

Patient Name:

Gender: Male

Study Date: 11/06/2018

DOB:

Facility: DexaFit Minneapolis

* OVERVIEW



HEART DISEASE RISK



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HEART DISEASE RISK SUMMARY*

Your heart disease risk is an estimate of the likelihood of existing narrowing of your arteries due to coronary artery disease (CAD). If your coronary arteries narrow, they can't supply enough oxygen-rich blood to your heart — especially when it's beating hard, such as during exercise.

Because CAD often develops over decades, you may not notice a problem until you have a significant blockage or a heart attack.

The higher your risk score (0 to 100), the higher the likelihood of CAD complications.







*IMPORTANT SAFETY INFORMATION

The DexaFit Dx test is designed for informational purposes as a general risk assessment tool and has not been cleared or approved by the Food and Drug Administration (FDA) at this time. DexaFit, Inc developed the DexaFit Dx test utilizing a substantial database of de-identified DXA, VO2 max, and resting metabolic rate (RMR) data from as early as 2014. Through retrospective analysis and the application of artificial intelligence (AI), the DexaFit Dx AI system was trained with over 5 billion realworld data points to evaluate risk factors and prevalence of diseases, with a particular focus on coronary artery disease (CAD). It should not be used or interpreted as a definitive diagnosis of CAD, type 2 diabetes (T2D), or any other chronic conditions. If you have any concerns about your DexaFit Dx test results after receiving them, we strongly recommend seeking professional guidance or additional testing from a qualified healthcare provider.

FAQS

What is coronary artery disease?

Coronary artery disease (CAD) is a narrowing or blockage of your coronary arteries, usually due to plaque buildup. Your coronary arteries supply oxygen-rich blood to your heart. Plaque buildup in these arteries limits how much blood can reach your heart.

Picture two traffic lanes that merge into one due to construction. Traffic keeps flowing, just more slowly. With CAD, you might not notice anything is wrong until the plaque triggers a blood clot. The blood clot is like a concrete barrier in the middle of the road. Traffic stops. Similarly, blood can't reach your heart, and this causes a heart attack.



You might have CAD for many years and not have any symptoms until you experience a heart attack. That's why CAD is a "silent killer."

Other names for CAD include coronary heart disease (CHD) and ischemic heart disease. It's also what most people mean when they use the general term "heart disease."

How common is coronary artery disease?

CAD is the leading cause of death in the U.S. and around the world. This is true for both males and females.

How does CAD affect my body?

The main complication of coronary artery disease is a heart attack. This is a medical emergency that can be fatal. Your heart muscle starts to die because it's not receiving enough blood. You need prompt medical attention to restore blood flow to your heart and save your life.

Over the years, CAD can also weaken your heart and lead to complications, including:

- Arrhythmias (like atrial fibrillation). Cardiac arrest.
- · Cardiogenic shock.
- Heart failure.





What causes coronary artery disease?

Atherosclerosis causes coronary artery disease. Atherosclerosis is the gradual buildup of plaque in arteries throughout your body. When the plaque affects blood flow in your coronary arteries, you have coronary artery disease.

Plaque consists of cholesterol, waste products, calcium and fibrin (a substance that helps your blood clot). As plaque continues to collect along your artery walls, your arteries become narrow and stiff.

Plaque can clog or damage your arteries, which limits or stops blood flow to a certain part of your body. When plaque builds up in your coronary arteries, your heart muscle can't receive enough blood. So, your heart can't get the oxygen and nutrients it needs to work properly. This condition is called myocardial ischemia. It leads to chest discomfort (angina) and puts you at risk for a heart attack.

What are the symptoms of coronary artery disease?

Angina, or chest pain and discomfort, is the most common symptom of CAD. Angina can happen when too much plaque builds up inside arteries, causing them to narrow. Narrowed arteries can cause chest pain because they can block blood flow to your heart muscle and the rest of your body.

For many people, the first clue that they have CAD is a heart attack. Symptoms of heart attack include:

- · Chest pain or discomfort (angina)
- · Weakness, light-headedness, nausea (feeling sick to your stomach), or a cold sweat
- Pain or discomfort in the arms or shoulder
- Shortness of breath

Over time, CAD can weaken the heart muscle. This may lead to heart failure, a serious condition where the heart can't pump blood the way it should.

What are the risk factors for coronary artery disease?

There are many risk factors for coronary artery disease. Some you can't control. Others you may be able to control by making lifestyle changes or taking medications. Talk with your provider about the risk factors listed below and how you can manage them.

Risk factors you can't control (non-modifiable risk factors)

Age: As you get older, your risk for CAD goes up.

Family history: You have a higher risk if your biological family members have heart disease. It's especially important to learn if they have premature heart disease. This means they were diagnosed at a young age.

Lifestyle factors that raise your risk

- · Circadian dysregulation
- Diet
- · Lack of physical activity
- Sleep deprivation
- \cdot Overweight or obese
- Smoking, vaping , other tobacco use

Risk factors that affect women

- Early menopause (before age 40).
- Endometriosis.
- · History of gestational diabetes, eclampsia or preeclampsia.
- Use of hormonal birth control.





How is coronary artery disease diagnosed?

There are four main categories of existing technology to determine existence of CAD. They are, in order of increasing (perceived) accuracy: blood tests, noninvasive functional tests, noninvasive anatomical testing and invasive coronary angiography. A few common methods used today are described below:



Blood Test

The most typical use of blood tests for CAD is to determine the risk of developing CAD over a set time period.

- Framingham Risk Score Coronary Heart Disease (FRS-CHD). The score is created from results of different blood marker levels in combination with age, blood pressure, existence of type 2 diabetes, and whether the patient smokes.
- Age- and sex- related gene expression score (AEGES) is used on patients with newly-diagnosed heart failure with reduced ejection fraction (HFrEF).

Functional Tests:

Common functional tests used to screen for CAD include exercise ECG and stress echocardiography.

- * Exercise electrocardiogram (ECG) measures symptoms or ischemia development in response to exercise stimuli.
- Stress echocardiography is performed through exercise or pharmacologic stimuli to increase your heart rate to peak levels and take ultrasound images of your heart to determine whether your heart muscles are getting enough blood and oxygen while you exercise.

Anatomical Tests:

Coronary Artery Calcium Score (CACS) and Coronary CT Angiogram (CCTA) are the typical tests used using CT, though imparting a significant amount of radiation. They are typically only used for individuals suspected of CAD, and they would not be deemed screening methods.

- CACS is a non-contrast CT scan with an applied simple, non-ML/AI algorithm that looks in the coronary arteries for calcium buildup and plaque.
- CCTA uses CT and contrast dye to view 3D pictures of your heart as it moves and detect blockages in your coronary arteries.

Cardiac catheter/invasive coronary angiography (ICA):

The historical gold standard has been the ICA. During the procedure a long, thin, flexible tube called a catheter is inserted into a blood vessel in your groin or arm. Using X-ray images as a guide, the tip of the catheter is passed up to the heart and coronary arteries.

A special type of dye called contrast medium is injected through the catheter and X-ray images (angiograms) are taken. The contrast medium is visible on the angiograms, showing the blood vessels the fluid travels through. This clearly highlights any blood vessels that are narrowed or blocked.

The procedure is usually carried out under local anaesthetic, so you're awake while the procedure is carried out, but the area where the catheter is inserted will be numbed.



What is the advantage of DexaFit Dx over traditional methods used to screen for coronary artery disease?

Cardiovascular disease is the #1 killer of humans every year, almost doubling the number of deaths caused by cancer. And the most significant form of cardiovascular disease is CAD. It affects nearly half the adult population, and for those that die from a heart attack, 60% don't see it coming because they won't have any prior symptoms. We developed DexaFit Dx to make it possible to identify these asymptomatic cases before it's too late.

Historically, there was no way to detect CAD consistently without the use of invasive procedures or CT scans with excessive radiation exposure to patients. These options were also inappropriate for asymptomatic cases and patients with comorbidities.

But by applying the DexaFit Dx AI system to images from DXA full-body scans, we created a safe and reliable way for anyone to discover their risk for CAD. DXA is widely available due to its decades of adoption for diagnosing osteoporosis, safe for patients, and more importantly, easy to do and affordable.



By combining CAD and T2D detection with DXA's original use case (diagnosing osteoporosis), DexaFit Dx offers a simple, safe, and affordable way to discover your risk for three of the most common chronic diseases impacting millions worldwide.

What are the risk factors for coronary artery disease?

The DexaFit Dx AI system was developed using real-world clinical data from a de-identified database of DXA, VO2 max, and RMR data that measure leading indicators of all-cause mortality. The DXA scan image pixel data and breath-by-breath gas analysis from VO2 max/RMR tests provided over 5+ billion data points to explore and use to train the AI system.

Body composition parameters, including bone mineral content, lean mass, total body (BF), and visceral fat were measured by FDA-approved DXA systems known for their clinical-grade accuracy and precision. Oxygen consumption (VO2), carbon dioxide production (VCO2), resting energy expenditure (REE), maximal heart rate (Max HR) and respiratory exchange ratio (RER) were measured by breath-by-breath gas analysis using FDA-approved cardiopulmonary exercise testing (CPET) systems. Over time, the AI system was trained with this data to detect coronary artery disease from the DXA scan alone.

Specifically, the AI was trained to analyze the DXA images to detect anatomical features within them, as well as processing the images to detect relationships within the tissues and the mathematical structures in the tissues. The DXA scan images include a "skeleton" image, a "composition" image, a "tissue" image, and a "tissue composition" image, among others. These images contain different information about the bone, lean, and adipose tissue at each pixel, all of which allows the AI to combine them in ways that provide more detail than what humans see when they look at a DXA scan image.



"Orderly" Healthy Body Composition Distribution



"Chaotic" Unhealthy Body Composition Distribution

The AI system has found that the more chaotic the distribution of lean and adipose tissue, the more likely it is that the patient is CAD positive. In fact, bodies that are objectively on the healthiest end of the spectrum can be so well ordered that they are indistinguishable from simple sinusoidal curves (mathematical curve that describes a smooth periodic oscillation). Bodies that are objectively some of the most unhealthy have what appear to be completely chaotic distributions of the density of their tissues.



How accurate is the DexaFit Dx test?

See below for a comparison of DexaFit Dx's AI to other modalities used to screen for CAD:

Test	Population	Sensitivity	Specificity
Stress Echo	Overall	84-87%	72-77%
SPECT	Overall	83-84%	79-85%
PET	Suspected CAD	90-91%	82-91%
CACS	Suspected CAD	98-99%	35-40%
ССТА	Suspected CAD	98.2%	81.6%
DexaFit DX	Overall	96.957%	98.778%

Sensitivity and specificity are critical metrics that assess a test's ability to correctly classify a person as having or not having a specific disease.

Sensitivity

Sensitivity, often referred to as the true positive rate, indicates the percentage of people with a disease who will have a positive result in the test. A highly sensitive test is one that correctly pinpoints patients with a disease.

For example, a 100% sensitive test will accurately detect all patients with the disease. However, achieving 100% sensitivity in a clinical test is quite unusual. A test with 90% sensitivity will correctly identify 90% of patients with the disease, but will overlook 10% of patients who indeed have the disease.

Specificity

The specificity of a test, or the true negative rate, is the percentage of people without the disease who will have a negative result. It measures the test's effectiveness in identifying patients who do not have a disease. A test with 100% specificity will accurately determine 100% of patients who do not have the disease, whereas a 90% specific test will correctly identify 90% of patients without the disease.

Highly specific tests are most useful when the result is positive and can efficiently confirm patients who have a certain disease. However, it might not be practical to use a test with low specificity for screening, as many disease-free individuals may screen positive, potentially leading to unnecessary diagnostic procedures.

Important Note: The DexaFit Dx AI does not claim to have 100% sensitivity or specificity, nor should it be used as the sole basis for any medical decisions. There is a possibility of false positive or false negative results. Furthermore, it's crucial to understand that DexaFit Dx is designed for informational purposes and does not provide a definitive diagnosis. Sensitivity and specificity listed are subject to change based on demographic variables.



What can I do if my CAD risk score is high?

If you have concerns about your DexaFit Dx test results after receiving them, we recommend seeking professional guidance or additional testing from a qualified healthcare provider. A high score does not mean you are CAD positive.

Should your healthcare provider or care team confirm CAD, or at least suspect an increased risk for it in the future, they may suggest the following steps to help lower your risk for heart attack or worsening heart disease:

- Lifestyle changes, such as eating a healthier diet, increasing physical activity, optimizing your circadian rhythm, improving sleep, reaching a healthy weight, and quitting smoking
- Medicines to treat risk factors for CAD
- Surgical procedures to help restore blood flow to the heart

What questions should I ask my healthcare provider?

If you haven't been diagnosed with coronary artery disease, consider asking:

- What are my risk factors for coronary artery disease?
- What can I do to lower my risk?
- What lifestyle changes are most important for me?
- What medications would lower my risk, and what are the side effects? How long do I need to stay on these medications?

If you have coronary artery disease, some helpful questions may include:

- What can I do to slow down disease progression?
- What's the best treatment plan for me?
- What lifestyle changes should I make?
- What medications do I need, and what are the side effects?
- Will I need a procedure or surgery? What does the recovery look like?
- Are there support groups or resources you can recommend?

Do you offer additional guidance or support for CAD prevention?

If you don't currently have a healthcare provider or wish to work with someone new, you may submit the questionnaire linked below to receive personalized recommendations for support. We will vet our network of health and wellness providers and recommend the ones we feel are a good fit for your personal situation and goals.

SCAN OR CLICK THE QR CODE BELOW TO OPEN THE FORM



How often should I get the DexaFit Dx test?

We recommend getting an annual scan at a minimum to monitor your risk and overall health.

