Overview

Useful For
An adjunct to cytology examination of fine-needle aspiration specimens to confirm or exclude presence of parathyroid tissue in the biopsied area

Highlights
Measurement of parathyroid hormone (PTH) in fine-needle aspiration biopsies (FNAB) washings could be used to discriminate thyroid tissues from enlarged parathyroid glands and also to facilitate parathyroid localization prior to surgery.

This test is best used as an adjunct to cytology examination to confirm or exclude the presence of parathyroid tissue in the biopsied area.

PTH values of 100 pg/mL and above are suggestive of the presence PTH-secreting tissue at the site biopsied or along the needle track.

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 specimen collection 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 aliquot 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.

Specimen Minimum Volume
1-1.5 mL

Reject Due To

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fine Needle Wash</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>4 hours</td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information
Parathyroid hormone (PTH) is produced and secreted by the parathyroid glands, which are located along the posterior aspect of the thyroid gland. PTH analysis in rinse material obtained from fine-needle aspiration biopsies (FNAB) has gained popularity to discriminate thyroid tissues from enlarged parathyroid glands and also to facilitate parathyroid localization prior to surgery. Various groups have reported on the utility of this technique with specificity of 91% to 100% and sensitivity of 91% to 100%. Measuring PTH in the rinse material proved very useful in cases of nondiagnostic cytology. Comparing the results of the PTH rinse material with serum PTH is highly recommended. An elevated PTH in the serum could falsely elevate PTH in the washings if the rinse is contaminated with blood. In these cases, only PTH values significantly higher than the serum should be considered as true positives.

Cytologic examination and measurement of PTH can be performed on the same specimen. To measure PTH, the fine-needle aspirate (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. Specimen collection is critical for the performance of the assay and the needle should be rinsed with a minimal volume. Each FNA needle from a single biopsied area is washed with 0.1 to 0.5 mL of normal saline. The washes from a single area are pooled (final volume 1-1.5 mL). PTH levels are measured in the saline wash.

Reference Values
An interpretive report will be provided.

Interpretation
Parathyroid hormone (PTH) values less than 100 pg/mL suggest the biopsied site does not contain PTH-secreting tissue.

PTH values greater than or equal to 100 pg/mL are suggestive of the presence PTH-secreting tissue at the site biopsied or along the needle track. This result is dependent on accurate sampling and a total needle wash volume of greater 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 the biopsy should be considered.

Cautions
**Twelve hours before this test, do not** take multivitamins or dietary supplements containing biotin or vitamin B7 that are commonly found in hair, skin and nail supplements and multivitamins.

This test cannot distinguish between benign and malignant parathyroid tissue.

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.

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
A retrospective review of Mayo Clinic parathyroid hormone analysis in fine-needle aspiration biopsy washings ordered clinically between June 2008 and May 2011 identified 42 specimens with confirmed parathyroid tissue (n=19) and nonparathyroid tissue (n=23). The assay showed 100% specificity and 74% sensitivity for the detection of parathyroid tissue using a value greater than or equal to 100 pg/mL as positive.
Clinical Reference


Performance

Method Description

The saline needle-wash specimen is analyzed with the Roche Diagnostics PTH reagent assay performed on the Roche cobas 6000. The Roche cobas assay for determining intact parathyroid hormone (PTH) employs a sandwich test principle in which a biotinylated monoclonal antibody reacts with the N-terminal fragment (1-37) and a monoclonal antibody labeled with a ruthenium complex(a) reacts with the C-terminal fragment (38-84). Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier. The antibodies used in this assay are reactive with epitopes in the amino acid regions 26-32 and 37-42. (Package insert: Roche PTH reagent, Roche Diagnostics Corp, Indianapolis, IN July 2010)

For all samples with PTH concentrations above 40 pg/mL, a dilution series is performed. A linear dilution excludes hooking and most major interferences. Samples that contain PTH concentrations less than 40 pg/mL are spiked with exogenous PTH 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
Test Definition: PTHFN
PTH, FNAB, Needle Wash

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
83970

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTHFN</td>
<td>PTH, FNAB, Needle Wash</td>
<td>88106-0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTHF</td>
<td>PTH, FNAB, Needle Wash</td>
<td>88106-0</td>
</tr>
<tr>
<td>SITEA</td>
<td>Site</td>
<td>39111-0</td>
</tr>
</tbody>
</table>