TruArray® MDR-TB

Rapid, accurate identification of rifampin/isoniazid susceptibility

FAST | EASY | AFFORDABLE | SAFE | RELIABLE

TruArray MDR-TB Test for Identifying Drug Resistant Strains of *Mycobacterium tuberculosis*

OVERVIEW

Quick and reliable identification of drug resistant strains of *Mycobacterium tuberculosis* (MTB) from bacterial culture or human sputum is challenging. Existing systems are typically too large for crowded labs, require a large investment in capital equipment, are too complex to use without extensive training, or do not sample across a broad enough range of resistance markers.

The highly accurate and reliable TruArray MDR-TB test is the first portable, bench-top test to identify susceptibility to rifampin and isoniazid, using a single, workflow-integrated approach. And, unlike other methods that may take days, weeks, or even months to test for drug resistance, TruArray MDR-TB delivers results in a few hours.

Drug	Gene	Targeted Codons
Rifampin	*rpoB*	Most common mutations, including those at codons 516, 526, 531 and 533
Isoniazid	*katG, inhA*	katG codons: 315 inhA codons: 8, 15 and 17
None	*IS6110*	*Mycobacterium tuberculosis* complex
None	*IS1245*	*Mycobacterium avium*

TruArray MDR-TB identifies genetic markers associated with susceptibility to rifampin and isoniazid by screening for the most common mutations in the rpoB, katG *and* inhA *genes. The test also differentiates between* M. tuberculosis *and* M. avium.

TRUARRAY® MDR-TB TEST CAPABILITIES

- **Integrated Workflow:** Akonni TruDiagnosis® Systems utilize the TruDx™ 1000 Reader, TruCycler™ Satellite Thermal Cycler and Akonni TruTip™ DNA extraction kits for workflow-integrated extraction, amplification, hybridization, detection, and analysis.
- **Broad Coverage:** Identifies the most common resistance mutations for rifampin and isoniazid. Also differentiates between *M. tuberculosis* and *M. avium*.
- **Sensitive and Specific:** Utilizes the polymerase chain reaction to offer reproducible genotyping with as little as 500 pg of DNA.

TRUARRAY MDR-TB TEST BENEFITS

- **Rapid:** Starting from samples of 100 µl to 1.5 ml or more, the TruArray MDR-TB test delivers definitive results in a few hours – representing a significant time advantage compared to the 2+ or more days required for line-probe assays and 2-3 weeks for gold standard culture methods.
- **Accurate:** Simultaneous analysis from a single sample removes variability and delivers results you can trust.
- **Portable and Field Ready:** Affordably priced, easily operated by a single lab-trained technologist, portable and with a small bench-top footprint.

MARKETS

INFECTIOUS DISEASES
GENETIC DISEASES
ONCOLOGY
PHARMACOGENETICS
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Akonni Biosystems

TRUARRAY ADVANTAGE

In 2002, Akonni Biosystems acquired an exclusive license for medical applications of gel-element array technology developed by the Engelhardt Institute for Molecular Biology and Argonne National Laboratories. Since then, Akonni has significantly advanced the technology through improvements in manufacturing and providing an integrated, sample-to-answer capability for testing laboratories or low-resource settings. The technology is now supported by over 100 scientific publications and 30 issued or pending patents. TruArray tests are well positioned to be the industry leader in providing molecular diagnostic tests.

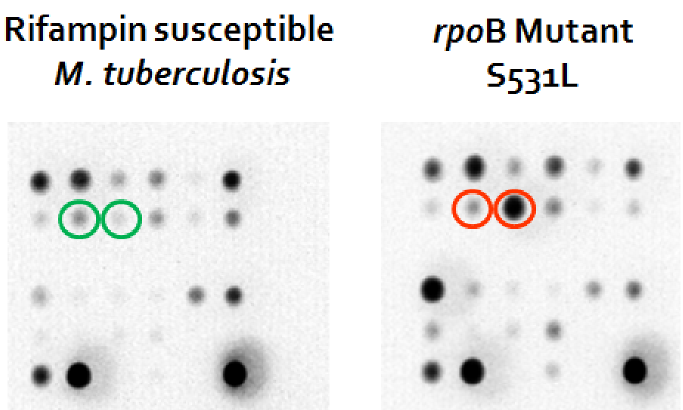

Image of a TruArray MDR-TB test result demonstrating how the system differentiates between rifampin-susceptible and rifampin-resistant MTB.

YOUR TRUARRAY MDR-TB TEST KIT

Akonni TruArray MDR-TB tests are available as pre-packaged kits providing all materials and reagents needed to perform 10 tests. For best results, we recommend using Akonni TruArray MDR-TB tests as part of an integrated workflow that includes the TruTip Kits for *Mycobacterium tuberculosis* DNA extraction, the TruCycler Satellite Thermal Cyclers for amplification and hybridization, and the TruDx 1000 Readers for image capture, data processing, data analysis, and reporting.

FDA STATUS

All Akonni Biosystems tests are currently for Research Use Only and are not for use in diagnostic procedures. Akonni is working to develop these products into Food & Drug Administration (FDA)-cleared diagnostic tests.

TO ORDER

200-10100 — **TruArray MDR-TB test kit for detecting multiple drug resistant tuberculosis in heat-killed culture.** Includes all primers, buffers and reagents required to perform 10 tests.

100-10000 — **TruDiagnosis System for multiplexed molecular diagnosis.** Includes the Akonni TruDx 1000 Reader, Akonni TruCycler Satellite Thermal Cycler, and laptop computer with data collection and analysis software. Systems include one year warranty against defective parts. Accepts international AC; 90-264V, 50-60 Hz AC.

300-10100 — **TruTip DNA Kit for *Mycobacterium tuberculosis* (60 LPT).** Includes tips and buffers required to perform 60 extractions.

300-10101 — **TruTip DNA Extraction Kit for *Mycobacterium tuberculosis* (240 LPT)*.*** Includes tips and buffers required to perform 240 extractions.

To order call +1 301.698.0101

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For Research Use Only. Not for use in diagnostic procedures. No claim or representation is intended for the diagnosis, prevention, or treatment of a disease.

Protected by 1 or more U.S. Pat: 6,460,094; 6,442,734; 6,795,949; 7,096,435. Other patents issued and pending.