

## Overview

### Useful For

Assessing antibody response to the tetanus toxoid vaccine, 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.

### Method Name

Enzyme Immunoassay (EIA)

### 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:** 0.5 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

0.4 mL

### Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

Gross icterus	Reject
---------------	--------

**Specimen Stability Information**

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

**Clinical & 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 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 (> or =0.01 IU/mL)

Unvaccinated: Negative (<0.01 IU/mL)

**Interpretation**

Results greater than or equal to 0.01 suggest a vaccine response.

A tetanus toxoid booster should be strongly 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 with 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 enzyme-linked immunosorbent assay (ELISA) were also evaluated by the EuroImmuno Anti-Tetanus Toxoid IgG ELISA. Results are summarized in the table:

Table. Comparison of the EuroImmuno and Binding Site Anti-Tetanus Toxoid IgG ELISAs

		Binding Site IgG ELISA		
		Positive	Negative	Total
EuroImmuno 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. Boland Birch T, Bleck TP. Tetanus (*Clostridium tetani*). In Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020:2948-2953
2. Gergen PJ, McQuillan GM, Kiely M, et al. A population-based serologic survey of immunity to tetanus in the United States. N Engl J Med. 1995;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, et al. Persistence of antibody after accelerated immunization with diphtheria/tetanus/pertussis vaccine. BMJ. 1991;302(6791):1489-1491
5. Rubin RL, Tang FL, Chan EK, et al. IgG subclasses of anti-tetanus toxoid antibodies in adult and newborn normal subjects and in patients with systemic lupus erythematosus, Sjogren's syndrome, and drug-induced autoimmunity. J Immunol. 1986;137(8):2522-2527
6. Simonsen O, Bentzon MW, Heron I. ELISA for the routine determination of antitoxic immunity to tetanus. J Biol Stand. 1986;14(3):231-239

### Performance

#### Method Description

The Anti-Tetanus Toxoid enzyme-linked immunosorbent assay provides a quantitative in vitro assay for detecting 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-labeled anti-human 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

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
TTIGS	Tetanus Toxoid IgG Ab, S	53935-3

Result ID	Test Result Name	Result LOINC® Value
TETG	Tetanus IgG Ab	26643-7
DEXTG	Tetanus IgG Value	53935-3