GeneXpert Test

What is GeneXpert or Xpert MTB/RIF Test?

The GeneXpert or Xpert MTB/RIF is a cartridge-based nucleic acid amplification test (NAAT) or molecular test for Tuberculosis. The GeneXpert diagnoses TB by detecting the presence of TB bacteria, as well as testing for resistance to the drug Rifampicin.

In December 2010, the World Health Organization (WHO) endorsed the Xpert MTB/RIF for use in tuberculosis (TB) endemic countries. According to the Centers for Disease Control and Prevention (CDC) in 2015, the Xpert MTB/RIF test was "revolutionizing TB control by contributing to the rapid diagnosis of TB disease and drug resistance.

How is GeneXpert Test done?

A sputum sample (or other samples) is collected from the patient with suspected TB. The sample is mixed with the reagent that is provided with the assay, and a cartridge containing this mixture is placed in the GeneXpert machine. All processing from this point on is fully automated.

How the test works?

The Xpert MTB/RIF detects DNA sequences specific for Mycobacterium tuberculosis and rifampicin resistance by polymerase chain reaction. It is based on the Cepheid GeneXpert system, a rapid, simple-to-use cartridge based nucleic acid amplification test (CBNAAT).

The Xpert® MTB/RIF purifies and concentrates Mycobacterium tuberculosis bacilli from samples, isolates genomic material from the captured bacteria by sonication and subsequently amplifies the genomic DNA by PCR. The process identifies most of the clinically relevant Rifampicin resistance inducing mutations in the RNA polymerase beta (rpoB) gene in the Mycobacterium tuberculosis genome in a real time format using fluorescent probes called molecular beacons. Results are obtained from unprocessed sputum samples in 90 minutes,

Is GeneXpert a PCR?

Yes, the Cepheid GeneXpert system is innovative cartridge based semi-automated real-time polymerase chain reaction (PCR) nucleic acid amplification technology, which can simultaneously detect MTB and Rifampicin (RIF) resistance in less than 2 hours.

Is CBNAAT and GeneXpert same?

Yes, the development of the Xpert® MTB/RIF assay for the GeneXpert platform is considered as an important breakthrough in the fight against TB. CBNAAT provides a robust and a promising role in early diagnosis of TB in head and neck as well as other cases of smear negative TB such as TB-HIV and MDR TB.

What sample is used for GeneXpert?

Sputum sample and other samples as specified by WHO. Blood and stool are not recommended for use. A person suspected of having TB needs to give a sputum sample, which the health care worker than places in a small tube

How accurate is GeneXpert? What is the Sensitivity and Specificity of GeneXpert Test?

Diagnostic efficacy of GeneXpert was assessed in 85 MTB culture positive cases with the overall sensitivity, specificity, PPV and NPV at 95% confidence interval of 98.6% (92.3–99.8), 100% (78–100), 100% (94.7–100) and 93.8% (69.7–98.9) respectively.

Commercial Information:

S. No.	Test Name	Test Code	MRP	Technique	Specimen	Temperature	Special Instructions for Sample Collection	Run days at Section	TAT / Reported on
1	Gene Xpert /TB Xpert	SMO10040	2200	Real Time PCR	BAL/Bronchial washings: Submit as much as possible 3 - 5 ml. (1 ml. Minimum) in a sterile, plastic, screw capped container. Send Refrigerated. DO NOT FREEZE. Specify type of specimen on container and TRF. Sputum: Submit morning's first freshly voided samples i.e. 5 -10 ml. (1 ml. Minimum) sputum/ 20 - 40 ml. (10 ml. Minimum) urine in sterile, screw capped container. Send Refrigerated. DO NOT FREEZE. Menstrual Blood will not be acceptable	2-8°C	DO NOT FREEZE Menstrual Blood will not be acceptable for sample processing	Every day if received before 10:00 am	Next Working Day by 7:00 p.m.