ENGLISH

Immunochromatographic test for the visual detection of anti tetanus antibodies in human serum, plasma or whole blood, to aid in the determination of immune status.

TE-20B / S-GZ-20 (20 tests)
TE-40B / S-GZ-40 (40 tests)

In vitro Diagnostic (Professional use only)

1. INTRODUCTION

a) Clinical context
Tetanus is even today a worldwide problem: several hundred thousand people all over the world are affected each year by this toxigenic infection.
Tetanus toxin, a potent microbial toxin produced by Clostridium tetani, has a molecular weight of 150 000 and consists of a heavy chain which contains the site that binds to nerve cells and a light chain which is thought to contain the toxic moiety of the molecule. Tetanus toxin is assumed to exert its main pathogenic action in the central nervous system by inhibiting the release of neurotransmitter.
Mass immunization with tetanus toxoid (the formalin-inactivated toxin) has proved fully effective in protecting populations against tetanus. A knowledge of the immune status of a population against tetanus may have practical applications. It may assist in checking the efficacy of the immunization schedules adopted and the persistence of immunity. It may also be helpful to the clinicians in a hospital's emergency room in the choice of the correct antitetanus prophylaxis for patients at risk for tetanus.
It is generally admitted in the literature that a patient:
- is slightly or not protected when the titer of anti-tetanus antibodies in the serum is < 0.1 IU/ml;
- is correctly protected when the titer is ≥ 0.1 IU/ml

b) Significance of the test
The patients admitted to the emergency unit with open wounds and thus, with a risk of tetanus, sometimes make mistakes about their immune status.
This is the reason why the physician can decide to give no booster to a patient believing to be immunized while really unprotected or to give a booster to a patient believing to be unprotected while really vaccinated.

In the first case, the patient risks tetanus while in the second, the patient risks hyperimmunization.
The knowledge of the immune status of a patient at risk for tetanus would be helpful to the physicians in hospital emergency rooms in their choice of the correct antitetanus prophylaxis. Determination of the level of tetanus antibodies is an efficient way of knowing the immune status. Moreover, getting a result quickly is one more advantage.
This is possible with the TETANOS QUICK STICK which can determine the immune status of a patient within 10 minutes. This test detects antibody levels ≥ 0.1 IU/ml in serum which corresponds to a sufficient protection.
According to the result of the TETANOS QUICK STICK and according to the infectious risk of the wound, the physician is able to choose the adapted prophylaxis.

2. PRINCIPLE OF THE TEST

TETANOS QUICK STICK is a rapid one-step immunoassay based on the immunochromatographic principle. The method uses a combination of tetanus toxoid coated on the solid phase and a mix of colloidal gold conjugates including the tetanus toxoid-dye conjugate. The human blood or serum or plasma sample is added to the appropriate sample well of the TETANOS QUICK STICK and the diluent is then added to the same well.
The diluent flows through the absorbent pad, carrying the toxoid-dye conjugate along the chromatographic strip which forms a complex with the anti-tetanus IgGs present in the sample. These complexes react with the immobilized toxoid to form a pink line in "T" window.
If no anti-tetanus IgGs are present, the test window "T" will remain clear.
The excess of gold conjugates binds to a control reagent immobilized in the "C" window forming a pink line indicating that the test has been carried out correctly.

3. KIT CONTENTS

TE-20B / S-GZ-20 (20 tests):

Each kit contains everything needed to perform 20 tests.
- 20 test units individually packaged in aluminium pouch (single use) with 20 disposable plastic pipettes.
  The stick is included in the test unit, which has 2 windows:
  - sample and diluent dispensing well
  - T: area where the test line appears
  - C: area where the control line appears.
- 1 diluent vial of 5 ml PBS pH 7.2; detergent 0.1% and sodium azide 0.05%
- Instruction leaflet

TE-40B / S-GZ-40 (40 tests):

Each kit contains everything needed to perform 40 tests.
- 40 test units individually packaged in aluminium pouch (single use) with 40 disposable plastic pipettes.
  The stick is included in the test unit, which has 2 windows:
  - sample and diluent dispensing well
  - T: area where the test line appears
  - C: area where the control line appears.
- 2 diluent vials of 5 ml PBS pH 7.2; detergent 0.1% and sodium azide 0.05%
- Instruction leaflet
- 40 safety lancets

4. PRECAUTIONS

1. For in vitro diagnostic use.
2. Do not use the test if the aluminium pouch is damaged.
3. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour.
   Alternatively, they can be treated with 0.5 to 1% solution of sodium hypochlorite for one hour before disposal.
4. Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
5. Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
6. Avoid any contact between hands and eyes or nose during specimens collection and testing.
7. Enzyme Reagent Diluent contains 0.05 % sodium Azide as an antimicrobial preservative. Users should be aware of its toxic properties if absorbed or ingested; also that disposal of this reagent should be accompanied by copious flushing with water to avoid accumulation of explosives alts in plumbing systems.

5. STORAGE AND STABILITY

- TETANOS QUICK STICK kit should be stored at any temperature between 4° to 30°C.
- Do not freeze the test kit.
- You can use the kit until the expiry date indicated on the box.

6. SPECIMEN COLLECTION

1. TETANOS QUICK STICK test is performed on human blood, serum, plasma (citrate or EDTA) or re-calcified plasma.
2. Patients samples are best performed if tested immediately. Specimens should be refrigerated immediately at 2-8°C following collection up to 3 days. If the testing within 3 days is not possible, sera and plasmas should be frozen (-20°C).
   If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents.
3. Specimens containing precipitate may give inconsistent tests results. Such specimens should be clarified prior to assaying (5' at 1000g).

7. TEST PROCEDURE

1. Remove the desired number of TETANOS QUICK STICK test units from the protective wrapper (by tearing along the split) and place on a level surface.
2. Label test unit with patient name or identification number.
3. The test can be performed on whole blood, serum or plasma.

   * On whole blood
   The finger should be cleaned properly. After puncture with a single use lancet, fill the pipette with specimen, dispense the correct volume of blood with the plastic pipette into the sample well. (see scheme)

   * On serum or plasma
   Dispense 20 µL of specimen (see scheme) into the sample well.

4. Add 3 drops of diluent within 10 seconds, holding the flask vertically above the sample well and avoiding touching it with the dropper.
5. The test should be read 10 minutes after adding the diluent to the sample well.

If no colored liquid appears in the second window after 2 minutes, you can add one more drop of diluent in the sample well.

8. INTERPRETATION OF RESULTS

1. Test validation:
   One pink colored line appears in the control window ("C") showing that the test has been carried out correctly.

2. Test interpretation:

- No apparent colored line in the test window (T): the test is negative for anti-tetanus antibodies.

- In addition to the colored line in control window ("C"), a clearly distinguishable pink colored line also appears in the test window ("T") indicating a positive result and that the sample contains anti-tetanus antibodies.
  Differences of intensity and width may occur between the lines in the test window and the test control window but this does not affect the interpretation of the results.

- Inconclusive : If no line appears in the control window the test should be repeated with another test unit.

3. TQS reader interpretation:

   The test can be read using a TQS reader. This TQS reader display negative or positive results depending of the level of antibodies present in the sample. The result is printed on a receipt (see to the TQS reader instruction use : Code H-GY-000).

9. QUALITY CONTROL PROCEDURE

Good laboratory practice recommends the use of control materials to ensure proper kit performance.
A positive calibrated anti-tetanus serum as a means of quality control testing can be used for this purpose.
Add 1 drop of positive control (Code S-GZ-C2, available on request) to the sample well, then 3 drops of diluent to the same well, then run the test as under Test Procedure.

10. EXPECTED VALUES

Typically, TETANOS QUICK STICK will detect any level of anti-tetanus antibodies
≥ 0.1 I.U/ml in serum
≥ 0.2 IU/ml in whole blood.
Usually this level of sensitivity shows up 10 minutes after addition of the diluent to the test unit.

11. PERFORMANCE CHARACTERISTICS

A. Precision

1. Intra-assay
Within run precision was determined by using 10 replicates of 3 specimens containing respectively 0, 0.5 and 20 IU/ml. The negative and positive values were correctly identified 100 % of time.

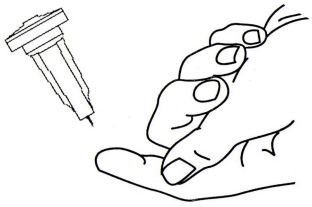
2. Inter-assay
Between runs precision was determined by using the same 3 specimens containing 0, 0.5 and 20 IU/ml in 10 independent assays and tested with 3 different lots of TETANOS QUICK STICK test units. The negative and positive values were correctly identified 100 % of the time.

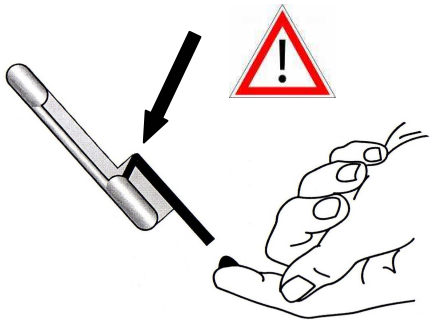
B. Clinical validation

200 serum samples were tested by GAMMA using a Gamma Tetanus ELISA kit and the TETANOS QUICK STICK.

Number of samples	**34**	**9**	**157**
Titer (ELISA) IU/ml	<0.1	0.1 ≥ titer ≥ 0.14	>0.14

The 34 samples < 0.1 IU/ml are negative in TQS.
The 157 > 0.14 are positive in TQS.
For the 9 samples between 0.1 and 0.14 IU/ml, after a second confirmation test, six samples are discrepant: 0.10, 0.11 and 0.12 IU/ml in ELISA while negative with the TQS.





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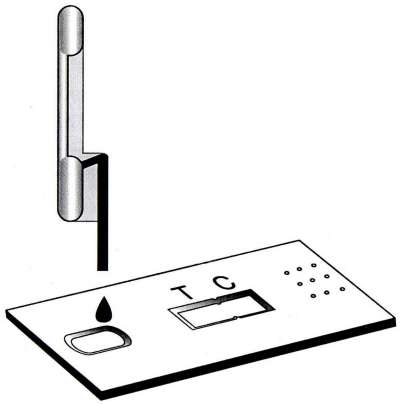
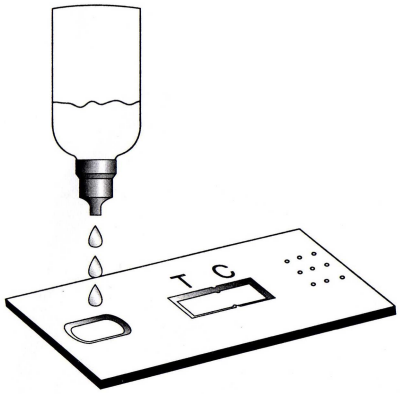


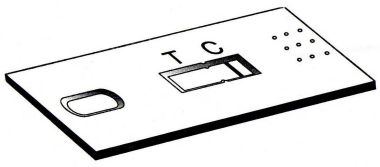


en) Correct Filling
(fr) Remplissage Correct
(it) Livello di riempimento adeguato

(en) 1. Dispense 1 drop of sample in sample well
2. Within 10 seconds, dispense 3 drops of diluent in sample well
Read results after 10 minutes

(fr) 1. A l'aide de la pipette, déposer la totalité du sang dans la fenêtre de dépôt
2. Ajouter rapidement (dans les 10 secondes) 3 gouttes de diluant dans la fenêtre de dépôt
Lire les résultats après 10 minutes

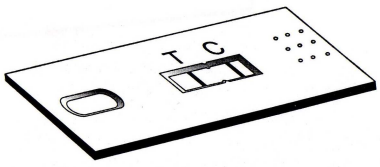
(it) 1. Dispensare una goccia del campione nel pozzetto di reazione.
2. Tra i 10 secondi, dispensare 3 gocce di diluente nel medesimo pozzetto
Leggere il risulato dopo 10 minuti



Negative
One coloured band appears in control windows (C)

Négatif
Une ligne colorée apparaît dans la zone contrôle (C)

Negativo
1 banda colorata compare solamente nelle zona di controllo (C)



Positive
Two coloured band appear in test (T) and colored (C) windows

Positif
2 lignes colorées apparaissent dans la zone test (T) et la zone contrôle (C)

Positivo
2 bande colorate compaiono rispettivamente nella zona del test (T) e nella zona di controllo (C)