Test Definition: INSFT

Insulin, Free and Total, S

Overview

Useful For

Assessing free (bioactive) insulin concentrations in patients with known or suspected insulin antibodies

Highlights

Patients treated with exogenous insulin preparations might develop autoantibodies against insulin.

If significant differences between the total and free insulin concentrations are detected, the presence of insulin antibodies is suspected.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
INSF	Insulin, Free, S	No	Yes
INSTO	Insulin, Total, S	Yes, (Order as INS)	Yes

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation:

1. Fasting (8 hours)

2. **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.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. Avoid hemolysis

2. Label specimens with corresponding draw times.

3. Serum-gel tubes should be centrifuged within 2 hours of collection.

4. Red-top tubes should be centrifuged and aliquoted within 2 hours of collection.

5. Send specimen refrigerated

Additional Information: If multiple specimens are drawn, send separate order for each specimen.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Autopsy/postmortem specimen	Reject

Specimen Minimum Volume

0.75 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	180 days	
	Ambient		

Clinical & Interpretive

Clinical Information

Insulin is produced by the beta cells of the pancreas. It regulates the uptake and utilization of glucose and is also involved in protein synthesis and triglyceride storage.

Circulating insulin antibodies develop after diabetic patients are treated with exogenous insulin preparations. The presence of insulin antibodies has 2 main consequences:

1. Insulin antibodies will directly bind to insulin, making it unavailable for metabolic activity.

2. Insulin antibodies may adversely affect the binding characteristics of insulin in immunoassays, making reliable quantitation difficult.

Free (bioactive) insulin could be measured after polyethylene glycol (PEG) precipitation of insulin antibodies and their bound insulin. If insulin antibodies are not present, the free and total insulin should be equivalent. The laboratory will report results of the total insulin (without PEG precipitation) and the free insulin (with PEG precipitation).

Reference Values

FREE INSULIN:

2.6-24.9 mcIU/mL

TOTAL INSULIN:

2.6-24.9 mcIU/mL

Interpretation

If insulin antibodies are not present, the free and total insulin should be equivalent. A significant difference between total and free insulin is suggestive of the presence of insulin antibodies.

During prolonged fasting, when the patient's glucose is reduced to less than 40.0 mg/dL, elevated insulin level plus elevated levels of proinsulin and C-peptide suggest insulinoma.

In patients with insulin-dependent diabetes mellitus, insulin levels generally decline.

In the early stage of noninsulin-dependent diabetes mellitus (NIDDM), insulin levels are either normal or elevated.

In the late stage of NIDDM, insulin levels may also decline as levels of proinsulin decrease.

Cautions

Human antimouse antibodies (HAMA) may interfere with the assay.

Hemolysis interferes with this assay, as insulin-degrading peptidases are released from erythrocytes. This assay has 100% cross-reactivity with recombinant human insulin (Novolin R and Novolin N). It does not recognize other commonly used analogues of injectable insulin (ie, insulin lispro, insulin aspart, and insulin glargine).

Clinical Reference

1. Lupsa BC, Chong AY, Cochran EK, Soos MA, Semple RK, Gorden P: Autoimmune forms of hypoglycemia. Medicine (Baltimore). 2009 May;88(3):141-153

2. Sapin R, Le Galudec V, Gasser F, Pinget M, Grucker D: Elecsys insulin assay: free insulin determination and the absence of cross-reactivity with insulin lispro. Clin Chem. 2001 Mar;47(3):602-605

3. Sacks DB: Diabetes mellitus. In: Rifai N, Horvath AR, Wittwer CT, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 6th ed. Elsevier; 2018:1160-1200

Performance

Method Description

The Roche Cobas insulin method is a sandwich electrochemiluminescence immunoassay that employs a biotinylated monoclonal insulin-specific antibody and a monoclonal insulin-specific antibody. Insulin in the specimen reacts with both the biotinylated monoclonal insulin-specific antibody (mouse) and the monoclonal insulin-specific antibody (mouse) labeled with a ruthenium complex, forming a sandwich complex. Streptavidin-coated microparticles are added and an interaction occurs between the biotin and streptavidin, binding the complex to the solid phase. The 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 voltage to the electrode induces the chemiluminescent emission, which is then measured.

For free insulin, specimen immunoglobulins are precipitated by adding an equal volume of 25% polyethylene glycol (PEG). The precipitate is removed by centrifugation and the supernatant analyzed using the method described above.(Package insert: Roche Insulin reagent, Roche Diagnostics; 2013)

PDF Report

No

Specimen Retention Time

2 weeks

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

83527-Free Insulin

83525-Total Insulin

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
INSFT	Insulin, Free and Total, S	48615-9

Result ID	Reporting Name	LOINC®
INSTO	Insulin, Total, S	20448-7
INSF	Insulin, Free, S	6901-3