

You "Otter" Know about PTH

*(Parathyroid Hormone Testing
and Renal Patient Care)*

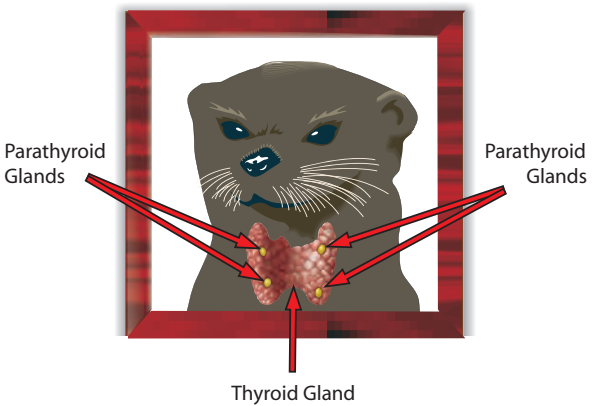


Notes:



SCANTIBODIES
Clinical Laboratory

For More Information Please Call:
1-866-249-1212
or visit our website at:
www.scltesting.com



What is PTH?

Parathyroid hormone or PTH is an important hormone in the human body which affects many bones and tissues. PTH lets the body know when to add or take away minerals like calcium, magnesium and phosphorus from the bones. Since our bones are constantly being rebuilt with new bone—referred to as “bone turnover”—this hormone plays a vital role in bone health. When the kidneys are not functioning normally or the PTH hormone is out of balance, bones can “turnover” either too fast or too slowly. For the dialysis patient's physician, it is vital to know the level of PTH to properly guide the patient's therapy and care and provide for optimum bone health. This is accomplished when the physician orders a blood test which is called a “PTH Assay” to measure the level of PTH in the patient's system.

Where does PTH come from?

PTH is a molecule of 84 amino acids which comes from the four tiny

parathyroid glands embedded in the thyroid gland in the front of the neck. Too much PTH in the body (which can occur when the kidneys fail) results in hyperparathyroidism, or high PTH. It can cause a patient to feel bone pain, anemia and weakness. High PTH can also result in blocked and clogged arteries, nerve problems and a weakened immune system. Weak bones cannot produce healthy new red blood cells. High bone turnover may be managed with calcium and vitamin D. However, too much calcium and vitamin D can cause health problems of another kind.

For over 50 years it was assumed that there was only one parathyroid hormone in the human body. In 1998, Scantibodies Laboratory discovered that a second hormone (a large fragment called 7-84 PTH) was also secreted from the parathyroid gland and that this hormone caused an opposite effect on the body to that of the full 84 amino acid PTH molecule. High calcium and vitamin D levels can cause the parathyroid gland to produce and release an excessive amount of this 7-84 PTH hormone resulting in a condition called Adynamic Bone Disease. Since it is important to know the correct value when measuring PTH, Scantibodies developed a way to accurately measure the amount of both the 1-84 PTH and the 7-84 PTH hormones. Knowing the amount of

both hormones allows your physician to have a better understanding of the health of your bones.

Adynamic Bone Disease

Recent research has shown that greater than one out of every two renal patients develop Adynamic Bone Disease – a condition which can be caused by the action of the 7-84 PTH fragment as it works against the 1-84 PTH in the body. This results in lowering the rate of bone turnover. This condition makes the bones unable to use or

1-84 PTH: A parathyroid hormone molecule of 84 amino acids, discovered over 50 years ago. Most tests are done assuming that they measure only this hormone—BUT they are also measuring...

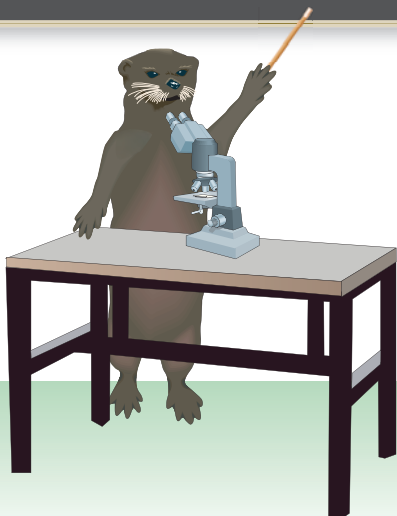


1-84 PTH Molecule

7-84 PTH: A large fragment of the PTH molecule discovered in 1998, which has an opposite effect on the body to that of 1-84 PTH. SCL developed a way to accurately measure both 1-84 and 7-84 PTH hormones.



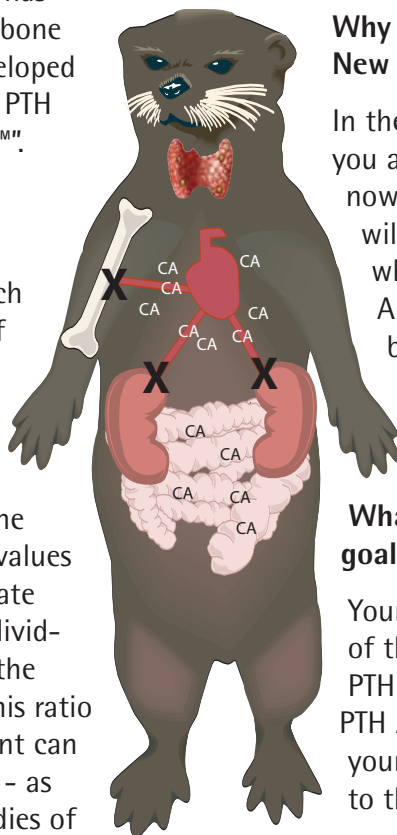
7-84 PTH Molecule



"buffer" calcium and phosphate, which leads to a build-up of the minerals in the arteries and soft tissues of the body. This build-up of minerals is called "calcification" and has been proven to be a dangerous and sometimes fatal condition. The majority of adynamic bone disease patients are not identified with standard PTH testing methods—one test—usually an intact PTH test. In the past, a painful and costly biopsy has been the only way to get a true bone status. So Scantibodies Labs developed a new and better way of testing PTH and called it the "PTH Accuratio™".

How Does the PTH Accuratio™ Work?

By using a "whole PTH test" which tests the entire 1-84 molecule of PTH, and then a new "total intact PTH test" which tests the value of the 7-84 molecule of PTH, a ratio of these two values can be calculated. From the patient's blood sample, the two values are measured and used to calculate the Accuratio™. This is done by dividing the amount of 1-84 PTH by the amount of 7-84 PTH. By using this ratio value, the bone status of a patient can be predicted with 94% accuracy - as proven by huge bone biopsy studies of more than 2,000 patients. By using this bone status information, the physician can better select the correct therapy.



How Does this New Accuratio™ Test Panel Benefit the Dialysis Patient?

Rather than the physician arbitrarily prescribing routine vitamin D or calcium therapy based on a single, incomplete assay, the Accuratio™ value allows the physician to know the status of the patient's bones and more precisely what is needed to achieve a healthy PTH level.

Why is my PTH Level Higher with this New Testing?

In the past, your doctor may have given you a target level for the PTH value. But now, using the Accuratio™, he or she will have a better understanding of what the correct value should be. Also, it has been proven in bone biopsy studies that the PTH target values for African American and Caucasian patients are very different.

What Should be My New Target PTH goal?

Your doctor will be able to advise you of the correct target value for your PTH level, based on the results of the PTH Accuratio™ and the condition of your bones. Your body is very sensitive to these conditions while you are on

As shown by this diagram, Adynamic Bone Disease is a condition which causes calcium to build up in the body. This causes a variety of needless ailments that can be treated properly by using the Accuratio.

dialysis and your doctor can better prescribe the correct supplements or therapy as part of your treatment plan.

What about Billing and Insurance for these New Tests?

Consistent with their policy of reimbursing for *medically necessary* tests, Medicare does reimburse for both tests that are needed to calculate the PTH Accuratio™ value. Your doctor will decide when the tests should be ordered based on your medical diagnosis and necessity.

Some individual insurance carriers include lab services that include PTH testing as part of their combined rate. If you are not covered by Medicare or Medicaid, and have private health insurance, you should ask your dialysis clinic to verify with Scantibodies Clinical Lab that your health insurance reimburses for the



Scantibodies PTH assay.

You do not need to sign a billing consent form with SCL, as we are considered an indirect treatment provider. This means we provide our testing based on the order of the physician or dialysis clinic, and report results directly to the healthcare provider—not the patient.

In cases where an insurance company needs to be billed, SCL does offer this service on the patient's behalf. Co-pays or deductibles are the responsibility of the patient.

The Advantages of PTH Testing with SCL versus other Labs:

Scantibodies Clinical Laboratory (SCL) is dedicated to determining the true measurement value in each patient blood sample and supplying better diagnostic information to physicians for better patient care. SCL "goes the extra mile" to provide quality and consistency in results and reporting by:

- Testing all patient samples in duplicate
- Calibrating the equipment with each batch of samples (less than 200 samples per batch)
- Evaluating normal distribution statistics to ensure accuracy

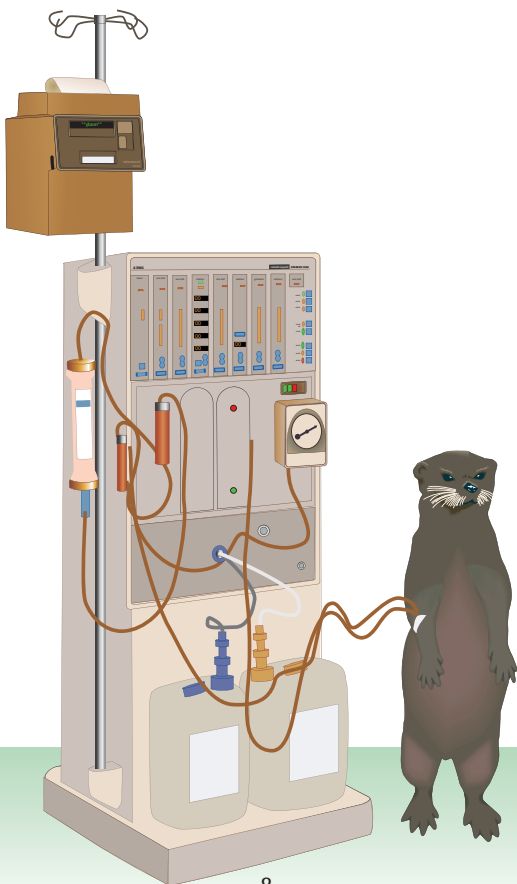
- Performing monthly evaluations on each aspect of testing:

- the requisition • the order • the test
 - the reagent • the equipment
- quality control • the reporting process

All these steps are taken to be certain that your clinicians and physicians are given the best diagnostic information possible to guide your care.



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PTH Tracking Chart:

2000

1900

1800

1700

1600

1500

1400

1300

1200

1100

1000

900

800

700

600

500

400

300

200

100

0

Date

Date

Date

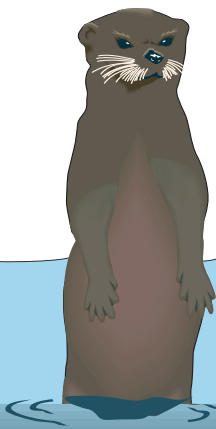
Date

Date

Date

Your Goal PTH level is: _____

**You "Otter" Use
The PTH Accuratio™**



An education service of Scantibodies
Laboratories, manufacturer of
3rd Generation PTH Assays.

PTH Accuratio™

1-84 PTH / 7-84 PTH ratio