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

Calcitonin in needle washes 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 to Mayo Clinic Laboratories for analysis.

Necessary Information
The biopsied site of each specimen must be clearly identified in LIS and/or 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 1.5mL

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. Refrigerate within 1 to 2 hours of collection and 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

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<tr>
<th>Hemolysis</th>
<th>Mild OK; Gross reject</th>
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<td>Lipemia</td>
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<tr>
<td>Icterus</td>
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Specimen Stability Information

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<tr>
<th>Specimen Type</th>
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<tbody>
<tr>
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<tr>
<td></td>
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Clinical and 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-positives.

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 (MTC), 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 of less than or equal 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 washout if serum calcitonin is significantly elevated. If blood was present in the washout, only calcitonin values significantly higher than the serum should be considered as true positives.

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.

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 (FNA) 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**


**Performance**

**Method Description**

Testing of the saline needle-wash specimen is performed on the Roche cobas e601. 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 is 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: Roche Calcitonin, Roche Diagnostics, 2014-03, v1)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

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

**Analytic Time**

Same day/1 day

**Maximum Laboratory Time**

3 days

**Specimen Retention Time**

12 months

**Performing Laboratory Location**

Rochester
Test Definition: CATLN
Calcitonin, FNAB, Lymph Node

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
82308

LOINC® Information

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