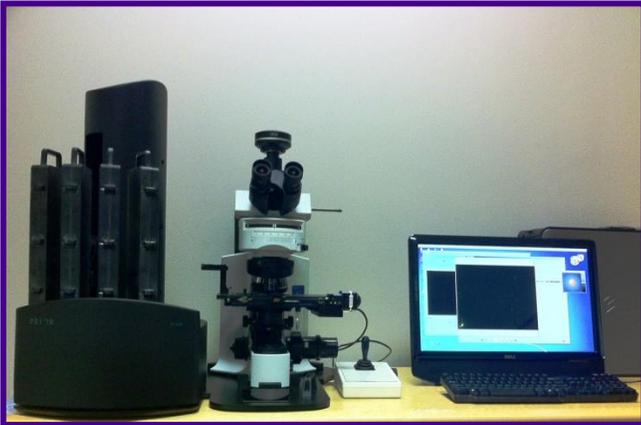


TECHNICAL DATA SHEET

Signature Mapping TBDx™

Adding Vision to Sputum Microscopy



Signature Mapping TBDx™ a revolution in sputum smear microscopy for the detection of tuberculosis. For the first time image processing has been added to the diagnostic process of routine smear microscopy. Through the integration of state-of-the-art digital image processing science and the leveraging of an embedded technology (microscope), a new diagnostic platform has emerged for the 21st Century.

TBDx is a fully integrated, fully automated hardware-software solution for the automated detection of tuberculosis under Auramine O staining conditions. The solution can be as simple as a single slide automated stage configuration for extremely low volume labs or research facilities, a four-slide automated stage configuration for moderate volume lab situations, or the robust 200-slide autoloader system for high production environments.

Ease of Use

A step-by-step guide for setup and process initialization is provided. The graphical user interface features large control icons, and when combined with the touchscreen capabilities of the high-resolution monitor, produces a simple to understand pathway to operations, tools and features. Even non-computer savvy users will be able to quickly and intuitively operate the entire system.

Image Capture & Focus

Our patent-pending autofocus process scans the sputum specimens to determine the optimal z-positioning, the height profile of the specimen, and manages the microscope stage for the collection of the highest quality images possible. The focusing process calculates the sputum's topography to ensure precise focusing while scanning. When using transcribed slides the process to locate the sputum specimen and to initiate the FOV capture process is greatly reduced in time and the FOVs captured are of the highest quality.

Accuracy

The entire TBDx integrated solution has been engineered to interact seamlessly, producing consistent image acquisition quality and trouble-free operation. Inherent in the design is a client-server-based data management system and storage solution developed specifically for the application. Interfacing the microscopist with the Decision Support Quick View module allows the microscopist to use their training to quickly adjudicate even the most challenging of slides.

Storage

Digital FOVs are stored, along with patient data, in a structure that enables instant, controlled access locally or from anywhere in the world. Each user is provided with easy-to-use, icon driven interfaces that allow total navigation within and among images. Thumbnail images are provided for quick scan capability. Because the images comply with DICOM standards there is no degradation in image quality over time or through digital transmission.

TBDx Captured Image – Auramine O

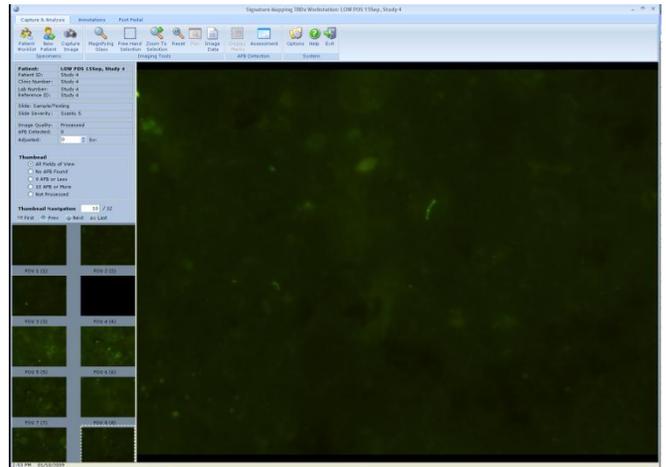


TBDx Visualization of Captured Image



Integrated with the Microscope are Essential Enabling Technologies

- Motorized microscope stage fitted with a 1, 4, or 8 slide insert for point-of-care & research laboratory applications.
- Automated 200-slide autoloader to simplify the processing and management of vast numbers of slides. Includes a barcode reader for patient data capture and recording to a laboratory information system.
- Digital camera embedded in the microscope for high-quality image capture.
- Computer with a touchscreen monitor for high resolution image display and ease-of-use.
- *Signature Mapping SMDS™* automation software to control the movement of the integrated hardware components.
- *Signature Mapping TBDx™* automated tuberculosis detection software including: load assessment by FOV and slide, image review options, and patient reporting system.
- *Signature Mapping Decision Support Quick View™* to reduce microscopist workload, focus training and experience on the most challenging cases, and add the human's specificity bias to the final diagnosis by more finely differentiating suspected TB bacilli.
- Viewing Module displays digital FOVs, detected AFBs, and provides the ability to zoom, navigate, and review the images in an alternative visualization.

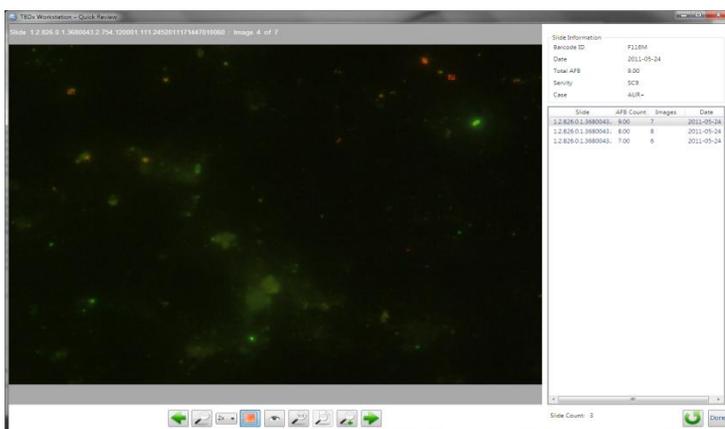


Signature Mapping SMDS™

Successful digital microscopy depends on automation control software to seamlessly handle the movement of slides and capture of high-quality digital images, whether processed by our 200-slide autoloader or an automated stage. *SMDS* includes:

- software automation to inventory patient slides;
- adjust for z-axis variations;
- auto-focus the embedded digital camera; and,
- collect 100 high-quality digital images for automated detection or microscopist review.

Signature Mapping Decision Support Quick View™



A major benefit of the automated detection capabilities of *TBDx* is that the microscopist no longer has to expend long, tedious, and low sensitivity efforts reviewing every FOV on every slide. *TBDx* operates with high sensitivity and PPV on high severity P+ - P+++ cases and a high NPV on negative cases. As a result, the area of most need is the final determination of suspected scanty cases where the microscopist expertise, training and experience return the greatest value. To facilitate the process of review, *TBDx* offers a decision support tool to assist in the quick review of scanty cases. Only those FOVs with a positive detection, on scanty only cases, will be presented to the microscopist for analysis. The approximate number of FOVs to be reviewed will be between 1.2% - 1.4% of all FOVs captured on all slides processed.