AAZ
Votre santé sous contrôle

TetaQuick®

CE

Rapid Test for the Determination of Immune Status with Tetanus Ref. TR-TET-001

INDICATION FOR USE

TetaQuick® is a solid-phase immunochromatographic assay for the rapid and qualitative detection of antibodies to *Clostridium tetani* in human whole blood, serum or plasma. This test is used to determine the immune status against tetanus.

INTRODUCTION

Tetanus is an acute, serious infectious disease that can lead to death. It is caused by a toxin produced by *Clostridium tetani*.
When a wound is contaminated with soil, spores of *Clostridium tetani* can grow and release a toxin that can lead to generalized muscle spasms and stiffness.
Tetanus prevention is based on vaccination with an toxoid, which confers significant and long-lasting immunity since 91% of subjects are still immune 10 years after vaccination. However, in industrialized countries, although rare, tetanus has not disappeared, despite an efficient vaccination system.
In an emergency context of consultation for injury, management is based on wound washing and disinfection and immunization by injection of tetanus toxoid and/or tetanus antitoxin immune globulin. During the consultation, the patient's vaccination status with regard to tetanus is best assessed by examining the vaccination record or, failing that, and most often in practice, by questioning the patient. However, French data show that the vaccination record is not available in 90-95% of cases and various studies have shown that patients do not know or are unaware of their real vaccination status1.
The difficulty of accessing this data leads a majority of emergency departments to resort to the use of rapid immunochromatographic tests to define the patient's vaccination status with regard to tetanus and to implement appropriate prophylaxis[2,3,4].

PRINCIPLE OF THE TEST

TetaQuick® is a lateral flow immunochromatographic assay. The test uses human antibodies to IgG (test line) immobilized on a nitrocellulose strip. The conjugate (tetanus toxin antigens labeled with colloidal gold) is also integrated into the strip.
When the blood sample is added to the sample well (S) and then the buffer to the buffer well (B), the IgG antibodies, if present, bind to the anti-tetanus toxin conjugates, forming antigen-antibody complexes.
These complexes migrate through the nitrocellulose membrane by capillary action. When the complexes meet the line of the corresponding immobilized antibody, the complexes are trapped and form a burgundy band that confirms the reactivity of the assay. The absence of a coloured band in the test region indicates a negative result.

EQUIPMENT PROVIDED

- 10 sealed pouches each containing a test cassette, a 50µl pipette and a moisture absorber
- 10 Buffer Bottles
- 10 Safety Lances
- 10 alcohol swabs
- 1 user manual

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection containers (for venous blood only)
- Centrifuge (for obtaining plasma only)
- Laboratory pipettes (if using venous blood or plasma/serum only)
- Timer

CONSERVATION AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). Do not freeze the kit. The kit is stable until the expiry date printed on the kit. REMOVE THE CASSETTE FROM THE SEALED POUCH ONLY JUST BEFORE DEPOSITING THE SAMPLE.

WARNINGS AND PRECAUTIONS

- For professional in *vitro* diagnostic use only for professionals. Do not use after the expiration date indicated on the package.
- Read the entire procedure carefully before performing the test. Failure to follow the procedure may result in incorrect results .
- Do not use if the sealed pouch is damaged or the buffer tube is broken.
- The test cassette is for single use. Do not reuse under any circumstances.
- Handle all specimens as if they contained infectious agents. Follow the safety instructions for microbiological hazards and follow the procedures in place for the proper disposal of samples.
- Wear protective clothing such as lab coats, disposable gloves, and goggles during procedures.
- Humidity and temperature can affect the results.
- The equipment used must be disposed of in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

TetaQuick® can be made from serum blood or plasma.

For fingerstick whole blood samples (use of the 50µL pipette):
- Collect blood as described in the "Procedure" section below.

To collect whole blood samples by venipuncture:
- Collect a blood sample treated with anticoagulants (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.

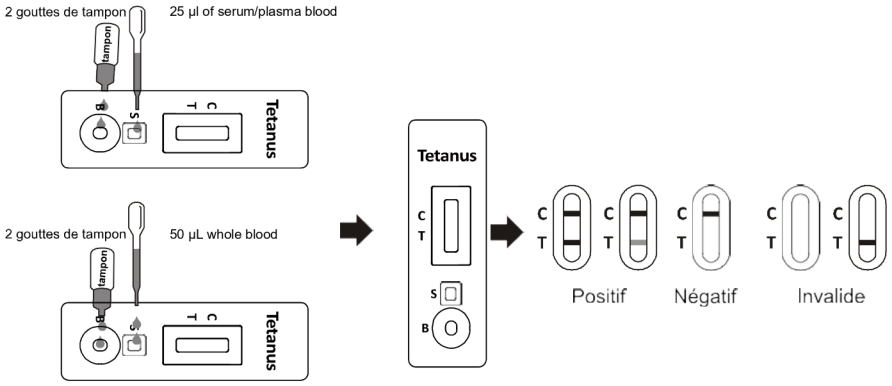
To collect serum or plasma samples:
- Collect whole blood by venipuncture.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.

Perform the test immediately after sample collection. Do not leave samples at room temperature for long periods of time. Serum and plasma samples can be stored at a temperature between 2 and 8°C for up to 3 days. For long-term storage, samples should be stored at a temperature below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be performed within 2 days of collection. Do not freeze whole blood samples. Whole blood taken from the fingertip should be tested immediately.
Allow samples to reach room temperature before testing. Frozen samples must be completely thawed and thoroughly mixed before performing the test. Samples should not be frozen and thawed repeatedly.
If samples are to be shipped, they must be packaged in accordance with local regulations regarding the transport of infectious agents.

PROCEDURE

Ensure that the sample and test components are at room temperature (15-30°C) before proceeding with the test. Remove the cassette from the sealed pouch and just before performing the test.

1. Place the cassette on a flat, clean surface.
2. Perform the test as follows, depending on the type of sample:
   - For **fingerstick whole blood samples (use of the 50µL pipette)**
     - Disinfect the fingertip with the alcohol swab
     - Using the lancet, prick the side with the fingertip. Form a large drop of blood suspended.
     - Hold the pipette horizontally and bring the end of the pipette into contact with the blood. The pipette fills automatically. Fill it in to the black line.
     - Hold the pipette vertically over the cassette and transfer the entire (approx. 50 µL) to the sample well (S) then add 2 drops of buffer (approx. 80 µL) to the buffer well (B) and start the timer.
   - For **venous whole blood samples** : collect **50µl** of blood sample using a laboratory pipette and place it in the sample well (S) of the cassette. Immediately add 2 drops of buffer (approx. 80µl) to the buffer well (B) of the cassette and start the timer.
   - For **serum or plasma samples** : take **25µl** of serum/plasma sample using a laboratory pipette and place it in the sample well (S) of the cassette. Immediately add 2 drops of buffer (approx. 80µl) to the buffer well (B) of the cassette and start the timer.
3. Wait for the coloured stripe(s) to appear.
   Read the results at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF THE RESULTS

Positive : The control line (C) and the test line (T) appear in the result window. This indicates a positive outcome.

Negative : Only the control line (C) appears in the result window. This indicates a negative result.

Invalid : The control line (C) does not appear in the result window. Insufficient sample volume or incorrect execution of the procedure are the most likely reasons for the control line to fail. Review the procedure and repeat the test with a new test cassette. If the problem persists, stop using the kit and contact your local distributor.

Note: The intensity of the color in the test area (T) may vary depending on the concentration of tetanus antibodies present in the sample. Therefore, any color shade in the test area should be considered positive.

QUALITY CONTROL

Internal quality control
Internal quality control is included in the test. The appearance of a control red line (C) confirms that the test procedure has been followed correctly.

BOUNDS

- TetaQuick® is intended for *in vitro* diagnostic use. The test should be used for the detection of tetanus antibodies in whole blood, serum or plasma samples only. Neither the quantitative value nor the rate of increase in the concentration of tetanus antibodies can be determined by this qualitative test.
- Failure to follow the test procedure may adversely affect the performance of the test and/or invalidate the test result.
- A negative result may occur if the antibodies detected are not present at the stage of the disease at which the sample is collected or if the level is below the detection limit of the test.
- The haematocrit of whole blood should be between 25% and 65%.

PERFORMANCE

The TetaQuick® test was evaluated against another rapid test. A total of 70 positive and 85 negative samples were collected. The sensitivity and specificity results obtained are summarized in the following table:

Technique		**Reference Test**		**Total**
TetaQuick®	Results	Positive	Negative	
	Positive	69	1	70
	Negative	1	84	85
Total		70	85	155

Relative sensitivity: 98.6% (95%CI*: 92.3%-99.9%)
Relative specificity: 98.8% (95%CI*: 93.6%-99.9%)
Accuracy: 98.7% (95%CI*: 95.4%-99.8%)
* Confidence intervals

Limit of detection (positivity threshold or cut off)
According to WHO recommendations, the minimum detection concentration for antibodies to tetanus has been set at 0.1 IU/mL5.

Precision
Within: 4 samples (one negative, one low positive, one medium positive, and one strong positive) were tested 10 times each. Samples were correctly identified in more than 99% of the time.

Inter-batch : 4 samples (one negative, one weak positive, one medium positive and one strong positive) were tested 10 times out of 3 batches. Samples were correctly identified in more than 99% of the time.

Prozone or Hook Effect
No prozone effects were detected at a concentration of up to 45 IU/mL.

Cross-reactions
The substances listed below have been tested. The

results showed no cross-reaction.

HIV	*Rubella virus*	*Hepatitis A virus IgG*
Hepatitis B virus	*Pertussis IgG*	*Varicella-zoster virus IgG*
Pale treponeme IgG	*Epstein-Barr virus IgG*	*IgG of mycoplasma pneumonia*
Cytomegalovirus IgG	*Herpes simplex virus IgG*	*Toxoplasma gondii IgG*
IgG of diphtheria toxoid	*Rheumatoid factor*	

Interference
The results showed no interference.

The kit was tested for possible interference with visibly hemolysed and lipemic samples, as well as serum samples containing elevated bilirubin levels. The results showed no interference. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin, up to 1,000 mg/dL bilirubin, and up to 2,000 mg/dL human serum albumin.

LITERATURE REFERENCES

1. Elkharrat D. et al, Impact of guidelines to alter antitetanus prophylaxis practices and reduce costs in the emergency department. Am J Ther. 1999; 6, (4): 203-9.
2. Thiebaux A. et al. Clinical and economic interest of a rapid miosis test in evidence of tetanus immunoprotection. J. Pharm. Clin. 2003; 22, (1): 31-35.
3. Colombet I. et al. Diagnosis of Tetanus Immunization status: Multicenter Assessment of a Rapid Biological Test. Blinking. & Diagn. Lab. Immunol. 2005; 12, (9): 1057-1062.
4. Stubbe M. et al. Improving tetanus prophylaxis in the emergency department: a prospective, double-blind cost-effectiveness study. Belgian Society of Emergency and Disaster Medicine. Emerg Med J. 2007; 24, (9): 648-53.
5. Borrow R. et al., WHO, The immunological basis for immunization series. Module 3 Tetanus updated. 2006.

SYMBOL LEGEND

	Read the user manual	Σ	Number of tests per kit		Maker
IVD	For use in *in vitro diagnostics* only		Expiry date		Do not reuse
2°C 30°C	Store between 2 and 30°C	LOT	Lot number	REF	Reference
CE	CE marking				

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