

## Overview

### Useful For

Aiding in evaluation of pituitary tumors, amenorrhea, galactorrhea, infertility, and hypogonadism

Monitoring therapy of prolactin-producing tumors

### Method Name

Electrochemiluminescence Immunoassay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### 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.

#### Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:** 0.6 mL

### 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 lipemia	OK
Gross icterus	OK

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
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Serum	Refrigerated (preferred)	7 days	
	Frozen	90 days	
	Ambient	24 hours	

## Clinical & Interpretive

### Clinical Information

Prolactin is secreted by the anterior pituitary gland and controlled by the hypothalamus. The major chemical controlling prolactin secretion is dopamine, which inhibits prolactin secretion from the pituitary. Prolactin is released from the pituitary in response to thyrotropin-releasing hormone and other factors.

Prolactin is the principal hormone that controls the initiation and maintenance of lactation. In normal individuals, prolactin concentrations increase in response to physiologic stimuli such as sleep, stress, exercise, sexual intercourse, and hypoglycemia, and concentrations are also elevated during pregnancy, lactation, postpartum, and in a newborn infant.

Hyperprolactinemia is the most common hypothalamic-pituitary disorder encountered in clinical endocrinology. Pathologic causes of hyperprolactinemia include prolactin-secreting pituitary adenoma (prolactinoma, which is more frequent in females than males and accounts for approximately 40% of all pituitary tumors), functional and organic disease of the hypothalamus, primary hypothyroidism, compression of the pituitary stalk, chest wall lesions, renal insufficiency, polycystic ovarian disease, and ectopic tumors.

Hyperprolactinemia often results in loss of libido, galactorrhea, oligomenorrhea or amenorrhea, and infertility in premenopausal females, and loss of libido, impotence, infertility, and hypogonadism in males. Postmenopausal and premenopausal women, as well as men, can also suffer from decreased muscle mass and osteoporosis.

Prolactinomas may rarely present in childhood or adolescence. In girls, disturbances in menstrual function and galactorrhea may be seen, whereas in boys, delayed pubertal development and hypogonadism are often present. The treatment options are the same as in adult patients.

### Reference Values

#### Males

<18 years: not established

> or =18 years: 4.0-15.2 ng/mL

#### Females:

<18 years: not established

> or =18 years: 4.8-23.3 ng/mL

For SI unit Reference Values, see <https://www.mayocliniclabs.com/order-tests/si-unit-conversion.html>

### Interpretation

In general, serum prolactin concentrations parallel tumor size in patients with prolactinomas. Macroadenomas (>10 mm in diameter) are typically associated with serum prolactin concentrations above 250 ng/mL, and a concentration above

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500 ng/mL is diagnostic of a macroprolactinoma. Moderately increased concentrations of serum prolactin are not a reliable guide for determining whether a prolactin-producing pituitary adenoma is present.

After initiation of medical therapy of prolactinomas, prolactin levels should decrease substantially in most patients; in 60% to 80% of patients, normal levels should be reached. Failure to suppress prolactin levels may indicate tumors resistant to the usual central-acting dopamine agonist therapies; however, a subset of patients will show tumor shrinkage despite persistent hyperprolactinemia. Patients who show neither a decrease in prolactin levels nor tumor shrinkage might require additional therapeutic measures.

In patients where a discrepancy between pituitary tumor size and prolactin elevation is observed, a test for false-low serum prolactin (hook effect) should be performed by serial dilution. See PLPMA / Prolactin, Pituitary Macroadenoma, Serum. This assay should demonstrate no high-dose hook effect at prolactin concentrations up to approximately 12,500 ng/mL.(1)

Multiple medications can cause increased prolactin concentration including estrogens, dopamine receptor blockers (eg, phenothiazines), dopamine antagonists (eg, metoclopramide, domperidone), alpha-methyldopa, cimetidine, opiates, antihypertensive medications, and other antidepressants and antipsychotics.

In patients with asymptomatic hyperprolactinemia, assessment for macroprolactin (prolactin bound to immunoglobulin) is suggested. Macroprolactin is detected by differing degrees depending on the immunoassay used to measure prolactin. This assay shows low reactivity with most forms of macroprolactin. Macroprolactin should be evaluated in asymptomatic hyperprolactinemic subjects or when pituitary imaging studies are not informative. See MCRPL / Macroprolactin, Serum.

### **Cautions**

Serum prolactin measurements are not recommended during pregnancy in patients with prolactinomas. The test results are uninterpretable in this setting and may lead to unnecessary testing triggered by higher than normal prolactin levels.

For assays employing antibodies, the possibility exists for interference by human antianimal antibodies (ie, heterophile antibodies) in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, (eg, HAMA), that interfere with immunoassays. This may falsely elevate or falsely decrease the results.

Interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur.

### **Clinical Reference**

1. Package insert: Roche E170/cobas e601/e602 Prolactin II. Roche Diagnostics; 01/2019
2. Demers LM, Vance ML: Pituitary function. In: Burtis CA, Ashwood ER, Bruns DE, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed. Elsevier Saunders Co; 2006:1976-1981
3. Schoft C, Schofl-Siegert B, Hinrich Karstens J, et al: Falsely low serum prolactin in two cases of invasive macroprolactinoma. *Pituitary*. 2002;5:261-265
4. Casanueva FF, Molitch ME, Schlechte JA, et al: Guidelines of the Pituitary Society for the diagnosis and management of prolactinomas. *Clin Endocrinol*. 2006;65:265-273
5. Melmed S, Casanueva FF, Hoffman AR, et al: Diagnosis and treatment of hyperprolactinemia: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2011 Feb;96(2):273-288

## Performance

### Method Description

The Prolactin II method employs 2 monoclonal antibodies specifically directed against prolactin. A biotinylated monoclonal antibody and a second monoclonal antibody labeled with a ruthenium complex react with prolactin in the sample to form a sandwich complex. After the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured. (Package insert: Elecsys Prolactin II. Roche Diagnostics; 01/2019)

### PDF Report

No

### Day(s) Performed

Monday through Sunday

### Report Available

Same day/1 to 2 days

### Specimen Retention Time

7 days

### 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 Regional Manager. For assistance, contact [Customer Service](#).

### Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

### CPT Code Information

84146

### LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
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PRL	Prolactin, S	20568-2
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Result ID	Test Result Name	Result LOINC® Value
PRL	Prolactin, S	20568-2