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# UCT and partners develop test that diagnoses TB Meningitis within two hours

The University of Cape Town, in partnership with Antrum Biotech, have developed a new rapid test that is able to diagnose TB meningitis – a major cause of death in Southern Africa – within two hours. The test is currently undergoing validation to enter the global market.

Until now, diagnostic tests have not been as quick or as sensitive as they need to be. Finding a sensitive, rapid test for TB meningitis has been elusive, but thanks to BioFISA II funding and researchers at Antrum Biotech, one has been developed.

Professor Keertan Dheda, the director of the Centre for Lung Infection and Immunity at UCT, says: "Detection under the microscope only works 5% of the time. Smear microscopy is a very poor test.

"Another existing test for TB meningitis involves growing the bug in the lab in a culture, and there are problems with that too."

This culture-based test has a sensitivity of only 60% to 70%, and it can take four to eight weeks to give a result. "By then most people would have died, or they would have developed severe disabilities due to the disease," says Dheda.

The GeneXpert DNA detection test for TB is widely used in South Africa, but studies show that it is not sensitive enough to detect TB meningitis, but the test has limited sensitivity. "Although it is rapid in getting the answer on the same day, the problem is that it detects TB meningitis in only 50-60% of cases; we have a major unmet need for a more sensitive test," says Dheda.

"Preliminary results from our studies show a vast improvement in sensitivity when compared to GeneXpert," he says.

Khilona Radia, CEO of Antrum Biotech, says: "The accurate diagnosis of TB meningitis represents an unmet need in public health, with problems of missed diagnosis and misdiagnosis affecting health outcomes. The greatest need for the test is in populations with a high burden of TB and HIV; particularly in sub-Saharan Africa where the test will be

evaluated and launched. The long-term goal of this project is to reduce global TB meningitis deaths."

Two percent of TB cases, which are caused by Mycobacterium tuberculosis, develop into an infection of the membranes around the central nervous system (meninges). This TB meningitis can cause death or disability, especially in children, but is easily treatable if diagnosed early.

Funding from the BioFISA II programme has allowed researchers to develop the test further, and it is now undergoing a series of validation studies in southern African populations to pin down its sensitivity more accurately. This will include comparative sensitivity to GeneXpert.

Antrum Biotech and its partners plan continue with validation studies even after the test goes on sale in the near future.

"There will be even larger studies and studies by different groups of people in different parts of the world to confirm the results that we found in southern Africa," Dheda says.

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