



ENDOCRINOLOGY

Thyroid Testing Services

Assessing Thyroid Disease in Your Patients



Labcorp offers best-in-class thyroid testing across the continuum of care. Our expertise in endocrinology can support diagnosis of thyroid disorders, including hyper- and hypothyroidism, evaluation of autoimmune diseases such as Graves' disease and Hashimoto's thyroiditis, and confirmation of and monitoring of thyroid cancer.

Labcorp offers healthcare providers direct access to specialized offerings and services.

- Endocrine Sciences, Labcorp's endocrinology center of excellence, Endocrine Sciences, is a state-of-the-art laboratory that focuses on delivering highly precise and sensitive endocrine testing services.
- Dianon Pathology is leading at the forefront of providing anatomic pathology services such as:
 - Specialized endocrine pathology requisition
 - Full-color reports with photomicrographs
 - Dedicated cytopathology staff with expertise in thyroid pathology



Thyroid Function

Screening for thyroid disease is important.



It is estimated that 20 million Americans suffer from some form of thyroid disease and most are unaware of their condition¹

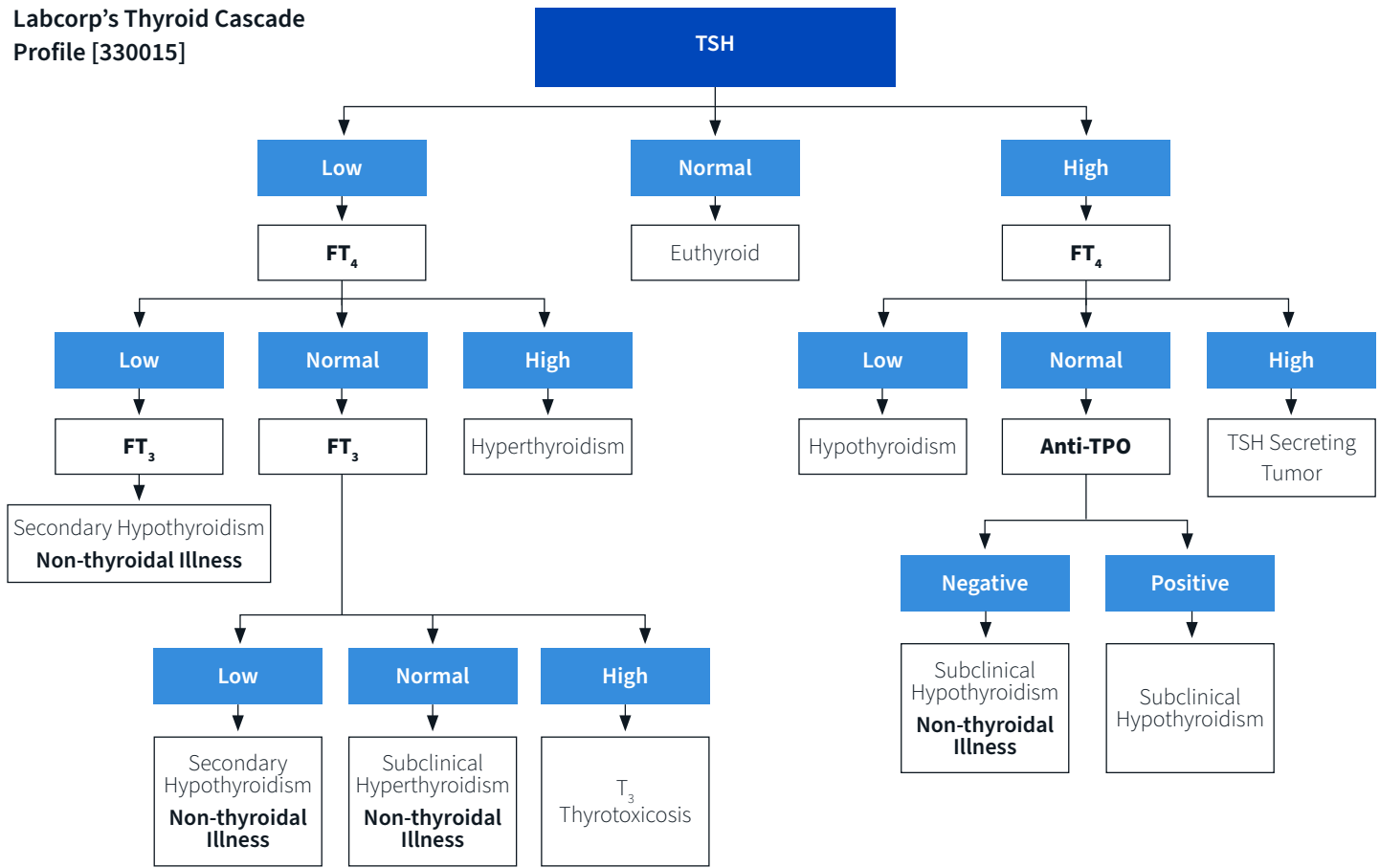
- One woman in eight will develop a thyroid disorder during her lifetime and are significantly more likely than men to have thyroid problems¹
- Consider screening type 1 diabetes patients for autoimmune thyroid disease soon after diagnosis²
- Hypothyroidism accounts for approximately 80% of patients with thyroid disorders³

Labcorp Thyroid Cascade

The panel is based on a cascade algorithm that selects specific assays based on the results of previously performed tests, which are necessary to arrive at the most appropriate and cost-effective laboratory diagnosis of thyroid dysfunction.

Labcorp's **Thyroid Cascade Profile [330015]** was designed as a diagnostic tool to aid in the initial diagnosis of common adult thyroid disorders. This panel is not intended for use in pediatric patients or in monitoring patients receiving treatment for thyroid disease with either ablative or suppressive therapy. It would also not be appropriate to use this panel to diagnose primary thyroid neoplasm. Clinical practice guidelines from the American Thyroid Association promote the use of thyroid-stimulating hormone (TSH) as the first test in the screening process.⁴ The Thyroid Cascade Profile only uses the latest generation ultrasensitive TSH testing.

Labcorp's Thyroid Cascade Profile [330015]



Autoimmune Thyroid Disease

Diagnosing whether hyper- or hypothyroidism is caused by an autoimmune disease is critical for patient care and treatment.

Graves' Disease

- The most common form of hyperthyroidism and accounts for 80% of all cases⁵
- Graves' Disease results from the autologous production of thyrotropin receptor antibodies (TRAb) or thyroid stimulating immunoglobulins (TSI) directed against the TSH receptor that cause continual stimulation of the thyroid to produce thyroxine (T₄) and triiodothyronine (T₃)⁶
- The presence of TRAb antibodies is highly suggestive of Graves' Disease and has a specificity of 99%⁴

Hashimoto's Thyroiditis

- In the United States, the most common cause of hypothyroidism is chronic autoimmune thyroiditis (Hashimoto's thyroiditis) which can result in thyroid failure
- Five to 10 times more common in women than in men
- Hypothyroidism most commonly results from primary gland failure, which accounts for 90-95% of all cases. Many of these patients show evidence of an autoimmune origin of thyroid failure, with >75% developing anti-thyroid peroxidase antibodies (anti-TPO) and/or antithyroglobulin (anti-Tg) antibodies
- The TSH level is usually very high (>10.0 U/mL) with depression of FT₄. Patients who are suspected to have autoimmune thyroiditis, and who are seronegative for anti-TPO or anti-Tg antibodies, may also be tested for the presence of TRAb antibodies, which may be present in early Graves' Disease⁷

Thyroid Cancer

The detection and diagnosis of thyroid cancer are crucial

- Thyroid nodules are common, especially in older adults
- Up to half of adults examined through thyroid ultrasonography have nodules⁸
- Of those nodules, 10% to 15% are cancerous⁹
- Common thyroid tumors have high survival rates when diagnosed and treated correctly, with more than 90% survival at 10 years
- Younger patients who receive appropriate treatment can achieve survival rates approaching 100%¹⁰

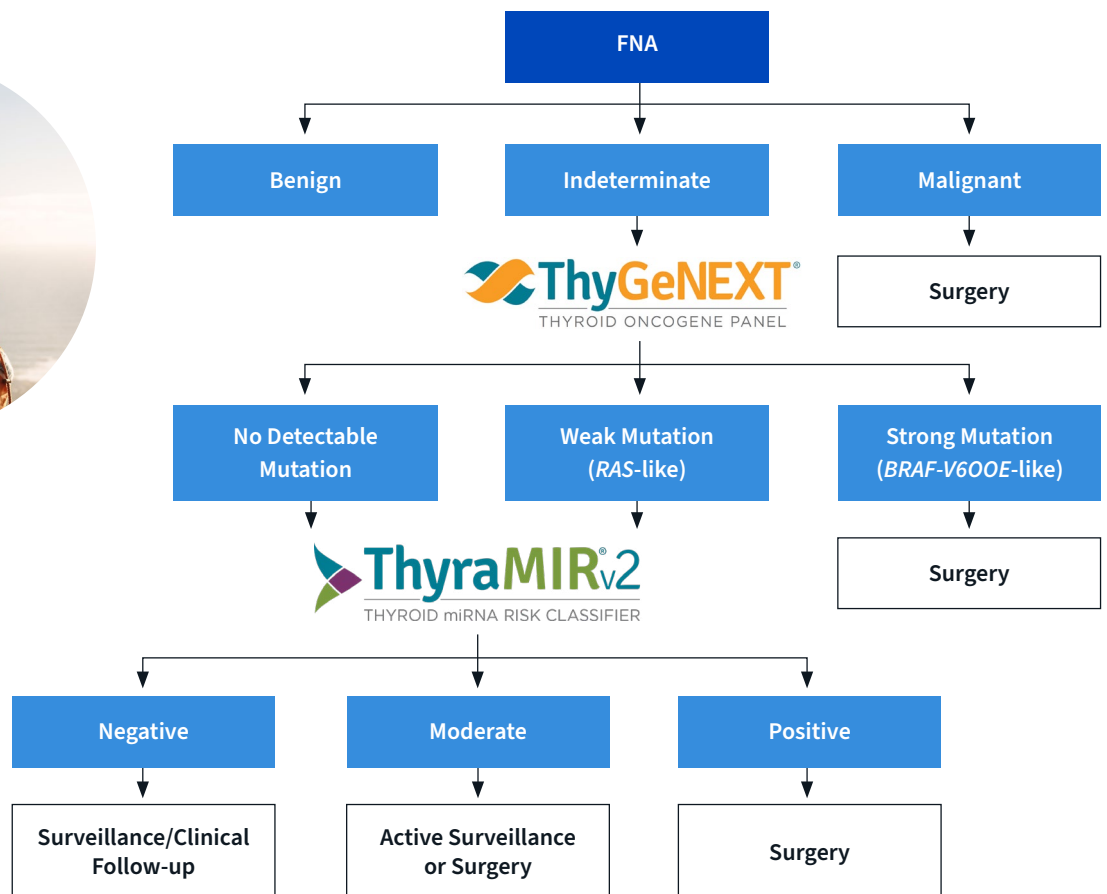
Fine-needle aspiration (FNA) helps differentiate between benign and malignant nodules¹¹

- Labcorp offers several test options for detecting and diagnosing thyroid cancer using fine needle aspiration (FNA) biopsies

Thyroid Cancer Confirmatory Testing

If FNA results are indeterminate, Labcorp provides molecular confirmation using **ThyGeNEXT** and **ThyraMIRv2**.

- Only testing platform that utilizes both mutational and microRNA markers
- ThyGeNEXT[®] includes the primary mutations associated with thyroid malignancy including but not limited to *BRAF*, *RET*, *TERT*, *ALK*, *RET/PTC*, *RAS*, *PTEN*, *PAX8/PPAR γ* and *PIK3CA*¹²
- ThyraMIRv2 includes 11 microRNA markers and is performed if ThyGeNEXT[®] is negative or not fully indicative of malignancy¹³
- Results include risk assessment result interpretation and mutation information
- Labcorp also offers an option for the Thyroid FNA test with indeterminate reflex to ThyGeNEXT[®] only, and utilize the Bethesda system nomenclature for thyroid FNA cytology results



Thyroid Cancer Monitoring

Once thyroid cancer has been diagnosed and treated, patients must be closely monitored for cancer recurrence.

- Thyroglobulin is a protein secreted only by thyroid tissue
- After thyroidectomy, thyroglobulin levels are recommended to detect recurrence of thyroid cancer¹¹
- Patients with MTC are also monitored with calcitonin and CEA testing as recommended by American Thyroid Association guidelines¹⁴

Labcorp offers enhanced sensitivity for thyroglobulin and thyroglobulin antibody testing to monitor for thyroid cancer recurrence.

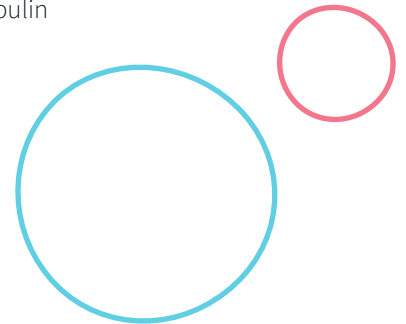
- Serum thyroglobulin (Tg) is primarily used in the postoperative management of differentiated thyroid cancer (DTC)
- Thyroglobulin antibody (TgAb) is detected in an estimated 25% of patients with DTC.¹¹ In those patients, there is a risk of interference with Tg measurement using immunometric (IMA) methods that can lead to false-negative (inappropriately low or undetectable) Tg results^{11,15}
- Even low antibody concentrations can interfere with Tg measurements¹⁵

Labcorp's Thyroglobulin antibody and Thyroglobulin test options offer a dual assay strategy for Tg in an effort to minimize the potential effect of TgAb interference.

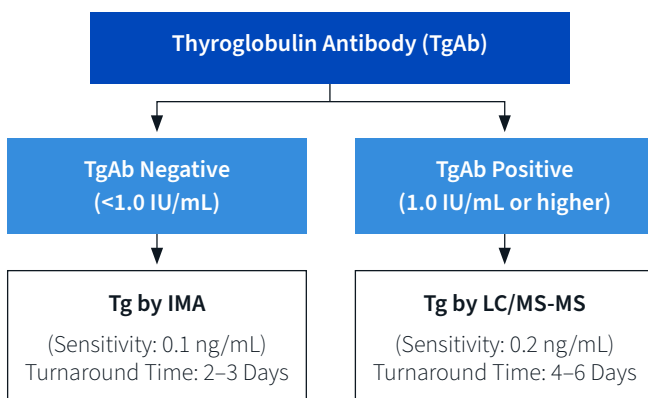
- Specimens are tested for TgAb using a sensitive IMA. Specimens with TgAb below the detectable limit (<1.0 IU/mL) are tested for Tg by sensitive second-generation IMA
- Specimens with any measurable TgAb levels (≥1.0 IU/mL) are tested for Tg by either LC/MS-MS or radioimmunoassay (RIA), which is less prone to interference by TgAb¹⁵

Labcorp offers thyroglobulin testing for lymph node aspirate diluted in saline.

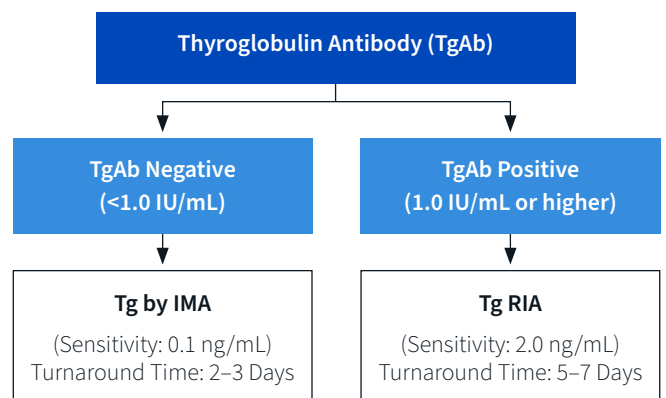
- Aspirate material from lymph nodes can be tested for the presence of thyroglobulin if there is suspicion that thyroid cancer has spread to the lymphatic system¹⁶
- The lymph node aspirate is collected and washed into a 1 mL saline solution, and the saline solution is tested for the presence of thyroglobulin



Thyroglobulin Antibody and Thyroglobulin, IMA or LC/MS-MS [042045]

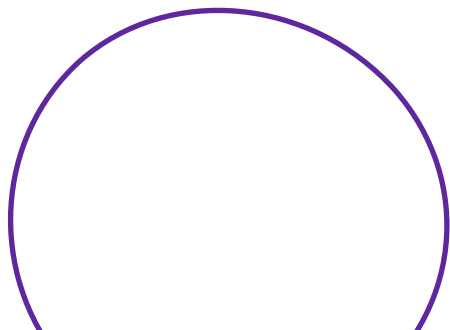


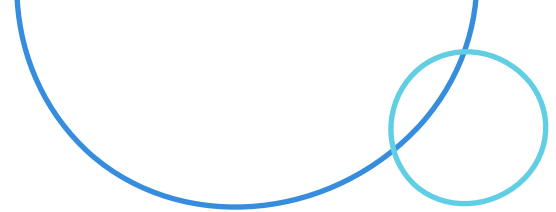
Thyroglobulin Antibody and Thyroglobulin, IMA or RIA [042060]



Thyroid Testing Options

| Test Name | Number | Methodology | Specimen | Container | Storage |
|---|----------------|---|---|--|--|
| Thyroid Testing Services | | | | | |
| Thyroid Cascade Profile: TSH with automatic reflex (as diagnostically warranted) to FT4 , FT3 , and/or TPO antibodies | 330015 | ECLIA | 2.0 mL serum Minimum: 1.0 mL | Red-top tube or gel- barrier tube | Room Temperature |
| Thyroxine (T4) | 001149 | ECLIA | Serum: 1 mL (adult), 0.8 mL (pediatric) Minimum: 0.5 mL (adult), 0.3 mL (pediatric) | Red-top tube or gel- barrier tube | Room Temperature |
| Thyroid-stimulating Hormone (TSH) | 004259 | ECLIA | 0.8 mL serum Minimum: 0.3 mL | Red-top tube or gel- barrier tube | Room Temperature |
| Thyroxine (T4) Free, Dialysis/Mass Spectrometry++ | 501902* | Direct dialysis mass spectrometry; HPLC/ MS | 1.0 mL serum (preferred) or plasma Minimum: 0.5 mL | Red-top tube or lavender-top (EDTA) tube | Freeze (preferred) or refrigerate |
| Thyroxine (T4), Free, Direct, Serum | 001974 | ECLIA | 0.8 mL serum Minimum: 0.3 mL | Red-top tube or gel- barrier tube | Room Temperature |
| Thyroxine-binding Globulin (TBG), Serum | 001735 | ECLIA | 0.5 mL serum Minimum: 0.3 mL | Red-top tube or gel- barrier tube | Room Temperature |
| Triiodothyronine (T3) | 002188 | ECLIA | 0.8 mL serum Minimum: 0.3 mL | Red-top or gel-barrier tube | Room Temperature |
| Triiodothyronine (T), Free | 010389 | ECLIA | 0.8 mL serum Minimum: 0.3 mL | Red-top tube or gel- barrier tube | Room Temperature |
| Triiodothyronine (FT3), Free, Dialysis and LC-MS/MS++ | 503600* | Equilibrium dialysis and HPLC/MS-MS | 1.0 mL serum Minimum: 0.3 mL | Red-top tube, gel-barrier tube, lavender-top (EDTA) tube, or green-top (sodium heparin) tube | Freeze (preferred) or refrigerate |
| General Autoimmune Screen | | | | | |
| Thyroglobulin Antibody | 006685 | ICMA | 1.0 mL serum | Red-top tube or gel- barrier tube | Room Temperature |
| Thyroid Antibodies (includes Thyroglobulin Antibody, (TPO) Antibodies) | 006684 | See individual test descriptions | 2.0 mL serum | Red-top tube or gel- barrier tube | Room Temperature |
| Thyroid Peroxidase (TPO) Antibodies | 006676 | ECLIA | 0.8 mL serum Minimum: 0.3 mL | Red-top tube or gel- barrier tube | Room Temperature |





| Test Name | Number | Methodology | Specimen | Container | Storage |
|---|----------------|---|---|---|-------------------------------------|
| Graves' Disease Autoimmune Screen | | | | | |
| Thyroid-Stimulating Immunoglobulin (TSI) | 140749 | "ImmuLITE 2000 TSI assay designed for the specific Semi-Quantitative detection of stimulating autoantibodies using a bridging format and human TSH receptor fragment chimeric recombinant proteins" | "3.0 mL serum EDTA or heparin Minimum: 0.3 mL" | Red-top tube, gel-barrier tube, lavender-top (EDTA) tube, or green-top (heparin) tube | Refrigerate |
| TSH Receptor Antibody (TRAb/TBII) | 500538* | Binding inhibition assay | 1.0 mL serum Minimum: 0.3 mL | Red-top tube or gel- barrier tube | Ambient (same day) or freeze |
| Thyroid Cancer Screen | | | | | |
| Calcitonin (Thyrocalcitonin) | 004895 | ICMA | 1.0 mL serum Minimum: 0.4 mL | Red-top tube or gel- barrier tube | Freeze |
| Fine Needle Aspiration Cytology | 009001 | Morphologic analysis | "Aspirated material Recommend using Labcorp Collection kit: Catalog No FNAK10" | Slide(s); Coplin jar(s) | Refrigerate |
| ThyGeNEXT® with reflex to ThyraMIR® | 824826 | Next Generation Sequencing Technology | Thyroid Fine Needle Aspirate (FNA) biopsy | RNA Retain® | Room temperature |
| Thyroid Cancer Monitoring | | | | | |
| Calcitonin (Thyrocalcitonin) | 004895 | ICMA | 1.0 mL serum Minimum: 0.4 mL | Red-top tube or gel- barrier tube | Freeze |
| Carcinoembryonic Antigen (CEA) | 002139 | ECLIA | 0.8 mL serum Minimum: 0.3 mL | Red-top tube or gel- barrier tube | Refrigerate |
| Thyroglobulin Antibody and Thyroglobulin, IMA or LC/MS-MS | 042045 | IMA or LC/MS-MS | 3 mL serum (two tubes, 1.5mL each) Minimum: 2 mL | Red-top tube or gel- barrier tube | Room temperature |
| Thyroglobulin Antibody and Thyroglobulin, IMA or RIA | 042060 | IMA or RIA | 3mL serum (two tubes, 1.5mL each) Minimum: 2mL | Red-top tube or gel- barrier tube | Room temperature |
| Thyroglobulin, Lymph Node Aspirate | 502380* | ICMA | "Lymph node aspirate in 1.0 mL saline Recommend using Labcorp Collection kit: Catalog No 38621G" | Lymph Node Collection Kit and saline vial | Freeze |

Labcorp offers a dedicated endocrine hotline

Labcorp recognizes the unique needs you have when caring for your patients with endocrine disorders. We are proud to offer a direct hotline to provide you easy access to our scientific and clinical team for technical consultation. Our hotline team can also answer general questions about endocrine-related testing and specimens.

Endocrine Hotline: 877-436-3056

Monday – Friday | 8:00am – 9:00pm EST

Saturday | 9:00am – 6:00pm EST



References

1. American Thyroid Association (ATA). General Information/Press Room. ATA website: <https://www.thyroid.org/media-main/press-room/>. Accessed June 28, 2023.
2. American Diabetes Association. 4. Comprehensive medical evaluation and assessment of comorbidities: standards of medical care in diabetes—2019. *Diabetes Care*. 2019 Jan;42(Suppl 1):S34-S45.
3. Hollowell JG, Staehling NW, Flanders, WD, et al. Serum TSH, T(4), and thyroid antibodies in the United States population (1988 to 1994): National Health and Nutrition Examination Survey (NHANES III). *J Clin Endocrinol Metab*. 2002 Feb;87(2):489-499.
4. Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association Guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. *Thyroid*. 2016 Oct;26(10):1343-1421.
5. Akram S, Eifenbein DM, Chen H, Schneider DF, Sippel RS. Assessing American Thyroid Association Guidelines for total thyroidectomy in Graves' disease. *J Surg Res*. 2020 Jan;245:64-71.
6. Gurnell M, Halsall DJ, Chatterjee VK. What should be done when thyroid function tests do not make sense? *Clin Endocrinol (Oxf)*. 2011 Jun;74(6):673-678.
7. Garber JR, Cobin RH, Gharib H, et al. Clinical Practice Guidelines for hypothyroidism in adults: cosponsored by the American Association of Clinical Endocrinologists and the American Thyroid Association. *Endocr Pract*. 2012 Nov-Dec;18(6):988-1028.
8. Frates MC, Benson CB, Charboneau JW, et al. Management of thyroid nodules detected at US: Society of Radiologists in Ultrasound consensus conference statement. *Radiology*. 2005 Dec;237(3):794-800.
9. American Cancer Society. What is thyroid cancer? American Cancer Society website: <https://www.cancer.org/cancer/thyroid-cancer/about/what-is-thyroid-cancer.html>. Accessed September 13, 2019.
10. Clayman G. What to know about papillary thyroid cancer. HealthCentral website: <https://www.healthcentral.com/condition/thyroid-cancer/papillary-thyroid-cancer>. Accessed July 2023.
11. Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer. *Thyroid*. 2016 Jan;26(1):1-133.
12. Lupo MA, Walts AE, Sistrunk JW, et al. Multiplatform molecular test performance in indeterminate thyroid nodules. *Diagn Cytopathol*. 2020 Dec;48(12):1254-1264.
13. Finkelstein SD, Sistrunk JW, Malchoff C, et al. A retrospective evaluation of the diagnostic performance of an interdependent pairwise microRNA expression analysis with a mutation panel in indeterminate thyroid nodules. *Thyroid*. 2022 Nov;32(11):1362-1371.
14. Wells SA, Asa SL, Dralle H, et al. Revised American Thyroid Association guidelines for the management of medullary thyroid carcinoma. *Thyroid*. 2015 Jun;25(6):567-610.
15. Spencer C, Petrovic I, Fatemi S, LoPresti J. Serum thyroglobulin (Tg) monitoring of patients with differentiated thyroid cancer using sensitive (second-generation) immunometric assays can be disrupted by false-negative and false-positive serum thyroglobulin autoantibody misclassifications. *J Clin Endocrinol Metab*. 2014 Dec;99(12):4589-4599.
16. Borel AL, Boizel R, Faure P, et al. Significance of low levels of thyroglobulin in fine needle aspirates from cervical lymph nodes of patients with a history of differentiated thyroid cancer. *Euro J Endocrinol*. 2008 May;158(5):691-698.



Visit the online test menu at **Labcorp.com** for additional test options and full test information, including CPT codes and specimen collection instructions.

