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 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.
A Diagnostic System for Tuberculosis Detection and Results Reporting

Signature Mapping TBDx™ Software Specifications

**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**
Dectects 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

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.