PreventID® **TB Combo**

Manual (FOR PROFESSIONAL USE)

REF KST55010G5
KST55010GP

Intended Use

The **PreventID® TB Combo** rapid test is a multi-antigen chromatographic immunoassay for the qualitative detection of human anti-TB (*M. tuberculosis*, *M. bovis* and *M. africanum*) antibodies (all isotypes: IgG, IgM, IgA etc.) in whole blood, serum or plasma (heparin). The test is intended for the use as an aid in the diagnosis of TB. The test does not recognize BCG antibodies.

Introduction

Tuberculosis (TB) is – along with AIDS and Malaria – the most widely spread infectious disease worldwide. The World Health Organization (WHO) estimated 2015 more than 10 million new TB cases worldwide and tuberculosis accounts for 2 millions deaths annually. If not treated properly, TB disease can be fatal. Two-thirds of the world's tuberculosis-infected people reside in Asia and Africa and this will have a significant impact on the control of TB in other countries as a result of increased immigration.
TB is caused by the tubercle bacillus *Mycobacterium tuberculosis*, and rarely by *M. bovis* or *M. africanum*. The initial pulmonary infection usually goes unnoticed with lesions healing, sometimes leaving traces of calcified scar tissue. The infection may however progress to pulmonary tuberculosis, or through blood or lymphatic spread produce miliary, meningeal or other extrapulmonary involvement.

Materials

Materials Provided

- Test devices (with sample droppers), individually packed TEST
- Manual

Materials Required but not Provided: Alcohol pad, sterile lancet, clock; for whole blood: blood collection tubes for anti-coagulated blood sample (sodium heparin or lithium heparin)

Storage and Stability

The **PreventID® TB Combo** test devices should be stored at room temperature or refrigerated (4–30 °C). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the pouch. Do not use it beyond the expiry date.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimen.
3. Wear protective gloves and wash hands thoroughly after performing the test.
4. Avoid splashing or aerosol formation while handling specimen and performing the test.
5. All samples and materials used should be treated as potentially infectious and disposed in a biohazard container. Clean all contaminated objects and surfaces carefully.
6. Do not use test if the pouch is torn or if the membrane of the test device is visibly damaged.
7. Read the instruction carefully before performing the test.
8. Do not mix reagents from different lots
9. If you have any questions please contact Preventis GmbH.

Specimen Collection and Test Procedure

1. Remove the test device from the pouch.
2. Place the test device on a flat, dry surface, the sample application window directed to the right side *(Fig. 1)*.

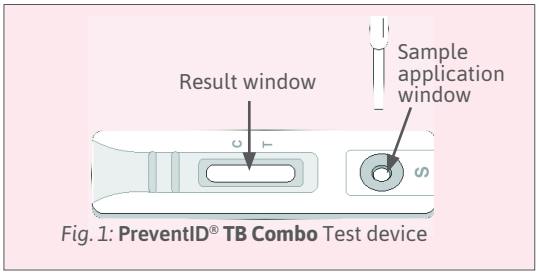

Fig. 1: **PreventID® TB Combo** Test device

3. a) **Whole blood**
   - Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing.
   - Hold the sample dropper above the test device and add 1 hanging drop into the sample application window. After the drop is absorbed, add another hanging drop. Repeat the procedure until a **total of 3 hanging drops** have been added to the sample application window.

   b) **Plasma / Serum**
   - Centrifuge whole blood to get plasma/serum specimen.
   - Hold the sample dropper above the test device and add 1 hanging drop into the sample application window. After the drop is absorbed, add another hanging drop.
   - If specimens are not immediately tested, they should be refrigerated at 2–8 °C. Specimens should be at room temperature before running a test.
   - Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
4. As the test begins to work, you will see purple colour move across the result window in the center of the test device.
5. Interpret test results **at 10 to 15 minutes**. Do not interpret the test after 20 minutes.

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Test Interpretation *(Fig. 2)*

A coloured **control line (C)** at the left side of the result window indicates that the test has run correctly.

The test result is indicated by the appearance or non-appearance of a coloured **test line (T)** on the right side of the result window.

Positive:
If both test (T) and control (C) lines appear in the result window, the test is positive: Antibodies against *M. tuberculolsis*, **M. bovis** or *M. africanus* have been detected in the sample *(Fig. 2a)*.

Negative:
A solitary control line (C) in the result window indicates a negative result *(Fig. 2b)*. No antibodies against *M. tuberculosis, M. bovis* or *M. africanus* have been detected.

Invalid:
If no control line (C) is visible after performing the test, the test result is considered invalid *(Fig. 2c)*. The test result is also considered invalid if only the test line (T), but no control line (C) appears. In this case, the test must be repeated with a new test device.

Fig. 2a
positive

Fig. 2b
negative

Fig 2c
invalid

invalid

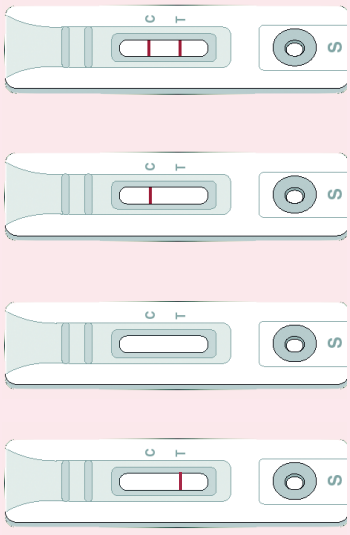

Fig. 2: **PreventID® TB Combo** Test Interpretation

Beware: The above interpretation time is based on reading the test results at room temperature (15–30 °C). If the test components have been stored beneath 15 °C they have to be adapted to room temperature before testing.

Test characteristics

Clinical Sensitivity and Specificity

The sensitivity and specificity determination of **PreventID® TB Combo** was performed with sputum smear alone and with sputum smear / blood culture combination (Gold Standard).
It is important to note that the sputum smear and blood culture detects Tb antigen while **PreventID® TB Combo** detects antibody to Tb.
For the purpose of this comparison, any count of bacillus is considered to be Tb positive.

Conclusion: In comparison with sputum smear, **PreventID® TB Combo** has a sensitivity of 93.7 % (74/79) and specificity of 89.6 % (198/221).

Specificity

The specificity was assessed by studying blood samples from human Tb antibody negative and positive subjects spiked with microorganisms such as M. kansasii, Campylobacter fetus, Campylobacter jejunii and E. coli. These samples were tested using the **PreventID® TB Combo** by a replicate of 10.
The Tb positive samples all showed a positive result, the Tb negative samples all showed negative results, so the spiked microorganisms do not interfere with the test.

Test Limitations

Although the **PreventID® TB Combo** test is very accurate in detecting antibodies against M. tuberculosis, M. bovis and/or M. africanus, a low incidence of false results can occur. There have been few cases reported of false-negative results in HIV-positive samples of AIDS patients. Other clinically available tests are required if questionable results are obtained.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

References

1. Robert-Koch-Institut, http://www.rki.de (Status 2017-05-18)
2. Dixon RE: Symposium on nosocomial infections (Parts I,II and III). Am J Med 70:379-473, 631-744, 899-986, 1981.
3. Pennington JE: Respiratory Infections: Diagnosis and management. New York, Raven Press, 1983.

Short Instruction PreventID® TB Combo

1. Remove the test device and the sample dropper from the pouch. Place the test device on a flat, dry surface.
2. Let **3 hanging drops** of whole blood or serum/plasma flow into the sample application window.
3. Interpret the test result at **10 to 15 minutes.** Do not interpret the test after 20 minutes.

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Status: 2018-12-04

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests
Keep away from sunlight	

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