



IDAHO DEPARTMENT OF HEALTH & WELFARE

C.L. "BUTCH" OTTER – GOVERNOR
RICHARD M. ARMSTRONG – DIRECTOR

ELKE SHAW-TULLOCH, MHS – ADMINISTRATOR
DIVISION OF PUBLIC HEALTH
450 West State Street, 4th Floor
P.O. Box 83720
Boise, Idaho 83720-0036
PHONE 208-334-6996
FAX 208-334-6581
EMAIL ShawE@dhw.idaho.gov

Frequently Asked Questions for Molecular Detection of Drug Resistance (MDDR) to *Mycobacterium tuberculosis* complex

Who orders the MDDR?

The Idaho Bureau of Laboratories (IBL) automatically reflexes the MDDR test for all initially identified *Mycobacterium tuberculosis* (TB) cultures received or recovered in the laboratory.

Since MDDR is part of the TB testing algorithm at IBL, there is no need for a separate doctor's request for the MDDR test.

Is there a fee associated with the MDDR test?

There is currently no fee associated with this test.

What is the MDDR?

The MDDR is a laboratory developed test that is intended to detect specific gene mutations in *M. tuberculosis* complex, which if present, suggest drug resistance to Isoniazid or Rifampin.

At this point, the MDDR test can only be performed on **cultures** of *M. tuberculosis* complex.

What is the turnaround time?

Once TB has been recovered in culture and identified as TB complex, the process to run the MDDR will be approximately 2 working days.

Traditional drug susceptibility testing (DST) takes 14-21 days from the time of recovery and identification of TB complex.

What are the limitations?

Approximately 95% of TB isolates resistant to Rifampin will demonstrate at least one mutation in the *rpoB* gene and approximately 85% of TB isolates resistant to Isoniazid will demonstrate at least one mutation in the *katG* or *inhA* genes. The lack of detection of a mutation in these genes does not guarantee susceptibility to Isoniazid or Rifampin. All molecular results require confirmation by phenotypic testing; IBL will automatically perform traditional drug susceptibility testing using culture based methods.

The *Mycobacterium tuberculosis* molecular detection of drug resistance (MDDR) assay was designed and validated with research reagents and procedures by IBL and is not FDA approved. These results are intended to be used in conjunction with other clinical information in determining patient diagnosis and treatment.