

Xpert® MTB/RIF

Two-hour detection of MTB and resistance to rifampicin.

*Go from test and wait
to test and **treat**.*



CE IVD In vitro diagnostic medical device

defining *on-demand* molecular diagnostics.

“If you were to inoculate an Xpert® MTB/RIF test at the same time you started preparing your acid fast smears, by the time you finished reading the smears, the Xpert MTB/RIF test result would be ready, telling you if your positive acid fast smear was TB *and* if the strain was resistant to rifampicin, which is an excellent surrogate marker for MDR-TB. I’m sure Koch and Pasteur would not only be delighted with the technological advance, they would probably say, **‘It’s about time’.**”

Fred Tenover, Ph.D.
Cepheid Senior Director of Scientific Affairs



The Need

Current Testing Methodologies Are Too Slow

According to the World Health Organization (WHO), *Mycobacterium tuberculosis* (MTB) is considered to be vastly under diagnosed today, despite approximately 500,000 new active cases reported in the WHO European region during 2007. This is a direct result of current MTB testing methods requiring weeks to deliver a definitive result, which can lead to patients being left untreated or placed on ineffective therapies. These patients may continue to spread MTB to others in the community, increasing the disease burden.

Drug Resistant Strains

With the worldwide re-emergence of TB, multi-drug resistant (MDR) and extensively drug resistant (XDR) strains have become an even greater threat. According to the WHO Global Tuberculosis Control Report 2009, there may be more than 500,000 cases of MDR-TB worldwide. Current testing for drug resistance can take more than 4 weeks, leading to higher mortality and the further spread of MDR strains.

The Solution

Xpert® MTB/RIF

- Simultaneous detection of both MTB and rifampicin resistance, a marker for MDR strains
- Unprecedented sensitivity for detecting MTB — even in smear negative, culture positive specimens
- Results in two hours; requires no instrumentation other than the GeneXpert® System
- On-demand results enable physicians to treat rapidly and effectively

Sensitive

- Hemi-nested PCR increases sensitivity
- Highly sensitive for confirmation of both smear positive and smear negative samples
- Robust sonication/mechanical DNA extraction procedure
- Internal extraction control assures extraction performance

XPRT® MTB/RIF ASSAY VERSUS AFB AND CULTURE STATUS

		AFB-		AFB+
		Culture POSITIVE	Culture NEGATIVE	Culture POSITIVE
Xpert MTB/RIF	MTB DETECTED	70	3	275
	MTB NOT DETECTED	7	171	0

SENSITIVITY: **98.0%**
SPECIFICITY: **98.3%***

* The sensitivity of the Xpert MTB/RIF assay in patient samples classified as smear negative, culture positive (S-C+) is 90.9% (70/77) and 100% (275/275) for those classified (S+C+).

Specific

- The Xpert MTB/RIF assay uses 3 specific primers and 5 unique molecular probes to ensure a high degree of specificity
- Assay targets the *rpoB* gene, which is critical for identifying mutations associated with rifampicin resistance
- No cross reactions were observed with many other bacterial species tested, including a comprehensive panel of Mycobacteria

***rpoB* GENE 81 bp RIF RESISTANCE DETERMINING REGION**



Efficient

- Rapid, on-demand results mean infected patients can be placed in isolation efficiently and treated with the appropriate therapeutics effectively
- *Mycobacterium tuberculosis* — treat and isolate
- Rapid detection of rifampicin-resistance not only guides individual patient therapy but aids with infection control and public health activities as well

PERFORMANCE CHARACTERISTICS OF THE XPRT MTB/RIF ASSAY COMPARED TO DRUG SUSCEPTIBILITY TESTING FOR RIFAMPICIN (RIF)

		DST	
		RIF Resistant	RIF Sensitive
Xpert MTB/RIF	RIF Resistance DETECTED	58	4
	RIF Resistance NOT DETECTED	2	280

SENSITIVITY: **96.7%**
SPECIFICITY: **98.6%**
PPV: **93.6%**
NPV: **99.3%**

Advantage: Test and Treat

Xpert® MTB/RIF

- Results in 2 hours, available on-demand
- *M. tuberculosis* detected/not detected
- Rifampicin resistance

AFB Smear Test

- Results in 2–24 hours
- Acid fast bacilli present/absent

Culture Testing Results: 2–4 Weeks

- MTB detected/not detected

Testing for Drug Resistance Results: 2–4 Weeks

- Resistance detected/not detected

Workflow: Self contained cartridge – just add sample

Pour Sample Reagent into sample tube.

Incubate for 15 minutes at room temperature.
(Acceptable sample types: unprocessed sputum or sediment from concentrated specimen.)



1

Pipette diluted sample into cartridge.



2

Insert cartridge and start assay.



3

TOTAL HANDS-ON TIME = 2 MINUTES

ORDERING INFORMATION

Xpert® MTB/RIF (10 Cartridges with Sample Reagent) Catalog No. GXMTB/RIF-10

References:

1. Reducing the Global Burden of Tuberculosis: The Contribution of Improved Diagnostics. *Nature* 444 (2006): 49–57
2. Hernández-Garduño E, Cook V, Kunimoto D, Elwood RK, Black WA, Fitzgerald JM: Transmission of tuberculosis from smear negative patients: a molecular Epidemiology study. *Thorax* 2004, 59:286–290
3. National Institute for Clinical Excellence (NICE) Clinical Guideline 33, 2006

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