EMPE Diagnostics
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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.

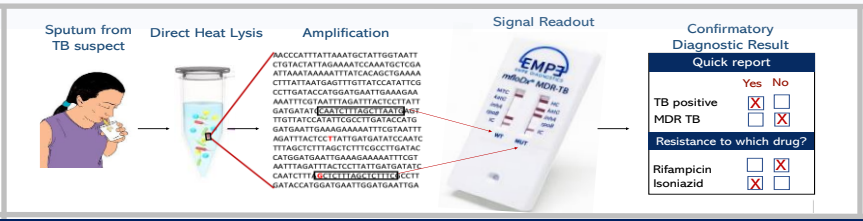
Europe and Tuberculosis

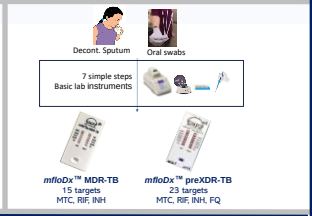
- The WHO region of Europe has the highest incidence of MDR-TB in the world.
- 1 in 3 cases of pulmonary TB in the Region is resistant to rifampicin.
- In only 62% of pulmonary TB patients the rifampicin resistance status is known.
- Successful treatment outcome for RR/MDR-TB patients is only 57.2%.

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™* 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

- 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