

INNOVUS

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A METHOD FOR DIAGNOSING TUBERCULOSIS

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A diagnostic test suitable for all patients including children.



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BRIEF DESCRIPTION

A method for speedy and accurate diagnosis of tuberculosis (TB) and a device to perform the diagnosis have been developed. The method entails the identification of biomarkers that confirm the presence of TB in a patient. The diagnostic device used in the method can detect and indicate the presence of biomarkers in a blood sample. The blood sample, which can be either plasma or serum, is collected into the device where the levels of up to 5 host biomarkers are measured directly in the serum or plasma. If the marker levels are above a certain threshold, it will be indicative of the presence of TB.

TARGET MARKET

- Public and private hospitals
- National tuberculosis control programs
- Health ministries

VALUE PROPOSITION/BENEFITS

Tuberculosis is one of the developing world's biggest killers, second only to HIV/AIDS. The 9.4 million new cases and 1.7 million deaths each year are partially due to problems with diagnosing the disease timely and accurately. Currently, the diagnosis of TB can take up to 42 days and provides an accuracy rate of only 50%. This new method of diagnosing TB in a patient is fast and accurate. In addition, the new diagnostic method doesn't depend on a sample of sputum which is often of poor quality or difficult to obtain. Instead a blood sample is used.

COMPETITIVE ADVANTAGE

- Diagnosis is rapid. Results will be confirmed within 15 – 20 minutes after providing a blood sample.
- The new method produces accurate results. Human error is excluded as the results will be read by a hand-held device.
- The diagnostic test is suitable for all patients, including children.
- The blood sample is easy to get and the test is simple to do. The test can be performed by nurses in remote settings.
- The diagnostic test is affordable - it doesn't require a laboratory with laboratory equipment or a stable electricity supply.
- Improved health service. Patients can go to a clinic for consultation, get their results and medication at point of care within one hour.

The ultimate advantage of the new diagnostic method will be the millions of lives saved worldwide thanks to accurate and timely diagnosis of the disease.

TECHNICAL DESCRIPTION

The invention comprises two aspects: the collection of blood or serum in a device and the detection of novel biomarkers for the presence of the disease tuberculosis. Biomarkers for TB are detected from different groups of biomarkers.

The device used in the diagnostic process can collect a blood sample and detect and indicate the presence of biomarkers in the blood sample. The capture agents and indicators are present in the device and once the blood sample has been loaded onto the device, the sample is brought into contact with the capture agents, which are allowed to bind to the biomarkers if present. The indicator will signify when binding has occurred. Different means for detecting binding of the capture agent to the biomarker are possible.

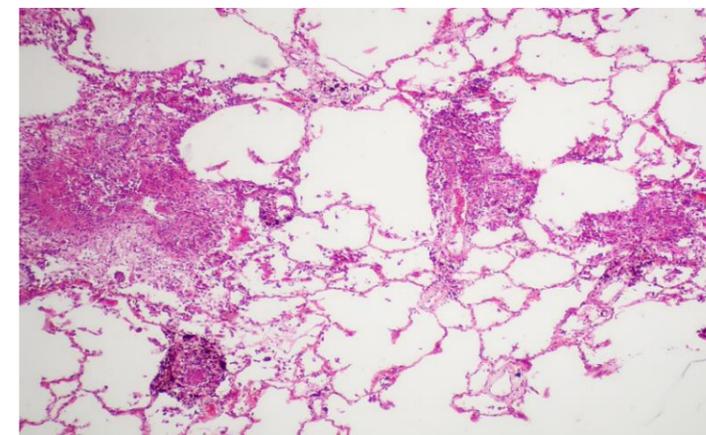
In particular the device is a hand-held lateral flow device.

The invention also includes a kit for diagnosing TB in a blood sample with instructions for performing the method of diagnosing.

INNOVATION STATUS

A South African provisional patent application (no. 2014/01456) has been filed for this innovation.

A cost effective diagnostic test with high accuracy results



Lung - miliary tuberculosis

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