

**Overview****Useful For**

Evaluation of patients with suspected systemic infection, in particular infection caused by gram-negative bacteria

Evaluation of patients with suspected chronic inflammatory disorders, such as rheumatoid arthritis, inflammatory bowel disease, or ankylosing spondylitis

**Method Name**

Electrochemiluminescence

**NY State Available**

Yes

**Specimen****Specimen Type**

Plasma EDTA

**Specimen Required**

**Collection Container/Tube:** Lavender-top (EDTA)

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.5 mL

**Collection Instructions:**

1. Immediately after specimen collection, place the tube on wet ice.
2. Centrifuge at 1,500 x g for 10 minutes and aliquot plasma.
3. Freeze specimen within 30 minutes.

**Specimen Minimum Volume**

0.3 mL

**Reject Due To**

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Frozen (preferred)	21 days	

Specimen Type	Temperature	Time	Special Container
	Refrigerated	24 hours	

## Clinical and Interpretive

### Clinical Information

Tumor necrosis factor (TNF)-alpha is expressed primarily by activated monocytes as part of the innate immune response to various microbes, gram-negative bacteria in particular.(1) TNF-alpha is synthesized as a type II membrane protein, which can be cleaved by a membrane-associated metalloproteinase. The subunit that is released will polymerize to form a homotrimer, which is the circulating form of TNF-alpha. The primary function of TNF-alpha is to recruit other leukocytes to the site of infection and to stimulate their activation. TNF-alpha also has some systemic effects, including induction of fever through action on the hypothalamus. In cases of severe gram-negative bacterial infection, septic shock can occur. Septic shock is induced by large-scale production of inflammatory cytokines, including TNF-alpha. This disorder is characterized by hypotension, disseminated intravascular coagulation, tachycardia, and increased respiration, and can be fatal.

Dysregulation of TNF-alpha expression is thought to be a critical pathogenic mechanism in numerous autoimmune diseases, including inflammatory bowel disease (IBD), rheumatoid arthritis (RA), and ankylosing spondylitis (AS).(2)

There are currently 5 monoclonal antibodies approved by the FDA for blockage of TNF-alpha as a clinical treatment.(3,4) The different drugs are approved for various diseases, with some available for treatment of pediatric IBD and juvenile RA.

### Reference Values

< or =2.8 pg/mL

### Clinical Reference

1. Clark IA: How TNF was recognized as a key mechanism of disease. *Cytokine Growth Factor Rev* 2007;18:335-343
2. Bradley JR: TNF-mediated inflammatory disease. *J Pathol* 2008;214:149-160
3. Horiuchi T, Mitoma H, Harashima S, et al: Transmembrane TNF-alpha: structure, function and interaction with anti-TNF agents. *Rheumatology* 2010;49:1215-1228
4. Willrich MAV, Murray DL, Snyder MR: Tumor necrosis factor inhibitors: clinical utility in autoimmune diseases. *Trans Res* 2015;165:270-282

## Performance

### Method Description

The tumor necrosis factor (TNF)-alpha cytokine assay measures human cytokines in a 96-well spotted plate. The assay employs a sandwich immunoassay format where capture antibodies are coated on a single spot on the bottom of each well. Diluted samples, calibrators, and controls are added and to the plate. If present, TNF-alpha will bind to the capture antibodies. After incubation, a solution containing detection antibodies conjugated with electrochemiluminescent labels is added. After a final incubation, a buffer is added that creates the appropriate chemical environment for electrochemiluminescence. The plate is then read on the Sector Imager 2400. The machine applies a voltage that causes bound labels to emit measurable light. The Sector Imager 2400 measures the

intensity of emitted light and correlates it to a set of standards of known quantity via a 4-point logistics curve fitting method. (Package Insert: Human TNF-alpha V-plex, Mesoscale Discovery, Rockville, MD 20850 USA, 2014)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Thursday, 3 p.m.

**Analytic Time**

1 day

**Maximum Laboratory Time**

8 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees and 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 Regional Manager. 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. This test has not been cleared or approved by the U.S. Food and Drug Administration.

**CPT Code Information**

83520

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
TNFA	Tumor Necrosis Factor, P	3074-2

Result ID	Test Result Name	Result LOINC Value
63022	TNF, P	3074-2