Overview

Useful For
Assessment of an antibody response to the tetanus toxoid vaccine, which should be performed at least 3 weeks after immunization

An aid to diagnose immunodeficiency

Method Name
Enzyme Immunoassay (EIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.4 mL

Reject Due To

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

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>30 days</td>
<td></td>
</tr>
</tbody>
</table>
Clinical and Interpretive

Clinical Information
Tetanus results from contamination of wounds or lacerations with *Clostridium tetani* spores from the environment. The spores germinate to actively replicating bacterial cells localized within the wound and produce the heat-labile toxin, tetanospasmin. Tetanospasmin attaches to peripheral nerve endings and travels to the central nervous system (CNS) where it blocks inhibitory impulses to motor neurons and leads to severe, spastic muscle contractions, a classic characteristic of tetanus.

The disease is preventable by vaccination with tetanus toxoid (formaldehyde-treated tetanospasmin), which stimulates development of antitetanus toxoid antibodies. In the United States, tetanus toxoid is administered to children as part of the combined diphtheria, tetanus, and acellular pertussis (TDaP) vaccine.

Two to 3 weeks following vaccination, a patient's immunological response may be assessed by measuring the total antitetanus toxoid IgG antibody level in serum. An absence of antibody formation postvaccination may relate to immune deficiency disorders, either congenital or acquired, or iatrogenic due to immunosuppressive drugs.

Reference Values
Vaccinated: Positive (≥0.01 IU/mL)
Unvaccinated: Negative (<0.01 IU/mL)

Interpretation
Results ≥0.01 suggest a vaccine response.

A tetanus toxoid booster should strongly be considered for patients with anti-tetanus toxoid IgG values between 0.01 and 0.5 IU/mL.

Some cases of tetanus, usually mild, have occasionally been observed in patients who have a measurable serum level of 0.01 to 1.0 IU/mL.

Cautions
This test should not be used to diagnose tetanus infection. The diagnosis of tetanus is by clinical observation. A positive wound culture for the agent of tetanus, *Clostridium tetani*, may support but does not confirm, the diagnosis. Toxin assays for tetanospasmin may be useful, but are only available in a few laboratories.

The results obtained from this assay are not diagnostic proof of lack of protection against tetanus or the presence/absence of immunodeficiency.

Supportive Data
A total of 227 serum samples prospectively submitted to our laboratory for routine antitetanus toxoid IgG testing by the Binding Site Anti-Tetanus Toxoid IgG ELISA were also evaluated by the Eurolimmun Anti-Tetanus Toxoid IgG ELISA. Results are summarized in the table below:

<table>
<thead>
<tr>
<th>Comparison of the Eurolimmun and Binding Site Anti-Tetanus Toxoid IgG ELISAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Binding Site IgG ELISA</td>
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</tbody>
</table>

Document generated September 15, 2020 at 8:18pm CDT
<table>
<thead>
<tr>
<th>EurolImmun IgG ELISA</th>
<th>Positive</th>
<th>220</th>
<th>0</th>
<th>220</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative</td>
<td>6(a)</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>226</td>
<td>1</td>
<td>227</td>
</tr>
</tbody>
</table>

a) 3 of the 6 samples tested positive by the anti-Tetanus Toxoid IgG Quantitative Multiplex Bead Assay at ARUP.

% Positive Agreement: 97.4% (220/226); 95% Confidence Interval (95% CI): 94.2-98.9%

% Negative Agreement: 100% (1/1); 95% CI: 16.8-100%

% Overall Agreement: 97.4% (221/227); 95% CI: 94.2-98.9%

Clinical Reference


Performance

Method Description

The EurolImmun Anti-Tetanus Toxoid ELISA provides a quantitative in-vitro assay for detection of human IgG-class antibodies to Tetanus toxoid. The test kit contains reagent wells coated with tetanus toxoid. In the first reaction step, diluted patient samples are incubated in the wells. In the case of positive samples, specific IgG antibodies will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled anti-human IgG (enzyme conjugate) catalyzing a color reaction.(Package insert: Anti-Tetanus Toxoid ELISA (IgG) Test instruction, EurolImmun US, Morris Plains, New Jersey 02/25/2016)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 9 a.m.

Analytic Time
Test Definition: TTIGS
Tetanus Toxoid IgG Ab, S

Same day/1 day

Maximum Laboratory Time
4 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
86317

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>TTIGS</td>
<td>Tetanus Toxoid IgG Ab, S</td>
<td>53935-3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
<tr>
<td>TETG</td>
<td>Tetanus IgG Ab</td>
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</tr>
<tr>
<td>DEXTG</td>
<td>Tetanus IgG Value</td>
<td>53935-3</td>
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