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A novel automatic molecular test for detection of multidrug resistance tuberculosis in sputum specimen: A case control study

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#### ACCEPTED MANUSCRIPT

### 1 A Novel Automatic Molecular test for Detection of Multidrug

- 2 Resistance Tuberculosis in Sputum Specimen: A Case Control Study
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- 12 Key words: minilab; multidrug resistance; tuberculosis

#### 13 Abstract

- MiniLab tuberculosis (ML TB) assay is a new automatic diagnostic tool for diagnosis of
- 15 multidrug resistance tuberculosis (MDR-TB). This study was conducted with aims to know the
- 16 performance of this assay. Sputum sample from 224 TB suspects was collected from tuberculosis
- suspects seeking medical care at Beijing Chest hospital. The sputum samples were directly used
- 18 for smear and ML TB test. The left sputum sample was used to conduct Xpert MTB/RIF, Bactec
- 19 MGIT culture and drug susceptibility test (DST). All discrepancies between the results from DST,
- 20 molecular and phenotypic methods were confirmed by DNA Sequencing. The sensitivity and
- 21 specificity of ML TB test for detecting MTBC from TB suspects were 95.1% and 88.9%,
- 22 respectively. The sensitivity for smear negative TB suspects was 64.3%. For detection of RIF
- resistance, the sensitivity and specificity of ML TB test were 89.2% and 95.7%, respectively. For
- detection of INH resistance, the sensitivity and specificity of ML TB test were 78.3% and 98.1%,
- 25 respectively. ML TB test showed similar performance to Xpert MTB/RIF for detection of MTBC

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