

IgG4, Immunoglobulin Subclasses, Serum

# Overview

## **Useful For**

Supporting the diagnosis of IgG4-related disease

### **Method Name**

Turbidimetry

## **NY State Available**

Yes

# **Specimen**

# **Specimen Type**

Serum

# **Ordering Guidance**

This test only quantitates the IgG4 protein. If quantitation of all IgG subclass types is desired, order IGGS / IgG Subclasses, Serum.

## **Specimen Required**

**Patient Preparation:** 

Fasting: 12 hours, 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 serum

Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

# Specimen Minimum Volume

Serum: 0.5 mL

## **Reject Due To**

Gross	Reject
hemolysis	
Gross lipemia	Reject
Gross icterus	OK



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## **Specimen Stability Information**

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

# Clinical & Interpretive

### **Clinical Information**

The most abundant immunoglobulin isotype in human serum is IgG. IgG immunoglobulins are comprised of 4 subclasses, designated IgG1 through IgG4. Of total IgG, approximately 65% is IgG1, 25% is IgG2, 6% is IgG3, and 4% is IgG4. Each IgG subclass contains structurally unique portions of the constant region of the gamma heavy chain.

IgG subclass 4-related disease is a systemic inflammatory disease of unknown etiology, most often occurring in middle-aged and older men. Several organ systems can be involved, and the disease encompasses many previous and newly described diseases such as autoimmune pancreatitis; Mikulicz disease and sclerosing sialadenitis; inflammatory orbital pseudotumor; chronic sclerosing aortitis; Riedel thyroiditis, a subset of Hashimoto thyroiditis; IgG4-related interstitial pneumonitis; and IgG4-related tubulointerstitial nephritis. These entities may be characterized by tumor-like swelling of the involved organs with infiltration by numerous IgG4-positive plasma cells with accompanying fibrosis. In addition, elevated serum concentrations of IgG4 are found in at least 50% of patients diagnosed with IgG4-related disease.

The diagnosis of IgG4-related disease may require a tissue biopsy of the affected organ demonstrating the aforementioned histological features. It is recommended that patients suspected of having an IgG4-related disease have their serum IgG4 measured.

### **Reference Values**

0-<5 months: < or =19.8 mg/dL 5-<9 months: < or =20.8 mg/dL 9-<15 months: < or =22.0 mg/dL 15-<24 months: < or =23.0 mg/dL 2-<4 years: < or =49.1 mg/dL 4-<7 years: < or =81.9 mg/dL 7-<10 years: 1.0-108.7 mg/dL 10-<13 years: 1.0-121.9 mg/dL 13-<16 years: < or =121.7 mg/dL 16-<18 years: < or =111.0 mg/dL > or =18 years: 2.4-121.0 mg/dL

#### Interpretation

Elevated concentration of IgG4 is consistent with, but not diagnostic of, IgG4-related disease.

#### Cautions

Elevations in serum IgG4 concentrations are not specific to IgG4-related disease; they are also found in disorders such as



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multicentric Castleman disease, allergic disorders, Churg-Strauss syndrome, sarcoidosis, and other conditions.

Undetected antigen excess is a rare event but cannot be excluded. Results should always be interpreted in conjunction with other laboratory tests and clinical evidence.

# **Clinical Reference**

- 1. Cheuk W, Chan JKC. IgG4-related sclerosing disease: a critical appraisal of an evolving clinicopathologic entity. Adv Anat Pathol. 2010;17(5):303-332
- 2. Zen Y, Nakanuma Y. IgG4-related disease: a cross-sectional study of 114 cases. Am J Surg Pathol. 2010;34(12):1812-1819
- 3. Bateman AC, Deheragoda MG. IgG4-related systemic sclerosing disease-an emerging and under-diagnosed condition. Histopathology. 2009;55(4):373-383
- 4. Vidarsson G, Dekkers G, Rispens T. IgG subclasses and allotypes: from structure to effector functions. Front Immunol. 2014;5:520
- 5. Maslinska M, Dmowska-Chalaba J, Jakubaszek M. The role of IgG4 in autoimmunity and rheumatic diseases. Front Immunol. 2022;12:787422
- 6. Wallace ZS, Naden RP, Chari S, et al. The 2019 American College of Rheumatology/European League Against Rheumatism classification criteria for IgG4-related disease. Ann Rheum Dis. 2020;79(1):77-87. doi:10.1136/annrheumdis-2019-216561

### **Performance**

## **Method Description**

The determination of the soluble antigen concentration by turbidimetric methods involves the reaction with specific antiserum to form insoluble complexes. When light is passed through the suspension formed a portion of the light is transmitted and focused onto a photodiode by an optical lens system. The amount of transmitted light is indirectly proportional to the specific protein concentration in the test sample.

Concentrations are automatically calculated by reference to a calibration curve stored within the instrument. (Package inserts: Optilite IgG4. The Binding Site Group, Ltd; 07/2019)

## **PDF Report**

No

### Day(s) Performed

Monday through Friday

## Report Available

1 to 2 days

## **Specimen Retention Time**

14 days

# **Performing Laboratory Location**



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Mayo Clinic Laboratories - Rochester Superior Drive

### **Fees & Codes**

### **Fees**

- Authorized users can sign in to <u>Test Prices</u> 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 <u>Customer Service</u>.

### **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**

82787

## **LOINC®** Information

Test ID	Test Order Name	Order LOINC® Value
IGGS4	IgG4, Ig Subclasses	2469-5

Result ID	Test Result Name	Result LOINC® Value
IGGS4	IgG4, Ig Subclasses	2469-5