

## Overview

### Useful For

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

### 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             |