
Lab Dept:	Chemistry
Test Name:	TSH, SENSITIVE

General Information

Lab Order Codes:	TSH
Synonyms:	Thyroid Stimulating Hormone; Ultra sensitive TSH; Thyrotropin
CPT Codes:	84443 – Thyroid stimulating hormone (TSH)
Test Includes:	TSH concentration reported in uIU/mL.

Logistics

Test Indications:	TSH is synthesized and secreted by the anterior pituitary. TSH is responsible for stimulating cell reproduction and hypertrophy. Secondly, TSH stimulates the thyroid gland to synthesize and secrete T3 and T4. The measurement of circulating TSH is important in evaluating hyperthyroidism.
Lab Testing Sections:	Chemistry
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1 day
Special Instructions:	N/A

Specimen

Specimen Type:	Blood
Container:	Preferred: SST (Red, marble or gold) top tube Alternate: Green top (Li Hep) tube, Lavender top (EDTA) tube, NaHep tube
Draw Volume:	1.5 mL (Minimum: 0.6 mL) blood
Processed Volume:	0.5 mL (Minimum: 0.2 mL) plasma/serum
Collection:	Routine venipuncture

Special Processing: Lab Staff: Centrifuge specimen, remove plasma/serum aliquot into a plastic sample cup. Store at 2-8 degrees Centigrade for up to 7 days.

Patient Preparation: None

Sample Rejection: Mislabeled or unlabeled specimen

Interpretive

Reference Range:

Age:	Range (uIU/mL):
0 – 5 days:	0.5 – 15.2
6 days – 2 months:	0.5 – 11.0
3 – 11 months:	0.5 – 8.4
1 – 5 years:	0.5 – 6.0
6 – 10 years:	0.4 – 4.8
11 – 19 years:	0.4 – 4.3
>=20 years:	0.3 – 4.2

Critical Values: N/A

Limitations: Results should be used in conjunction with other data; eg, symptoms, results of other tests, and clinical impressions.

If the TSH results are inconsistent with clinical evidence, additional testing is recommended to confirm the result.

Suspected hyperthyroidism based on low or undetectable TSH levels should be confirmed with additional thyroid function testing along with other clinical information.

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as Alinity i TSH that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal human serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.

Methodology:

Homogeneous Sandwich Chemiluminescent Immunoassay

Abbott Alinity i TSH Reagent Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL, 60064, USA. February 2018

Abbott Alinity i TSH Calibrator Kit Package Insert, Abbott Diagnostics Division, Abbott Park, IL, 60064, USA. December 2017

Abbott Architect TSH Reagent Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL, 60064, USA. November 2015

Abbott Architect TSH Calibrator Kit Package Insert, Abbott Diagnostics Division, Abbott Park, IL, 60064, USA. November 2015

CALIPER Reference Interval Studies, accessed 10/27/2020, <https://caliper.research.sickkids.ca/#/>

National Committee for Clinical Laboratory Standards (NCCLS) (2002) Clinical Laboratory Technical Procedure Manuals; Approved Guideline-Fourth Edition GP2-A4

Burtis CA, Ashwood ER, editors (2006) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed. St Louis, MO: Elsevier Saunders

Bio-Rad Immunoassay Plus Control Product Insert

Updates:

8/29/2005: Method previously listed as Two Site Sandwich Immunoassay Direct Chemiluminescence standardized to WHO 3rd IRP reference material.

10/1/2008: Name change to include Sensitive

7/22/14: Method change, previously listed as Competitive Chemiluminescent Immunoassay

2/9/2016: Update alt tube type

11/24/2020: Updated for method Abbott Alinity, removed method Siemens Vista

1/26/2021: Updated reference ranges|

2/11/2021: Updated collection containers

9/28/2021: Added EDTA as alternate tube.

10/12/2021: Updated reference ranges