

EMPE Diagnostics

Sweden • India

www.empediagnostics.com

Novel detection platform for antibiotic resistance

early detection of TB and MDR-TB limit transmission and saves lives

World and Tuberculosis

- Tuberculosis (TB) is a leading infectious disease killer worldwide.
- No country is free from TB. In 2022, 10.6 million people developed TB and more than 4000 people die every day.
- Multi-drug resistance tuberculosis (MDR-TB) with its high death rates is major global health challenge.
- Only a limited amount of drugs are available to effectively treat MDR-TB and only 2 in 5 cases have access to correct treatment.

Europe and Tuberculosis

- The WHO region of Europe has the highest incidence of MDR-TB in the world.
- 1 in 3 cases of pulmonary TB in the Region is resistant to rifampicin.
- In only 62% of pulmonary TB patients the rifampicin resistance status is known.
- Successful treatment outcome for RR/MDR-TB patients is only 57.2%.

Challenge & EMPE's solution

- Lack of point-of-care tests for quick diagnosis of MDR-TB is a major challenge for TB control.
- User-friendly, inexpensive and reliable early-stage diagnostics are urgently needed.
- EMPE Diagnostics has developed *mfloDx*TM technology (patents granted) a diagnostic platform combining a molecular technology (padlock probes and rolling circle amplification) and visual biosensors (ultrasensitive lateral flow) to detect the presence of bacteria and antibiotic resistance.
- Currently EMPE has developed rapid molecular test kits to detect world's leading infectious killer, *Mycobacterium tuberculosis* and susceptibility or antibiotic resistance to the major anti-TB drugs, in just 3 hours, without any expensive equipment.
- EMPEs mission is to help the clinicians across the world to quickly detect TB and to start treatment with correct antibiotics, from the first clinical meeting, even at rural health care centers.



Achievements & Clinical results

- · Patents granted in 17 countries. Commercial license received for the first MDR-TB test kit.
- Operations in two sites: Sweden (global R&D) & India (Global manufacturing & sales).
- ISO13485 certified Manufacturing Unit capable of producing 9-24 million kits per year.
- Received ~7 M EUR in grants mainly from Bill and Melinda Gates Foundation and the European Innovation Council.

Detection of TB (N= 210 + 220)									
Diagnostic parameters (%)		Pooled samples		Smear positive sputum	Diagnostic parameters (%)		Pooled samples		Smear positive sputum
Clinical specificity		97		-	Clinical specificity		100		-
Clinical sensitivity		83		92	Clinical sensitivity		97		100
Detection of drug resistance									
Parameters (%)	Pooled samples		Smear positive sputum		Parameters (%)	Pooled samples		Smear positive sputum	
	RIF	INH	RIF	INH		RIF	INH	RIF	INH
Specificity	98	96	98	97	Specificity	100	100	*	*
Sensitivity	100	100	100	100	Sensitivity	93	95	100	100
	Diagnos parameters Clinical spec Clinical sens Parameters (%) Specificity Sensitivity	Diagnostic parameters (%) Clinical specificity Clinical sensitivity Parameters Poo (%) RIF Specificity 98 Sensitivity 100	Diagnostic Poole parameters (%) sampl Clinical specificity 97 Clinical sensitivity 83 Parameters Pooled samples RIF INH Specificity 98 96 Sensitivity 100 100	Diagnostic parameters (%) samples constraints of the samples constraints of the samples constraints of the samples constraints	Detection of TE Diagnostic parameters (%) Semicle samples Detection positive sputime Clinical specificity 97 - Clinical specificity 97 - Clinical specificity 97 - Clinical specificity 97 - Parameters Pooled samples Specificity 97 Specificity 97 - - RIF INH RIF INH Specificity 98 96 98 97 Sensitivity 100 100 100 100	Detection of TB (N=210 + 220 Diagnostic parameters (%) Samples samples Smear positive sputum Diagnos parameters Clinical specificity 97 - Clinical specificity 02 20 Clinical specificity 97 Clinical specificity 97 - Clinical specificity 03 83 90 Clinical specificity Parameters samples Specificity 97 Parameters (%) Specificity 98 96 97 Specificity 98 96 97 Specificity 100 100 100 Specificity	$\begin{array}{c c c c c } \hline \begin{tabular}{ c c c } \hline Diagnostic \\ parameters (\%) & samples & Snear \\ positive \\ samples & source \\ \hline \end{tabular} \en$	Detection of TB (N= 210 + 220) Diagnostic parameters (%) Spoled samples Smear positive sputum Diagnostic parameters (%) Poole samples Clinical specificity 97 - Clinical specificity 100 Clinical specificity 97 - Clinical specificity 97 Clinical specificity 97 - Clinical specificity 97 Clinical specificity 97 - Clinical specificity 97 Parameters Specificity 97 Detection d'rug resistance Pooled Samples Specificity 98 96 97 Specificity 100 100 Specificity 98 98 97 Specificity 100 100 Specificity 93 95	Detection of TB (N= 210 + 220) Diagnostic parameters (%) Pooled samples Smear positive sputium Diagnostic parameters (%) Pooled samples Clinical specificity 97 - Clinical specificity 100 Clinical specificity 93 92 Clinical specificity 97 Detection of trug resistance Parameters (%) Pooled samples RIF INH RIF INH RIF RIF NH RIF Specificity 98 96 98 97 Specificity 100 100 Sensitivity 100 100 100 Sensitivity 93 95 100

- Sensitivity: 92 100%; Specificity: 93 100%
- LOD: 5 genomic DNA copies.
- Sputum sample to result: 3 5 hours
- Samples per batch: 32 48

Unique Sellling Points:

- Easily scalable
- Customisable
- Detects multiple diseases
- Probes several DNA/RNA mutations
- Identifyies microbe and its AMR profile
- Only standard lab equipment is required
- No special instruments/infrastructure is needed
- · Semiskilled personnel can esily perform the test
- Inexpensive compared to other tests
- Sample to result in 3 hours!

Associates, funders & collaborators











Unique Sellling Pointer