New Mexico
Surveillance Testing and Contact Tracing Plan

Background

On November 25, 2020, Walmart and Sam's Club (collectively "Walmart") entered into an agreement with the New Mexico Department of Health and the New Mexico Environment Department to establish mandatory surveillance testing and identify close contacts at Walmart's facilities in New Mexico. The agreement also required the creation and implementation of this Plan which explains the actions to be implemented.

Surveillance Testing

Subject to available testing supplies, Quest Diagnostics (or other providers as needed) will assign a self-administered test to each individually identified associate in the state of New Mexico for testing to be conducted on all associates every two weeks.

On a weekly basis (days may vary based on scheduling and number of associates) Walmart will implement self-administered tests to approximately 50% of the associates at each facility. The following week, the remaining approximately 50% of associates at each facility will undergo the self-administered testing. Associates will be provided accommodations to complete the testing onsite and drop boxes to place the completed test specimens for shipment to Quest (or other provider). This testing regimen will be repeated every week until Walmart's Chief Medical Officer, with input from the state, believes it is prudent based on community pandemic data and other factors, to adjust the testing process on a facility by facility basis.

Quest (or other providers as needed) will include information with each self-test kit that provides the associate with clear and appropriate information regarding the purpose of the test, the type and reliability of the test, and how the test will be performed. In addition, each self-test kit will contain clear information for associates on interpreting their results, who will receive the results, and how the results will be used. Examples of the information that will be provided is attached as Exhibit A.

Associates who refuse to be tested will be placed on a Level 1 Emergency Leave and will be informed of such through the required training on the Plan.

Any associate that tests positive will be instructed to notify management at his/her respective facility and to self-isolate and not return to work until they are no longer considered contagious as described in the New Mexico Department of Health's *Policies for the Prevention and Control of COVID-19 in New Mexico*. Associates who have tested positive and remain asymptomatic, will not be retested for at least ninety (90) days.

Contact Tracing

Upon learning of a confirmed COVID-19 case, Walmart will notify the New Mexico Environment Department Occupational Health and Safety (OSHA) program within four (4) hours via the following online form: https://nmgov.force.com/rapidresponse/s/

In addition, upon learning of a confirmed COVID-19 case, Walmart will immediately implement protocols to identify close contacts in accordance with CDC and New Mexico guidelines. A close contact is defined by the state of New Mexico as an associate staying in the same close environment within 6 feet (2 meters) of a confirmed COVID-19 case for 3 minutes or more or anyone who had contact with the associate's body fluids and/or secretions such as where coughed on/sneezed on, shared utensils or saliva while the case was ill (beginning 2 days prior to illness onset and continuing until resolution of illness).

Close contacts of the confirmed COVID-19 case will be assessed from 48 hours prior to the date of onset of symptoms or 48 hours prior to test collection date for asymptomatic cases.

With the exception of Healthcare Personnel, Walmart will require all close contacts of a confirmed COVID-19 case to be quarantined in accordance with New Mexico Department of Health's *Policies for the Prevention and Control of COVID-19 in New Mexico*. Once a close contact is quarantined, as an essential business Walmart may administer a follow up test to a close contact, likely via delivery of a test kit to the associate's residence, and upon receiving a negative test result, the close contact may return to work and will continue to be subject to daily health screenings, be required to wear a mask, and participate in ongoing bi-weekly testing.

Upon learning of a confirmed COVID-19 case, Walmart will implement its Sanitation Protocol for cleaning and disinfecting work areas accessed by the confirmed COVID-19 case as appropriate for the specific work environment and area as well as continuing the ongoing and routine cleaning and disinfecting of facilities.

Training and Communication

Walmart will post this Plan or a summary in a conspicuous location at each facility for associates to inspect for as long as the agreement and Plan remain in effect. In addition, Walmart will provide and document training on the elements of the Plan to all associates.

Walmart will submit the Plan to both: NMENV-OSHA@state.nm.us and NMDOH-COVID-PLAN@state.nm.us.

Nuevo México
Las pruebas de monitoreo y seguimiento del Plan de contacto

Antecedentes

El 25 de noviembre, 2020, Walmart y Sam's Club (colectivamente "Walmart") firmaron un acuerdo con el Departamento de Salud de Nuevo México y el Departamento de Medio Ambiente de Nuevo México para establecer el monitoreo de las pruebas obligatorias e identificar los contactos cercanos en las instalaciones de Walmart en Nuevo México. El acuerdo también exige la creación y aplicación de este plan, el cual explica las acciones a implementarse.

Pruebas de Monitoreo

Sujeto a la disponibilidad de suministros de pruebas, Quest Diagnostics (u otros proveedores como sea necesario) asignará una prueba auto administrada a cada asociado individualmente en el estado de Nuevo México para las pruebas a realizarse en todos los asociados cada dos semanas.

Una vez por semana (el día puede variar según los horarios y el número de asociados) Walmart pondrá en práctica las pruebas auto administradas para aproximadamente el 50% de los asociados de cada instalación. La siguiente semana, el resto de aproximadamente un 50% de los asociados en cada instalación se someterá a una prueba auto administrada. Los asociados recibirán acomodo en la tienda para realizarse las pruebas y habrá buzones para colocar la prueba realizada para su envío a Quest (u otro proveedor). Este régimen de prueba se repetirá cada semana hasta que el Walmart's Chief Medical Officer, con aportes del Estado, considere que basado a la base de datos de la pandemia en la comunidad y otros factores, se pueda ajustar el proceso de pruebas en alguna de nuestras instalaciones.

Quest (u otros proveedores como sea necesario) incluirá un kit con la información de las pruebas auto administradas con información clara y oportuna sobre el propósito de la prueba, el tipo y la fiabilidad de la prueba, y cómo se llevará a cabo la prueba. Además, cada uno de los kit de pruebas contendrá información clara para los asociados para interpretar sus resultados, que recibirá los resultados, y cómo los resultados serán utilizados. Ejemplos de la información que será proporcionada se adjunta como Anexo A.

Los asociados que se nieguen a administrarse la prueba, serán colocados en Licencia de Emergencia nivel 1 y habrán sido informados de acuerdo a los términos de este Plan.

Cualquier asociado que salga positivo será instruido para notificar a la gerencia de sus respectivas instalaciones, será aislado y no volverá a trabajar hasta que ya no se considere contagioso, como se describe en el Departamento de Salud Políticas de Prevención y Control de COVID-19 en Nuevo México. Asociados que han sido positivos y permanezcan asintomáticos, no volverán a realizar la prueba por al menos noventa (90) días.

Localización Contacto

Al enterarse de un caso confirmado COVID-19, Walmart notificará al Departamento de Medio Ambiente Salud y Seguridad Ocupacional (OSHA) de Nuevo Mexico dentro de cuatro (4) horas a través del siguiente formulario en línea: https://nmgov.force.com/rapidresponse/s/

Además, una vez conozca de un caso confirmado de COVID-19, Walmart, inmediatamente implemente los protocolos para identificar los contactos cercanos en conformidad con las directrices del CDC y Nuevo México. Un contacto cercano es definido por el estado de Nuevo México como un asociado que ha estado en el mismo entorno cercano dentro de 6 pies (2 metros) de un caso confirmado COVID-19, 3 minutos o más o con quien tuvo contacto con fluidos corporales del asociado y/o secreciones, como cuando tosió, compartió utensilios (a partir de 2 días antes de la enfermedad y continúa hasta la resolución de la enfermedad).

Contactos cercanos de un caso positivo de COVID-19, se evaluarán a partir de 48 horas de a la fecha de aparición de síntomas o 48 horas antes de la fecha del recogido de pruebas para los casos asintomáticos.

Con excepción del personal médico, Walmart requerirá de todos los contactos cercanos de un caso confirmado COVID-19 se pongan en cuarentena, de conformidad con el Departamento de Salud *Políticas de Prevención y Control de COVID-19 en Nuevo México*. Una vez que un contacto cercano esté en cuarentena. Walmart, podrá administrar un seguimiento de la prueba para un contacto cercano, probablemente a través de la entrega de un kit de prueba para el asociado, y, al recibir un resultado negativo, el contacto puede volver a trabajar y seguirá siendo sometido diariamente a exámenes de salud, se debe llevar una mascarilla, y participar en las pruebas bi-semanales.

Al enterarse de un caso confirmado COVID-19, Walmart implementará su Protocolo de Saneamiento para la limpieza y desinfección de las áreas de trabajo como un entorno de trabajo apropiado y, así como la continuación de las actuales rutinas de limpieza y desinfección en las diferentes áreas.

Adiestramiento y Comunicación

Walmart publicará este plan o un resumen en una ubicación destacada en cada instalación para que los asociados puedan ver el acuerdo y el Plan en vigor. Además, Walmart ofrecerá un documento de capacitación para los términos de este plan.

Walmart presentará el plan: NMENV-OSHA@state.nm.us y NMDOH-COVID-PLAN@state.nm.us.

Quest Diagnostics invites you to participate in the SARS-CoV-2 (COVID-19) testing program.

The enclosed materials include everything you need to collect and submit your specimen to Quest Diagnostics for testing. There are no special food or medication restrictions. Simply follow the instructions and return the specimen and requisition in the provided packaging.

Why should I participate?

- You may be at high risk of having the virus.
- Completing the self-collection test can give you the knowledge you need to help keep you and your loved ones safe. If you do test positive, you should quarantine yourself following the CDC's guidelines and inform anyone who you have been in contact within the past 2 weeks.

Before you participate, view this video to see a demo of the self-collection: bit.ly/COVID19selfcollection.

Please be sure to use the pre-printed return label included in your kit and send your specimen back to Quest Diagnostics prior to 3PM on the same day of your collection. If you have any questions about your collection, please contact the Quest Diagnostics Service Center at 1.855.332.2533.

Results

Results will be available within 3-5 business days of Quest receiving your specimen. If your result is positive for COVID-19, you will receive a phone call from the physician who authorized this test order.

Please note that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and,
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

In good health,

Quest Diagnostics

Informed Consent/HIPAA Authorization
(COVID-19)
[Paper Version]

BY CONTINUING WITH THE TEST, YOU ACKNOWLEDGE THAT YOU HAVE READ, ACCEPTED, AND AGREED TO BE BOUND BY THIS INFORMED CONSENT. IF YOU DO NOT AGREE TO THE INFORMED CONSENT, YOU WILL NOT BE ABLE TO USE OR RECEIVE THE SERVICES.

You have requested to participate in a testing program offered by Quest Diagnostics Incorporated (Quest Diagnostics), in coordination with your employer, for diagnostics testing for the detection of COVID-19 and/or antibody testing ("Testing").

The Testing program will have physician oversight provided by PWN Remote Care Services, PW Medical Professional and certain other contractually affiliated professional entities and PWNHealth, LLC (the administrative services provider of the professional entities) (collectively, "PWNHealth"). PWNHealth will provide the following services, including, without limitation, evaluation of the test request, ordering of tests (if appropriate), receipt of Test results and telehealth consults ("Consults") (the "PWNHealth Services").

In order to participate in the Testing, I acknowledge and agree to the following:

- I am the individual who will provide the sample for the Testing.
- I am at least eighteen (18) years of age.
- I have read and understand the information I have been provided about the Testing. Additional information is also available at the CDC website https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- The information I have provided in connection with the Testing is correct to the best of my knowledge. I will not hold PWNHealth or its health care providers for any errors or omissions that I may have made in providing such information.
- My health information and results will be shared with PWNHealth, including its physicians and staff, in connection with the Testing and PWNHealth Services.
- The Testing and the PWNHealth Services do not constitute treatment of any condition, disease or illness. I understand that a positive antibody test does not confer immunity.
- While Quest Diagnostics implements safeguards to avoid errors, as with all laboratory tests, there is a chance of a false positive or false negative result.
- I am responsible for following the instructions I have been provided to receive my Testing results when available.
- If I receive an abnormal result on a COVID diagnostic Test, I understand that a PWNHealth care coordinator will attempt to call me to review the results, offer education and explain the next steps I should take. The PWNHealth care coordinator may leave me a voicemail but will not include my test results in any voicemail message. If I receive an abnormal result and have not connected with a PWNHealth care coordinator, I understand that I should not delay following up with my personal physician. I also understand that if I am not able to be reached, PWNHealth's Care Coordination Team will mail a follow-up letter to the residential address I provided when I requested Testing (the letter will not include my testing results). I understand that I will not receive an alert call for results of an antibody Test. PWNHealth may also contact me to follow up on my symptoms and experience.
- I understand that after receiving my results, I will have the opportunity for a telemedicine Consult with a PWNHealth physician to answer any questions I may have; however, no treatment or prescriptions will be provided.
- I certify that throughout the duration of the PWNHealth Services I receive, including my Consult, I will be physically present in the state of residence I provided or other state of which I have notified PWNHealth.
- I am responsible for forwarding any results to my primary care or other personal physician and for initiating follow up with such physician for treatment.
- I will not make medical decisions without consulting a healthcare provider or disregard medical advice from my healthcare provider or delay seeking such advice based on information as a result of the Testing including use of the PWNHealth Services.

- If I receive an abnormal result, my name and result may be disclosed to my state health agency in accordance with applicable law.

I understand that PWNHealth Services, including Consults, are delivered by health care providers who are not in the same physical location as I am using electronic communications, information technology or other means, including the electronic transmission of personal health information. I also understand that:

- A PWNHealth physician will determine whether or not Testing and PWNHealth Services, including a telehealth encounter, are appropriate for me.
- I have the right to withdraw my consent to the use of telehealth in the course of my care at any time by emailing PWNHealth at covid19@pwnhealth.com.
- Any video feed from the Consult will not be retained or recorded by PWNHealth.
- My health and wellness information pertaining to telehealth services are governed by the PWNHealth Notice of Privacy Practices.
- I may need to see a health care provider in-person for diagnosis, treatment and care.
- There are potential risks associated with the use of technology, including disruptions, loss of data and technical difficulties.
- There are alternative services, such as visiting a primary care provider, an emergency room, or an urgent care facility; however, I chose to proceed with the PWNHealth Services at this time.

I understand that if I have any questions before or after Testing, I can email covid19@pwnhealth.com and I will be connected with a member of the PWNHealth Care Coordination Team, including a physician, if requested or as otherwise applicable.

I authorize Quest Diagnostics and PWNHealth to use the email address and phone number I provided at the time I requested the Testing to contact me in connection with the PWNHealth Services and Testing. I am responsible for contacting my employer to notify them of any changes to my mailing address, email address, phone number or other information that I provided.

I understand that Testing is voluntary and that I may withdraw my consent to Testing at any time prior to my appointment for Testing by contacting Quest Diagnostics at 866-448-7719.

I specifically authorize the transfer and release of my information as described herein and in the PWNHealth Notice of Privacy Practices, including my medical history that I provided, my Test Results and other identifiable health information provided by or about me in connection with the Testing and the PWNHealth Services to, between and among myself and the following individuals, organizations and their representatives: (a) PWNHealth and its affiliates, and their staff, agents and healthcare providers and (b) Quest Diagnostics and its staff and agents to perform the Testing and PWNHealth Services and as required by law.

I have the right to revoke this Informed Consent/HIPAA authorization in writing at any time, except that the revocation will not apply to any information already disclosed by the parties referenced in this authorization. This authorization will expire ten (10) years from the date ofthis authorization. My written revocation must be submitted to the following: Quest Diagnostics Privacy Office at:

Quest Diagnostics
500 Plaza Drive
Secaucus, NJ 07094 USA
Attn: Privacy Officer

I have read this Informed Consent/HIPAA Authorization carefully, and all my questions were answered to my satisfaction. I hereby consent to participate in the Testing and PWNHealth Services pursuant to the terms set forth herein.

Your COVID-19 test specimen is being processed by Quest Diagnostics®

Quest Diagnostics®

Getting your COVID-19 test results
PWNHealth is the ordering physician for your test. Anyone with a positive result will receive a phone call from a PWNHealth physician regarding the positive result and recommended next steps. Additionally, you can access your result at My.QuestForHealth.com.

Visit QuestDiagnostics.com/home/Covid-19/ for current test processing times.

How to get your test results online

1. Visit My.QuestForHealth.com
2. Log in using the username and password you created
   - If you did not log in to place your COVID-19 self-collection kit order, please register on the site using the information provided by your employer
   - You are able to reset your password on the site, if needed
3. In the Results section of your dashboard, select View Results
4. You will be able to download a PDF of your results, indicating if you tested positive or negative for COVID-19
5. If you tested positive, you will receive a call from a PWNHealth physician to prompt appropriate medical follow-up and quarantine

If you have any questions about viewing your results, please contact our Service Center at 1.855.332.2533.

SARS-CoV-2 (COVID-19) Return-to-work testing: General FAQs

1. What is SARS-CoV-2 (COVID-19)?

COVID-19 (formally known as 2019-nCoV) is the name for the respiratory syndrome caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The World Health Organization has declared COVID-19 an international public health emergency.

2. What are the symptoms of COVID-19?

Reported illnesses have ranged from mild symptoms to severe illness and death for confirmed coronavirus disease 2019 (COVID-19) cases. These symptoms may appear 2-14 days after exposure, and include fever, new or worsening cough, and/or shortness of breath. If you develop emergency warning signs for COVID-19, including trouble breathing, persistent pain or pressure in the chest, confusion, and/or bluish lips or face, get medical attention immediately. Please reference the Centers for Disease Control and Prevention (CDC) for the most updated list of symptoms.

3. How is COVID-19 spread?

The virus is thought to spread mainly from person to person, between people who are in close contact with one another (within about 6 feet), and through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. There is currently no vaccine to prevent coronavirus disease 2019 (COVID-19). The best way to prevent illness is to avoid being exposed to this virus.

4. Who should be tested for COVID-19?

The CDC has guidance for who should be tested, but decisions about testing are at the discretion of state and local health departments and/or individual clinicians. Please note that when it comes to helping the nation in this time of crisis, Quest Diagnostics is focusing on this prioritization with offerings and testing availability.

For more information on priority levels, please visit the CDC's website.

COVID-19 Return-to-work testing: Molecular testing FAQs

5. What is the Quest Diagnostics COVID-19 molecular (NAAT) test?

The molecular test for SARS-CoV-2 (COVID-19) from Quest Diagnostics is a reverse Nucleic Acid Amplification Test (NAAT) test that looks for the presence of viral RNA in a respiratory specimen.

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and,
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

6. What is sensitivity and specificity?

In medical diagnosis, test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate), whereas test specificity is the ability of the test to correctly identify those without the disease (true negative rate).

7. What is the sensitivity/specificity of the Quest LDT, Hologic, and Roche assays?

For molecular tests we are using the Quest LDT, Roche, and Hologic tests.

The FDA EUA site has manufacturing information for all 4 of the molecular tests. The sensitivity and specificity for the tests are listed in the Instructions For Use (IFU) documents that are linked to under each record. The manufacturers are responsible for providing this information for their tests. Below are links to the IFU documents.

- Quest LDT IFU: https://www.fda.gov/media/136231/download
- Roche IFU: https://www.fda.gov/media/136049/download
- Hologic Panther Fusion IFU: https://www.fda.gov/media/136156/download
- Hologic Panther COVID-19 molecular assay IFU: https://www.fda.gov/media/138096/download

The assays listed on the FDA website as authorized by the FDA as an Emergency Use Authorized (EUA) method for molecular COVID-19 testing for ALL assay systems are ANALYTICALLY Validated. FDA EUA authorized assays have NOT been clinically validated.

8. Can a person test negative and later test positive for COVID-19?

A negative result means that the virus that causes COVID-19 was not found in the person's sample. In the early stages of infection, it is possible the virus will not be detected. For COVID-19, a negative test result for a sample collected while a person has symptoms likely means that the SARS-CoV-2 (COVID-19) virus is not causing their current illness.

For more information on each virology test Quest Diagnostics performs, visit the following:

- Quest LDT: https://www.fda.gov/media/136231/download
- Roche: https://www.fda.gov/media/136049/download
- Hologic Panther Fusion: https://www.fda.gov/media/136156/download
- Hologic Panther COVID-19 molecular assay: https://www.fda.gov/media/136153/download

9. What is the likelihood of an employee receiving a false negative result?

The COVID-19 molecular tests in use at Quest Diagnostics under an Emergency Use Authorization (EUA) from the FDA include our lab-developed test (LDT) and the Roche assay. FDA has not required that assays be clinically validated for this emergency use; all assays in use at Quest have been analytically validated. Formal studies of "false negative" rates are not FDA-required for any EUA tests and therefore no studies have been performed on the assays used at Quest. To read about the analytical performance of the COVID-19 molecular tests in use at Quest, see the publicly available information located on the FDA website.

10. Can an employee have a specimen collected for SARS-CoV-2 molecular testing at a Patient Service Center (PSC)?

No. PSCs will not be collecting specimens for molecular tests. Anyone with active COVID-19 symptoms should not go to a PSC. All molecular specimen collection should be completed through self-collection (observed or unobserved) or by a healthcare provider.

11. Previously you mentioned you were using a mid-turbinate nasal swab. Why did you switch to an anterior nares nasal swab?

The FDA required the switch to the anterior nares swab to make the self-collection process easier and less invasive for participants. In addition to the easier collection method, Quest Diagnostics has also added additional testing on each self-collected specimen to ensure the collection was completed. More information on this additional test is presented in question 12 on the following page.

12. Can an employee receive a false positive result?

The Quest SARS-CoV-2 RT-molecular test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other patients potentially infected with COVID-19, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

13. How long will it take for my employees to get their SARS-CoV-2 (COVID-19) molecular test results?

Turnaround times may vary due to high demand. For current estimates, visit https://newsroom.questdiagnostics.com/COVIDTestingUpdates.

14. How will my employees receive their molecular test results?

Individuals will be able to receive their molecular test results online at My.QuestForHealth.com. In addition, if a test is positive, employees will receive a phone call from PWNHealth, the medical oversight provider, to provide guidance on appropriate medical follow-up care.

15. Will participants receive a printed copy of their molecular test results?

No. At this time individuals will not receive a physical copy of their molecular test results. Results will only be available online.

16. What if a specimen is unable to be processed?

The invalids process is determined by the employer in conjunction with Quest Diagnostics. If applicable, per employer direction, employees who receive an invalid are able to complete another nasal swab.

17. Where does Quest Diagnostics conduct SARS-CoV-2 molecular specimen testing?

Quest is performing molecular testing at 12 laboratories in its national network. Three of these laboratories perform both the company's lab-developed Quest SARS-CoV-2 molecular test (which was granted FDA emergency use authorization on March 17) and the highly automated Roche cobas® SARS-CoV-2 Test. These labs are in San Juan Capistrano, CA; Chantilly, VA; and Marlborough, MA.

18. How long does Quest store molecular specimens before discarding them?

Generally, molecular test specimens are discarded 3 days following testing, with positive samples retained for approximately 5-7 days depending on demand and storage capacity.

19. Who developed the qualifying questionnaire that Quest is using? Is this questionnaire customizable?

PWNHealth, the organization providing medical oversight, developed the questionnaire and question logic based on CDC guidelines. The questionnaire is not customizable.

20. If an employee tests negative for the virus, can they return to work?

Quest Diagnostics provides results to the individual and does not make the determination if employees should or should not be eligible to return to work. Employers must set policies for whether or not an employee may return to work in accordance with their disaster relief policies and business needs. Quest Diagnostics cannot make the determination about whether an individual can return to work. Quest can only provide clinical information regarding the employee's COVID-19 status.

21. Why are race and ethnicity required on an eligibility file for molecular testing?

Many state and local public health departments are requiring race and ethnicity information to be reported along with positive and negative COVID-19 test results. In order to comply with these regulations, PWNHealth, the organization that orders medical testing and provides medical oversight for molecular testing through Quest Diagnostics, is requiring this information be present on all eligibility files for molecular testing programs they are overseeing.

22. Why are state and local health departments requiring race and ethnicity to be reported?

Having access to data such as race, age, ethnicity, etc. helps researches and public health officials learn how diseases may impact different groups of individuals in our communities. With this information, policymakers and public health administrators can then make informed decisions on how to best allocate public health resources and promote health equity. For more information on why demographic reporting is necessary during the COVID-19 pandemic, visit the John's Hopkins Coronavirus Resource Center.

COVID-19 Return-to-work testing: IgG Antibody testing FAQs

23. What is an antibody?

An antibody (also known as an immunoglobulin) is part of our body's response to a foreign molecule or pathogen (also known as an antigen) such as a virus or bacterium. This is valuable to fight off infection. Protective antibodies can provide immunity, so we do not become reinfected with the same viruses or bacteria. Antibodies are vital for our health. The protection antibodies provide may last a lifetime, or only a matter of months. And we don't always develop antibodies—or the right antibodies in sufficient quantity—to fight off all infectious diseases. It is not yet known how much protection the SARS-CoV-2 antibodies may provide, or for how long.

24. What is the Quest Diagnostics COVID-19 antibody test?

The Quest Diagnostics antibody test is a venipuncture blood draw that can be completed at a Quest Diagnostics Patient Service Centers (PSCs). The Quest antibody test detects the presence of IgG antibodies in the blood. It usually takes at least 10 days after symptom onset for IgG antibodies to reach detectable levels. An IgG positive result may suggest immunity after resolution of primary infection, but the relationship between IgG positivity and immunity to SARSCoV-2 has not yet been firmly established. During the SARS (SARs-CoV) outbreak, it was shown that presence of IgG is an indicator for immunity for up to 2 years.

The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, molecular testing for SARSCoV-2 is necessary. The test should not be used to diagnose acute SARS-CoV-2 infection. False positive results for the test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;·
- This test has been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and, · This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

25. Why can antibody specimens be collected at PSCs, but not COVID-19 molecular specimens?

COVID-19 molecular tests are looking for an active viral infection, and individuals who may need a molecular test are likely to be symptomatic and can infect others. In order to prevent the spread of the disease, PSCs will not be collecting molecular specimens. Individuals who may need antibody testing are those who are asymptomatic, have not had the disease, and/or have already recovered from the disease. They are less likely to infect others.

Quest Diagnostics will be requiring all individuals who visit a PSC (for antibody testing or other reasons) to wear a face covering and have their temperature taken upon arrival. Anyone who has a fever of 100.3 degrees or higher or exhibits symptoms of COVID-19 will have to reschedule their appointment.

26. If an employee tests positive for SARS-CoV-2 IgG antibodies, can they return to work?

A negative molecular test (no current infection) and a test that is positive for IgG antibodies suggest prior exposure and/or a prior infection which may be resolved or resolving. With other coronaviruses, the presence of antibodies indicated some protection against reinfection ("protective immunity"). Whether this is true of the SARS-CoV-2 antibodies is not yet proven. Employers must set policies for whether or not an employee may return to work in accordance with their disaster relief policies and business needs. Quest Diagnostics cannot make the determination if an individual can return to work. Quest can only provide clinical information regarding the employee's antibody status.

27. How long will it take for my employees to get their antibody test results?

Turnaround times may vary due to high demand. For current estimates, visit https://newsroom.questdiagnostics.com/COVIDTestingUpdates.

28. How will my employees receive their antibody test results?

Individuals will be able to receive their antibody test results online at My.QuestForHealth.com.

29. Will participants receive a printed copy of their antibody test results?

Yes. Individuals will be able to see their antibody testing results online and will also receive a paper results report in the mail approximately 10-15 days after their appointment.

30. What does it mean to have a detectable SARS-CoV-2 IgG result?

A positive IgG antibody test result suggests recent or prior infection with SARS-CoV-2. It usually takes at least 10 days after symptom onset for IgG detectable levels to be reached. Patients tested prior to this time may be negative for SARS-CoV-2 IgG antibodies. An IgG positive result may suggest an immune response to a primary infection with SARS-CoV-2, but the relationship between IgG positivity and immunity to SARS-CoV-2 has not yet been firmly established.

31. If an employee has been diagnosed with COVID-19 disease, when should they get an antibody test performed?

If an individual was suspected of having (or diagnosed with) COVID-19 disease, they should wait to obtain an IgG antibody test until they are both symptom free and at least 10 days since symptoms began in order to allow enough time for IgG antibodies to develop to detectable levels.

32. Which assays is Quest Diagnostics using to conduct antibody testing for COVID-19?

In order to maximize our capacity and flexibility for testing in this time of need, Quest Diagnostics is utilizing several technologies to perform antibody testing for COVID-19, including those developed by Ortho Clinical, EUROIMMUN, and Abbott. The tests developed by Orhto Clinical, EUROIMMUN, and Abbott have both received FDA EUA for processing in clinical laboratories. Quest may add more manufacturers in the future to adjust the supply situation.

33. Is it true that serology tests for COVID-19 have a high false-positive rate?

There are many point of care (POC) tests out in the market that have not been validated and/or have no EUA from the FDA. Many of these fingerstick tests show false positives or false negatives. This has resulted in the FDA being more restrictive with those testing options. All SARS-CoV-2 serology tests used by Quest Diagnostics have been analytically validated by the manufacturers and analytically verified by Quest to ensure quality.

34. What is the sensitivity and specificity for SARS-CoV-2 (COVID-19) IgG antibody testing from Quest?

Sensitivity is normally used in the context of measuring sensitivity to detect the disease, however, in the context of serology, you are only measuring sensitivity to antibodies, not SARS-CoV-2. Because antibody testing is not used for diagnosis, sensitivity is less important than specificity. The focus is on maximizing specificity for IgG so that we have no false positives. Quest Diagnostics ensures that tests offered for SARS-CoV-2 IgG are extensively validated by manufacturers to be highly specific. Quest is also performing our own supplementary validation using stringent acceptability criteria for precision, reproducibility, accuracy, method comparison, cross reactivity and clinical performance before starting patient testing.

Quest is using 3 antibody tests manufactured by Ortho Clinical, Abbott, and EUROIMMUN. As stated in literature provided by Ortho Clinical, the snalytical specificity is 100%. As stated in literature provided by Abbott, analytical specificity of the Abbott IgG antibody test is 99.4%. As stated in literature provided by EUROIMMUN AG, analytical specificity of the EUROIMMUN Anti-SARS-CoV-2 ELISA IgG antibody test is 98.5-99%.

The FDA does not consider SARS-CoV-2 IgG antibody tests to be diagnostic for COVID-19. Diagnostic testing for COVID-19 disease relies on RNA detection. Therefore, the importance of IgG "sensitivity" is not paramount. FDA and other experts are emphasizing specificity over sensitivity. Both tests are highly accurate. Specificity in banked sera was around 98-100% in several populations. Sensitivity in patients at least 14 days after symptom onset was reported as 100%.

Sources:
Centers for Disease Control and Prevention. 2020. Coronavirus Disease 2019 (COVID-19). Accessed April 15, 2020
https://www.cdc.gov/coronavirus/2019-ncov/index.html

Li-Ping Wu, et.al. Duration of antibody responses after Severe Acute Respiratory Syndrome. *Emerg Infect Dis*. 2007: 13(10);1562-1564. doi: 10.3201/eid1310.070576