Test Definition: FSH

Follicle-Stimulating Hormone (FSH), Serum

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

Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.6 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial 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

Gross hemolysis	Reject

Gross lipemia	OK
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Ambient	24 hours	
	Frozen	180 days	

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 male and female individuals.

Reference Values

Males
<12 months: < or =3.3 IU/L
12 months-5 years: < or =1.9 IU/L
>5 years-10 years: < or =2.3 IU/L
>10 years-15 years: 0.6-6.9 IU/L
>15 years-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
12 months-10 years: 0.5-6.0 IU/L
>10 years-15 years: 0.9-8.9 IU/L

>15 years-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 l: 0.6-4.1 IU/L
Stage ll: 0.3-5.8 IU/L
Stage lll: 0.1-7.2 IU/L
Stage lV: 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.

Interpretation

In both male and female patients, 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 female patients
-Primary hypogonadism in male patients

Normal or decreased FSH in:
-Polycystic ovary disease in female patients

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

Cautions

Serum biotin concentrations up to 1200 ng/mL do not interfere with this assay. Concentrations up to 1200 ng/mL may be present in specimens collected from patients taking extremely high doses of biotin up to 300 mg per day.(1) In a study among 54 healthy volunteers, supplementation with 20 mg/day biotin resulted in a maximum serum biotin concentration of 355 ng/mL 1 hour post-dose.(2)

No clinically significant cross-reactivity has been demonstrated with thyrotropin (formerly 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. Saint Paul LP, Debruyne D, Bernard D, Mock DM, Defer GL: Pharmacokinetics and pharmacodynamics of MD1003 (high-dose biotin) in the treatment of progressive multiple sclerosis. Expert Opin Drug Metab Toxicol. 2016;12(3):327-344. doi: 10.1517/17425255.2016.1136288
2. Grimsey P, Frey N, Bendig G, et al: Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. Int J Pharmacokinet. 2017 Sep;2(4):247-256. doi: 10.4155/ipk-2017-0013
3. Holmes DT, Bertholf RL, Winter WE: Pituitary function and pathophysiology. In: Rifai N, Chiu RWK, Young I, Burnham CAD, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:767-804
4. Nerenz RD, Boh B: Reproductive endocrinology and related disorders. In: Rifai N, Chiu RWK, Young I, Burnham CAD, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023:846-884

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, which is measured by a photomultiplier.(Package insert: Elecsys FSH. Roche Diagnostics; 09/2021)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 to 2 days

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

83001

LOINC® Information

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

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