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

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
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</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Plasma EDTA</td>
<td>Frozen (preferred)</td>
<td>21 days</td>
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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

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
Test Definition: TNFA
Tumor Necrosis Factor, P

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

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<td>Tumor Necrosis Factor, P</td>
<td>3074-2</td>
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<tr>
<td>63022</td>
<td>TNF, P</td>
<td>3074-2</td>
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