Developments in diagnosis of TB in children and adolescents

Pamela Nabeta

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✓ I have no, real or perceived, direct or indirect conflicts of interest that relate to this presentation.
Stool processing method: proof of concept & initial validation

**A Novel Sample Processing Method for Rapid Detection of Tuberculosis in the Stool of Pediatric Patients Using the Xpert MTB/RIF Assay**

Padmapriya P. Banada1, Uvistra Naidoo2, Srinidhi Deshpande1, Farina Karim2, JoAnne L. Flynn3, Melanie O’Malley3, Martin Jones4, Oliver Nanassy5, Prakash Jeena5, David Alland1

**Table:**

<table>
<thead>
<tr>
<th></th>
<th>Respiratory Xpert</th>
<th>Sensitivity (95%CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single stool</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stool swab</td>
<td>44.4 (13.7-78.8)</td>
<td>99.6 (97.8-100)</td>
<td></td>
</tr>
<tr>
<td>0.6 g stool</td>
<td>44.4 (13.7-78.8)</td>
<td>99.2 (97.1-99.9)</td>
<td></td>
</tr>
<tr>
<td><strong>Combined stool 1 &amp; 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stool swab</td>
<td>50.0 (18.7-81.3)</td>
<td>99.2 (97.2-99.9)</td>
<td></td>
</tr>
<tr>
<td>0.6 g stool</td>
<td>70.0 (34.8-93.3)</td>
<td>98.4 (96.1-99.6)</td>
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</tr>
</tbody>
</table>

Sensitivity and specificity of Xpert stool assay as tested with pediatric clinical samples (Banada et al. PlosOne 2015).

**Performance of prototype assay** combined with Xpert MTB/RIF on stool, compared with Xpert MTB/RIF on respiratory samples (Walters et al. JCM 2018).
SPK: Final design under clinical evaluation
FUJIFILM SILVAMP TB LAM (FujiLAM)

• Designed for the POC in LMIC’s where patients seek care
• Enhanced sensitivity to detect TB in PLHIV
• High specificity for immediate treatment initiation
• High patient impact

1Dowdy et al. 2006, AIDS and Peter et al. 2016, Lancet ID
FujiLAM test device

TB Test Procedure

1. Add urine to the tube
2. Incubate for 40 minutes
3. Add two drops at position "1" and press "3"
4. On orange press "3"
5. Interpret result

80 minutes from sample collection to result

TB Test Principle

Gold conjugated primary antibody captures MTX-LAM in patient urine
Formation of the "sandwich" immune-complex through binding to the immobilized secondary antibody
Silver formation around the gold particle amplifies band intensity
First evaluation of FujiLAM

**Novel lipoarabinomannan point-of-care tuberculosis test for people with HIV: a diagnostic accuracy study**

Tobias Broger*, Bianca Sossen*, Elloise du Toit, Andrew D Kerkhoff, Charlotte Schutz, Elena Ivanova Reipold, Amy Ward, David A Barr, Aurélien Macé, Andre Trollip, Rosie Burton, Stefano Ongarello, Abraham Pinter, Todd L Lowary, Catharina Boehme, Mark P Nicol, Graeme Meintjes†, Claudia M Denkinger†

- 968 adults, HIV co-infected inpatients in a high-burden setting (frozen samples)
- Sensitivity of FujiLAM was significantly higher (22–35%) than AlereLAM
- Sensitivity 84.2% in patients with CD4 ≤100 cells per μL
Preliminary data on FujiLAM in children using frozen urine samples

FujiLAM performance in children
• Further details: e-poster session
• Ongoing assessment on fresh urine samples (FIND & RaPaed)
Thank you!