Tetanus toxoid

Enzyme immunoassays for the diagnostics of tetanus

ELISA ELISA kits are optimazed and validated for detection of specific IgG class antibodies in human serum and plasma

CE IVD Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Tetanus is a disease caused by the toxin produced by *Clostridium tetani*. The incidence of the disease has been reduced worldwide thanks to improved hygiene conditions and extensive vaccination prophylaxis. However, 400,000 to 800,000 people die from this infection every year. Most of these people live in developing countries. Vaccination-mediated protection decreases with age since tetanus antitoxin levels drop as an individual ages.

Adequate antibody protection is achieved by vaccination in childhood and subsequent booster doses. Protection starts at a anti-tetanus toxoid concentration of 0.1 IU/ml.

While the vaccine does not usually cause side effects, measuring antibody titre before the booster dose is recommended. This way, side effects such as local oedema, pain and fever can be prevented.

Sometimes, failure of the immune response may occur in patients with normal or high levels of all immunoglobulins and in patients with isolated immunodeficiencies. Therefore, normal immunoglobulin concentrations do not rule out a deficiency of anti-tetanus antibodies and the response to antigenic stimulation should be tested. If antibody tests are performed a long time after the primary and booster vaccination, abnormalities in the occurrence of cell interactions and the level of determined titres may occur.

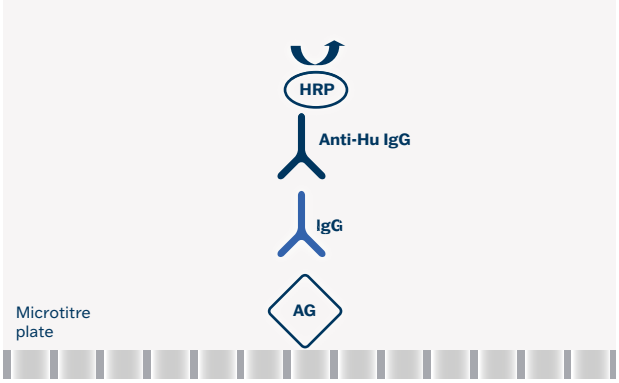
Interpretation of Results

Antibody concentrations in the standards included in the Tetanus Toxoid IgG ELISA kit are defined and expressed in International Units (IU/ml). Standards are calibrated according to the WHO 1st International Standard TE-3. This enables accurate and reproducible quantitative evaluation. Subsequent patient check-ups are possible.

Antibody level (IU/ml)	**Interpretation**
lower than 0.01	antibodies are negative: basic vaccination is needed
0.01 to 0.1	a booster dose is recommended
0.1 to 1	checking the antibody titre in 1–2 years is recommended
1 to 5	checking the antibody titre in 2–4 years is recommended
more than 5	checking the antibody titre in 4–8 years is recommended

Test Principle

The assays are based on a sandwich type of ELISA method.



Protocol Summary

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add Conjugate 100 µl – Including blank
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 15 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

Chemically inactivated tetanus toxin

Clinical Application

- Screening after vaccination
- Detection of antibody level before booster dose to avoid potential hyperimmunity damage

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- Calibrators included
- Quantitative evaluation of results (U/ml)

Advantages

- High diagnostic efficacy
- Good reproducibility
- High test dynamics
- Identical assay procedure
- Total assay time 1.5 hours
- Suitable for open automated systems
- Complex customer support

Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA Tetanus IgG	95.8%	92.9%

Ordering Information

ELISA

Cat. No	Product	No. of Tests
TeTG96	EIA Tetanus Toxoid IgG	96
SK-TeTG96	SmartEIA Tetanus Toxoid IgG	96

SmartEIA kits are designed for automated processing using the Agility® analyser

TestLine Clinical Diagnostics s.r.o.
Křižíkova 68, 612 00 Brno, Česká republika
+420 549 121 205 (209, 238)
trade@testlinecd.com
www.testlinecd.cz

TestLine Clinical Diagnostics s.r.o.
je držitelem certifikátů
ISO 9001 a ISO 13485

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