Test Definition: COL7

Anti-Collagen type VII, IgG Antibodies, Serum

Overview

Useful For

Initial screening test in the diagnosis of epidermolysis bullosa acquisita and other immunobullous diseases mediated by collagen VII

Testing Algorithm

For information see Autoimmune Blistering Disease Diagnostic Algorithm.

Special Instructions

- Autoimmune Blistering Disease Diagnostic Algorithm

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 2 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Ambient	14 days	
	Frozen	30 days	

Clinical & Interpretive

Clinical Information

Epidermolysis bullosa acquisita and certain other rare immunobullous diseases, including bullous lupus erythematosus, are caused by the development of IgG antibodies directed against collagen type VII, which lead to blisters and erosions that may heal with scarring. Circulating IgG autoantibodies against collagen type VII can be found in patient's serum in these conditions.

Reference Values

Collagen type VII
<20 RU/mL (negative)
> or =20 RU/mL (positive)

Interpretation

Antibodies to IgG collagen type VII have been shown to be present in patients with epidermolysis bullosa acquisita and certain other rare immunobullous diseases, including bullous lupus erythematosus.

Cautions

The results obtained with collagen type VII enzyme-linked immunosorbent assay kit serve as an aid to diagnosis and should be interpreted in the patient’s clinical context.

Performance of the assay on other matrices besides serum has not been established.

Clinical Reference

1. Chen M, Chan LS, Cai X, O'Toole EA, Sample JC, Woodley DT. Development of an ELISA for rapid detection of anti-type VII collagen autoantibodies in epidermolysis bullosa acquisita. J Invest Dermatol. 1997;108(1): 68-72
2. Holtsche MM, van Beek N, Hashimoto T, et al. Diagnosis of epidermolysis bullosa acquisita: multicentre comparison of different assays for serum anti-type VII collagen reactivity. Acta Derm Venereol. 2021;101(3):adv00420
3. Schmidt T, Hoch M, Lofti Jad SS, et al. Serological diagnostics in the detection of IgG autoantibodies against human collagen VII in epidermolysis bullosa acquisita: a multicentre analysis. Br J Dermatol. 2017;117(6):1683-1692
4. Komorowski L, Muller R, Vorobyev A, et al. Sensitive and specific assays for routine serological diagnosis of epidermolysis bullosa acquisita. J Am Acad Dermatol. 2013;68(3):89-95

Performance

Method Description

This enzyme-linked immunosorbent assay method detects and measures serum levels of antibodies of certain pemphigoid diseases. Calibrators and patient sera are added to microwells coated with collagen type VII antigens, allowing antibodies to react with the immobilized antigens. After washing to remove any unbound serum proteins, horseradish peroxidase-conjugate IgG is added and incubated. Following another wash step, the peroxidase substrate is added and allowed to incubate for an additional period. A stop solution is then added to each well to halt the enzymatic reaction and stabilize the color development. The assay can be quantified by measuring the reaction photometrically and plotting the results. The amount of antigen-specific bound antibody is proportional to the color intensity.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Varies

Report Available

1 to 7 days

Specimen Retention Time

30 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

83516

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
COL7	Anti-Collagen type VII, Serum	In Process

Result ID	Test Result Name	Result LOINC® Value

616879	COL7, S	94096-5