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**Evaluation report : Performance of TrueNat MTB and TrueNat MTB Rif  
conducted by the Mycobacteria National Reference Laboratory of Tunisia**

**Name of test :** TrueNat MTB and TrueNat MTB Rif

**Name of manufacturer:** Molbio Diagnostics Private Limited

**Configuration of panel :**

A total of 114 specimens (91 sputum and 23 extrapulmonary specimens) collected from suspected TB patients were analysed. Twenty five sputum from patients with other lung infections were introduced as controls.(table1)

**Table1 : Clinical specimens distribution**

Suspicion	Number
Pulmonary TB	66
Extrapulmonary TB	23
Negatif Control	25
Total	114

**Protocol :**

The study was prospective in nature. The sputum specimens were analysed using smear microscopy, culture, GeneXpert MTB/RIF and using the TrueNat MTB and TrueNat MTB Rif. A composite reference standard (CRS) comprising microbiological test results, clinical and radiological findings, and patient history was used to assess performance of the TrueNat MTB tests.

**Result summary :**

Among the panel, 46 were Smear (S)+, 49 Culture ( C ) +, 46 S+C+ and 3 S-C+.

Total number of CRS+ cases = 66/114, CRS- cases= 49/114

Sensitivity among S+C+ specimens= 100% (46/46).

Sensitivity among S-C+ specimens= 100% (3/3).

Specificity among CRS negative specimens= 100% (48/48).

Rifampicin resistance : 4 strains are resistant to rifampicin by proportion method and Xpert MTB/Rif, 3 strains are resistant by TrueNat MTB Rif, and for one strain, the test is indetermined.

**Table2 : Performance (% of cases detected) of molecular tests in various specimen categories :**

Test	S+ (N=46)	C+ (N=49)	S+C+ (N=46)	S-C+ (N=3)
Xpert MTB/Rif	100	95,9	97,8	66,6
TrueNat MTB	100	100	100	100


**Comments :**

The TrueNat MTB test is highly sensitive for S+C+ specimens and highly specific for CRS negative cases.

For the indetermined rifampicin case, the quantity of specimen wa snot enough.

The performance of TrueNat (MTB and MTB/Rif) is good and can used as a point of care test for detection of TB and Rifampicin resistance.

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