Diagnosing patients with TB at the first point of contact in the health care system using sensitive, easy-to-use, and affordable tests to enable appropriate treatment, arrest disease early, and halt transmission is critical to reach the WHO END TB Strategy. However, despite decades of research, significant investment, and over 400 reports on new biomarker candidates, only two confirmed biomarkers have translated into commercially available diagnostic tests. This lack of success is in large part due to a “dismal patchwork of fragmented research” which needs to be replaced with “a coordinated ‘big science’ approach” [Poste, Nature 2011].

FIND and partners are working to get to a true point-of-care test through a coordinated data sharing and analysis effort that feeds into a biomarker database. The database will facilitate the identification and verification of promising novel biomarker candidates and biomarker combinations.

The novel, centralized database dedicated to TB biomarker discovery and validation will provide curated data in an easily accessible format for researchers. Researchers and test developers will be invited to share their data. Data sharing will be secure and easily manageable, and will be governed by a data sharing agreement (finddx.org/specimen-banks). Researchers will be enabled to protect their intellectual property (IP). User-friendly data analysis tools will facilitate data synthesis and cross-study comparisons.

The database will allow the development of research networks that enable collaboration in key areas, such as the realization of validation studies and identification of new biomarker signatures that have the potential to meet performance, as specified in the target product profiles.

**CHALLENGES IN BIOMARKER RESEARCH**

Key issues that limit the impact of biomarker research:

- a lack of data & IP sharing
- science tends to stop at exploration studies
- a lack of coordination between stakeholders and similar research activities
- a lack of standards around biomarker validation
- failure to clearly articulate and benchmark a biomarker against the intended clinical use case

As a result, only two biomarkers are confirmed today - DNA & lipoarabinomannan.

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