BioVendor Group CLIA

Tetanus toxoid

Monitoring of Tetanus Toxoid IgG antibodies

Tetanus Toxoid IgG

Diagnostic panel:
Vaccination Monitoring

IVD CE 2265

The kits are CE-IVD certified and intended for professional use.

Designed for the platform Kleeya®

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.

Tetanus Toxoid IgG

Clinical applications

– Monitoring of Tetanus Toxoid IgG antibodies in human serum or plasma in the general population

Result interpretation

The level of antibodies (IU/ml) in the samples is calculated by the device based on the calibration curve for the batch. The interpretation of the results of quantitative test evaluation is given in the Table.

Quantitative interpretation in Units (IU/ml)

Antibody level (IU/ml)	Evaluation
< 0.01	Antibodies are negative: basic vaccination and serology is needed in 4 to 6 weeks.
0.01–0.1	A booster dose is recommended.
0.1–0.5	A booster dose is recommended.
0.5–1.0	It is recommended to give a booster vaccine or check the antibody titre in 2–3 years at the earliest.
1.0-5.0	It is recommended to check the antibody titre at the earliest in 5 years.
> 5.0	It is recommended to check the antibody titre at the earliest in 8 years.

Quantitative evaluation in international units was derived from the WHO international standard (13/240).

Antigens

CLIA Tetanus Toxoid
Tetanus toxoid recombinant fragment C

Measurement range of the kit

0.01-5.00 IU/ml

Correlation of methods

CLIA kits were compared to established ELISA kits from TestLine of the BioVendor Group. A 96–99% agreement was found between the compared methods.

Accuracy and analytical sensitivity

High precision ensures consistent and reliable results of each measurement:

Repeatability	Intra assay (within run)	5.25%
	Within-laboratory precision	8.39%

The excellent analytical sensitivity of determination and interval linearity allow precise quantification of the result:

Limit of detection	0.01 IU/ml
Limit of quantification	0.01 IU/ml
Linearity interval	0.02-5.00 IU/ml

Clinical function

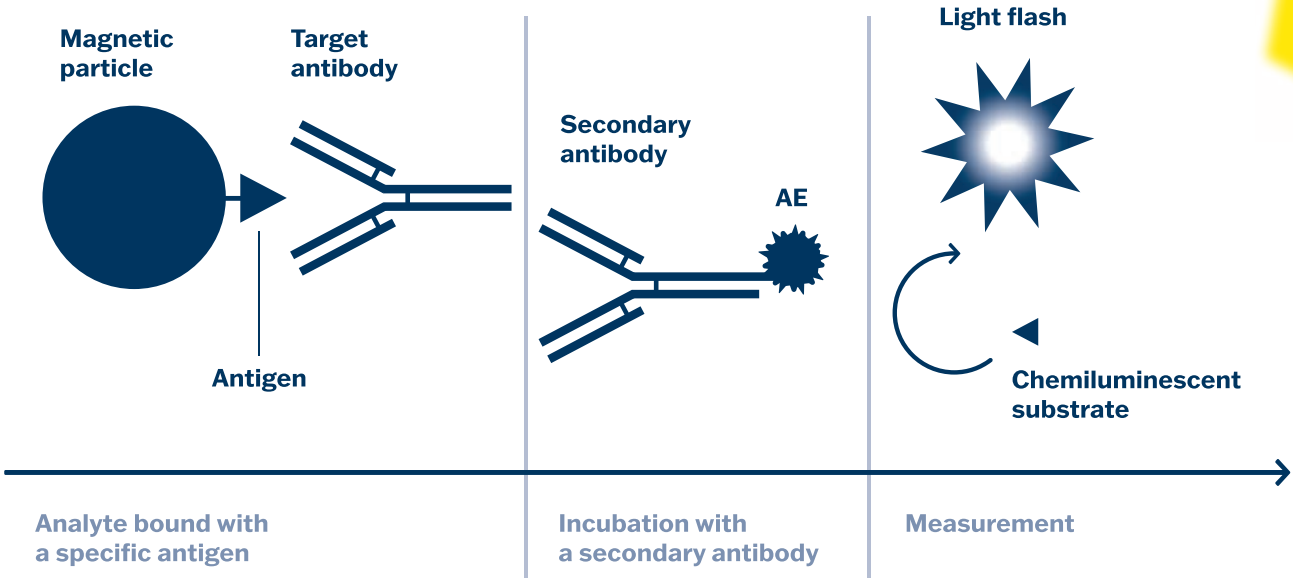
The quality of the CLIA Tetanus Toxoid IgG kit was verified within an external clinical performance study at a specialized laboratory according to the strict requirements of the European IVDR directive.

The obtained comparison of 220 clinical samples with a reference commercial kit demonstrated high level of agreement in categorization at clinically significant antibody concentrations.

Comparison with the reference method	At the limit concentration 0.10 IU/ml	95.33%
	At the limit concentration 0.50 IU/ml	92.78%

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines the use of magnetic particles for immunocomplex separation of the antigen and flash chemiluminescence for sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa® automated platform.



CLIA kits

Diagnostic CLIA kits are intended for the monitoring of Tetanus Toxoid IgG antibodies in human serum or plasma in the general population on a KleeYa® analyzer.
Results are reported in IU/ml.

Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Working strength reagent solution
- Control sera available as independent sets
- Results in IU/ml

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30-40 min)
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

Diagnostic CLIA kits are intended for the monitoring of Tetanus Toxoid IgG antibodies in human serum or plasma in the general population on a KleeYa® analyzer.

Kit	Catalogue number	Number of tests
CLIA Tetanus Toxoid IgG	CL-TeTG100	100

Control set

Each set contains two vials with positive and two vials with negative control serum with predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Control set CLIA	Catalogue number	Number of tests
Control set CLIA Tetanus Toxoid IgG	CL-TeTGCON	2 x 20

Contact us at

clia@biovendor.group

or visit our website

clia.biovendor.group

BIOVENDOR.GROUP

PRODUCER:

TestLine®

TestLine Clinical Diagnostics s.r.o.
Křižíkova 68
612 00 Brno
Czech Republic

ENIP1001