

Signature Mapping™ for Tuberculosis Detection Diagnostic System Automatic Detection of Tuberculosis in Sputum using an Analog Microscope

Benefits

- Integrated Imaging and Information Management Software for Automatic Detection of Tuberculosis in Sputum
- Solution includes Microscope, Digital camera, Computer and Detection Software
- Highly Accurate Detection Levels
 - Sensitivity > 85%
 - False Positives < ~.5 Per Image
 - Increase in sensitivity of scanty
- Immediate, Real-time Detection Ensures Faster Results and Significant Improvement in Results Turnaround Time
- Digitized Patient Records Allow Sharing and Become Part of the Electronic Medical Record
- Increase in Volume of Slides Screened
- Cost-Effective, Robust and Simple to Operate
- Leverages Existing Laboratory Microscopy Equipment and Established Smear Microscopy Processes
- Provides Access to Results via Integration with Clinical Information Systems
- Displaying and Viewing Images on a Monitor Eliminates Eye Fatigue and Makes the Slide Review Process Much Easier

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 BENEFITS

Signature Mapping TBDx automates the screening of the tubercle bacilli process and offers unparalleled accuracy in diagnosis. The automatic analysis facilitates the screening of larger numbers of slides and provides a cost-effective, highly accurate alternative to labor-intensive traditional slide analysis.

UNIQUE TECHNOLOGY

Signature Mapping TBDx detection algorithms are integrated into a clinical application which enables image acquisition, clinical diagnostic analysis, patient demographics capture, FOV analysis, annotation and results reporting. The system includes an image viewer and database which has been designed specifically for the viewing of TB images. There are various viewing and image manipulation tools which provide the user with the capability to effectively and efficiently analyze the image. The image viewer also provides a detailed summary report of each patient's findings including Load, Average Bacilli per Slide, Case Findings and more. The system enables the user to annotate the images and make changes to the detection results.

FUNCTIONALITY

Signature Mapping TBDx is a tuberculosis detection solution which integrates with an existing 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, processed with Signature Mapping detection algorithms. The image and the results are then displayed on the monitor. Each 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 workflow is described as:

1. Acquire Digital Image of the Slide Specimen Field of View
2. Perform the TB Detection and Analysis
3. Generation, Acceptance and Output of the Results

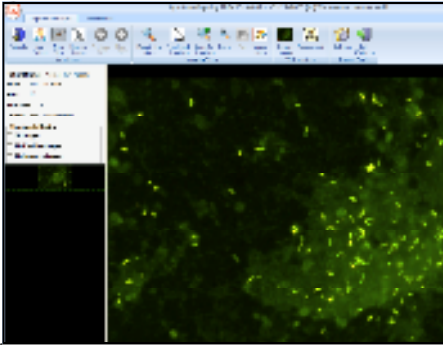
Signature Mapping TBDx consists of a computer-aided detection software called Signature Mapping™. This software processes the digital image by segmenting, segregating, extracting and classifying each target object in the field of view. The system counts individual bacillus to determine the load of each 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. The software-based Signature Mapping™ algorithms designed for have evolved from Guardian's patented core detection technology.

Signature Mapping TBDx can be 'retro-fitted' into existing laboratory environments and leverages existing laboratory equipment. By attaching a digital camera to the existing microscope and connecting it to a computer with a monitor, current throughput can be improved. An important feature of the system is the 'footpedal' which can be used to facilitate efficient capturing of the digital image. It is currently developed for use with auramine stained samples and can be adopted for use with Ziehl-Neelsen.



Signature Mapping™ for Tuberculosis Detection Diagnostic System

Signature Mapping TBDx™ Software Specifications



Signature Mapping TBDx software displays the image and identifies the tubercle bacilli.

Viewing Module

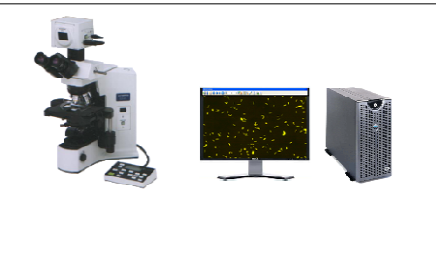
- Digitizes (into DICOM) the slide field of view and processes with Signature Mapping detection software
- Displays slide images, visualizations and shows detected areas of tuberculosis
- Ability to view, zoom, navigate, and manipulate digital images of slides
- Various annotation capabilities
- Audit tracking of slide/patient information
- Generates and outputs World Health Organization standard report results with manual data entry capabilities
- Intuitive user-interface and novel video-based help system
- Microsoft Windows based

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



Hardware Requirements



Requires Microscope, Digital Camera, Monitor and Computer

Computer

- Full-Size Desktop Form Factor
- 19" LCD Monitor or Larger
- CPU: Intel Core 2 Processor 2.66GHz or Higher
- Memory: 4GB DDR2-800MHz dual channel SDRAM
- Disk: 500GB 7200 rpm SATA 3Gb/s hard drive
- Operating System: Windows XP
- Video Card: 256 MB - Standalone AGP or PCI Card 1280x1024 32bit Support for Direct V9 and OpenGL
- Camera Interface: OHCI-Compliant IEEE1394 Fire-Wire
- Four USB 2.0 Ports
- Recommended Options
 - Foot Pedal (Used for Image Capture)
 - Norton All-in-One Security V2.0
 - UPS Backup

Olympus BX41 Microscope (BX2 Series) System

- UIS optical system
- Focus: Vertical stage movement: 25mm stage stroke with coarse adjustment limit stop, Torque adjustment for coarse adjustment knobs
- Stage mounting position variable, High sensitivity fine focusing knob (adjustment gradations: 1µm)
- Illuminator: Built-in Koehler illumination for transmitted light, 6V30W halogen bulb (pre-centered), Light preset switch
- Revolving nosepiece: Interchangeable reversed sextuple/quintuple nosepiece
- Observation tube: Widefield (F.N. 22); Widefield binocular, inclined 30° Widefield tilting binocular, inclined 5°-35° Widefield trinocular, inclined 30° Widefield ergo binocular, inclined 0°-25°
- Observation tube: Super widefield (F.N. 26.5) Super widefield trinocular, inclined 24°
- Stage: Ceramic-coated coaxial stage with left or right hand low drive control: with rotating mechanism and torque adjustment mechanism, optional rubber grips available

Image Capture

- Brand/Model: Olympus XC10
- Image Sensor: Color CCD
- Pixel Size: 6.45 µm x 6.45 µm
- Resolution: 1,376 x 1,032 pixels
- Firewire Cable

Note: Olympus BX41 Microscope and XC10 approved for usage.



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Guardian Technologies International, Inc. GDTI employs high-performance imaging technologies and advanced analytics to create integrated information management products and services. Guardian's technologies are focused on two primary markets: Homeland Defense and Healthcare Solutions. Guardian's homeland defense security technologies provide highly accurate threat-item detection at the image-scanning level, and the company's Healthcare Solutions for pathology and radiology improve information and process flow with state-of-the-art technology. [Stock Symbol: GDTI]