PERFORMANCE OF HOST BLOOD TRANSCRIPTOMIC SIGNATURES FOR DIAGNOSING AND PREDICTING PROGRESSION TO TUBERCULOSIS DISEASE IN HIV-NEGATIVE ADULTS AND ADOLESCENTS: A SYSTEMATIC REVIEW PROTOCOL.

Individual Study Quality Assessment Tool (QUADAS-2)

Study Title: ______________________________________________

Author: ________________ Publication year: __________ Study #_____

Study type: □ Diagnostic □ Predictive

Domain 1. Patient selection
   (a) Risk of bias: L/H/U
      ❖ Was a consecutive or random sample of patients enrolled? Y/N/U
      ❖ Was a case-control design avoided? Y/N/U
   (b) Applicability Concerns: L/H/U
      ❖ Is there concern that the included patients do not match the review question? Y/N/U

Domain 2. Index Test (Transcriptomic Signature)
   (a) Risk of bias: L/H/U
      ❖ Were the Transcriptomic signature test results interpreted without knowledge of the results of the MTB culture or Xpert/MTB RIF or Smear Microscopy? Y/N/U
   (b) Applicability Concerns: L/H/U
      ❖ Is there concern that the Transcriptomic signature test, its conduct, or interpretation differ from the review question? Y/N/U

Domain 3. Reference Standard (MTB Culture or Xpert/MTB RIF or Smear Microscopy)
   (a) Risk of bias: L/H/U
      ❖ Is the reference standard likely to correctly classify the target condition? Y/N/U
      ❖ Was MTB Culture or Xpert/MTB RIF or Smear Microscopy test results interpreted without knowledge of the results of Transcriptomic signature test? Y/N/U
   (b) Applicability Concerns: L/H/U
      ❖ Is there concern that the MTB Culture or Xpert/MTB RIF or Smear Microscopy, its conduct, or interpretation differ from the review question? Y/N/U

Domain 4. Flow and timing
   (a) Risk of bias: L/H/U
      ❖ Was there an appropriate interval between the index test and reference standard tests? Y/N/U
      ❖ Did patients in the study receive the same reference standard? Y/N/U
      ❖ Were all patients included in the analysis? Y/N/U

Overall Study Rating  L/H/U
For each domain, ‘risk of bias’ or ‘concerns regarding applicability’ will be scored as ‘L’ if all responses in that domain are scored as ‘Y’ and ‘H’ if any of the responses is ‘N’ and ‘U’ if we are unclear for all the responses.

Legend: Y=Yes; N=No; U=Unclear        H=high; L=Low; U=Unclear