

Overview

Useful For

As an adjunct to cytologic examination of fine-needle aspiration specimens in athyrotic individuals treated for medullary thyroid carcinoma to confirm or exclude metastases in enlarged or ultrasonographically suspicious lymph nodes

Highlights

Measurement of calcitonin in a fine-needle aspiration biopsy needle wash specimen improves the evaluation of suspicious lymph nodes in patients with a history of medullary thyroid carcinoma (MTC). when used in combination with cytology.

Calcitonin measurement in needle wash specimens is particularly useful in cases where the cytology result is nondiagnostic or indeterminate.

In athyrotic patients with a history of MTC, a fine-needle aspiration calcitonin value of 5.0 pg/mL and higher is suggestive of the presence of metastatic MTC in the biopsied lymph node.

Method Name

Electrochemiluminescence Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Fine Needle Wash

Shipping Instructions

Send specimen frozen.

Necessary Information

The biopsied site of each specimen **is required** and **must be** clearly identified in the LIS and/or batch sheet.

Specimen Required

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

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 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. Freeze within 2 to 4 hours of collection.

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

Gross hemolysis	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fine Needle Wash	Frozen (preferred)	7 days	
	Refrigerated	4 hours	

Clinical & Interpretive

Clinical Information

Calcitonin is a polypeptide hormone secreted by the parafollicular cells (also referred to as calcitonin cells or C-cells) of

the thyroid gland. Malignant tumors arising from thyroid C-cells (medullary thyroid carcinoma: MTC) usually produce elevated levels of calcitonin. MTC is an uncommon malignant thyroid tumor, comprising less than 5% of all thyroid malignancies. Measurement of serum calcitonin is used in the follow-up of patients who underwent surgical removal of the thyroid gland.

Studies have reported that the measurement of calcitonin in fine-needle aspiration biopsy (FNAB)-needle washes improves the evaluation of suspicious lymph nodes in patients with a history of MTC when used in combination with cytology. Comparing the results of calcitonin in the needle rinse with serum calcitonin is highly recommended. An elevated calcitonin in the serum could falsely elevate calcitonin in the washings if the rinse is contaminated with blood. In these cases, only calcitonin values significantly higher than the serum should be considered as true-positive results.

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

Reference Values

An interpretive report will be provided.

Interpretation

In athyrotic patients with a history of medullary thyroid carcinoma, a fine-needle aspiration calcitonin value of 5.0 pg/mL and greater is suggestive of the presence of metastatic MTC in the biopsied lymph node.

Calcitonin values less than 5.0 pg/mL suggest the lymph node does not contain medullary thyroid carcinoma. This result is dependent on accurate sampling and a total needle wash volume between 0.5 to 1.5 mL.

This test should be interpreted in the context of the clinical presentation, imaging, and cytology findings. If the results are discordant with the clinical presentation, a sampling error at the time of biopsy should be considered.

Cautions

Blood contamination during the biopsy might lead to false elevations of calcitonin in the fine-needle aspiration biopsy needle washing if serum calcitonin is significantly elevated. If blood was present in the washing, only calcitonin values significantly higher than the serum should be considered as true positive results.

In some immunoassays, the presence of unusually high concentrations of analyte may result in a high-dose "hook" effect. This may result in a lower or even normal measured analyte concentration. If the reported result is inconsistent with the clinical presentation, the laboratory should be alerted for troubleshooting.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. The presence of antibodies to streptavidin or ruthenium can also rarely occur and may also interfere in this assay. Caution should be used in interpretation of results and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Samples should not be taken from patients receiving therapy with high biotin or vitamin B7 doses (ie, >5 mg/day) until at

least 12 hours following the last biotin administration.

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

While the needle washes from several distinct needle passes or aspirations from a single area should be pooled, biopsies from different areas should be submitted as separate specimens.

Supportive Data

Eighty-one lymph node washings were analyzed for calcitonin and thyroglobulin (as an indicator of the presence of metastatic thyroid tissue). All lymph node washings had a calcitonin value less than 5.0 pg/mL. A retrospective analysis of calcitonin (CATN) fine-needle aspiration washings ordered clinically between 2008 and 2011 was performed. There were 65 samples in which the source was identified as lymph node. Calcitonin was undetectable (<5.0 pg/mL) in 57% of cases and greater than 30 pg/mL in 37% of cases. In 6% of cases, CATN was between 5 and 30 pg/mL.

Clinical Reference

1. Trimboli P, Rossi F, Baldelli R, et al: Measuring calcitonin in washout of the needle in patients undergoing fine needle aspiration with suspicious medullary thyroid cancer. *Diagn Cytopathol*. 2012 May;40(5):394-398
2. Boi F, Maurelli I, Pinna G, et al: Calcitonin measurement in wash-out fluid from fine needle aspiration of neck masses in patients with primary and metastatic medullary thyroid carcinoma. *J Clin Endocrinol Metab*. 2007 Jun;92(6):2115-2118
3. Kudo T, Miyauchi A, Ito Y, Takamura Y, Amino N, Hirokawa M: Diagnosis of medullary thyroid carcinoma by calcitonin measurement in fine-needle aspiration biopsy specimens. *Thyroid*. 2007 Jul;17(7):635-638
4. Trimboli P, D'Aurizio F, Tozzoli R, Giovannella L: Measurement of thyroglobulin, calcitonin, and PTH in FNA washout fluids. *Clin Chem Lab Med*. 2017 Jun;55(7):914-925

Performance

Method Description

The Roche human calcitonin (hCT) assay is a sandwich, electrochemiluminescence immunoassay that employs a biotinylated monoclonal hCT-specific antibody and a monoclonal hCT-specific antibody. Calcitonin in the specimen reacts with both the biotinylated monoclonal hCT-specific antibody and the monoclonal hCT-specific antibody labeled with a ruthenium complex, forming a sandwich complex. Streptavidin-coated microparticles are added, and the mixture aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of voltage to the electrode induces the chemiluminescent emission, which is then measured.(Package insert: Elecsys Calcitonin. Roche Diagnostics; 07/2020)

For all samples with high concentrations of hCT, a dilution series is performed. A linear dilution excludes hooking and most major interferences. Samples that contain low hCT concentrations are spiked with exogenous hCT to identify possible interferences that may cause a false-low result.

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

12 months

Performing Laboratory Location

Rochester

Fees & 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 account representative. 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 US Food and Drug Administration.

CPT Code Information

82308

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CATLN	Calcitonin, FNAB, Lymph Node	75709-6

Result ID	Test Result Name	Result LOINC® Value
CATL	Calcitonin, FNAB, Lymph Node	75709-6
SITEB	Site	39111-0