DIAGNOSTIC TEST ACCURACY AND PREDICTIVE VALUES OF MTB Gene Xpert, CRP quantitative, CRP semi-quantitative, Urine LAM using Culture as the gold standard

The study evaluates the diagnostic performance of multiple tuberculosis (TB) diagnostic methods, including MTB Gene Xpert, CRP quantitative, CRP semi-quantitative, and Urine LAM, using culture as the gold standard. Various measures of diagnostic accuracy, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), were computed to assess the reliability and effectiveness of these tests.

The MTB Gene Xpert test demonstrated a moderate sensitivity of 52.0% (95% CI: 44.6–59.3, p = 0.033), indicating that it correctly identified approximately half of the true positive cases. However, it exhibited a high specificity of 95.9% (95% CI: 94.7–96.8, p < 0.001), suggesting strong discriminatory power in detecting true negatives. The PPV was 61.5% (95% CI: 53.5–69.0), indicating that a positive result had a moderate probability of being a true positive. The NPV was 94.1% (95% CI: 92.7–95.2, p = 0.745), reinforcing its reliability in ruling out TB in negative cases.

CRP quantitative testing demonstrated a higher sensitivity of 59.4% (95% CI: 52.0–66.4) compared to MTB Gene Xpert, indicating an improved ability to detect true positives. However, its specificity was significantly lower at 76.2% (95% CI: 73.9–78.4), suggesting a higher rate of false positives. The PPV was notably low at 23.9% (95% CI: 20.1–28.1), whereas the NPV remained high at 93.7% (95% CI: 92.2–95.0). These findings suggest that while CRP quantitative testing improves sensitivity, it does so at the cost of specificity.

2 by 2 table of MTB Gene Xpert Vs Culture

|  |  |  |
| --- | --- | --- |
|  | MTB Gene xpert |  |
| Culture (Gold standard) | Positive | Negative |
| Positive | 91 | 84 |
| Negative | 57 | 1336 |

2 by 2 table of CRP quantitative Vs Culture

|  |  |  |
| --- | --- | --- |
|  | CRP quantitative |  |
| Culture (Gold standard) | Positive | Negative |
| Positive | 104 | 71 |
| Negative | 331 | 1062 |

Diagnostic test accuracy and predictive values of MTB gene Xpert and CRP quantitative

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Variable | Test | Estimate | SE | Lower CI | Upper CI | P-value |
| Sensitivity(%) | MTB Gene Xpert | 52.0 | 3.8 | 44.6 | 59.3 | 0.033\* |
|  | CRP quantitative | 59.4 | 3.7 | 52.0 | 66.4 |  |
| Specificity(%) | MTB Gene Xpert | 95.9 | 0.5 | 94.7 | 96.8 | <0.001\* |
|  | CRP quantitative | 76.2 | 1.1 | 73.9 | 78.4 |  |
| PPV(%) | MTB Gene Xpert | 61.5 | 4.0 | 53.5 | 69.0 | <0.001\* |
|  | CRP quantitative | 23.9 | 2.0 | 20.1 | 28.1 |  |
| NPV(%) | MTB Gene Xpert | 94.1 | 0.6 | 92.7 | 95.2 | 0.745 |
|  | CRP quantitative | 93.7 | 0.7 | 92.2 | 95.0 |  |

For CRP semi-quantitative testing, sensitivity was found to be the highest among the individual tests at 69.0% (95% CI: 62.0–75.5, p < 0.001), indicating a stronger ability to detect TB cases. The specificity was 67.6% (95% CI: 65.1–70.0, p < 0.001), a moderate level compared to the other tests. The PPV was 21.1% (95% CI: 18.0–24.6), reflecting a high proportion of false positives, while the NPV remained high at 94.6% (95% CI: 93.0–95.8, p < 0.001), reinforcing its effectiveness in ruling out TB.

Urine LAM testing exhibited the lowest sensitivity at 33.1% (95% CI: 26.6–40.4), indicating that it failed to detect a significant proportion of true positive cases. However, its specificity was high at 94.6% (95% CI: 93.3–95.7), suggesting a strong ability to correctly identify negative cases. The PPV was 43.6% (95% CI: 35.5–52.1), and the NPV was 91.8% (95% CI: 90.3–93.2), further confirming its high reliability in ruling out TB in negative cases. These results indicate that Urine LAM testing is highly specific but lacks sensitivity, limiting its utility in early detection.

2 by 2 table of CRP semi-quantitative Vs Culture

|  |  |  |
| --- | --- | --- |
|  | CRP semi-quantitative |  |
| Culture (Gold standard) | Positive | Negative |
| Positive | 121 | 54 |
| Negative | 425 | 941 |

2 by 2 table of Urine LAM Vs Culture

|  |  |  |
| --- | --- | --- |
|  | Urine LAM |  |
| Culture (Gold standard) | Positive | Negative |
| Positive | 58 | 117 |
| Negative | 75 | 1318 |

Diagnostic test accuracy and predictive values of CRP semi-quantitative and Urine LAM

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Variable | Test | Estimate | SE | Lower CI | Upper CI | P-value |
| Sensitivity(%) | CRP Semi-quantitative | 69.0 | 3.5 | 62.0 | 75.5 | <0.001\* |
|  | Urine LAM | 33.1 | 3.6 | 26.6 | 40.4 |  |
| Specificity(%) | CRP Semi-quantitative | 67.6 | 1.3 | 65.1 | 70.0 | <0.001\* |
|  | Urine LAM | 94.6 | 0.6 | 93.3 | 95.7 |  |
| PPV(%) | CRP Semi-quantitative | 21.1 | 1.7 | 18 | 24.6 | <0.001\* |
|  | Urine LAM | 43.6 | 4.3 | 35.5 | 52.1 |  |
| NPV(%) | CRP Semi-quantitative | 94.6 | 0.7 | 93 | 95.8 | <0.001\* |
|  | Urine LAM | 91.8 | 0.7 | 90.3 | 93.2 |  |

The Combination of Diagnostic Methods

The combination of MTB Gene Xpert with CRP quantitative and semi-quantitative testing resulted in an improved sensitivity of 72.0% (95% CI: 65.0–78.2, p = 0.062), demonstrating an enhanced ability to detect TB cases compared to the individual tests. However, the specificity decreased to 65.5% (95% CI: 62.9–67.9), suggesting a trade-off with an increased false-positive rate. The PPV remained low at 20.8% (95% CI: 17.7–24.1, p = 0.015), whereas the NPV was high at 94.9% (95% CI: 93.3–96.1, p = 0.062), reinforcing its reliability in ruling out TB.

Similarly, the combination of Urine LAM with CRP quantitative and semi-quantitative testing resulted in a sensitivity of 69.7% (95% CI: 62.6–76.1) and a specificity of 64.5% (95% CI: 62.0–67.0). The PPV remained low at 19.8% (95% CI: 16.8–23.1), while the NPV was 94.4% (95% CI: 92.8–95.7). These findings suggest that combining tests can improve sensitivity but at the cost of specificity and PPV.

Finally, the combination of MTB Gene Xpert with Urine LAM yielded a sensitivity of 53.7% (95% CI: 46.3–60.9, p = 0.062) and a specificity of 92.3% (95% CI: 90.8–93.6, p = 0.062). The PPV was 46.8% (95% CI: 40.0–53.7, p < 0.001), which was higher than for the other combined tests, while the NPV was 94.1% (95% CI: 92.7–95.2, p = 0.166). These results indicate that the addition of Urine LAM to MTB Gene Xpert does not significantly enhance sensitivity but maintains a high specificity and NPV.

Overall, the findings suggest that while combining diagnostic tests can enhance sensitivity, it often results in decreased specificity and lower PPV. MTB Gene Xpert remains the most specific test, while CRP semi-quantitative provides the highest sensitivity. The choice of diagnostic method should therefore depend on the clinical context, balancing the need for sensitivity in case detection with the requirement for specificity to minimize false positives.

2 by 2 table of MTB + CRP(Quantitative and semi quantitative)Vs Culture

|  |  |  |
| --- | --- | --- |
|  | MTB + CRP(Quantitative and semi quantitative) |  |
| Culture (Gold standard) | Positive | Negative |
| Positive | 126 | 49 |
| Negative | 481 | 912 |

2 by 2 table of Urine LAM + CRP(Quantitative and semi quantitative) Vs Culture

|  |  |  |
| --- | --- | --- |
|  | Urine LAM + CRP(Quantitative and semi quantitative) |  |
| Culture (Gold standard) | Positive | Negative |
| Positive | 122 | 53 |
| Negative | 494 | 899 |

Diagnostic test accuracy and predictive values of MTB + CRP(Quantitative and semi quantitative) and Urine LAM + CRP(Quantitative and semi quantitative)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Variable | Test | Estimate | SE | Lower CI | Upper CI | P-value |
| Sensitivity(%) | MTB + CRP(Quantitative and semi quantitative) | 72.0 | 3.4 | 65.0 | 78.2 | 0.062 |
|  | Urine LAM + CRP(Quantitative and semi quantitative) | 69.7 | 3.5 | 62.6 | 76.1 |  |
| Specificity(%) | MTB + CRP(Quantitative and semi quantitative) | 65.5 | 1.3 | 62.9 | 67.9 | 0.062 |
|  | Urine LAM + CRP(Quantitative and semi quantitative) | 64.5 | 1.3 | 62.0 | 67.0 |  |
| PPV(%) | MTB + CRP(Quantitative and semi quantitative) | 20.8 | 1.6 | 17.7 | 24.1 | 0.015\* |
|  | Urine LAM + CRP(Quantitative and semi quantitative) | 19.8 | 1.6 | 16.8 | 23.1 |  |
| NPV(%) | MTB + CRP(Quantitative and semi quantitative) | 94.9 | 0.7 | 93.3 | 96.1 | 0.062 |
|  | Urine LAM + CRP(Quantitative and semi quantitative) | 94.4 | 0.7 | 92.8 | 95.7 |  |

2 by 2 table of MTB + Urine LAM

|  |  |  |
| --- | --- | --- |
|  | MTB + Urine LAM |  |
| Culture (Gold standard) | Positive | Negative |
| Positive | 94 | 81 |
| Negative | 107 | 1286 |

Diagnostic test accuracy and predictive values of MTB + Urine LAM

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Variable | Test | Estimate | SE | Lower CI | Upper CI | P-value |
| Sensitivity(%) | MTB + Urine LAM | 53.7 | 3.8 | 46.3 | 60.9 | 0.062 |
| Specificity(%) | MTB + Urine LAM | 92.3 | 0.7 | 90.8 | 93.6 | 0.062 |
| PPV(%) | MTB + Urine LAM | 46.8 | 3.5 | 40.0 | 53.7 | <0.001 |
| NPV(%) | MTB + Urine LAM | 94.1 | 0.6 | 92.7 | 95.2 | 0.166 |