

Product Specification:

TotalLab™ 1D 21 CFR v12

General

- Fully automatic, single button press complete image analysis within area of interest if required
- Instant access to refinement of any analysis step
- Alternative step-wise image analysis for each step
- Facility to load and save user preferences, including parameters and display options, prior to analysis
- Automatic PDF report generator
- Ruler options to display lane names, numbers and MWs

Lane Creation

- Automatic lane detection
- Export and import of lane templates
- Manual lane detection
- Multi-tier analysis
- Move, resize and bend multi-box
- Move, resize and bend individual lanes
- Add grimaces to account for band distortion
- Delete lanes

Background Subtraction

- Automatic methods
 - Rolling ball
 - Rubber band
 - Minimum profile
 - Valley to valley
 - Lane edge subtract
- Manual methods
 - Image rectangle
 - Image stripe
 - Manual baseline

Band Detection

- Fully automatic band detection
- Adjustable peak parameters:
 - Minimum peak
 - Noise reduction
 - % max peak of lane or gel
- Band edge detection methods:
 - Single edge
 - Automatic detection
 - Fixed width
 - % peak
- Manual editing of peak and edge detection in image and lane profile windows
- Snap to peak editing
- Automatic band measurements

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- View band measurements in measurements table
- Wide range of data fields to display in measurements table
- Histograms for viewing band data
- View multiple lane profiles either stacked or overlaid
- Export lane profile information
- Edit Band Name and display on Image and in table
- Automatic Dendrogram creation

Profile Deconvolution

- Fit Gaussian curves to profile
- One Gaussian per band
- Manual adjustments of Gaussian
- FWHM (Full Width Half Max) measurement of bands

Molecular Size / pI Calibration

- Library of standards
- Add new standards
- Edit existing standards
- Automatic assignment of standard bands
- Propagation by Rf between standards
- 6 curve fitting methods
- MWs automatically displayed in measurements table
- pI standards can increase or decrease

Quantity Calibration

- Range of methods to quantify:
 - Selected bands
 - Individual lanes
 - Average of selected bands
 - Total of selected bands
- Manually assign known values to bands
- Range of calibration units
- View interpolated and extrapolated values in measurements table

Additional Analysis Features

- Supports multiple image formats:
 - .tiff
 - .gel
 - .jpg
 - .bmp
 - .gif
 - .png
 - .img (Fuji format)
- Access to all analysis functions in “wizard-style” interface
- Image editor tool accessible from any module for image manipulation including:
 - Crop
 - Rotate
 - Filter
 - Flip
- Storage of image properties and image edits performed using the image editor
- On-the-fly recalculation after all editing
- Invert intensity measurements facility
- Simple data transfer to Microsoft Excel, clipboard or file
- Comprehensive Help menu and tutorial files
- Context-specific help panes
- Tool tips on all features
- Adjust contrast/brightness/colour of image
- Comprehensive and customisable image annotations
- Customisable image and table display options
- User-definable colour display options

- Zoom control for image viewing
- Magnify and panning tools
- Print preview

System Access

- Uses Windows security model to restrict access to software (User names and passwords)
- User logon required when starting the software
- Three levels of access, Supervisor, User and Viewer enabled by IT administration
- Password copying disabled on logon screen

Data Integrity and Security

- Data stored in Secure Storage Area which can be set up by IT administration
- Data stored as human readable xml files
- Software will not analyse or store corrupted data (altered outside of the software system)
- No analysis possible on non 21 CFR Part 11 module data
- No analysis possible on images being analysed by another user
- Archiving option to backup entire experiment data and history
- Multiple versions of experiment can be stored
- Any version of experiment retrievable for read only viewing

Audit Trails

- Security Audit trail records all administration tasks and user logons, logoffs and approval signatures. Logon success and failures recorded
- Version Control Audit trail records all global experiment actions such as storing a version of the experiment, approving an experiment and analysing the image
- Experiment Audit report records all the actions required to repeat the experiment (lane creation, band detection etc.)
- Audit trails include the name of the user together with time and date of action

Electronic Signatures

- Supervisors can approve completed experiments
- Approval requires re-entering of password details (an electronic signature)
- Analysis reports state whether experiment approved or not
- Name, date, time and reason for approval is recorded with sign off

Validation Documentation

- Design document describing map between software and 21 CFR Part 11 rule to aid validation of software
- Audit response document to answer standard audit questions

Hardware and Software Requirements

Operating systems: Windows 2000, Windows XP, Windows Vista and Windows 7

(Please note: you require Administrator privileges for installation. To use the software you do not need Administrator privileges).

Processor: 1.4 GHz

Memory: Minimum 256Mb, recommended 512Mb

Free hard disk space: Recommended 5Gb

- Minimum and recommended specifications are important in order to provide good software performance and reduce installation and operational issues.
- A general rule to note is that with running any software the more RAM a system has the better
- For optimal performance in higher end products or where users may be pushing systems to the limit use the “recommended” specifications