
Overview**Useful For**

Ascertaining whether ovulation occurred in a menstrual cycle

Assessment of infertility

Evaluation of abnormal uterine bleeding

Evaluation of placental health in high-risk pregnancy

Determining the effectiveness of progesterone injections when administered to women to help support early pregnancy

Workup of some patients with adrenal disorders

Method Name

ElectrochemiluminescenceImmunoassay

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: 1 mL

Collection Instructions:

1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged and aliquoted within 2 hours of collection.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	180 days	
	Refrigerated	72 hours	
	Ambient	8 hours	

Clinical and Interpretive

Clinical Information

Sources of progesterone are the adrenal glands, corpus luteum, and placenta.

Adrenal Glands:

Progesterone synthesized in the adrenal glands is converted to other corticosteroids and androgens and, thus, is not a major contributor to circulating serum levels unless there is a progesterone-producing tumor present.

Corpus Luteum:

After ovulation, there is a significant rise in serum levels as the corpus luteum begins to produce progesterone in increasing amounts. This causes changes in the uterus, preparing it for implantation of a fertilized egg. If implantation occurs, the trophoblast begins to secrete human chorionic gonadotropin, which maintains the corpus luteum and its secretion of progesterone. If there is no implantation, the corpus luteum degenerates and circulating progesterone levels decrease rapidly, reaching follicular phase levels about 4 days before the next menstrual period.

Placenta:

By the end of the first trimester, the placenta becomes the primary secretor of progesterone.

Reference Values

Males:

<4 weeks: Not established

4 weeks-<12 months: < or =0.66 ng/mL (confidence interval 0.63-0.94 ng/mL)

12 months-9 years: < or =0.35 ng/mL

10-17 years: Concentrations increase through adolescence and puberty

12 months-9 years: < or =0.35 ng/mL

> or = 18 years (central 90th %): <0.20 ng/mL

> or = 18 years: <0.20 ng/mL (Reference intervals are central 90th % of healthy population)

Females:

<4 days old: Not established

4 days-<12 months: < or =1.3 ng/mL (confidence interval 0.88-2.3 ng/mL)

12 months-9 years: < or =0.35 ng/mL

10-17 years: Adult concentrations are attained by puberty

12 months-9 years: < or =0.35 ng/mL

Adult (central 90th %):

-Follicular phase: < or =0.89 ng/mL

-Ovulation: < or =12 ng/mL

-Luteal phase: 1.8-24 ng/mL

--Pregnancy

---1st trimester: 11-44 ng/mL

---2nd trimester: 25-83 ng/mL

---3rd trimester: 58-214 ng/mL

> or = 18 years:

Reference intervals are central 90th % of healthy population

-Follicular phase: < or =0.89 ng/mL

-Ovulation: < or =12 ng/mL

-Luteal phase: 1.8-24 ng/mL

-Post-menopausal: < or =0.20 ng/mL

--Pregnancy

---1st trimester: 11-44 ng/mL

---2nd trimester: 25-83 ng/mL

---3rd trimester: 58-214 ng/mL

Pediatric reference intervals adopted from the CALIPER study. www.sickkids.ca/caliperproject/index.html The Hospital for Sick Children. Toronto, Canada.

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

Interpretation

Ovulation results in a midcycle surge of luteinizing hormone (LH) followed by an increase in progesterone secretion, peaking between day 21 and 23. If no fertilization and implantation has occurred by then, supplying the corpus luteum with human chorionic gonadotropin-driven growth stimulus, progesterone secretion falls, ultimately triggering menstruation. Typically, day 21 to 23 serum progesterone concentrations of more than 10 ng/mL indicate normal ovulation and concentrations below 10 ng/mL suggest anovulation, inadequate luteal phase progesterone production, or inappropriate timing of sample collection.

Increased progesterone concentrations are occasionally seen with some ovarian cysts, molar pregnancies, rare forms of ovarian cancer, adrenal cancer, congenital adrenal hyperplasia, and testicular tumors. Increased progesterone may also be a result of overproduction by the adrenal glands.

Low concentrations of progesterone may be associated with toxemia in late pregnancy, decreased ovarian function, amenorrhea, ectopic pregnancy, and miscarriage.

Cautions

Assessment of the function of the corpus luteum requires correlation with the phase of the menstrual cycle.

Taking estrogen and progesterone supplements can affect results.

As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from specimens drawn from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes

In rare cases, interference due to extremely high titers of antibodies to ruthenium and streptavidin can occur.

Clinical Reference

1. Lippe BM, LaFranchi SH, Lavin N, et al: Serum 17-alpha-hydroxyprogesterone, progesterone, estradiol, and testosterone in the diagnosis and management of congenital adrenal hyperplasia. *J Pediatr* 1974;85:782-787
2. Haymond S, Gronowski AM: In *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. Fourth edition. Edited by CA Burtis, ER Ashwood, DE Bruns. St. Louis, Elsevier, Inc, 2006, pp 2097-2152
3. CALIPER Database. The Hospital for Sick Children. Toronto, Canada. Available at: www.sickkids.ca/caliperproject/index.html

Performance

Method Description

Testing is performed using the Roche Cobas e601/602. The Roche Progesterone III assay is a competitive immunoassay using electrochemiluminescence detection. Patient specimen and biotinylated progesterone-specific antibody are incubated to produce immunocomplexes. The amount of immunocomplexes formed is dependent on the progesterone concentration in the sample. Then, streptavidin-coated microparticles and a progesterone derivative labeled with a ruthenium complex are added to the reaction mixture and occupy the open sites still present on the biotinylated antibodies by formation of an antibody-hapten complex. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin. Next, the reaction mixture is aspirated into measuring cell where the bound microparticles are magnetically captured onto the electrode surface and unbound substances are removed. Voltage is applied to the electrode inducing a chemiluminescent emission which is then measured against a calibration curve to determine the amount of progesterone in the patient specimen. (Package insert: Roche

Progesterone III. Roche Diagnostics, Indianapolis, IN)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 day

Specimen Retention Time

7 days

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 cleared, approved or is exempt by the U.S. 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

84144

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PGSN	Progesterone, S	83109-9

Result ID	Test Result Name	Result LOINC Value
PGSN	Progesterone, S	83109-9