

# TUBERCULOSIS AND LUNG DISEASE

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## Colorimetric detection of active pulmonary tuberculosis using gold nanoparticles

Hesham EL-Samadony

Ministry of Health, Egypt

Since 2006, nanodiagnosics for tuberculosis (TB) have witnessed considerable development. Around thirty-five TB nanoassays have been partially or fully characterized. Accuracy, low-cost, and short time-to-result represent the common properties of proposed platforms. Among variable metals, gold NPs are the most used in the proposed platforms. Despite several advantages and high potential, translation into clinical use has not been reached. Most of the published reports do not proceed beyond proof of concept. This study aims to evaluate clinical performance of TB nanodiagnostic in clinical sputum samples using anionic unmodified gold nanoparticles. The study follows diagnostic case-control design where 60 participants are involved. Briefly, TB DNA was extracted from sputum samples and unmodified anionic gold nanoparticles were directly added to TB amplicon after amplification of TB IS6100 loci using conventional PCR. Colorimetric result was obtained after 15 min by direct visualization. Sputum culture (BACTEC™ MGIT™) was used as the reference test. Results of nano-gold assay were compared with those obtained by sputum

smear microscopy and chest X-ray. Our assay prototype shows concordance with culture results, and higher clinical performance than sputum smear and chest X-ray. Obtained sensitivity was 95% and specificity 100%. The total turnaround time was 3 hours, and the obtained lower limit of detection was 11.2 ng/ μl TB DNA. Future studies are needed to lower assay cost through optimizing DNA extraction protocol using simple reagents. DNA amplification could be performed using Loop mediated isothermal amplification (LAMP) or rolling circle amplification (RCA) to minimize cost. Future studies could adopt diagnostic test accuracy study (DTA) design for accurate assessment of assay performance. To the best of our knowledge, this is the first study to assess performance of TB nanodiagnostic by using unmodified gold nanoparticles in real clinical settings. Our prototype shows potential for point-of-care use in developing countries where TB burden prevails.

e: [helsamadony@umaryland.edu](mailto:helsamadony@umaryland.edu)