervisor’s FSIS designee during:
  • Test administration (swabbing nares) AND
  • Reading test result
  • The observation could be either in person or virtually
• Storage: Store kit between 34–86°F (1–30°C)
  • Room temperature, not extreme heat or extreme cold

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
Safer Federal WorkForce, Updated January 2022
How to Perform Testing

1. Wash your hands thoroughly for at least 20 seconds before the test. Make sure your hands are dry.
2. Unpack the test components from the tray.
3. Remove the test cassette and place it on a flat, clean surface.
4. Locate the extraction vial and gently peel off the aluminum foil seal, being sure to keep the vial upright and place it in the packaging tray.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
How to Perform Testing

5. Locate a nasal swab and remove from the pouch. Be careful not to touch the swab tip.
6. Gently insert the swab no more than 3/4 inch into the LEFT nostril. Then, slowly rotate the swab at least 5 times in a circular path for a total of 15 seconds. If you have questions, see the CDC Guidelines.
7. Gently remove the swab from the LEFT nostril and place directly into the RIGHT nostril, repeating the process of rotating at least 5 times in a circular path for a total of 15 seconds. Remove the swab from the RIGHT nostril.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
How to Perform Testing

8. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.
9. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.
10. Close the vial by pushing the cap firmly onto the vial.
11. With your finger, mix thoroughly by flicking the bottom of the vial.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), November Updated 2021
How to Perform Testing

12. Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow THREE (3) drops of sample to fall into the sample well.

13. Start a timer. Read the result at **10 minutes**. The test result should **not be read after 15 minutes**. Do not move or lift the test cassette during this time.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
How do I know if I have a negative test result?

- Only one purple-colored line only next to “C” indicates a negative result.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
How do I know if I have a positive test result?

- One purple-colored line next to “C” and one blue-colored line next to “T” indicates COVID-19 positive result.
- Important: Look very closely! The color intensity in the test region will vary.
- Any faint colored line in the test region should be considered as positive.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
What do I do if I have a positive test result?

- A positive test result indicates that antigens from SARS-CoV-2 were detected.
- The person is very likely to be infected with the virus and presumed to be contagious.
- Test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.
- You should self-isolate at home and avoid contact with others as per CDC recommendations to avoid spreading the virus to others.
- Alert your health care provider of the result as follow-up care or testing may be indicated.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
If you have a positive test result: Leave Workplace, Notify Supervisor, Report Result, and Alert Health Care Provider

- Immediately notify their supervisor or appropriate FSIS-designated supervisory point of contact, and the supervisor is expected to follow the USDA COVID-19 Workplace Safety Plan
- Employees who test positive for COVID-19 may not physically report to a FSIS worksite until they complete CDC recommended isolation, even if they are asymptomatic, and regardless of vaccination status, and regardless of whether they perform mission critical duties
- If an employee is required to isolate for probable or confirmed COVID-19 and is unable to telework, the employee may request sick leave, accrued annual leave, or other forms of earned paid time off (e.g., compensatory time off or credit hours) or unpaid leave in this situation, as appropriate
- Alert health care provider right away that tested positive by an antigen self-test and seek follow-up care with healthcare provider
  - If test positive and are more likely to get very sick from COVID-19, treatments are available that can reduce chances of being hospitalized or dying from the disease
  - Medications to treat COVID-19 must be prescribed by a healthcare provider and started as soon as possible after diagnosis to be effective. Contact a healthcare provider right away to determine if you are eligible for treatment, even if your symptoms are mild right now.

If you have a positive test result: Leave Workplace, Notify Supervisor, and Alert Health Care Provider

- Reporting COVID as a work-related injury/illness:
  - Employee will complete the CA-1 and submit to their supervisor who, in turn, will forward to FSIS Workers’ Compensation at askworkerscomp@usda.gov
  - If the injury/illness has been determined by DOL to be work-related, then the supervisor will also log the injury/illness onto the OSHA 300 form.
  - The supervisor informs the chain of command and the regional FSIS Safety and Occupational Health Specialist
  - The Specialist will provide information on recordkeeping standards for OSHA compliance. Under OSHA’s recordkeeping requirements, in case of a workplace exposure where (1) there is a confirmed case of COVID-19, (2) the case is work-related (as defined by 29 CFR 1904.5), and (3) the case involves one or more relevant recording criteria (set forth in 29 CFR 1904.7) (e.g., medical treatment beyond first aid, days away from work), the case must be recorded in the Safety Management Information System for official recording of it on the OSHA Illness and Injury Log.
  - Any employee who works onsite and who fails to report a positive result to their supervisor or agency designee will be referred for potential disciplinary action.
  - Employees who do not work onsite are encouraged, but are not required, to report a positive COVID-19 result

If you have a positive test result: Leave Workplace, Notify Supervisor, and Alert Health Care Provider

• The supervisor reports the positive result up through their respective Program Areas’ chain of command. The Program Area COVID Reporting point of contact will consolidate the results using the COVID reporting spreadsheet and submit it to the OM Significant Incident Preparedness and Response Staff (SIPRS). SIPRS will include in the total cases for the FSIS COVID Impact Report and enter the information into the USDA tracker. The reporting spreadsheet should clearly document that the positive was a result of the USDA screening and diagnostic program.

• Employees who have been working onsite must report if they receive a positive COVID-19 result via this form. Employees who do not work onsite are encouraged, but are not required, to report a positive COVID-19 result.

• All positive COVID-19 cases reported must be entered into the Department’s COVID Positive Test Dashboard which is accessible by the Pandemic Coordinators and follow FSIS’ protocol for positive test reporting.

**If you have a positive test result: Leave Workplace, Notify Supervisor, and Alert Health Care Provider**

- Employees working onsite must notify supervisors if they have received notice, through official State, Local, Tribal, or Territorial contact tracing efforts, that they may have had a close contact in the workplace. If an FSIS supervisor is made aware of a work-related close contact outside of official State, Local, Tribal, or Territorial contact tracing efforts, they should notify all employees who have been exposed at close contact at the workplace and proceed based on the exposed employees’ vaccination status:
  - Employees who are **up to date** on their COVID-19 vaccines and have had a close contact may remain at the worksite as long as they remain asymptomatic and wear a mask indoors at all times and outdoors when around other people. These employees should be tested at least 5 calendar days after exposure in order to continue being physically present at the worksite, even if they do not have symptoms
  - Exposed employees who are fully vaccinated, but are not up to date on their vaccines (e.g., have not received recommended booster doses), may not be physically present at the worksite for at least 5 days and should get tested at least 5 calendar days after their last close contact exposure
  - Not fully vaccinated employees may not be physically present at the worksite for at least 5 days and should get tested at least 5 calendar days after their last close contact exposure

If you have a positive test result: Leave Workplace, Notify Supervisor, and Alert Health Care Provider

- USDA’s Workplace Safety Plan outlines workplace flexibilities for employees that are close contacts, including telework, use of accrued leave, Leave Without Pay, and administrative leave
- Reporting of COVID-related concerns: If an employee is concerned that the establishment is not adequately providing controls to prevent the spread of COVID-19, the employee can complete a 4791-27 form and send it to their supervisor

If you have a positive test result while on official travel

• In accordance with the Safer Federal Workforce Task Force guidance and the USDA COVID-19 Workplace Safety Plan, FSIS employees should adhere strictly to CDC guidance for domestic and international travel before, during, and after official travel.

• Official travel is travel conducted under an official travel authorization.

• If an employee has a probable or confirmed case of COVID-19 while on official travel:
  • Pursuant to Executive Order 13991 and consistent with CDC guidance, the individual is to follow CDC isolation protocols.
  • The employee will not undertake further travel, including return travel, for 10 full days after their first day of symptoms, or after the date of a positive viral test for asymptomatic individuals.
  • FSIS will cover all travel and lodging expenses, as well as the cost of any diagnostic testing, in these circumstances.

Source: Safer Federal Workforce, Accessed June 2022
If you have a positive test result while on official travel

- If FSIS determines that an employee absolutely must undertake urgent, necessary, and mission-critical return travel during days 6-10 after the first day they experience symptoms, or after the date of a positive test for an asymptomatic individual, then the employee is to take other precautions for the entire duration of their travel during the 10 days after their first day of symptoms, or after the date of a positive test for an asymptomatic individual, including wearing a well-fitting mask when around others and, to the extent possible, avoiding eating and drinking around others, avoiding environments such as dining facilities and gyms where they may be unmasked around others, avoiding people who are immunocompromised or at high risk for severe disease, and avoiding nursing homes and other high-risk settings.

Source: Safer Federal WorkForce, Accessed June 2022
How do I know if I have an invalid result?

- **Invalid barcode or absence of a purple-colored line next to “C.”**
- Re-test with a COVID-19 test may be needed.
- An invalid test result indicates that your test has experienced an error and is unable to interpret the result of the test.
- You will need to re-test with a new test.
- If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the retest.
- The supervisor will order an additional test kit.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
Performance Specifications and Limitations

- Check the expiration date
  - If the expiration date on test has already passed, contact propertymanagement@usda.gov for the updated expiration date
  - FDA has updated the shelf-life expiration date to 9 months when tests are stored at 1–30°C
- Do not use expired tests or components that are damaged
- Employees may voluntarily elect to perform additional confirmatory testing 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
- A negative test result indicates that antigens from SARS-CoV-2 were not detected from the specimen. However, a negative result does not rule out COVID-19 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.

Source: CareStart COVID-19 Antigen Home Test - Letter of Authorization (fda.gov), Updated November 22, 2022
CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated November 2021
CareStart COVID-19 Antigen Home Test - Expiration Date Notice (fda.gov), Updated January 22, 2022
Can the Test be Thrown into the Garbage after Use?

Yes, dispose of all used test kit components and swab samples in household trash.

Source: CareStart COVID-19 Antigen Home Test - User Instructions (fda.gov), Updated 2021
Reporting Results

- Emails containing COVID-19 test results are medical records.
- Optional: To further promote privacy and IT security, the employee may select “encrypt-only” from the option tab in Outlook.
- This will ensure proper controls are implemented for the sharing of sensitive data via email. The employee may also encrypt/password protect any attached files to be shared via email (PDF, Word, etc.) for added protection.
- The Rehabilitation Act requires that test results be kept confidential and limits who may have access to such information.

The Privacy Act statement for the testing requirements will refer to the Government-wide system of records (OPM/GOVT-10) for employee medical files (EMFs), which is governed by OPM regulations (5 C.F.R. part 293, subpart E). [https://www.saferfederalworkforce.gov/faq/testing/](https://www.saferfederalworkforce.gov/faq/testing/), Accessed May 2022.

Questions?

• Refer questions to your supervisor

• For questions regarding ordering test kits, Supervisors or Program Resource Managers may contact the FSIS Office of Management, Administrative Services Division, Property Management Branch at propertymanagement@usda.gov

• All other questions should be directed to fsisfeedback@usda.gov
Abbott BinaxNOW COVID-19 Antigen Self Test
EUA 210264
Objectives

• Provide instructions for employees who are performing COVID-19 tests
• Learn about the type of test FSIS will be using for testing
• Learn procedures for COVID-19 testing and how to understand test results

These interim considerations on SARS-CoV-2 testing strategies for non-healthcare workplaces during the COVID-19 pandemic are based on what is currently known about the transmission and severity of COVID-19 and is subject to change as additional information becomes available.

COVID-19 Voluntary Use of COVID-19 Self Test Kits

These instructions are for employees who:

1. Become symptomatic while at the workplace
   • Can perform the test at the same time symptoms develop

2. Employees who have been exposed to persons with COVID-19 at the physical worksite or in the performance of their official duties can perform testing
   • An employee who has no symptoms and has been exposed should perform the test at least **five days** after the employee last had close contact with someone with COVID-19
   • An employee who has developed symptoms should perform the test at the same time symptoms develop

Quarantine and Isolation, Updated March 30, 2022
Self-Testing | CDC, Updated March 9, 2022
Stay Up to Date with Your Vaccines | COVID-19 | CDC, Updated April 21, 2022
Safer Federal Workforce, Accessed May 2022
COVID-19 Voluntary Use of COVID-19 Self Test Kits

Additional reasons for self-tests include:

3. Testing prior to, and immediately following, travel in accordance with CDC guidance
4. Testing of employees attending large scale meetings prior to the start of the meeting, daily for the full duration of the meeting, and after the conclusion of the meeting
COVID-19 Voluntary Use of COVID-19 Self Test Kits

Additional reasons for self-tests include:
5. Testing by employees at the physical worksite who are not fully vaccinated and who have no symptoms according to CDC guidance
   • If an employee is not fully vaccinated and would like to voluntarily be tested, the employee can perform testing on a weekly basis when COVID-19 Community Levels are MEDIUM or HIGH.

6. Any other work-related reason where an employee requests a COVID test. No justification or documentation is required
   • Employees can request test kits from their supervisor, and no proof of worksite exposure is needed

Quarantine and Isolation, Updated March 30, 2022
Self-Testing | CDC, Updated March 9, 2022
Stay Up to Date with Your Vaccines | COVID-19 | CDC, Updated April 21, 2022
Safer Federal Workforce, Accessed May 2022
Employee Responsibilities: Positive Test Results

• FSIS employees who test positive for COVID-19 may not physically report to a USDA worksite until they complete CDC recommended isolation, even if they are asymptomatic, and regardless of vaccination status, and regardless of whether they perform mission critical duties.

• If an employee has received a FSIS provided COVID-19 test and receives a positive result, they must immediately notify their supervisor or appropriate FSIS-designated supervisory point of contact, and the supervisor is expected to follow the USDA COVID-19 Workplace Safety Plan guidance.
COVID-19 Quarantine and Testing Guidance After Exposure

- Up to date on vaccines means a person has received all recommended COVID-19 vaccines, including any booster dose(s) when eligible
- Employees who are persons exposed to COVID-19 and not up to date on COVID-19 vaccines should quarantine for at least five days
- Employees up to date on COVID-19 vaccines or had confirmed COVID-19 within the last 90 days and have completed isolation do not need to quarantine
- If an employee has no symptoms, perform test at least five days after the employee last had close contact with someone with COVID-19
  - If the employee who was exposed develops symptoms consistent with COVID-19 during the workday prior to five days, the employee must immediately isolate, wear a mask, notify their supervisor, and promptly leave the workplace
  - The employee can perform testing the same day symptoms develop
  - This applies both to employees who were exposed to COVID-19 at the physical worksite who are not up to date on their vaccinations, as well as employees who are up to date on their vaccinations

USDA COVID-19 Workplace Safety Plan, Updated January 14, 2022
Quarantine and Isolation, Updated January 9, 2022
Stay Up to Date with Your Vaccines, January 16, 2022
COVID-19 Screening Testing Guidance for USDA Employees, Accessed May 2022
BinaxNOW™ COVID-19 Antigen Self Test

**Device:** BinaxNOW COVID-19 Antigen Self Test  
**EUA**\(^1\) **Number:** EUA210264  
**Company:** Abbott Diagnostics Scarborough, Inc.  
**Product Details:**  
- Non-prescription  
- Lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2

---

**EUA** = Emergency Use Authorization, On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives.

[BinaxNOW COVID-19 Antigen Self Test - Individual Fact Sheet](https://fda.gov) Updated April 4, 2022
Indications: Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with:

- Self-collected anterior nasal swab sample from individuals aged 15 years or older, or adult collected anterior nasal swab sample from individuals aged two years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19.
- Self-collected anterior nasal swab sample from individuals aged 15 years or older with symptoms of COVID-19 within the first seven days of symptom onset.

EUA = Emergency Use Authorization, On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives.

Source: BinaxNOW COVID-19 Antigen Self Test - Letter of Authorization (fda.gov), Updated April 4, 2022
BinaxNOW COVID-19 Antigen Self Test - Individual Fact Sheet (fda.gov), Updated April 4, 2022
Test Type: Rapid Antigen Serial Self-Test

- Antigen tests detect proteins from the virus
- Molecular tests detect genetic material from the virus
- Antibody tests look for antibodies that are made by the immune system

Source: COVID-19 Tests and Collection Kits Authorized by the FDA: Infographic | FDA Updated September 2021
BinaxNOW COVID-19 Antigen Self Test - Individual Fact Sheet (fda.gov), Updated April 4, 2022
Test Type at FSIS: Rapid Antigen Serial Self-Test

- **Rapid:** results are available in **15 minutes**
- **Antigen:** detect specific **proteins** on the surface of virus
- **Self-test:** Employee will collect their own sample

Source: USDA COVID-19 Workplace Safety Plan, Updated March 31, 2022
COVID-19 Tests and Collection Kits Authorized by the FDA: Infographic | FDA Updated September 2021
BinaxNOW COVID-19 Antigen Self Test - Individual Fact Sheet (fda.gov), Updated April 4, 2022
Safer Federal WorkForce, Accessed May 2022
COVID-19 Screening Testing Guidance for USDA Employees, Accessed May 2022
Potential Risks and Benefits

SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. The test is used to detect this protein antigen.

Potential risks include:
- Possible discomfort or other complications that can happen during sample collection
- Possible incorrect test result

Potential benefits include:
- The results of this test may help limit the spread of COVID-19 to your family, your colleagues, and others in your community
- The results, along with other information, can help your healthcare provider make informed recommendations about your care

Source: BinaxNOW COVID-19 Antigen Self Test - Individual Fact Sheet (fda.gov) Updated April 4, 2022
BinaxNOW™ video in Spanish:

https://fast.wistia.net/embed/iframe/laz6wbihfn
How to perform testing

- Follow the test instructions:
  - “BinaxNOW COVID-19 Antigen Self Test Instructions” provided as a hard copy with the kit OR
  - Follow digital electronic-based step-by-step “BinaxNOW COVID-19 Antigen Self Test Instructions” either via a website or by downloading the “NAVICA App” mobile application onto a compatible smartphone
- Review the fact sheet
- The test should be observed by the supervisor or by the supervisor’s FSIS designee during:
  - Test administration (nasal swab) AND
  - Reading test result
  - The observation could be either in person or virtually
- Storage: Store kit between 35.6-86°F (2-30°C)
  - Room temperature, not extreme heat or extreme cold

BinaxNOW COVID-19 Antigen Self Test - Individual Fact Sheet (fda.gov) Updated April 4, 2022
BinaxNOW COVID-19 Antigen Self Test - Instructions for Use Home Test (fda.gov), Updated November 2021
Safer Federal WorkForce, Accessed May 2022
How to perform testing

• Wash your hands thoroughly for at least 20 seconds before the test. Make sure your hands are dry.
• Open the test kit
• 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well
• A nasal swab specimen is self-collected
• Swab 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
• 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 after 15 minutes based on the presence or absence of visually detectable pink/purple-colored lines
• Test results should not be read after 30 minutes

How do I know if I have a negative test result?

A negative result will have only one pink or purple line on the top half of the results window where it says "control."

Source: BinaxNOW: What You Need to Know | Abbott Newsroom, Updated March 21, 2022
BinaxNOW COVID-19 Antigen Self Test - Instructions for Use Home Test (fda.gov), Updated November 2021
BinaxNOW COVID-19 Antigen Self Test - Letter of Authorization (fda.gov), Updated April 4, 2022
How do I know if I have a positive test result?

- To check for a positive result, look at the result window for two pink or purple lines
- **Even a faint line next to the word "sample" on the test card is a positive result**
- 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
- Individuals who test positive should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary

Look very closely!
The bottom line can be very faint. Any pink/purple line visible here is a Positive Result.

[BinaxNOW COVID-19 Antigen Self Test - Instructions for Use Home Test (fda.gov)](https://www.fda.gov), Updated November 2021
If you have a positive test result: Leave Workplace, Notify Supervisor, and Alert Health Care Provider

• Immediately notify their supervisor or appropriate FSIS-designated supervisory point of contact, and the supervisor is expected to follow the USDA COVID-19 Workplace Safety Plan
• Employees who test positive for COVID-19 may not physically report to a FSIS worksite until they complete CDC recommended isolation, even if they are asymptomatic, and regardless of vaccination status, and regardless of whether they perform mission critical duties
• If an employee is required to isolate for probable or confirmed COVID-19 and is unable to telework, the employee may request sick leave, accrued annual leave, or other forms of earned paid time off (e.g., compensatory time off or credit hours) or unpaid leave in this situation, as appropriate
• Alert health care provider right away that tested positive by an antigen self-test and seek follow-up care with healthcare provider
  • If test positive and are more likely to get very sick from COVID-19, treatments are available that can reduce chances of being hospitalized or dying from the disease
  • Medications to treat COVID-19 must be prescribed by a healthcare provider and started as soon as possible after diagnosis to be effective. Contact a healthcare provider right away to determine if you are eligible for treatment, even if your symptoms are mild right now.

COVID-19 Treatments and Medications, Updated April 29. 2022.
If you have a positive test result: Leave Workplace, Notify Supervisor, and Alert Health Care Provider

- Reporting COVID as a work-related injury/illness:
  - Employee will complete the CA-1 and submit to their supervisor who in turn, will forward to FSIS Workers’ Compensation at askworkerscomp@usda.gov
  - If the injury/illness has been determined by DOL to be work-related, then the supervisor will also log the injury/illness onto the OSHA 300 form.
  - The supervisor informs the chain of command and the regional FSIS Safety and Occupational Health Specialist
    - The Specialist will provide information on recordkeeping standards for OSHA compliance. Under OSHA’s recordkeeping requirements, in case of a workplace exposure where (1) there is a confirmed case of COVID-19, (2) the case is work-related (as defined by 29 CFR 1904.5), and (3) the case involves one or more relevant recording criteria (set forth in 29 CFR 1904.7) (e.g., medical treatment beyond first aid, days away from work), the case must be recorded in the Safety Management Information System for official recording of it on the OSHA Illness and Injury Log.
  - Any employee who works onsite and who fails to report a positive result to their supervisor or agency designee will be referred for potential disciplinary action.
  - Employees who do not work onsite are encouraged, but are not required, to report a positive COVID-19 result

If you have a positive test result: Leave Workplace, Notify Supervisor, Report Result, and Alert Health Care Provider

• The supervisor reports the positive result up through their respective Program Areas’ chain of command. The Program Area COVID Reporting point of contact will consolidate the results using the COVID reporting spreadsheet and submit it to the OM Significant Incident Preparedness and Response Staff (SIPRS). SIPRS will include in the total cases for the FSIS COVID Impact Report and enter the information into the USDA tracker. The reporting spreadsheet should clearly document that the positive was a result of the USDA screening and diagnostic program.

• Employees who have been working onsite must report if they receive a positive COVID-19 result via this form. Employees who do not work onsite are encouraged, but are not required, to report a positive COVID-19 result.

• All positive COVID-19 cases reported must be entered into the Department’s COVID Positive Test Dashboard which is accessible by the Pandemic Coordinators and follow FSIS’ protocol for positive test reporting.

If you have a positive test result: Leave Workplace, Notify Supervisor, Report Result, and Alert Health Care Provider

- Employees working onsite must notify supervisors if they have received notice, through official State, Local, Tribal, or Territorial contact tracing efforts, that they may have had a close contact in the workplace. If an FSIS supervisor is made aware of a work-related close contact outside of official State, Local, Tribal, or Territorial contact tracing efforts, they should notify all employees who have been exposed at close contact at the workplace and proceed based on the exposed employees’ vaccination status:
  - Employees who are up to date on their COVID-19 vaccines and have had a close contact may remain at the worksite as long as they remain asymptomatic and wear a mask indoors at all times and outdoors when around other people. These employees should be tested at least 5 calendar days after exposure in order to continue being physically present at the worksite, even if they do not have symptoms
  - Exposed employees who are fully vaccinated, but are not up to date on their vaccines (e.g., have not received recommended booster doses), may not be physically present at the worksite for at least 5 days and should get tested at least 5 calendar days after their last close contact exposure
  - Not fully vaccinated employees may not be physically present at the worksite for at least 5 days and should get tested at least 5 calendar days after their last close contact exposure

If you have a positive test result: Leave Workplace, Notify Supervisor, Report Result, and Alert Health Care Provider

- USDA’s Workplace Safety Plan outlines workplace flexibilities for employees that are close contacts, including telework, use of accrued leave, Leave Without Pay, and administrative leave.
- Reporting of COVID-related concerns: If an employee is concerned that the establishment is not adequately providing controls to prevent the spread of COVID-19, the employee can complete a [4791-27 form] and send it to their supervisor.

If you have a positive test result while on official travel

- In accordance with the [Safer Federal Workforce](https://www.saferfederalworkforce.com) Task Force guidance and the [USDA COVID-19 Workplace Safety Plan](https://www.usda.gov), FSIS employees should adhere strictly to CDC guidance for [domestic](https://www.cdc.gov) and [international](https://www.cdc.gov) travel before, during, and after official travel.
- Official travel is travel conducted under an official travel authorization.
- If an employee has a probable or confirmed case of COVID-19 while on official travel:
  - Pursuant to Executive Order 13991 and consistent with CDC guidance, the individual is to follow CDC [isolation](https://www.cdc.gov) protocols.
  - The employee will not undertake further travel, including return travel, for 10 full days after their first day of symptoms, or after the date of a positive viral test for asymptomatic individuals.
  - FSIS will cover all travel and lodging expenses, as well as the cost of any diagnostic testing, in these circumstances.

Source: [Safer Federal Workforce](https://www.saferfederalworkforce.com), Accessed June 2022
If you have a positive test result while on official travel

- If FSIS determines that an employee absolutely must undertake urgent, necessary, and mission-critical return travel during days 6-10 after the first day they experience symptoms, or after the date of a positive test for an asymptomatic individual, then the employee is to take other precautions for the entire duration of their travel during the 10 days after their first day of symptoms, or after the date of a positive test for an asymptomatic individual, including wearing a **well-fitting mask** when around others and, to the extent possible, avoiding eating and drinking around others, avoiding environments such as dining facilities and gyms where they may be unmasked around others, avoiding people who are **immunocompromised or at high risk for severe disease**, and avoiding nursing homes and other high-risk settings.

Source: Safer Federal WorkForce, Accessed June 2022
How do I know if I have an invalid result?

If the results window has any of the following, the test result may be invalid:

- No lines appear by control or sample
- The control line is blue and not pink/purple
- There is a pink/purple line by sample, but no line by control
- The control line is blue, but the sample is pink/purple
- If you see an invalid result, and aware of an error made when performing the test (e.g., adding more than 6 drops), review the instructions and then re-perform test using a new test card pouch and swab
- The supervisor will order an additional test kit
- If there is an invalid result and instructions were followed, contact the Abbott BinaxNOW Helpline: +1 833-637-1594

**Note:** See other side to read about what your results mean.

[BinaxNOW COVID-19 Antigen Self Test - Instructions for Use Home Test (fda.gov)](https://www.fda.gov/media/135274/download), Updated November 2021
Performance Specifications and Limitations

- Check the expiration date
  - If the expiration date on test has already passed, contact propertymanagement@usda.gov for the updated expiration date
  - FDA has updated the shelf-life expiration date to 15 months when tests are stored at room temperature
- Do not use expired tests or components that are damaged
- Employees may voluntarily elect to perform additional confirmatory testing with a molecular test for negative results 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
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed
- Negative results 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

BinaxNOW COVID-19 Antigen Self Test EUA210264 Notice of Updated Shelf-Life, Updated January 7, 2022
Can the BinaxNOW Self Test be thrown into the garbage after use?

You can recycle the box, but should dispose of the test card, nasal swab and test solution in common waste in accordance with the manufacturer’s instructions for use.

Source: BinaxNOW: What You Need to Know | Abbott Newsroom, Updated March 11, 2022
Reporting Results

- Emails containing COVID-19 test results are medical records
- Optional: To further promote privacy and IT security, the employee may select “encrypt-only” from the option tab in Outlook
- This will ensure proper controls are implemented for the sharing of sensitive data via email. The employee may also encrypt/password protect any attached files to be shared via email (PDF, Word, etc.) for added protection
- The Rehabilitation Act requires that test results be kept confidential and limits who may have access to such information

The Privacy Act statement for the testing requirements will refer to the Government-wide system of records (OPM/GOVT-10) for employee medical files (EMFs), which is governed by OPM regulations (5 C.F.R. part 293, subpart E). [https://www.saferfederalworkforce.gov/faq/testing/](https://www.saferfederalworkforce.gov/faq/testing/), Accessed May 2022.

Questions?

• Refer questions to your supervisor

• For questions regarding ordering test kits, Supervisors or Program Resource Managers may contact the FSIS Office of Management, Administrative Services Division, Property Management Branch at propertymanagement@usda.gov

• All other questions should be directed to fsisfeedback@usda.gov