

HAINS MYCOBACTERIUM TUBERCULOSIS SECOND LINE DRUG RESISTANCE PROFILE

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(PCR, Line probe assay)

Type of Sample	Sputum/bronchoalveolar lavages/bronchial aspirates/Culture growth
Mycobacterium tuberculosis complex	Detected/Not detected / inhibition
Fluoroquinolones	Resistance Detected/Not detected
Capreomycin	Resistance Detected/Not detected
Viomycin	Resistance Detected/Not detected
Amikacin	Resistance Detected/Not detected
Kanamycin	Resistance Detected/Not detected
Ethambutol	Resistance Detected/Not detected

Interpretation

RESULT	MTB COMPLEX
Inhibition	Indicates presence of inherent inhibitors in the sample submitted
Resistance Detected	Possible resistance of Mycobacterium tuberculosis complex to the drug
Resistance Not detected	Possible sensitivity of Mycobacterium tuberculosis complex to the drug

Note

1. This Qualitative assay based on Line probe technology is used for molecular genetic identification of M. tuberculosis complex which includes M. tuberculosis, M. africanum, M. bovis subsp. bovis, M. bovis subsp. caprae, M. bovis BCG, M. microti, M. canettii & M. pinnipedii
2. Resistance can be detected by either the absence of binding of the amplified fragment to the wild type probes or binding to the mutation probes
3. Ambiguous results may be seen in cases of mixed infection, infection with more than one strain of Mycobacterium and heteroresistant strains. This depends on the ratio of mutated and non-mutated sequences.
4. The limit of detection of the assay is 10^3 bacteria/ml
5. It is recommended to verify the mono-resistant results to individual drugs by phenotypic results
6. This assay detects only the listed mutations. Mutations of other genes / gene regions shall not be detected by the assay
7. All results must be correlated with clinical findings and other investigations
8. Mycobacterium culture is recommended in case inhibition is detected

Comment

This assay can detect the following mutations:

- Subunit A of DNA gyrase (*gyrA* locus) – G88A, G88C, A90V, S91P, D94A, D94N, D94Y, D94G mutations confer resistance to Fluoroquinolones.
- 16srRNA gene detects resistance to Aminoglycosides. A1401G mutation confers resistance to Capreomycin, Amikacin & Kanamycin ; C1402T mutation confers resistance to Capreomycin, Viomycin & Kanamycin; G1484T mutation confers resistance to Capreomycin, Amikacin, Viomycin & Kanamycin.
- Arabinosyltransferase (*embB* locus) – M306I / M306V mutations confer resistance to Ethambutol.

Usage

Multidrug-resistance (MDR-TB) shows resistance to two of the core Antitubercular drugs Isoniazid & Rifampicin. XDR – TB or extensively drug-resistant tuberculosis in addition shows resistance to any of the Fluoroquinolones and to at least one of three injectable second-line drugs like Amikacin, Capreomycin or Kanamycin.