

Heart-healthy and Stroke-free Living with Dr. Amy L. Doneen, DNP, ARNP

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# Should You Get A COVID-19 Antibody Test?

Wondering if that cold, cough or flu-like illness you had a few weeks or months ago was actually COVID-19? Or is it possible that you've already recovered from the virus without any symptoms?

More than 150 commercial antibody tests claim to offer answers, by checking for signs that your body has already fought off the infection. As policy makers, scientists and healthcare providers discuss how to reopen the country, widespread use of such testing has been touted by some officials as a strategy to identify people who may be immune and could therefore safely return to work and normal life.

However, antibody testing has been extremely controversial, since the accuracy of these tests — which the FDA had

allowed to be sold without any review — varies widely. Indeed as dubious — and even outright fraudulent — products have flooded the market along with legitimate tests from reputable labs, some critics have compared the situation to "the wild, wild West." Amid a storm of criticism, the FDA announced on May 4 that it has set new standards for COVID-19 antibody testing to help ensure its quality and accuracy. Here is a look at the latest information about these tests, plus key takeaways for patients from the BaleDoneen Method.

#### What is COVID-19 serological testing?

Also known as antibody testing, serological testing analyzes a sample of the patient's blood (collected with a fingerstick or from a vein) to check for antibodies to SARS-CoV-2, the virus that causes COVID-19. Also known as immunoglobulins, antibodies are Y-shaped proteins that the body produces to fight invading viruses. Therefore, the presence of COVID-19 antibodies in the blood indicates a prior

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sixty percent of Americans experience daily stress and worry, according to a new Gallup poll. The survey reveals what Gallup labels an "unprecedented" surge in the number of anxious Americans, sparked by the financial and medical fears brought on by the ongoing COVID-19 pandemic. While it's extremely understandable to feel tense during this very strange and frightening time, chronic stress can take a toll on your cardiovascular health. In fact, a large study conducted in 52 countries around the world found that psychological factors, including stress, nearly tripled risk for a heart attack!

The good news, however, is that even in this stressful era, there are simple, but remarkably effective ways to dial down tension and anxiety while also improving your mood, sleep, blood pressure, levels of inflammation and other markers of arterial and health. Here's a look at seven simple stress-busters that are backed by solid science, some of which take in effect in just 60 seconds!

## PRACTICE MINDFUL MEDITATION

Mindfulness involves focusing on the present moment in an open, non-judgmental way, while letting stressful thoughts about the past or future drift away. Many studies have reported a wide range of health benefits from this simple practice, including lower risk for age-related mental decline, reductions in blood pressure, decreased blood markers of inflammation, decreased chest pain in heart patients, and improved mood. Try a basic meditation

such as this: Sit quietly for 10 minutes and pay attention to your breathing or a mantra (focus word) that you repeat silently as you allow distracting thoughts or worries to drift away like wisps of smoke. You may find it helpful to gaze at a meditation object, such as a smooth stone.

#### LIGHT UP YOUR LIFE

For the best effects, do this first thing in the morning; raise the shades, let the sunlight in and, if possible, have breakfast close to a window that lets in lots of light. Researchers at the University of Toronto suggest that lightening up can boost your mood for the whole day, help you to sleep better and keep you alert.

#### **LAUGH**

A good laugh expands blood vessels and increases blood flow to the heart, a recent study found. Laughter yoga, which combines deep yogic breathing and self-triggered mirth, is also a great way to relax after a stressful day. A recent study also found that after just three weeks of laughter yoga, study participants had significant drops in blood pressure.

## PLANT A FLOWER — OR GROW A GARDEN

In a <u>Dutch study</u>, volunteers were divided into two groups. Both groups were asked to perform a stressful task, but one group was also randomly assigned to 30 minutes of indoor or outdoor gardening afterwards. Those who had the opportunity to garden had significantly lower levels of the stress hormone cortisol, leading the researchers to conclude that working with plants provides effective relief from acute stress.

#### HAVE A CUP OF TEA

This quintessentially British response

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## May Recipe

## Lemon-Ginger Chicken Breasts with Green Beans

Ready in just 20 minutes, this easy recipe is low in calories but high in protein, flavor and heart-healthy ingredients. Rich in anti-inflammatory compounds, ginger is ranked as one of the world's healthy (and tastiest) spices. Studies suggest that it lowers cholesterol and blood sugar if consumed regularly and may also help fight such viral illnesses as colds and flu. Nutrients in citrus fruits have been linked to reductions in LDL (bad) cholesterol and triglycerides and increases in HDL (good) cholesterol. Fruits and vegetables are also an excellent source of fiber, offering such benefits as improved digestive health and decreased risk for heart attacks and strokes.

#### **INGREDIENTS**

- 4-6 skinless, boneless chicken breast halves
- 2 tablespoons of lemon zest, plus lemon slices for serving

Freshly ground pepper

- 2 tablespoons olive oil
- 3 cloves of garlic, minced
- 2 teaspoons grated fresh ginger
- 12-16 ounces green beans, ends trimmed and sliced into 1-inch pieces ½ cup water
- ½ cup fresh Italian parsley, coarsely chopped, for garnish



### **PREPARATION**

Season chicken with pepper and lemon zest. Heat olive oil in a large skillet over medium-high heat. Add chicken and sauté for four minutes. Flip chicken and add garlic, ginger, green beans and water. Cover, reduce heat to medium and simmer until chicken is cooked through (about 8 minutes). Transfer to a serving dish, garnish with parsley and lemon slices and enjoy!

Adapted from marthastewart.com and thespruceeats.com.

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to good news, bad news, stress, and just about any blip on the horizon really does work. Researchers at University College London found that people who drank black tea four times a day for six weeks had lower blood levels of the stress hormone cortisol after stressful tasks than those who drank a beverage that tasted just like tea but contained none of tea's components. While the researchers didn't identify the natural chemicals in tea responsible for the stress-busting effect, they said that the study showed that drinking tea quickly brought stress levels back to normal.

#### PLAY A FAVORITE SONG

Listening to enjoyable music (this will vary from one individual to another) can dilate (widen) arteries, increasing blood flow as much as statin medication or aerobic exercise, according to a study presented at the American Heart Association Scientific Sessions. Music also has beneficial effects on blood pressure and heart rate — but only if you listen to classical or meditation music. The study suggested that heavy metal or techno music is ineffective.

#### **COUNT YOUR BLESSINGS**

Sounds corny, but researchers at UCLA showed that focusing on what's really

important to you can diffuse stress. Here's how: They recruited 85 volunteers and asked them to fill out a questionnaire ranking their values from what matters most to what matters least. Half the volunteers were then asked to give a five-minute talk about what matters most to them in front of a heckling audience and the other half talked about what matters least. Before and after the speeches, the researchers measured levels of cortisol in all the students. The ones who affirmed their values had lower levels, despite the stressful situation, than the ones who spoke about non-meaningful values. Also try reminding yourself every day of the things great and small for which you are grateful.



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infection, whether or not the patient has experienced any symptoms of the disease. This test cannot detect the SARS-CoV-2 virus, just antibodies to it.

In most patients, antibodies typically appear during the second week of COVID-19 infection and start to reach peak levels two or more weeks after the onset of illness, according to the World Health Organization. That means that antibody testing may not detect the disease early enough to be useful for diagnosing people with current symptoms of the virus, such as coughing, shortness of breath, fever, chills, bluish lips or face, muscle pain, sore throat, headache and new loss of taste or smell. For people with active infections, the CDC and WHO recommend the virus test, which checks samples from the patient's respiratory system (such as nasal swabs) for the SARS-CoV-2 virus.

#### Are any of these tests FDA approved?

As of May 6, 2020, none of the tests have received formal FDA approval, a rigorous process that requires manufacturers to conduct large randomized double-blinded studies to show that the product is effective. However, 12 tests are listed on the FDA website as having received "emergency use authorization

(EUA)," a designation that allows unapproved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening conditions under certain conditions.

#### What are the new FDA rules?

Companies that are already marketing antibody tests are now required to file applications for EUA status within 10 business days, with these applications to include data on their tests. Makers of new tests will have to submit such applications within 10 business days of notifying the FDA of their intention to bring their product to market. FDA officials also reported that about 160 antibody tests are currently being marketed in the U.S. that have not received an EUA and that some makers of these tests have falsely claimed that their tests are approved or authorized by the FDA.

The FDA also has stated that it expects all antibody tests — whether produced by commercial manufacturers or labs — to meet certain standards for sensitivity (the ability to accurately detect antibodies in infected people) and specificity (being able to tell the difference between people who are infected with the SARS-CoV-2 virus and those who are not). In a statement issued on May 4, the FDA reported that one of the reasons why it took this action is that "unscrupulous

actors" were "marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans' anxiety" during the pandemic.

## How accurate is COVID-19 antibody testing?

Like all medical tests, the antibody test can yield incorrect results: either false positives (saying someone is infected when they aren't) or false negatives (saying someone isn't infected when they are). The FDA website reports that the 12 tests that have received its EUA have sensitivities (true positive rate) range from 77.4 percent to 100 percent and specificities (true negative rate) that range from 87.1 percent to 100 percent. However, the FDA points out that these numbers are "estimates" of "expected performance" derived from data provided by the tests' manufacturers, as opposed to peer-reviewed findings from large, randomized double-blinded clinical trials (the gold standard of scientific research).

Several small independent scientific studies have been done around the world to look at the reliability of various antibody tests. In general, scientists report that accuracy improves significantly if the test is done two or more weeks after the onset of the infection. In people

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who were tested soon after catching the virus (when their bodies may not have had time to develop antibodies to SARS-CoV-2), the accuracy of this type of testing can be as low as 40 percent, according to a recent paper in *Nature*.

In April, California scientists tested a dozen commercially available antibody tests, with each test used to analyze 300 blood samples from people with and without COVID-19. The study found that most of the tests had a true positive rate of 95 percent or higher. While that may sound like a high level of accuracy, the researchers point out that in areas with a low rate of infection, the number of people who get erroneous positive results will greatly exceed those who are actually infected. Another new study reported sensitivities ranging from 72 to 100 percent and specificities of 98 to 100 percent in an analysis of 15 COVID-19 serological tests.

For example, if the rate of COVID-19 in your town is 1 percent (meaning that one person in 100 is infected) and the false positive error rate on antibody test is 5 percent, then for each person with a past COVID-19 infection the test correctly identifies, five other uninfected people will get false positive results. One reason for this problem is that antibody tests may mistake antibodies for other types of coronaviruses (which include SARS, MERS and the common cold) for those developed after exposure to SARS-CoV-2.

# What are the potential benefits of antibody COVID-19 testing?

In the FDA's statement on its updated rules, the agency reported that high-quality antibody tests "can help us understand a person's and a population's exposure to COVID-19. A person who has been exposed to, and has recovered from COVID-19 will likely have antibodies in their blood. These tests may be important for guiding our next steps in the fight against this pandemic, such as by providing information on disease prevalence and the frequency of asymptomatic infection."

Another potential benefit cited by the FDA is that antibody tests can identify



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"potential donors of 'convalescent plasma,' an approach in which blood plasma containing antibodies from a recovered individual serves as a therapy for an infected patient with severe or immediately life-threatening disease." Therefore, if you test positive for a past infection, your blood plasma might help save the lives of people who are critically ill with COVID-19. This treatment is still experimental, but some papers have reported potential benefits.

#### If I test positive for COVID-19 antibodies, does that mean I am immune to it?

Unfortunately, because this virus is so new, scientists do not yet know if people who recover from the virus (or have it with no symptoms) develop lifelong or even short-term immunity. People who develop antibodies to the more dangerous coronaviruses, such as SARS and MERS, do appear to have some degree of immunity over the next few years, a 2017 study found. However, strains of the coronavirus that cause the common cold can re-infect the same person within 12 months, according to a new study by Columbia University. Or people who recover from of COVID-19 might develop resistance to one strain of the disease, but not others.

What's the bottom line on antibody testing for COVID-19?

It's important to remember that WHO and the CDC recommend against using this test for the diagnosis of COVID-19. In addition, none of these tests can indicate the level of immunity (if any) that the person has developed against the virus. We think it is prudent to wait for FDA-approved quantitative serology tests that provide specific and highly accurate information of the amount (or titer) of antibodies found in the patient's blood. This information would provide an opportunity to evaluate if the patient has mounted an immune system response strong enough to be protected against contracting or spreading the virus.

Moreover, since the FDA has just announced new standards for these tests — and is requiring more data on their quality and accuracy from the companies that manufacture them it makes sense to wait for new studies to evaluate the reliability of the tests that receive the agency's EUA. Most experts agree that to be truly useful, an antibody test should demonstrate an accuracy of 99 percent or above when tested on hundreds of patients in rigorously conducted clinical trials. However, we also feel that healthcare should be personalized, so we encourage patients who are considering these tests to discuss the pros and cons with their medical providers to make a truly informed decision.



