

Thyroid Stimulating Hormone, 3rd Generation

New Test: Thyroid Stimulating Hormone, 3rd Generation

Spectra Laboratories is pleased to announce the addition of a new test, **3rd Generation Thyroid Stimulating Hormone (TSH3)**. This 3rd Generation TSH assay will replace the current TSH assay. TSH3 provides a tenfold improvement in sensitivity over the previous method. In order to be designated a 3rd Generation TSH assay, a TSH method must have a functional sensitivity below a 0.020 mIU/L.^{1,2} The detectable limit of Spectra Laboratories' new 3rd Generation TSH assay has a functional level validated to 0.008 mIU/L.³

Spectra will no longer offer the current TSH assay because the new TSH3 assay provides the full testing range required for the determination of both hypothyroidism and hyperthyroidism. The American Thyroid Association (ATA) currently suggests a third generation TSH as the most cost effective strategy to detect thyroid disease.⁴ Many clinicians pair the TSH with FT4 to recognize euthyroid hyper- or hypothyroxinemia. The latter is common in nephrotic syndrome.⁵ TSH can also be helpful in determining whether an elevated T4 is indicative of hyperthyroidism or is due to decreased protein-binding site availability.⁴

The benefit of TSH3 is that, unlike 2nd generation TSH assays, TSH3 can measure levels below 0.020 mIU/L and can be used to distinguish the extremely low levels of TSH suppression of Graves' disease from the less severely suppressed TSH of non-thyroid illnesses.⁴

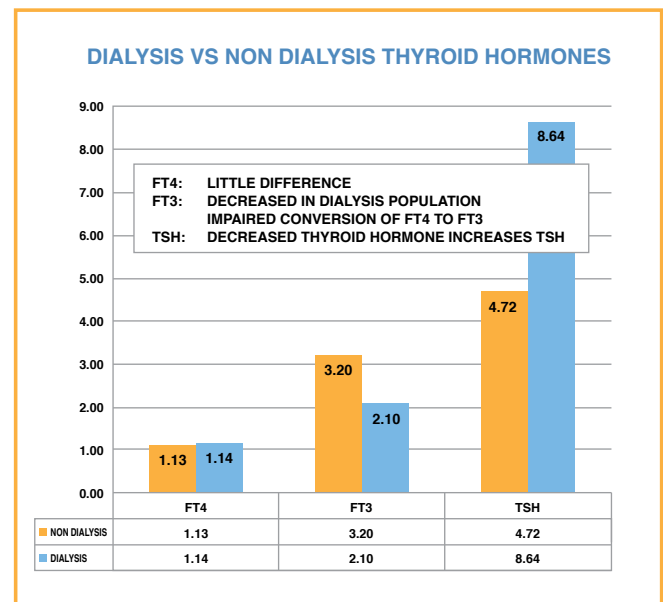
Reference Range

According to the ATA, >95% of the normal population will have a TSH level below 2.5 mIU/L with an average TSH level of approximately 1.5 mIU/L.⁴ Spectra has validated a TSH reference range of 0.300-3.000 mIU/L, which is also the range recommended by the American Association of Clinical Endocrinologists (AACE).

The ESRD population includes about 20% of individuals with TSH of up to 20 mIU/L and a normal free T4 consistent with non-thyroidal illness. ESRD patients with true hypothyroidism develop persistent values above 20 mIU/L.

TSH and the Dialysis Patient

The effects of uremia on dialysis patients are sometimes indistinguishable from symptoms of hypothyroidism.⁶ Peritoneal and hemodialysis do not directly affect the thyroid hormone levels, but a loss of protein in peritoneal dialysis can lead to a decrease in the total thyroxin levels.⁷ Dialysis patients may have decreased FT3 and FT4, and increased TSH levels and still be euthyroid.⁶ Abnormal thyroid results in dialysis patients are more commonly due to abnormal protein levels, malnutrition, or non-thyroid intercurrent illnesses than to actual thyroid dysfunction.⁶ Although decreases in thyroid hormones are generally associated with non-thyroid disease and malnutrition, dialysis patient decreases in FT3 are also due to decreased ability to convert FT4 to FT3 at the cellular level.⁹

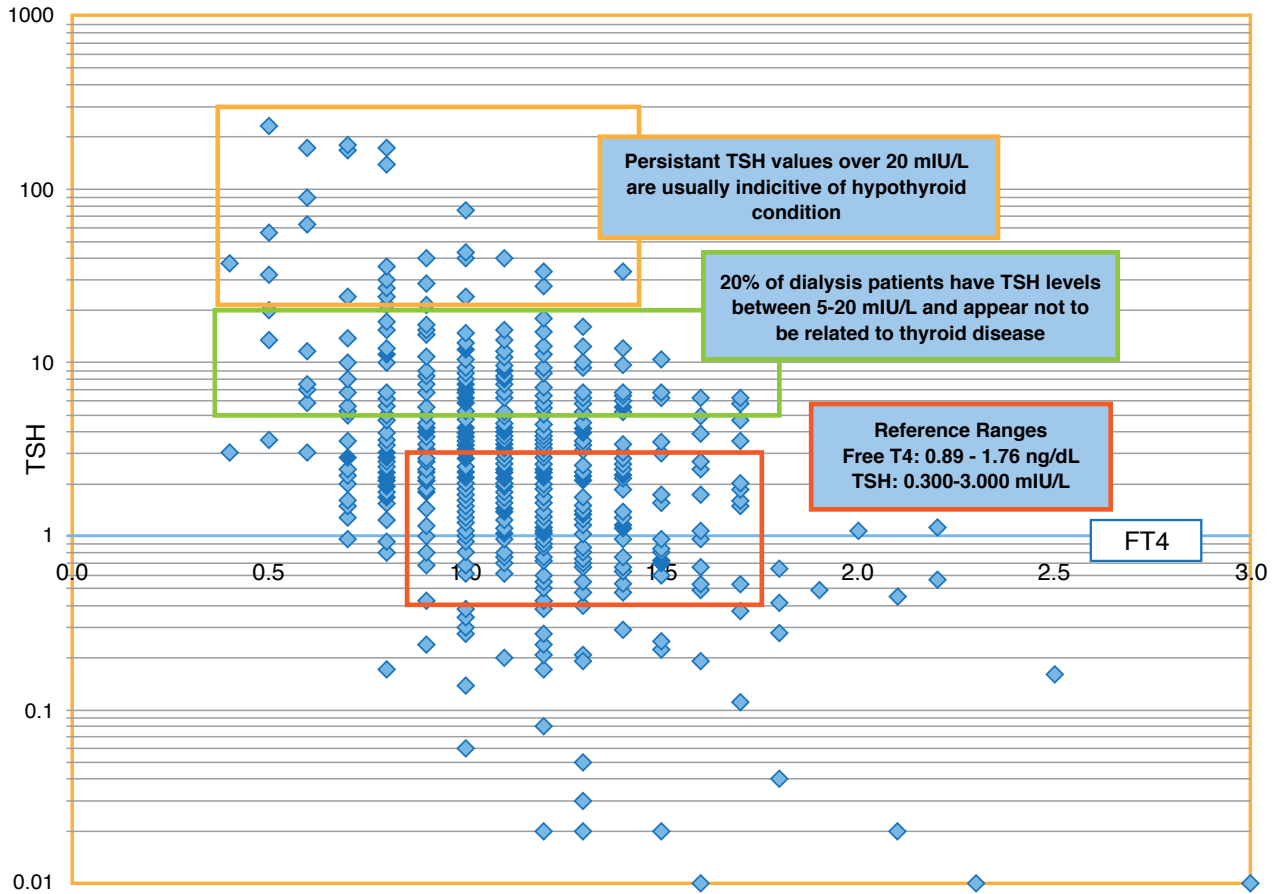


The new TSH3 assay provides the full testing range required for the determination of both hypothyroidism and hyperthyroidism.

Reference Range: 0.300-3.000 mIU/L

Although the average level of TSH in the general population is approximately 1.5 mIU/L, the mean TSH in the dialysis population is higher, with a significantly greater variation, compared to the general population. Free thyroid hormone can increase temporarily due to inflammation and following the administration of heparin due to the competition for the carrier proteins binding sites.¹⁰

DISTRIBUTION OF TSH and FT4 IN THE DIALYSIS POPULATION



These relatively mild decreases in FT3 and FT4 levels are not usually related to hypothyroidism but may, in part, contribute to the moderately increased TSH as compared to the normal population. Factors related to non-thyroid disease and the dialysis process result in 19-20% of dialysis patients having levels of TSH between 5 and 20 mIU/L.^{7,8} However, repeatedly decreased levels of FT4 and elevated TSH levels greater than 20 mIU/L may be indicative of true hypothyroidism.^{6,7} In addition, because of the prevalence of diabetes in the dialysis population, the incidence of primary hypothyroidism is increased (4%) in the ESRD population when compared to the normal population.⁶

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Spectra Laboratories, Inc.
525 Sycamore Drive • Milpitas, CA 95035 • 800-433-3773
8 King Road • Rockleigh, NJ 07647 • 800-522-4662
www.spectra-labs.com

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