Development of a rapid serological screening test for TB (TBRT project)

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TBRT objective

To develop a simple and rapid serological screening test for the detection of tuberculosis disease in the developing world.
Sputum microscopy

- Most used method for detection of active TB
- Sputum sample collection is demanding!

Photo: IL Haugen
Serodiagnostic tests for active TB
WHO negative policy recommendation

- First “negative” policy recommendation
  - GRADE process
  - 67 studies
  - 32 low- and middle-income countries
  - TDR evaluation
  - Sensitivity and specificity highly variable
- Commercial serological tests for active TB should not be used for diagnosis
- Provide inconsistent and imprecise findings
- May have adverse impact on patients’ health

http://www.who.int/tb/labatory/policy_statements/en
TBRT results

- > 2,500 serum/saliva samples collected
- Promising combination of Mtb Ag identified
- Cellular expression system
- 1 protein-based prototype ELISA
- Sensitivity 70%, specificity 95%
- ELISA prototype → rapid platform
- Mtb strain characterization
- Patent
Bio-Plex added signals from 5 antigens
Bio-Plex added signal from 9 antigens
Bio-Plex added signals from 5 antigens
**Serum** IgG 2 antigens
Ethiopian samples
Last 5 samples neg controls

**Saliva** IgG 2 antigens
Ethiopian samples
Last 5 samples neg controls
Sensitivity

- Clinical diagnostics
- Blood donor screening
- Public health tool

Improve sensitivity

- Additional antigens
- Plant cell system
- Host markers
- TB/HIV coinfection
Sensitivity wrt public health tool

**No rapid test**
- 110 TB+
- 10 TB+ referred (clinical symptoms)
- 100 TB+ to village
- 100 x 20 new TB infections (2000)

**Rapid test** 70% sens (100% spec)
- 110 TB+
- 10 TB+ referred (clinical symptoms)
- 70 TB+ referred (reactive test results)
- 30 TB+ to village
- 30 x 20 new TB infections (600)
TBRT consequences

- Reduce diagnostic delay
- Expedite referral & treatment
- Reduce Mtb infectious pool
- Limit Mtb transmission
- Curb TB pandemic
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TBRT Consortium

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