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

NY State Available
Yes

Specimen

Specimen Type
Serum

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.

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
**Test Definition: PGSN**

**Progesterone, S**

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</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>Serum</td>
<td>Frozen (preferred)</td>
<td>180 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>72 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>8 hours</td>
<td></td>
</tr>
</tbody>
</table>

**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

Test Definition: PGSN
Progesterone, S

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


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
Test Definition: PGSN
Progesterone, S

Progesterone III. Roche Diagnostics, Indianapolis, IN)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Sunday; Continuously

Analytic Time
Same day/1 day

Maximum Laboratory Time
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 or approved 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

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGSN</td>
<td>Progesterone, S</td>
<td>83109-9</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>PGSN</td>
<td>Progesterone, S</td>
<td>83109-9</td>
</tr>
</tbody>
</table>