Test Definition: 21OH

21-Hydroxylase Antibodies, Serum

Overview

Useful For

Investigating adrenal insufficiency

Aiding in the detection of those at risk of developing autoimmune adrenal failure in the future

Highlights

Addison disease is the most frequent cause of primary adrenal insufficiency.

Autoantibodies against 21-hydroxylase are present in up to 90% of Addison disease cases.

Measurement of anti-21-hydroxylase autoantibodies is useful in the evaluation of the cause of established primary adrenal insufficiency.

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

Testing for autoantibodies against 21-hydroxylase is recommended following confirmation of adrenal insufficiency to help differentiate between causes of primary adrenal insufficiency

Shipping Instructions

Ship specimen frozen on dry ice

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Red top
Acceptable: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL Serum
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

Serum: 0.2 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Adrenal insufficiency is caused by failure of the adrenal cortex to produce cortisol. This failure can result from loss of function of the adrenal glands (ie, primary adrenal insufficiency). This is most frequently caused by autoimmune adrenalitis or Addison disease accounting for 68% to 94% of cases. It can occur sporadically or in combination with other autoimmune endocrine diseases that together comprise type I or II autoimmune polyglandular syndrome (APS).

Antibodies that react with several steroidogenic enzymes (most often 21-hydroxylase) are present in the serum of up to 86% of patients with autoimmune primary adrenal insufficiency but only rarely in patients with other causes of adrenal insufficiency. Therefore, 21-hydroxylase autoantibodies are markers of autoimmune Addison disease, whether present alone or as part of type I or II APS. The measurement of 21-hydroxylase autoantibodies is an important step in the investigation of adrenal insufficiency and may aid in the detection of those at risk of developing autoimmune adrenal failure in the future.

Reference Values

Negative

Interpretation

This is a qualitative test. A positive result indicates the presence of autoantibodies to 21-hydroxylase and is consistent with Addison disease.

Utilizing an index value of <45 as a negative cutoff, this assay has a clinical sensitivity and specificity of 87.0% (95% CI: 79.4%-92.2%) and 99.3% (95% CI: 97.5%-99.8%), respectively.

Cautions

Lipemic or grossly hemolyzed serum should not be used in this assay.

Results should be interpreted in the context of clinical symptoms and adrenal functional confirmatory tests.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Charmandari E, Nicolaides NC, Chrousos GP. Adrenal insufficiency. Lancet. 2014;383(9935):2152-2167
2. Bancos I, Hahner S, Tomlinson J, Arlt W. Diagnosis and management of adrenal insufficiency. Lancet Diabetes Endocrinol. 2015;3(3):216-226
3. Bornstein SR, Allolio B, Arlt W, et al. Diagnosis and treatment of primary adrenal insufficiency: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016;101(2):364-389

Performance

Method Description

A reference preparation, controls, and patient specimens are incubated with a reaction enhancer overnight in a coated enzyme-linked immunosorbent assay (ELISA) plate. 21-Hydroxylase (21-OH) antibodies (Ab) act divalently and form a bridge between 21-OH Ab coated on ELISA plate wells and liquid phase 21-OH biotin. The resulting antigen-antibody-antigen complexes are then detected by the addition of streptavidin peroxidase and tetramethylbenzidine to produce a colorogenic reaction. Stop solution is added to halt the reaction, and absorbance is read using an ELISA plate reader. The absorbance of each well is directly proportional to the amount of antibody present. Positive and negative determinations are based on index values. Index values are calculated from the mean value of duplicate sample wells and compared to a reference value.(Package insert: 21-Hydroxylase Autoantibody [21-OHAb] ELISA Kit. Kronus; 04/2024)

PDF Report

No

Day(s) Performed

Wednesday

Report Available

3 to 9 days

Specimen Retention Time

2 weeks

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

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21-Hydroxylase Antibodies, Serum

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

83516

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
21OH	21-Hydroxylase Ab, S	85363-0

Result ID	Test Result Name	Result LOINC® Value
607788	21-Hydroxylase Ab, S	85363-0