MAYO CLINIC LABORATORIES

Test Definition: DTABS

Diphtheria/Tetanus Antibody Panel, Serum

Overview

Useful For

Assessing 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

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) 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 & 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.

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 where it blocks inhibitory impulses to motor neurons and leads to severe, spastic muscle contractions, a classic characteristic of tetanus.

Both diseases are preventable by vaccination with diphtheria toxoid, which stimulates antidiphtheria toxoid antibodies, and tetanus toxoid (formaldehyde-treated tetanospasmin), which stimulates development of antitetanus toxoid antibodies. In the United States, these toxoids are 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 antidiphtheria toxoid IgG antibody and total antitetanus toxoid IgG antibody levels in serum. An absence of either 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 be strongly 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 with a measurable serum level of 0.01 to 1.0 IU/mL.

Cautions

This assay does not provide diagnostic proof of lack of protection against diphtheria and tetanus 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.

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 enzyme-linked immunosorbent assay (ELISA) were also evaluated by the EuroImmun Anti-Diphtheria Toxoid IgG ELISA and results are summarized in Table 1.

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 Table 2:

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 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

1. 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
2. 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 Mar;332(12):761-766
3. 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(4):471-475
4. Ramsay ME, Corbel MJ, Redhead K, Ashworth LA, Begg NT: Persistence of antibody after accelerated immunization with diphtheria/tetanus/pertussis vaccine. Br Med J. 1991 Jun;302(6791):1489-1491
5. Centers for Disease Control and Prevention (CDC); National Center for Immunization and Respiratory Diseases, Division of Bacterial Diseases. Diphtheria. CDC; Updated September 9, 2022. Accessed October 27, 2022. Available at www.cdc.gov/diphtheria/index.html
6. Truelove SA, Keegan LT, Moss WJ, et al: Clinical and epidemiological aspects of diphtheria: a systematic review and pooled analysis. Clin Infect Dis. 2020 Jun;71(1):89-97

Performance

Method Description

The 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-labeled antihuman IgG (enzyme conjugate), catalyzing a color reaction.(Unpublished Mayo method)

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 & 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 account representative. 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. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
86317 x 2

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
DTABS	Diphtheria/Tetanus Ab Panel, S	101791-2

Result ID	Test Result Name	Result LOINC® Value
TETG	Tetanus IgG Ab	26643-7
DEXTG	Tetanus IgG Value	53935-3
DIPG	Diphtheria IgG Ab	45166-6
DEXDP	Diphtheria IgG Value	48654-8