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Combined multiplex analysis of serological response and a host marker from a TB study

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Background and aim: Infections with pathogens happens constantly and everywhere. For many pathogens, minor or disease unspecific symptoms leave them often undiagnosed or make a diagnosis difficult due to the lack of appropriate tests. Infection with *Mycobacterium tuberculosis* is one of the top 10 causes of deaths worldwide, but diagnosis of TB disease is time consuming, requires complex tests and electric powered lab space. Non-sputum biomarker-based tests are needed. Testing of antibody responses against pathogen derived antigens offers a simple and cheap method. However, the WHO does not recommend the use of serology-based ELISA or rapid tests on the market due to lacking sensitivity and specificity.

Methods: We have developed a multiplex serology assay for a broad screening of the antibody response towards four MTB antigens, including the glycolipid Lipoarabinomannan (LAM). In addition, IP10, a host response marker, has been quantified in a sandwich immunoassay. This leads to a unique combination of serology testing and protein quantification in a single multiplex assay. Validation data for this combination assay will be presented.

Results: Results showed that the parallel measurement of antibody response and quantification of IP-10 was possible. A combined evaluation of the markers provided a sensitivity of 80 % and specificity of 73 % in a first screening set with 476 serum samples.

Conclusion: In this case-control study, the measurement of 239 MTB positive and 237 MTB negative samples showed that HIV co-infection affects the clinical sensitivity of the assays. In the talk some hints will be given on critical assay development/validation steps and solutions for improvement.