Expression of interest: test developers to participate in Rutgers-FIND initiative for feasibility of novel diagnostics for TB in endemic countries (FEND-TB)

Note: up to three (3) pages max

General details	
Name of applicant	*List here the name of the main applicant and co-applicants. Can include name of company and/or principal investigator for lab-developed tests.*
Contact details	*Provide here contact details of corresponding investigators for further communication with FIND.*

Test details	
Name of test	*Provide here the name of test.*
Primary use case	*[ ] TB detection, [ ] drug susceptibility test, [ ] test for progression / incipient TB, [ ] treatment monitoring tool, [ ] LTBI / IGRA, [ ] other _____*
Type of technology	[ ] automated near-POC NAT [ ] automated POC NAT [ ] manual immunoassay [ ] automated immunoassay [ ] rapid-diagnostic test [ ] rapid-diagnostic test + reader [ ] digital diagnostic tool [ ] other: specify
Test description	*Briefly describe the assay. Must include information on:* • *Sample type* • *Sample pre-processing steps* • *Biomarker target (gene target, or antigen, antibody including isotype)* • *Reagents included in the kit* • *Control material (indicate if included in the kit)* • *Number of reactions per kit* • *Details on instrumentation/software (if applicable)* • *Extraction system compatibility (if applicable)*
Stage of development	*Briefly describe the stage of development of the assay and specific requests to FEND applicable to the assay (i.e. specific sample collection/transport procedures)*
Analytical performance	*As applicable and available, provide results from analytical performance studies and references to published papers. May include data on limit of detection (LOD), cross reactivity, and accuracy (i.e. test sensitivity and specificity). Include specimens tested and reference assay. If data still being generated, include a timeline of when additional analytical performance data will be available.*
Clinical performance	*Provide results from clinical performance studies and references to published papers, if available. Include reference assay.*
Cost	*Provide cost per kit or estimate.*
Ease of use (targeted user group)	*Provide details on the intended use level and requirements for training.*
Throughput	
Time-to-result	
Hands-on-time	
Stability	*If available, provide info on the stability of consumables under different environmental conditions, and stability of results.*

Regulatory and manufacturing status	*1) Is the product manufactured under QMS?* *2) How many tests and instruments have been made to date?* *3) State whether the test has received regulatory approval or is for research use only; state any plans for regulatory approval and projected timeline.*
Intellectual property status	*Provide details on the intellectual property (IP) and freedom-to-operate (F2O) status of the technology.*
Ongoing analytical and/or clinical evaluation	*Please briefly describe planned or ongoing analytical and/or clinical evaluations.*
Needs from FEND	*From your perspective what next steps are needed to take your test forward. E.g. further optimization on banked samples, demonstration of feasibility, clinical evaluation studies, modelling support?*

Organization details	
Type of organization	*Describe type of organization (e.g. academic research laboratory, government laboratory, registered company, etc.)*
Location	*Provide the location where your organization/company is registered.*
Website	*Provide the web link to your organization/company's website, if available.*
Test supply	*Is research group/organization/company the manufacturer of the test presented to FIND? ☐Yes ☐No* *If YES: please detail the location of manufacturing site and production capacity.* *If NO: please describe how end-users can obtain tests.*
Quality management system	*State any quality management system(s) and/or certification(s) in place for research & development and manufacturing (e.g. GxP, ISO, CLIA, etc.)*
Other products available in low- and middle-income countries	*List here the names of other products available, if applicable, and location(s) of relevant distribution channels.*