

## 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

Electrochemiluminescence Immunoassay (ECLIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Patient Preparation:** For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).

**Supplies:** Sarstedt Aliquot Tube 5 mL (T914)

#### Collection Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 1 mL

#### Collection Instructions:

1. Serum gel tubes should be centrifuged within 2 hours of collection and serum aliquoted into a plastic vial.
2. Red-top tubes should be centrifuged, and serum aliquoted into a plastic vial 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	
	Ambient	8 hours	
	Refrigerated	72 hours	

**Clinical & 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**

<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

> or = 18 years: <0.20 ng/mL

Reference intervals are central 90th percentile 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)

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

10-17 years: Adult concentrations are attained by puberty

> or = 18 years:

Reference intervals are central 90th percentile 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. <https://caliperproject.ca/caliper/database/>

For International System of Units (SI) conversion for Reference Values, see

<https://www.mayocliniclabs.com/order-tests/si-unit-conversion.html>.

### Interpretation

Ovulation results in a midcycle surge of luteinizing hormone 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 specimen 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 collected from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes.

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

### 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(6):782-7. doi:10.1016/s0022-3476(74)80340-9

2. Haymond S, Gronowski AM. In Burtis CA, Ashwood ER, Bruns DE, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed. Elsevier; 2006: 2097-2152

3. CALIPER Database. The Hospital for Sick Children. Available at: <https://caliperproject.ca/caliper/database/>

4. Cole T. Hormones. In: Rifai N, Chiu RWK, Young I, Burnham CA, Wittwer CT, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:chap 38

## Performance

### Method Description

Testing is performed using the Roche Cobas e801. 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: Elecsys Progesterone III. Roche Diagnostics; V4, 10/2022)

### PDF Report

No

### Day(s) Performed

Monday through Sunday

### Report Available

Same day/1 day

### Specimen Retention Time

7 days

### Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

## 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 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

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