Overview

Useful For
An adjunct in the evaluation of menstrual irregularities
Evaluating patients with suspected hypogonadism
Predicting ovulation
Evaluating infertility
Diagnosing pituitary disorders

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

Collection Instructions: Centrifuge and aliquot serum within 2 hours of collection.

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
</tbody>
</table>
**Test Definition: FSH**
Follicle-Stim Hormone (FSH), S

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**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>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>180 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>24 hours</td>
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</table>

**Clinical and Interpretive**

**Clinical Information**

Luteinizing hormone (LH) is a glycoprotein hormone consisting of 2 noncovalently bound subunits (alpha and beta). Gonadotropin-releasing hormone from the hypothalamus controls the secretion of the gonadotropins, follicle-stimulating hormone (FSH), and LH from the anterior pituitary.

The menstrual cycle is divided by a midcycle surge of both FSH and LH into a follicular phase and a luteal phase.

FSH appears to control gametogenesis in both males and females.

**Reference Values**

**Males**

<12 months: < or = 3.3 IU/L

> or = 12 months - < or = 5 years: < or = 1.9 IU/L

> 5 years - < or = 10 years: < or = 2.3 IU/L

> 10 years - < or = 15 years: 0.6 - 6.9 IU/L

> 15 years - < or = 18 years: 0.7 - 9.6 IU/L

> 18 years: 1.2 - 15.8 IU/L

**TANNER STAGES**

Stage I: < 1.5 IU/L

Stage II: < 3.0 IU/L

Stage III: 0.4 - 6.2 IU/L

Stage IV: 0.6 - 5.1 IU/L

Stage V: 0.8 - 7.2 IU/L

*Puberty onset occurs for boys at a median age of 11.5 (+/- 2) years. For boys there is no proven relationship between puberty onset and body weight or ethnic origin. Progression through Tanner stages is variable. Tanner
stage V (adult) should be reached by age 18.

Females

<12 months: 1.2-12.5 IU/L

> or =12 months-< or =10 years: 0.5-6.0 IU/L

>10 years-< or =15 years: 0.9-8.9 IU/L

>15 years-< or =18 years: 0.7-9.6 IU/L

Premenopausal:

Follicular: 2.9-14.6 IU/L

Midcycle: 4.7-23.2 IU/L

Luteal: 1.4-8.9 IU/L

Postmenopausal: 16.0-157.0 IU/L

TANNER STAGES*

Stage I: 0.6-4.1 IU/L

Stage II: 0.3-5.8 IU/L

Stage III: 0.1-7.2 IU/L

Stage IV: 0.3-7.0 IU/L

Stage V: 0.4-8.6 IU/L*Puberty onset (transition from Tanner stage I to Tanner stage II) occurs for girls at a median age of 10.5 (+/- 2) years. There is evidence that it may occur up to 1 year earlier in obese girls and in African American girls. Progression through Tanner stages is variable. Tanner stage V (adult) should be reached by age 18.

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

**Interpretation**

In both males and females, primary hypogonadism results in an elevation of basal follicle-stimulating hormone (FSH) and luteinizing hormone (LH) levels.

FSH and LH are generally elevated in:

- Primary gonadal failure

- Complete testicular feminization syndrome

- Precocious puberty (either idiopathic or secondary to a central nervous system lesion)

- Menopause (postmenopausal FSH levels are generally >40 IU/L)
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- Primary ovarian hypofunction in females
- Primary hypogonadism in males

Normal or decreased FSH in:
- Polycystic ovary disease in females

FSH and LH are both decreased in failure of the pituitary or hypothalamus.

Cautions
No clinically significant cross-reactivity has been demonstrated with thyrotropin (previously known as thyroid-stimulating hormone), luteinizing hormone, human chorionic gonadotropin, prolactin, or growth hormone.

Some patients who have been exposed to animal antigens, either in the environment or as part of treatment or imaging procedures, may have circulating anti-animal antibodies present. These antibodies may interfere with the assay reagents to produce unreliable results.

Clinical Reference


Performance

Method Description
In the Roche follicle-stimulating hormone (FSH) assay, the determination of the FSH is made with the aid of a biotinylated monoclonal FSH-specific antibody and a monoclonal FSH-specific antibody labeled with a ruthenium complex to form a sandwich complex. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission that is measured by a photomultiplier.(Package insert: FSH. Roche Diagnostics; 09/2018)

PDF Report
No

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

Analytic Time
### Test Definition: FSH
Follicle-Stim Hormone (FSH), S

- **Same day/1 day**
- **Maximum Laboratory Time**: 2 days
- **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
- **CPT Code**: 83001

#### LOINC® Information

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<thead>
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<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>FSH</td>
<td>Follicle-Stim Hormone (FSH), S</td>
<td>15067-2</td>
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<table>
<thead>
<tr>
<th>Result ID</th>
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