Diagnóstico da tuberculose (TB)

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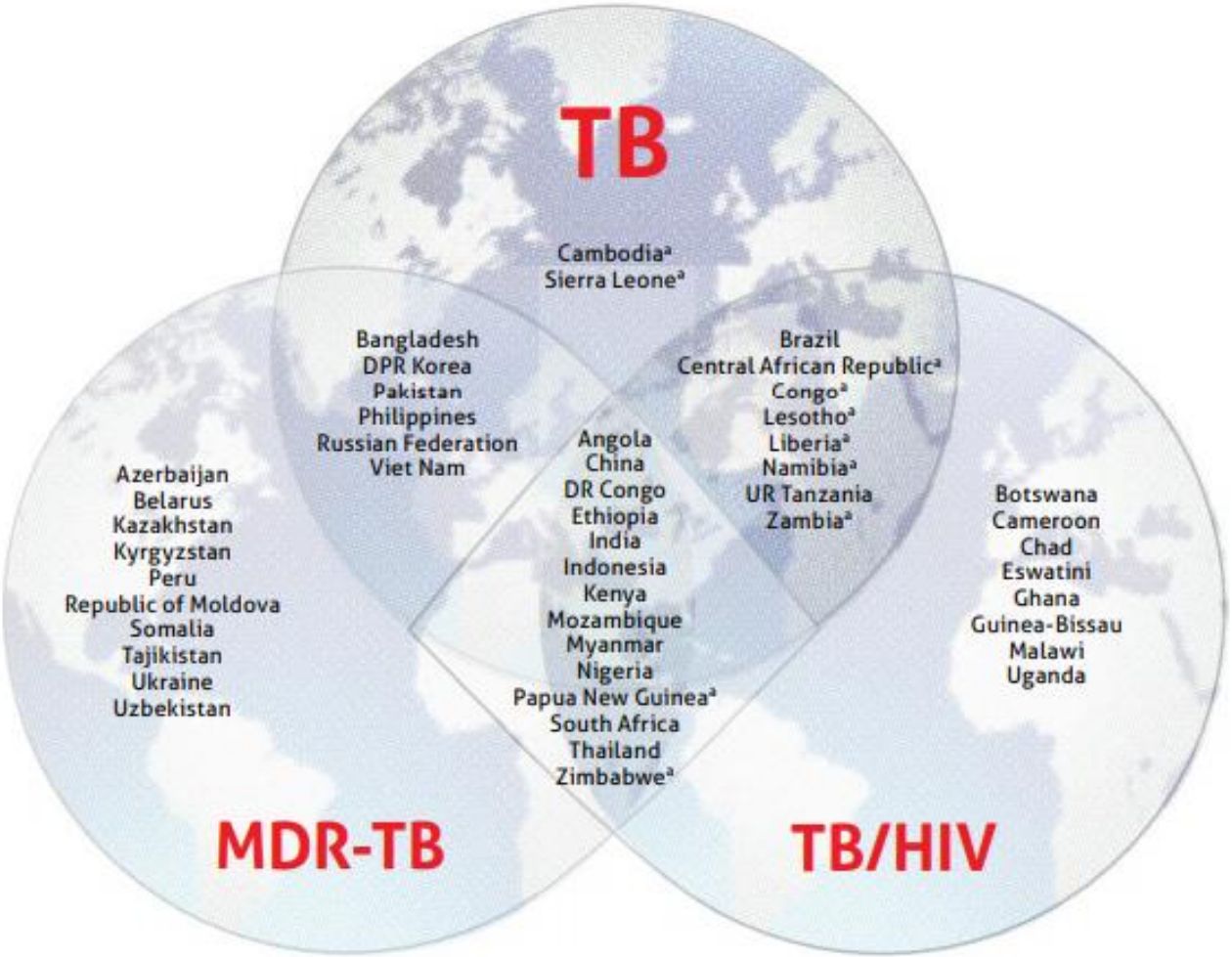
The three high-burden country lists for TB, TB/HIV and MDR-TB defined by WHO for the period 2016–2020, and their areas of overlap



[a] Indicates countries that are included in the list of 30 high TB burden countries on the basis of the severity of their TB burden (i.e. TB incident cases per 100 000 population per year), as opposed to the top 20, which are included on the basis of their absolute number of incident cases per year. Also see Table 2.4.

Testes diagnósticos

- Acurácia: sensibilidade/especificidade (característica do teste)
- Triagem e busca de casos: **elevada sensibilidade (acima de 90%)**
- Sintomático respiratório
  - Sensibilidade: **(deve ser maior que 90%)**
  - Especificidade: **(deve ser maior que 70%)**
- Confirmação diagnóstica: **elevada especificidade (acima de 95%)**

Valores Preditivos

- Quando usar os valores preditivos positivos e negativos
  - VPP – Qual o valor mínimo que decide tratar
    - **> 80%**
  - VPN – Qual o valor mínimo que afasta o diagnóstico do agravo investigado (TB) e passa a pensar em outro
    - **> 95%**

Diagnóstico Clínico, Radiológico e Laboratorial (Cedido pelo Prof. Afrânio Kritisk/UFRJ)

Diagnóstico clínico

Sintomático Respiratório
VISÃO SAÚDE PÚBLICA
- Tosse por mais de 2 a 3 semanas;

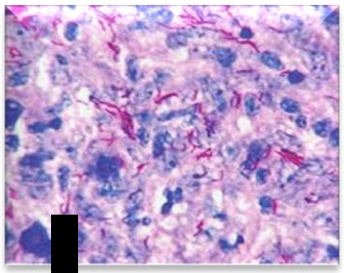
Sensibilidade 35%

Diagnóstico clínico

Sintomas Provável TB
VISÃO CLÍNICA
- Tosse por mais de 2 a 3 semanas;
- Sudorese noturna
- Febre vespertina
- Perda de peso
- Cansaço/Fagida

Sensibilidade 70-90%

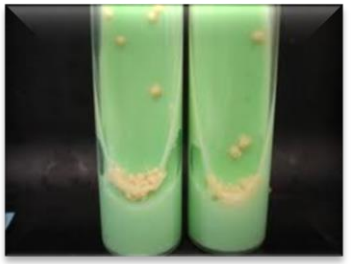
Diagnóstico laboratorial



Baciloscopia

- Simples
- Não invasivo;
- Sensibilidade (60-80%)

Amostra de escarro



Meio sólido
Cultura + TSA (método padrão)
Resultado 4 a 8 semanas

Sensibilidade da cultura
80% a 90%

Diagnóstico radiológico

Radiografia
Sensibilidade 70-90%

BACTEC MGIT 960®

MB/BactT

Meio líquido
Cultura + TSA (método padrão)
Resultado 2 a 4 semanas

Diagnóstico laboratorial molecular Recomendados pela OMS (especificidade acima de 95%) (Cedido pelo Prof. Afrânio Kritisk/UFRJ)

Xpert MTB/RIF (2010):

Sensibilidade: **90-93%**
Sensibilidade **~70%** (HIV+ e crianças)
Duração: 2 horas
Detecta resistência a rifampicina

Xpert Ultra (2017):

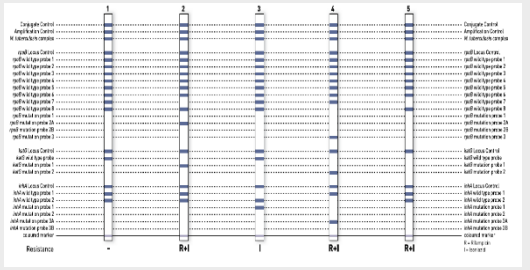
Maior sensibilidade (HIV+ e crianças)
Duração: menos de 2 horas
Detecta resistência a rifampicina

GenoType MTBDR Ver 2.0/Fita Hain (2016)

Maior sensibilidade **90-95%**
Duração: 24 horas
Detecta resistência a rifampicina e isoniazida

Recomendação da OMS em regiões de alta prevalência

Realizado em laboratório de Análises clínicas. Custo elevado



Realizado em laboratório de Biologia Molecular

Cartuchos Xpert MTB/RIF e MTB/RIF Ultra: diferenças

	MTB/RIF	MTB/RIF Ultra
Alvos	Região central do gene rpoB	Região centra do gene rpoB e Sequências de Inserção (IS6110 e IS1081)
Detecção da resistência	PCR em tempo real: 5 sondas de regiões complementares do gene rpoB	Curva de temperatura de *melting*: 4 sondas de regiões complementaresdo gene rpoB
Volume do escarro	2 ml	2 ml
Volume da PCR	25 µl	50 µl
Tempo de teste	± 110 min	65 – 87 min
Limite de detecção	114 CFU/ml	16 CFU/ml
Armazenamento	2 a 28°C	2 a 28°C

LF-LAM para o diagnóstico de tuberculose em pessoas vivendo com HIV

- Point-of care
- O teste é realizado em amostra de urina para diagnóstico da TB ativa em pessoas vivendo com HIV
- A incorporação do teste rápido de fluxo lateral para detecção de lipoarabinomanano (LF-LAM)- Aprovado no Conitec
- A tecnologia será uma alternativa de diagnóstico precoce da TB na população vivendo com HIV (CD4 abaixo de 100 células/mcL e quadro clinico grave)
- O LF-LAM terá sua aquisição de forma centralizada pelo Ministério da Saúde

http://www.aids.gov.br/pt-br/noticias/sus-incorpora-o-teste-rapido-lf-lam-para-o-diagnostico-de-tuberculose-em-pessoas-vivendo-0

Paul K. Drain J .Acquir Immune Defic Syndr 2015

Clinical impact of test results on diagnostic and treatment decisions, and eventually, patient outcomes

"Improved accuracy is not always a necessary prerequisite for improving patient health, nor does it guarantee other downstream improvements"

[di Ruffano et al. *BMJ* 2012;344:e686]

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Article - Human and Animal Health

Detection of Drug Resistant Mycobacterium Tuberculosis Strains Using Kit SIRE Nitratase®: a Multicenter Study

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HIGHLIGHTS

- The Kit SIRE Nitratase® is the only commercial test using the Nitrate Reductase Assay
- It is a know-how transference from the public university to the national industry.
- It can be implanted in the health system in countries with high TB burden
- Highlighting the good accuracy, less time to results and less laborious.

Abstract: (1) Background: The Commercial Kit SIRE Nitratase® PlastLabor, is a drug susceptibility test kit used to detect *Mycobacterium tuberculosis* resistance to first-line TB treatment drugs. The present study aimed at evaluating its performance in a multicenter study. (2) Methods: To determine its accuracy, the proportion methods in Lowenstein Jensen medium or the BACTEC™MGIT™960 system was used as a gold standard. (3) Results: The study revealed that the respective accuracies of the kit with 190 *M. tuberculosis* clinical isolates, using the proportion methods in Lowenstein Jensen medium or BACTEC™MGIT™960 system as a gold standard, were 93.9% and 94.6%, 96.9% and 94.6%, 98.0% and 97.8%, and 98.0% and 98.9%, for streptomycin, isoniazid, rifampicin, and ethambutol, respectively. (4) Conclusion: Thus, the kit can rapidly screen resistance to streptomycin, isoniazid, rifampicin, and ethambutol. Additionally, it does not require sophisticated equipment; hence, it can be easily used in the laboratories of low and middle income countries.

Keywords: tuberculosis, MDR, nitrate reductase, technology

ACTIVITY-BASIC COST – ABC				
Kit SIRE Nitratase		SIRE MGIT BACTEC (BD)	PROPORTION METHOD-LJ	
US$ 148,54	Clinical isolates	US$ 227,63	US$ 132,64	
US$ 136,12	Clinical samples			

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Major Article

Genotype®MTBDR*plus* and Xpert®MTB/RIF in the diagnosis of tuberculosis and resistant tuberculosis: cost analysis in a tertiary referral hospital

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Abstract

Introduction: The present study sought to assess the mean and activity based cost (ABC) of the laboratory diagnosis for tuberculosis through the application of conventional and molecular techniques—Xpert®MTB/RIF and Genotype®MTBDR*plus*—in a tertiary referral hospital in Brazil. **Methods:** The mean cost and ABC formed the basis for the cost analysis of the TB laboratory diagnosis. **Results:** The mean cost and ABC were US$ 4.00 and US$ 3.24, respectively, for a bacilloscopy; US$ 6.73 and US$ 5.27 for a Lowenstein-Jensen (LJ) culture; US$ 105.42 and US$ 76.56 for a drug sensitivity test (DST)–proportions method (PM) in LJ; US$ 148.45 and US$ 136.80 for a DST–BACTEC™ MGIT™ 960 system; US$ 11.53 and US$ 9.89 for an Xpert®MTB/RIF; and US$ 84.21 and US$ 48.38 for a Genotype®MTBDR*plus*. **Conclusions:** The mean cost and ABC proved to be good decision-making parameters in the diagnosis of TB and MDR-TB. The effective implementation of algorithms will depend on the conditions at each location.

Keywords: Tuberculosis. Mycobacteria. Diagnosis. Mean Cost. Activity Based Cost.

TABLE 1: Mean and activity based cost of conventional and molecular tests.

Method	Samples/Month	Mean Cost	ABC
Bacilloscopy	300	US$ 4.00	US$ 3.24
LJ Culture	150	US$ 6.73	US$ 5.29
Xpert®MTB/RIF	150	US$ 11.53	US$ 9.89
Genotype®MTBDR*plus*	15	US$ 84.21	US$ 48.38
PM-LJ	84	US$ 105.42	US$ 76.56
MGIT-DST	40	US$ 148.45	US$ 136.80

Exchange rate of US$ 1.00 = R$ 3.20 in 2017 according to the Brazilian Central Bank.

Obrigada

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