

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.

Reject Due To

Gross hemolysis Reject

Gross lipemia OK

Specimen Minimum Volume

0.5 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	180 days	
	Ambient		

Clinical & 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)
- 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

1. 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 Company; 2006:1984-1989
2. Haymond S, Gronowski AM: Reproductive related disorders. In: Burtis CA, Ashwood ER, Bruns DE, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed. Elsevier Saunders Company; 2006:2101-2127
3. Kulasingam V, Jung BP, Blastuig IM, et al: Pediatric reference intervals for 28 chemistries and immunoassays on the Roche cobas 6000 analyzer--A CALIPER pilot study. Clin Biochem. 2010 Sep;43(13-14);1045-1050. doi: 10.1016/j.clinbiochem.2010.05.008
4. Konforte D, Shea JL, Kyriakopoulou L, et al: Complex biological pattern of fertility hormones in children and adolescents: a study of healthy children from the CALIPER cohort and establishment of pediatric reference intervals. Clin Chem. 2013 Aug;59(8):1215-1227. doi: 10.1373/clinchem.2013.204123

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

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees & Codes**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

83001

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
FSH	Follicle-Stim Hormone (FSH), S	15067-2

Result ID	Reporting Name	LOINC®
FSH	Follicle-Stim Hormone (FSH), S	15067-2