

## A Diagnostic System for Tuberculosis Detection and Results Reporting

A Fully Automated AFB Detection System using Auramine Stained Sputum Slides Under Fluorescent Microscopy.  
System Provides Fully Automated Slide Feeding, Auto-focusing, Systematic Stage Navigation for Digital Field of View Capture.

### Highlights

- Automated Integrated Imaging and Information Management Software for Detection of Tuberculosis in Sputum
- Solution Includes Slide Loader and Automated Stage, Microscope, Digital Camera, Computer, High-Resolution Monitor and Detection Software
- Highly Accurate Detection Levels
  - Sensitivity > 90% per case
  - False Positives < 3.5% per FOV
- Immediate, Real-time AFB Detection
- Significant Improvement in Results Turnaround Time
- Continuous Processing of Slides Enables Substantial Increase in Volume of Slides Screened
- Cost-Effective, Robust and Simple to Operate
- Leverages Established Smear Microscopy Processes
- Provides Access to Results via Integration with Clinical Information Systems
- High Resolution Display Eliminates Eye Fatigue and Makes the Slide Review Process Faster and Much Easier
- Enables Decision Support Functionality and Provides Consistent and Reliable Performance

### Application

Tuberculosis (TB) is a pervasive and deadly infectious disease principally caused by Mycobacterium Tuberculosis. Tuberculosis most commonly attacks the lungs. The current manual microscopic sputum specimen analysis and diagnosis is tedious, labor intensive, time consuming, prone to human error and requires highly trained readers. Even with all these challenges, the World Health Organization (WHO) guidelines suggest that the best method for diagnosis of TB is by identification of tubercle bacilli in sputum smears using a light microscope with Ziehl-Neelsen stained specimens or under a fluorescence microscope with rhodamine/auramine stained sputa.

#### CLINICAL USAGE

**Signature Mapping TBDx** automates the screening of stained auramine slides and offers unparalleled accuracy in detecting TB using computer aided detection. After the technologist places 50 slides on the slide loader, the system will automatically will load each slide, digitize it and analyze each field of view (FOV) to determine a diagnostic case result. It is a unique high-speed, slide scanning system, producing digital field of views at optimum image quality. Signature Mapping TBDx facilitates the screening of large numbers of slides and provides a cost-effective, highly accurate alternative to labor-intensive traditional slide analysis.

#### UNIQUE TECHNOLOGY

**Signature Mapping TBDx** unique detection algorithms are integrated into a single clinical application which enables image acquisition, clinical diagnostic analysis, patient demographics, FOV analysis, annotation and results reporting. The system includes an image viewer and database which has been designed specifically for the management of TB cases.

**Signature Mapping TBDx** workstation viewer provides a patient assessment capability allowing the user to review suspected FOVs and to modify clinical results. There are various viewing and image manipulation tools which provide the user with the capability to effectively and efficiently analyze the patient slides. The system automatically accumulates statistics on each case at the field of view level including load, number of FOVs analyzed and AFB totals and averages. At the conclusion of the study a detailed patient results report is generated. The SQL database provides an excellent analysis and reporting tool for workload statistics.

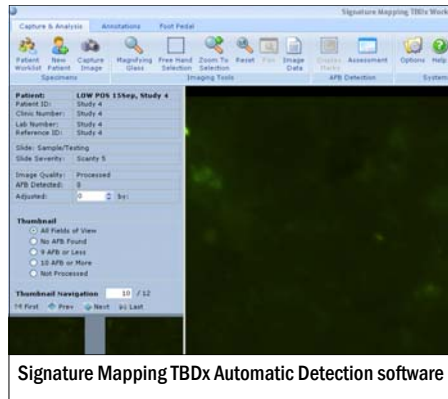
#### FUNCTIONALITY

**Signature Mapping TBDx** is a tuberculosis detection solution which integrates with an analog fluorescent microscope. A digital camera is attached to the microscope which then captures an image of the sputum sample in the field of view. The image is then digitized and processed with Signature Mapping detection algorithms. The image and the results are then displayed on the monitor. Each suspicious tuberculosis bacillus is identified by surrounding it with a red box. For each field of view, the system will count the total number of bacilli on each slide and report on the findings including the current load.

**Signature Mapping TBDx** consists of a computer-aided detection software called Signature Mapping™. This software processes the digital image by segmenting, segregating, extracting and classifying each target object in the field of view. The system counts individual bacillus to determine the load of each field of view and for the entire patient slide. Signature Mapping™ is the next generation image clarification, visualization, and computer-aided detection (CAD) in medical image processing. Each FOV is analyzed in real-time, performing TB detection in 1-2 seconds per FOV.

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## Signature Mapping TBDx™ Software Specifications



Signature Mapping TBDx Automatic Detection software

### Viewing Module

- Displays digitized FOVs, visualizations and indicated detected AFB's
- Ability to view, zoom, navigate, and manipulate digital images of slides
- Various annotation capabilities
- Audit tracking of slide/patient demographics
- Detected severity is load calculated by WHO guidelines
- Intuitive user-interface and novel video-based help system
- SQL Database provides image and results storage

### Detection and Image Processing Module

- Detects and annotates tuberculosis bacilli by drawing a box around each bacillus
- Real-time image processing
- Manages slide and field of view variations
- Data generation includes:
  - Load count and bacteria number per slide
  - Existence or non-existence of TB
  - Number of fields that were scanned
  - International grading for the total load

Patient Information			
Patient Name:	POSITIVE_AFB	Patient ID:	POS000000000000
Referring Physician:	DR. VIKAS KUMAR	Date of Birth:	05/25/1980
Detection Results			
Total AFB:	200.00	System Information:	WARNING: 0007
AFB per Field of View:	20.00	Field of View Processed:	08
Severity:	Pre	Fields of Views Not Processed:	0
Case:	Adult		

Assessment Screen

## Hardware Specifications



### A fully automated system with slide loader and barcode reader

Using a slide loader simplifies the processing and management of substantial numbers of slides immensely. The slide loader is fully integrated and holds up to 200 slides. The system always knows the exact position the actual slide comes from. It is set up for use with standard sized slides of 25 mm x 75 mm x 1 mm. A robotic arm places the slides into the stage holder of the Olympus microscope. The integrated barcode scanner facilitates highly-efficient workflow and eliminates data-entry errors for improved patient safety.

### Auto-stage controller

Provides precision navigation and auto focusing. Stage controller enables systematic FOV acquisition and hands-free movement.

### Microscope

The system is based on the upright BX Olympus research microscopes, which enables a range of modules to be easily added to meet the desired specification. They offer all properties for use in digital virtual microscopy including the extraordinary optical performance and logical structure. Numerous motorized components and the unique modular, ergonomic design ensure maximum efficiency. Each motorized component can be directly controlled, monitored and automated via the software. The standard microscope comes with the following: BX51 microscope frame; objectives: 4x PLAPON, 40x UPLSAPO; illumination: fluorescence using mercury vapor; motorized revolving nosepiece.

### Digital Camera

The Peltier cooled, 1376 x 1032 pixel camera offers exactly what users in diagnostics, research, development and quality assurance need: high resolution, fast frame rates and very high sensitivity with an excellent signal-to-noise ratio, broad dynamic range and superior image quality. As a result the camera offers images rich in detail and contrast with extraordinary low background noise. Digital camera performance optimized for laboratory requirements.



Automated Slide Sorter, Stage, Microscope, Digital Camera and Computer System

Computer system includes 21" LCD High-Resolution Monitor, Intel Quad Core Processors, 4 GB Memory, 1 Terabyte 7200 rpm SATA 3Gb/s Disk, Windows XP.



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Guardian Technologies International, Inc. GDTI employs advanced high-performance imaging technologies and advanced analytics to create integrated computer-aided detection products. Patented Signature Mapping software. [Stock Symbol: GDTI]