

Overview

Useful For

Detection of individuals with an ongoing immune process

First-tier screening test for congenital complement deficiencies

Method Name

Automated Liposome Lysis Assay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: Fasting preferred but not required

Supplies: Sarstedt Aliquot Tube 5 mL (T914)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. Immediately after specimen collection, place the tube on wet ice and allow specimen to clot.
2. Centrifuge at 4 degrees C and aliquot serum into 5 mL plastic vial.
3. Within 30 minutes of centrifugation, freeze specimen. Specimen must be placed on dry ice if not frozen immediately.

NOTE: If a refrigerated centrifuge is not available, it is acceptable to use a room temperature centrifuge, provided the specimen is kept on ice before centrifugation, and immediately afterward, the serum is aliquoted and frozen.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK

Gross icterus	OK
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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen	28 days	

Clinical & Interpretive**Clinical Information**

Complement (C) proteins are components of the innate immune system. There are 3 pathways to complement activation: the classical pathway, the alternative (or properdin) pathway, and the lectin (or mannan-binding lectin) pathway. The classical pathway of the complement system is composed of a series of proteins that are activated in response to the presence of immune complexes. A single IgM molecule or two IgG molecules are sufficient to trigger activation of the recognition complex initiated by C1q. The activation process triggers a cascade that includes an amplification loop. The amplification loop is mediated by C3, with cleavage of a series of proteins, and results in three main end products: anaphylatoxins which promote inflammation (C3a, C5a); opsonization peptides that are chemotactic for neutrophils (C3b) and facilitate phagocytosis; and the membrane attack complex (MAC), which promotes cell lysis.

The absence of early components (C1, C2, C3, C4) of the complement cascade results in the inability of immune complexes to activate the cascade. Patients with deficiencies of the early complement proteins are unable to generate the peptides that are necessary to clear immune complexes and to attract neutrophils or to generate lytic activity. These patients have increased susceptibility to infections with encapsulated microorganisms. They may also have symptoms that suggest autoimmune disease; complement deficiency may be an etiologic factor in the development of autoimmune disease.

Patients with deficiencies of the late complement proteins (C5, C6, C7, C8, and C9) are unable to form the MAC and may have increased susceptibility to neisserial infections.

Undetectable complement levels are found in patients with specific component deficiencies. Decreased complement levels are found in infectious and autoimmune diseases due to fixation and consumption of complement.

Reference Values

30-75 U/mL

Interpretation

Low levels of total complement (total hemolytic complement) may occur during infections, disease exacerbation in patients with systemic lupus erythematosus, and in patients with immune complex diseases such as glomerulonephritis.

Undetectable levels suggest the possibility of a complement component deficiency. Individual complement component assays are useful to identify the specific deficiency.

Cautions

As with all complement assays, proper specimen handling is of utmost importance to ensure that the complement

system is not activated before clinical testing.

Clinical Reference

1. Daha MR. Role of complement in innate immunity and infections. *Crit Rev Immunol*. 2010;30(1):47-52. doi:10.1615/critrevimmunol.v30.i1.30
2. Prohaszka Z, Varga L, Fust G. The use of 'real-time' complement analysis to differentiate atypical haemolytic uraemic syndrome from other forms of thrombotic microangiopathies. *Br J Haematol*. 2012;158(3):424-425. doi:10.1111/j.1365-2141.2012.09168.x
3. Cataland SR, Holers VM, Geyer S, Yang S, Wu HM. Biomarkers of terminal complement activation confirm the diagnosis of aHUS and differentiate aHUS from TTP. *Blood*. 2014;123(24):3733-3738. doi:10.1182/blood-2013-12-547067
4. Frazer-Abel A, Sepiashvili L, Mbughuni MM, Willrich MA. Overview of laboratory testing and clinical presentations of complement deficiencies and dysregulation. *Adv Clin Chem*. 2016;77:1-75. doi:10.1016/bs.acc.2016.06.001

Performance**Method Description**

An automated method is performed using liposomes as the target for the serum complement system. Dinitrophenyl (DNP)-labeled liposomes are sensitized with antibody to DNP. Serum complement causes lysis and release of entrapped glucose-6-phosphate dehydrogenase. Glucose-6-phosphate dehydrogenase reacts with glucose-6-phosphate and nicotinamide adenine dinucleotide (NAD[+]). NAD(+) is then reduced to NADH, and the conversion is measured at 340 nm. The assay correlates with the total complement assay based on sheep red blood cell lysis, has lower variability, and is simpler to perform. (Package insert: Fujifilm Autokit CH50. Fujifilm Wako Pure Chemical Corporation; 04/2018; Yamamoto S, Kubotsu K, Kida M, et al. Automated homogeneous liposome-based assay system for total complement activity. *Clin Chem*. 1995;41[4]:586-590)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 2 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

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

86162

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
COM	Complement, Total, S	4532-8

Result ID	Test Result Name	Result LOINC® Value
COM	Complement, Total, S	4532-8