Overview

Useful For
Determining a patient's immunological response to diphtheria toxoid vaccination
Aiding in the evaluation of immunodeficiency

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: 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>Condition</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
</tr>
<tr>
<td>Heat inactivated specimen</td>
<td>Reject</td>
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Specimen Stability Information

<table>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum</td>
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<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>30 days</td>
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</table>
Clinical and 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 antidiphtheria toxoid antibodies. In the United States, diphtheria toxoid is administered to children as part of the combined diphtheria, tetanus, and acellular pertussis (TdAp) vaccine. A patient's immunological response to diphtheria toxoid vaccination can be determined by measuring antidiphtheria 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.

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

Reference values apply to all ages.

Interpretation
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.

Cautions
This assay does not provide diagnostic proof of lack of protection against diphtheria or the presence of absence of immunodeficiency. Results must be confirmed by clinical findings and other serological tests.

Supportive Data
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:

| 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        | 211    |

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%

Clinical Reference


Performance

Method Description

The EuroImmun Anti-Diphtheria Toxoid IgG enzyme-linked immunosorbent assay (ELISA) kit provides a quantitative in vitro assay for detection of human IgG-class antibodies to diphtheria toxoid. The test kit contains reagent wells coated with diphtheria 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 insert: Anti-Diphtheria Toxoid ELISA [IgG] Test Instructions, EUROIMMUN US; 09/13/2017)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 9 a.m.

Analytic Time

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

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<th>Order LOINC Value</th>
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<td>DIPGS</td>
<td>Diphtheria Toxoid IgG Ab, S</td>
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<table>
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<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
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<tr>
<td>DEXDP</td>
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