



# High Value Labs: Testosterone and Vitamin D testing Clinical Collaboration Guide

*Right patient, right service, right time*

Last Reviewed: January 2024 - FINAL	
James Neifing, MD	Portland Diabetes and Endocrinology

**Background:** A significant amount of health care expenditures comes from low-cost, high-volume services. Vitamin D testing and testosterone-level testing are two examples where there are different levels of tests available that have significantly different costs, and often the less expensive one is appropriate. Additionally, there are opportunities to decrease the overall amount of testing, which contributes to the total cost of care for our patients.

## **Vitamin D:**

Clinical recommendations and evidence around screening for Vitamin D deficiency have gone through many changes in the last few years. These are some things we can currently say about Vitamin D testing:

There is insufficient evidence to support routine screening for Vitamin D deficiency in the general population. (USPSTF rec: I)

If there is concern about vitamin D deficiency in a patient who does not fit screening recommendations as below, it is cost-effective to empirically replace with 1000 IU of Vitamin D daily.

**25 OH Vitamin D:** It is reasonable to screen patients with the following risk factors for Vitamin D Deficiency:

- |   |  |
|---|--|
| Chronic kidney disease, stage ≥3                | Hypercalciuria   |
| Cirrhosis/chronic liver disease                 | Granulomatous diseases   |
| Malabsorption states                            | Obstructive jaundice/biliary tract disease   |
| Osteoporosis or other bony metabolism disorders | Chronic use of anticonvulsant medication or corticosteroids  |
| Rickets   | Parathyroid disorders  |
| Hypo- or hypercalcemia                          | Vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment. |

**1,25-OH Vitamin D:** This is a *significantly more expensive* test, and should only be ordered in the setting of the following conditions:

- |   |  |
|---|--|
| End-stage renal disease   | Severe Hypercalcemia   |
| Unexplained hypercalcemia (suspected granulomatous disease or lymphoma) | Unexplained hypercalciuria (suspected granulomatous disease or lymphoma) |
| Suspected genetic childhood rickets                                     | Suspected tumor-induced osteomalacia                                     |
| Nephrolithiasis or hypercalciuria                                       |  |

## **Clinical Scenarios and Vitamin D - What we know and don't know:**

- Elderly and fall risk: Most recent evaluation does not show benefit to fall risk with supplementation. (BMJ 2016;353:i1419)
- Musculoskeletal pain: There are no randomized controlled trials that show notable changes in outcomes after repletion of Vitamin D.

**NB:** Medicare is significantly restricting coverage for Vitamin D testing. They are not covering Vitamin D levels for screening purposes, and will only cover testing for the indications above.

## **Testosterone**

When to measure and replace testosterone in men is an area that is still somewhat controversial. This guide is not intended to drive that decision, but rather to clarify the differences in testing methodology. There are two different options for measuring serum testosterone: total testosterone, and total and free testosterone. There is a significant cost difference between these two tests, and the right test should be ordered for the appropriate indication. The two most common clinical scenarios for measuring a serum testosterone, accounting for most lab orders, are evaluating testosterone deficiency in men and evaluation of PCOS in women.

**Usually, if evaluating male patients for hypogonadism, a total testosterone is a sufficient test, and free testosterone is not needed.**

### **Total Testosterone**

- Used to evaluate for testosterone deficiency in men.
- Should be measured as a fasting AM level due to natural decline through the course of the day (normal ranges are based on AM levels) and need 2 low levels to consider treatment.
- Following testosterone treatment in transgender men.

### **Total and Free Testosterone**

- Used to evaluate Polycystic Ovarian Syndrome or hirsutism in women.
- Recommendations are NOT to measure free and total when evaluating male hypogonadism. In very obese patients with 2 borderline low levels, free and total may be helpful in establishing a diagnosis due to the slight decline in sex hormone binding globulin (SHBG).

### **What we know and what we don't know about testosterone deficiency in men:**

- There is a natural, mild decline in testosterone level in men associated with aging.
- There is disagreement about whether the lower limit of normal is <300 ng/dL or <200 ng/dL
- Replacing testosterone may improve sexual function, mood, and depressive symptoms associated with hypogonadism, but the evidence is unclear.
- The risks of testosterone replacement (prostate cancer, cardiovascular disease) are controversial, and should be monitored closely.
- Hb/Hct should also be monitored in patients on IM & transdermal replacement therapy.

**Contact:** If you have questions or comments about this guide or are interested in the development of future collaboration guides, please contact LHP medical director Albert Chaffin, M.D., at [achaffin@lhs.org](mailto:achaffin@lhs.org).

**Disclaimer:** No guideline can anticipate all the unique circumstances of patient care, and as such, there are times when good clinical judgement will result in, and will require deviation from this guideline. In those settings, the reason for such deviation from this guideline should be documented in the medical record.

**Appendix:** Choosing Wisely patient handouts regarding Vitamin D testing and Testosterone testing for erectile dysfunction

# Choosing Wisely<sup>®</sup>

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## Vitamin D tests

When you need them—and when you don't

**M**any people don't have enough vitamin D in their bodies. Low vitamin D increases the risk of broken bones. It may also contribute to other health problems. That's why doctors often order a blood test to measure vitamin D.

But many people do not need the test. Here's why:

### **A test usually does not improve treatment.**

Many people have low levels of vitamin D, but few have seriously low levels. Most of us don't need a vitamin D test. We just need to make simple changes to get enough vitamin D. We need to get a little more sun and follow the other advice on the next page.



Even if you are at risk for other diseases, like Type 2 diabetes and heart disease, a vitamin D test isn't usually helpful. The test results are unlikely to change the advice from your doctor. It is much more important for you to make lifestyle changes first—to stop smoking, aim for a healthy weight, and be physically active. And, like most other Americans, you should try to get enough vitamin D from sun and foods. And talk to your doctor about whether a supplement is needed.

### **Extra tests lead to extra treatments and costs.**

Getting tests that you don't need often leads to treatments you don't need, or treatments that can even be harmful. For example, if you take too much vitamin D, it can damage your kidneys and other organs.

One blood test for vitamin D does not cost much. But doctors are ordering tests more often than ever, and the vitamin D test is now the fifth most popular lab test for older adults. All of these tests add up. In 2015, Medicare spent \$337 million on vitamin D tests for seniors, up from \$323 million the year before.

### **When should you have a vitamin D test?**

Talk to your doctor about your risks. If you have one of these conditions, you might need a vitamin D test:

- **Osteoporosis:** This disease makes your bones weak, so they are more likely to break.
- **A disease that damages your body's ability to use vitamin D:** These are usually serious and ongoing diseases of the digestive system, such as inflammatory bowel disease, celiac disease, kidney disease, liver disease, pancreatitis, and others.

If your doctor suggests getting a vitamin D test, ask about your risks. If your risk is high, you should get the test. If your risk is low, ask if you can avoid the test. Ask if you can boost your vitamin D with sunlight and food, and possibly supplements.

If your doctor does need to keep track of your vitamin D levels, make sure the same test is used each time. Ask your doctor which tests are best.

This report is for you to use when talking with your healthcare provider. It is not a substitute for medical advice and treatment. Use of this report is at your own risk.

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## Treatment for erection problems

### When you need testosterone treatment—and when you don't

**M**ost men have problems with erections from time to time. But some men have erectile dysfunction, or ED. This is when it is difficult to get or keep an erection that's firm enough for sexual intercourse.

If you have ED, you may think that testosterone treatment will help. Testosterone is a male sex hormone. After age 50, men's levels of testosterone slowly go down and ED becomes more common. But unless you have other symptoms of low testosterone, you should think twice about the treatment. Here's why:

#### **Testosterone treatment usually isn't helpful for ED.**

Testosterone treatment has not been shown to improve erections in men with normal testosterone levels. And studies show that it does not help men with low testosterone levels if ED is their only symptom.



#### **ED usually has other causes.**

ED is almost always caused by low blood flow to the penis. This is a result of other conditions, such as hardening of the arteries, high blood pressure, and high cholesterol. These conditions narrow the blood vessels and reduce blood flow to the penis. Low testosterone may affect the desire for sex, but it rarely causes ED.

### **Testosterone replacement therapy has many risks.**

Testosterone treatment can cause the body to retain too much fluid. It can also cause acne, an enlarged prostate, and enlarged breasts. Other side effects include lower fertility; an increase in red blood cells; and an increase in sleep apnea symptoms.

Women and children should avoid touching unwashed or unclothed areas of skin where a man has applied testosterone gel. The gel can be transferred through skin contact.

Although available data is conflicting, the Food and Drug Administration (FDA) has concluded that increased cardiovascular risk (problems with the heart and blood vessels) associated with testosterone use is a possibility. The AUA recommends that only FDA-approved medications should be used and a physical evaluation and follow up are important.

### **Testosterone replacement therapy can be costly.**

Testosterone treatment can be an injection, a gel, or a patch that is put on the skin. All of these are costly. They may cost hundreds of dollars a month, depending on the treatment.

Men who use a testosterone treatment must use it indefinitely to get and keep the full effect.

### **When should you consider testosterone treatment for ED?**

If you've had trouble having erections for three months, talk to your doctor. He or she will ask about all your symptoms and give you a physical exam. Symptoms of low testosterone can include less of a sex drive, loss of body hair, breast growth, needing to shave less often, a drop in muscle size and strength, and bones that break more easily.

If you have some of these symptoms, your doctor may have you get a blood test to measure your testosterone levels. The blood test should be done more than once. It is best to do it in the morning when testosterone levels are highest.

If the tests show that you have low testosterone levels, your doctor should look for possible causes. For example, the low levels might be caused by a problem in the pituitary glands.

If no other cause is found, you can try testosterone treatment.

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