

Overview

Useful For

An adjunct to cytologic examination of fine-needle aspiration specimens in athyrotic individuals treated for differentiated thyroid cancer, to confirm or exclude metastases in enlarged or ultrasonographically suspicious lymph nodes

This test is **not useful for** screening asymptomatic individuals for neoplastic disease.

Highlights

Detection of thyroglobulin in fine-needle aspiration (FNA)-needle washes improves the evaluation of suspicious lymph nodes in patients with differentiated thyroid carcinoma.

Measurement of thyroglobulin is particularly useful in cases where the cytology result is nondiagnostic or indeterminate.

In athyrotic patients with a history of differentiated thyroid carcinoma, a FNA thyroglobulin value greater than 1 ng/mL suggests the presence of metastatic differentiated follicular cell-derived thyroid carcinoma.

Method Name

Immunoenzymatic Assay

NY State Available

Yes

Specimen

Specimen Type

Fine Needle Wash

Necessary Information

The biopsied site of each specimen must be clearly identified in LIS or on batch sheet.

Specimen Required

Patient Preparation: For 12 hours before this test do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Collection Container/Tube: Plain, plastic, screw-top tube

Specimen Volume: 1 to 1.5 mL

Collection Instructions:

1. Needle wash specimens for analysis should be collected in conjunction with cytology specimens.
2. Have saline available prior to start of procedure. **Saline is the only acceptable solution for needle washings.**
3. After each fine-needle aspiration biopsy (FNAB) has been collected and the material in the needle has been expelled onto a slide for cytologic analysis, attach the used FNAB needle to an empty syringe.

4. Withdraw between 0.10 mL and 0.25 mL of saline up through the needle until the saline starts to fill the hub of the needle or end of the syringe.
5. Expel this fluid back through the needle into a separate plastic screw-top tube. This is the needle washing used for analysis.
6. Repeat steps 2 through 4 for each needle pass of the same biopsied site and empty into the same tube, accumulating a total of 0.5 mL to 1.5 mL of fluid to send to the laboratory. (If more than 1 site is biopsied, see Additional Information)
7. Inspect specimen for visible blood or tissue contamination:
 - a. If bloody, centrifuge specimen and transfer supernatant to a new plastic aliquot tube (5-mL standard tube) to send to laboratory. The supernatant, not the cellular material, is used for analysis.
 - b. If specimen is clear, centrifugation is not necessary.
8. Refrigerate within 1 to 2 hours of collection. Send specimen frozen (preferred) or refrigerate to Mayo Clinic Laboratories for analysis.

Additional Information

1. If more than 1 site is biopsied, each washing material should be submitted on a separate tube and under a different order number.
2. A minimum of 0.5 mL is required for testing; however, the total collection volume should not exceed 1.5 mL. Sample volumes outside these parameters may be rejected.
3. **Do not send saline control. This test has been validated to rule-out saline matrix effect.**

Forms

If not ordering electronically, complete, print, and send an [Oncology Test Request](#) (T729) with the specimen.

Specimen Minimum Volume

0.5 mL

Reject Due To

Hemolysis	Mild OK; Gross reject
Lipemia	NA
Icterus	NA
Other	NA

Specimen Stability Information

Specimen Type	Temperature	Time
Fine Needle Wash	Frozen (preferred)	90 days
	Refrigerated	14 days

Clinical and Interpretive

Clinical Information

[Thyroglobulin \(Tg\) is a 660,000 molecular weight glycoprotein produced exclusively by the follicular cells of the thyroid. It is secreted into the follicular lumen, where it serves as the precursor of, and storage reservoir for, thyroxine \(T4\) and triiodothyronine \(T3\). T4 and T3 are released after Tg is endocytosed and proteolytically degraded in the thyrocyte. Since Tg is produced only by follicular thyrocyte-derived cells, measurement of serum Tg levels in athyrotic patients enables detection of persistence, recurrence, or metastasis of differentiated thyroid carcinoma. In addition, because of the thyroid specificity of Tg, its measurement in biopsy specimens of nonthyroidal tissues may assist in confirming and localizing metastatic disease.](#)

In the most common type of thyroid cancer, papillary thyroid carcinoma (PTC)-greater than 80% of all thyroid cancer cases, most metastatic disease occurs in loco-regional lymph nodes in the neck, which are easily examined by ultrasound. Most suspicious nodes undergo ultrasonography-guided fine-needle aspiration (FNA) cytology to determine a diagnosis. Unfortunately, in up to 20% of the specimens, inadequate cellularity or nonrepresentative sampling precludes the diagnosis.

Several studies have reported that the detection of Tg in fine-needle aspiration (FNA)-needle washes improves the evaluation of suspicious lymph nodes in patients with differentiated thyroid carcinoma.(1-3) A recent study reported that a Tg cutoff of 1 ng/mL for FNA-needle wash specimens provided 100% sensitivity and 96.2% specificity for the detection of metastatic thyroid carcinoma in lymph nodes.(3) The diagnostic performance of needle wash Tg at the 1-ng/mL cutoff compared favorably with cytology (95.1% overall agreement) and allowed accurate diagnosis in 18 of the 19 cases in which cytology was nondiagnostic or not performed.(3) Additionally, when measuring Tg in FNA-needle wash specimens, the clinical performance of FNA Tg is unaffected by the presence of Tg antibodies, a frequent problem when measuring Tg levels in serum.

Cytologic examination and measurement of Tg can be performed on the same specimen. To measure Tg, the FNA needle is rinsed with a small volume of normal saline solution immediately after a specimen for cytological examination has been expelled from the needle for a smear or CytoTrap preparation. Tg levels are measured in the needle wash.

Reference Values

[< or =1.0 ng/mL](#)

This cutoff has been validated for total needle wash volumes of < or =1.5 mL of normal saline. If wash volumes are substantially larger, a lower cutoff might apply.

Interpretation

[In athyrotic patients with a history of differentiated thyroid carcinoma, a fine-needle aspiration thyroglobulin \(FNA-Tg\) value greater than 1.0 ng/mL suggests the presence of metastatic differentiated follicular cell-derived thyroid carcinoma in the biopsied area.](#)

FNA-Tg measurements yield reliable results in most cases with nondiagnostic cytology, and are approximately equal in diagnostic accuracy to cytological examinations that are deemed sufficient for diagnosis.

Cautions

This test has been validated only in single lymph nodes from athyrotic patients. While the needle washes from several distinct needle passes or aspirations from a single node should be pooled, biopsies from different nodes should be submitted as separate specimens.

For specimens from other sources, call 800-533-1710.

Do not interpret FNA-Tg levels as absolute evidence of the presence or absence of malignant disease. Results should be used in conjunction with information from the clinical evaluation of the patient, cytology, and imaging procedures.

Immunometric assays can, in rare occasions, be subject to interferences such as "hooking" at very high analyte concentrations (false-low results) and heterophilic antibody interference (false-high results). If the clinical picture does not fit the laboratory result, these possibilities should be considered. While autoantibody interference (typically false-low results in immunometric assays) is reported to not be an issue for FNA-needle wash specimens, the report was based on a small number of cases; therefore, the possibility of autoantibody interference should also be considered.

Results are dependent on accurate sampling and a maximum needle wash volume of less than or equal to 1.5 mL.

Clinical Reference

1. Pacini F, Fugazzola L, Lippi F, et al: Detection of thyroglobulin in fine needle aspirates of nonthyroidal neck masses: a clue to the diagnosis of metastatic differentiated thyroid cancer. *J Clin Endocrinol Metab* 1992;74(6):1401-1404
2. Frasoldati A, Toschi E, Zini M, et al: Role of thyroglobulin measurement in fine-needle aspiration biopsies of cervical lymph nodes in patients with differentiated thyroid cancer. *Thyroid* 1999;9(2):105-111
3. Snozek CL, Chambers EP, Reading CC, et al: Serum thyroglobulin, high-resolution ultrasound, and lymph node thyroglobulin in diagnosis of differentiated thyroid carcinoma nodal metastases. *J Clin Endocrinol Metab* 2007;92(11):4278-4281

Performance

Method Description

For Mayo Clinic patients, any visibly blood-tinged samples are spun in a clinical centrifuge, and the supernatant is used for testing. If there is no visible blood contamination, the sample is used directly. Mayo Clinic Laboratories specimens should be evaluated for hemolysis before submission.

The saline needle-wash specimen is analyzed with the Beckman Access thyroglobulin (Tg) assay, a simultaneous 1-step immunoenzymatic (sandwich) assay performed on the Beckman Coulter UniCel DxI 800. A sample is added to a reaction vessel along with a biotinylated mixture of 4 mouse monoclonal anti-Tg antibodies, streptavidin-coated paramagnetic particles, and mouse monoclonal anti-Tg antibody-alkaline phosphatase conjugate. The biotinylated antibodies and the sample Tg bind to the solid phase, while the conjugate antibody reacts with a different antigenic site on the Tg molecule. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field, while unbound materials are washed away. The chemiluminescent substrate Lumi-Phos530 is added to the vessel and light generated by the reaction is measured with a luminometer. Light production is directly proportional to the concentration of Tg in the sample. The amount of analyte in the sample is determined from a stored, multipoint calibration curve. (Instruction manual: Access Thyroglobulin Assay. Beckman Coulter, Inc, Fullerton, CA, 2010)

For all samples with Tg concentrations greater than 1.0 ng/mL, a dilution series is performed. A linear dilution excludes hooking and most major interferences. Samples that contain Tg less than or equal to 1.0 ng/mL are spiked with exogenous Tg to identify possible interferences that may cause a false-low result.

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 6 a.m.-9 p.m.

Saturday; 6:30 a.m.-1 p.m.

Analytic Time

Same day/1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

12 months

Performing Laboratory Location

Rochester

Fees and Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

84432

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HTGFN	Thyroglobulin, FNA, Lymph Node	53920-5

Result ID	Test Result Name	Result LOINC Value
TGFN	Thyroglobulin, FNA, Lymph Node	53920-5
SITEJ	Site	39111-0