Test Definition: DTABS

Diphtheria/Tetanus Ab Panel, S

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

Test ID	Reporting Name	Available Separately	Always Performed
DIPGS	Diphtheria Toxoid IgG Ab, S	Yes	Yes
TTIGS	Tetanus Toxoid IgG Ab, S	Yes	Yes

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.

Specimen Minimum Volume

0.8 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

Gross icterus	Reject
Heat Inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	30 days	
	Frozen	30 days	

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, 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.

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%Â 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	Positive	220	0	220
	Negative	6(a)	1	7
	Total	226	1	227

a) 3 of the 6 samples tested positive by the anti-Tetanus Toxoid IgG Quantiative 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

1. Booy R, Aitken SJ, Taylor S, et al: Immunogenicity of combined diphtheria, tetanus, and pertussis vaccine given at 2, 3, and 4 months versus 3, 5, and 9 months of age. Lancet. 1992;339(8792):507-510

2. Maple PA, Efstratiou A, George RC, Andrews NJ, Sesardic D: Diphtheria immunity in UK blood donors. Lancet. 1995;345(8955):963-965

3. Bleck TP: *Clostridium tetani* (tetanus). In: Mandell GL, Bennett JE, Dolin R, eds. Principals and Practice of Infectious Disease. 5th ed. Churchill Livingstone;2000:2537-2543

4. Gergen PJ, McQuillan GM, Kiely M, Ezzati-Rice TM, Sutter RW, Virella G: A population-based serologic survey of immunity to tetanus in the United States. N Engl J Med. 1995;332:761-766

5. Bjorkholm B, Wahl M, Granstrom M, Hagberg L: Immune status and booster effects of low doses of tetanus toxoid in Swedish medical personnel. Scand J Infect Dis. 1994;26:471-475

6. Ramsay ME, Corbel MJ, Redhead K, Ashworth LA, Begg NT: Persistence of antibody after accelerated immunization with diptheria/tetanus/pertussis vaccine. Br Med J. 1991;302:1489-1491

7. Wagner KS, White JM, Lucenko I, et al: Diphtheria in the postepidemic period, Europe, 2000-2009. Emerg Infect Dis. 2012 Feb;18(2):217-225 doi: 10.3201/eid1802.110987

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

Day(s) Performed

Monday through Friday

Report Available

Same day/1 to 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 US Food and Drug Administration.

CPT Code Information

86317 x 2

LOINC® Information

Test Definition: DTABS

Diphtheria/Tetanus Ab Panel, S

Test ID	Test Order Name	Order LOINC Value
DTABS	Diphtheria/Tetanus Ab Panel, S	In Process

Result ID	Test Result Name	Result LOINC Value
TETG	Tetanus IgG Ab	33469-8
DIPG	Diphtheria IgG Ab	45166-6
DEXDP	Diphtheria IgG Value	48654-8
DEXTG	Tetanus IgG Value	53935-3