Overview

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

Aiding in the evaluation of immunodeficiency

This test should not be used to diagnose tetanus infection

Profile Information

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<tr>
<th>Test Id</th>
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<tbody>
<tr>
<td>DIPGS</td>
<td>Diphtheria Toxoid IgG Ab, S</td>
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<td>TTIGS</td>
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Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Specimen Volume: 1 mL

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

Reject Due To

| Gross hemolysis | Reject |
| Gross lipemia   | Reject |
| Gross icterus   | Reject |
| Heat Inactivated specimen | Reject |

Specimen Minimum Volume
0.8 mL
Specimen Stability Information

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<th>Specimen Type</th>
<th>Temperature</th>
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<tr>
<td></td>
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Clinical & Interpretive

Clinical Information

Diphtheria is an acute, contagious, febrile illness caused by the bacterium *Corynebacterium diphtheriae*. The disease is classically characterized by a combination of localized inflammation in the upper respiratory tract with the formation of a diphtheric pseudomembrane over the oropharynx, including the tonsils, pharynx, larynx, and posterior nasal passages. *C diphtheriae* produces a potent diphtheria exotoxin that is absorbed systemically and can lead to cardiac failure and paralysis of the diaphragm.

The disease is preventable by vaccination with diphtheria toxoid, which stimulates antidiaphtheria toxoid antibodies. In the United States, diphtheria toxoid is administered to children as part of the combined diphtheria, tetanus, acellular pertussis (TDaP) vaccine. A patient’s immunological response to diphtheria toxoid vaccination can be determined by measuring antidiaphtheria toxoid IgG antibody using this enzyme immunoassay technique. An absence of antibody formation postvaccination may relate to immune deficiency disorders, either congenital or acquired, or iatrogenic due to immunosuppressive drugs.

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, 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

**DIPHTHERIA TOXOID IgG ANTIBODY**

Vaccinated: Positive (> or = 0.01 IU/mL)
Unvaccinated: Negative (< 0.01 IU/mL)

Reference values apply to all ages.

**TETANUS TOXOID IgG ANTIBODY**

Vaccinated: Positive (> or = 0.01 IU/mL)
Unvaccinated: Negative (< 0.01 IU/mL)

Reference values apply to all ages.
**Interpretation**

**Diphtheria:**
Results of 0.01 IU/mL or more suggest a vaccine response.

A diphtheria toxoid booster should be considered for patients with antidiphtheria toxoid IgG values between 0.01 and less than 0.1 IU/mL.

**Tetanus:**
Results of 0.01 IU/mL or more suggest a vaccine response.

A tetanus toxoid booster should strongly be considered for patients with antitetanus 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 assay does not provide diagnostic proof of lack of protection again diphtheria or the presence of absence of immunodeficiency. Results must be confirmed by clinical findings and other serological tests.

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 or absence of immunodeficiency.

**Supportive Data**

**Diphtheria:**
A total of 211 serum samples prospectively submitted to our reference laboratory for routine testing for antidiphtheria toxoid IgG antibodies by the Binding Site Anti-Diphtheria Toxoid IgG ELISA were also evaluated by the EuroImmun Anti-Diphtheria Toxoid IgG ELISA and results are summarized in the table below.

| Table 1. Comparison of the EuroImmun and Binding Site Anti-Diphtheria Toxoid IgG ELISAs |
|---------------------------------|-----------------|-----------------|----------------|
|                                  | Binding Site IgG ELISA |                  |                  |
|                                  | Positive | Negative | Total |
| EuroImmun IgG ELISA             | Positive | 206      | 0        | 206 |
|                                  | Negative | 4(a)     | 1        | 5 |
| Total                            | 210      | 1        | 2011 |

a) 1 of 4 samples tested positive by the ARUP Quantitative Multiplex Bead assay for antidiphtheria toxoid IgG.

% Positive Agreement: 98.1% (206/210); 95% CI: 95.0-99.4%

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

% Overall Agreement: 98.1% (207/211); 95% CI: 95.1-99.4%
Tetanus:
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 Euroimmun Anti-Tetanus Toxoid IgG ELISA. Results are summarized in the table below:

| Table 2. Comparison of the Euroimmun and Binding Site Anti-Tetanus Toxoid IgG ELISAs |
|----------------------------------------|-----------------|-----------------|-----------------|
|                                       | Binding Site IgG ELISA |                 |                 |
|                                       | Positive          | Negative        | Total           |
| Euroimmun IgG ELISA                   | 220               | 0               | 220             |
|                                       | 6(a)              | 1               | 7               |
|                                       | Total             |                 | 227             |

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% 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 Euroimmun Anti-Diphtheria Toxoid enzyme-linked immunosorbent assay (ELISA) and Anti-Tetanus Toxoid ELISA provide quantitative in-vitro assays for detection of human IgG-class antibodies to diphtheria and tetanus toxoid, respectively.

The test kits contain reagent wells coated with either diphtheria or 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 antihuman IgG (enzyme conjugate) catalyzing a color reaction. (Package inserts: Anti-Tetanus Toxoid ELISA [IgG] Test instruction.
08/28/2017; Anti-Diphtheria Toxoid ELISA [IgG] Test instruction. EUROIMMUN US;08/18/2017)

PDF Report
No

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & Codes

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 US Food and Drug Administration.

CPT Code Information
86317 x 2

LOINC® Information

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