StripAssay®
Evaluator

Software Release 2
Documentation Revision
02/2016

CE

TABLE OF CONTENTS

1. STRIPASSAY® EVALUATOR

Features

StripAssay® Evaluator is the data recording and interpretation software for ViennaLab *StripAssay®* series of genetic assays.

The software is capable of automatic analysis of future products in the ViennaLab *StripAssay®* series through simple addition of the appropriate assay definition file (see chapter 13).

Please check http://www.viennalab.com for a list of available assays and for software updates.

System Requirements

- ⊙ **Computer:** PC with 1 GB RAM and a screen resolution of a least 1024x768 pixels (1280x1024 pixels or better recommended).

- ⊙ **Operating system:** Microsoft Windows 7 with Service Pack 1 or Microsoft Windows 10). The Microsoft .NET Framework 2.0 or >4.5 must be installed (included on the *StripAssay® Evaluator* installation CD or available directly from Microsoft via Windows Update or Microsoft Update).
  For installation, administrator privileges are required.

- ⊙ **Scanner:** 100% TWAIN-compatible scanner capable of at least 300x300 dpi optical resolution and a minimum A4 (210x297 mm^2) scanning area.
  Scanners from Canon (LiDE series) are recommended.
  Compatibility of scanners can be checked with *StripAssay® Evaluator* running in demo mode. See chapter 4 for details.

Many scanner drivers support a fully automatic mode requiring no user interaction. Such modes, however, are not suitable for manual scanning from within *StripAssay® Evaluator*. If available, please use "advanced" or "professional" modes where you can control scan resolution. It is also possible to scan images with your favorite scanning software and to later import these images into *StripAssay® Evaluator* using the Load Images function (see chapter 6 for more details about loading images). Generally it is recommended to mount strips onto *Collectors™* and use the Auto-Scan & Analyze function (see chapter 6).

2. SOFTWARE INSTALLATION

Depending on the way you have received your copy of *StripAssay® Evaluator*, you will have to take the steps outlined below. You need to be logged on as a member of the Administrators group to install the software and necessary drivers.

⊙ **Bundled with Hardware**

If you have received *StripAssay® Evaluator* together with the necessary hardware (computer running Microsoft Windows and a scanner), you will not have to take any further installation steps. *StripAssay® Evaluator* will be ready to use, and you should find an icon to start the software on the Windows desktop. Skip ahead to chapter 3.

⊙ **Received via Email or Download**

If you have received the software by email or download, it will likely be in the form of a single file named EvaluatorSetup.exe (it may be packaged in a ZIP archive; in this case, you will have to unzip the file first). To install the software, simply doubleclick EvaluatorSetup.exe. In case the Microsoft .NET Framework 2.0 has not been installed, you will be notified by the setup program and the installation will halt. You then first have to install the Microsoft .NET Framework 2.0, which can be done by running Microsoft Update (Start->All Programs->Microsoft Update), by visiting http://update.microsoft.com or by directly downloading the .NET Framework (dotnetfx.exe) from http://www.microsoft.com/downloads (enter .NET Framework 2.0 into the search field, and choose to download .NET Framework Version 2.0 Redistributable).

⊙ **CD or DVD**

If you have received *StripAssay® Evaluator* on a CD-ROM, put the CD into the computer's optical drive. The setup program should start automatically (if it does not, double-click EvaluatorSetup.exe in the root directory of the CD. Follow the instructions presented by the setup program. The Microsoft .NET Framework 2.0 is included on the CD in eight different languages. Should an appropriate version for your language version of Windows be missing, it is recommended that you download and install the corresponding language version (see above).

⊙ **Deinstallation**

To uninstall *StripAssay® Evaluator*, please follow the steps outlined in chapter 14.

⊙ **Full and Limited Versions**

StripAssay® Evaluator operates in full or limited mode depending on whether a so called "dongle" is plugged into one of the computer's USB ports. Data acquisition is disabled in the limited mode (without dongle), i.e. you cannot load or scan new images. However, it is possible to analyze and annotate strips and to print reports even in limited mode. *StripAssay® Evaluator* can be installed and unsed on any number of computers, but image acquisition is limited to the computer with the dongle.

To obtain a dongle, please contact your local ViennaLab distributor or ViennaLab Diagnostics GmbH directly.

3. NAVIGATING THE SOFTWARE

StripAssay® Evaluator organizes the analysis workflow in four steps, easily accessible via the main nagivation bar. Clicking on a tab will show a screen associated with the specific steps and tasks.

❶ **Start / Acquisition**   ❷ **Strips / Sample Info**   ❸ **Results**   ❹ **Reporting**
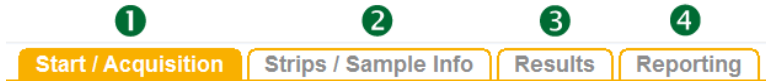
❶ Start / Acquisition

When starting a new analysis, general information about the assay is specified, such as assigning an ID to the assay document, naming the operator, filling in the assay lot number, the date, and any comments. When images of strips will not be scanned from *Collectors™*, the type of assay should be selected as well.

The data aquisition wizard shown on the right half of the screen will guide you through the image acquisition process (see chapter 5 and chapter 6 for more details).

❷ Strips / Sample Info

After images have been acquired, this screen allows to verify the correct placement of strips on the scanned images after automatic detection and to make necessary adjustments (or to manually place strips). Furthermore, the scanned images, named "sheets", can be rotated, cropped, or exported via the tools accessible on this screen. For more details, see chapter 7.

The sample info panel shown on the right side of this screen provides the opportunity to assign sample IDs (patient names, dates of birth, remarks) to individual strips as well as to whole sheets. See chapter 8 for more details on this topic.

❸ Results

The results screen shows an individual strip and the interpretation of its staining pattern, as well as present options to modify the recognized pattern, if necessary, and to edit the sample information associated with the particular

strip. Exporting and printing of a single strip is also possible from this screen. For more details, see chapter 9.

❹ Reporting

Finally, after strip results have been validated by the responsible assay operator/ analyst/physician, the results can be printed in the form of either a summary report or as detailed reports for each sample. Results can also be exported to a file that then can be imported into e.g. Excel. For more details on reporting see chapter 10, and for an overview of export options, see chapter 11.

See chapter 16 for a complete menu and button reference.

4. PROGRAM SETTINGS

When the software is started for the first time, or by going to Tools->Program Settings, the Program Settings dialog is shown.
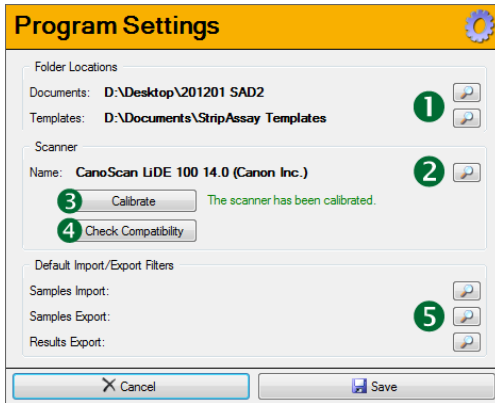

❶ Folder Locations

Here, you can change the default storage locations for assay documents (.sad2 files) and templates (.sat2 files). The defaults have been set during program installation and are subfolders in your usual documents folder.

❷ Scanner Selection

This item shows the currently selected scanner. To set or change the scanner that should be used by the software, click on the search button and select a scanner from the list. The scanner needs to be TWAIN-compatible (WIA drivers will not give satisfactory results). If you receive an error message stating that no TWAIN scanners are installed when you try to select a scanner, make sure that the scanner driver that was included with your scanner (or downloaded from the scanner manufacturer's homepage) has been properly installed, and double check that the scanner driver adheres to the TWAIN standard.

❸ **Scanner Calibration**

It is also indicated whether the selected scanner has been calibrated. To calibrate a scanner, click the Calibrate button and follow the instructions shown on the screen. Calibration only needs to be done once per scanner.
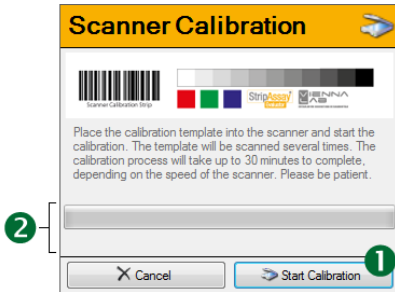
To perform scanner calibration, click the Start Calibration button (❶). Status messages and a progress bar will keep you informed about the process (❷).

❹ **Scanner Compatibility Check**

Compatibility of a scanner or scanner driver with *StripAssay® Evaluator* can be verified by running a scanner compatibility test. To run this test, click the Compatibility Check button. This will show the Scanner Compatibility dialog.
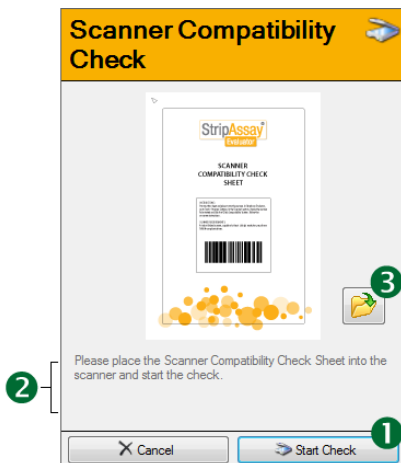
To start the compatibility check, first place the *Scanner Compatibility Check Sheet* in the scanner. The *Scanner Compatibility Check Sheet* can be printed from a PDF which can be accessed by clicking button ❸ (this requires Adobe Acrobat or another PDF reader to be installed). Then, click the Start Check button (❶) to initiate the test scan. The result of the test will be displayed in the status area (❷).

❺ Default Import / Export Filters

Here, you can set which import/export filters should be used for importing and exporting sample information data, and for exporting results. In a standard installation of *StripAssay® Evaluator*, only one filter per category is installed. For custom filters, please contact ViennaLab Diagnostics GmbH and ask for a quote.

5. PREPARATIONS (START)

To process strips with *StripAssay® Evaluator*, please follow the procedure outlined below.

Mounting of Strips

Place each processed strip onto one of the designated fields (❷) on the appropriate *Collector™* (supplied with the *StripAssay®* kit), align it with the schematic drawing using the red (top) and green/blue (bottom) marker lines, and fix it to the sheet with adhesive tape. Alternatively, any other support can be used, but automatic scanning and processing will not be possible then.
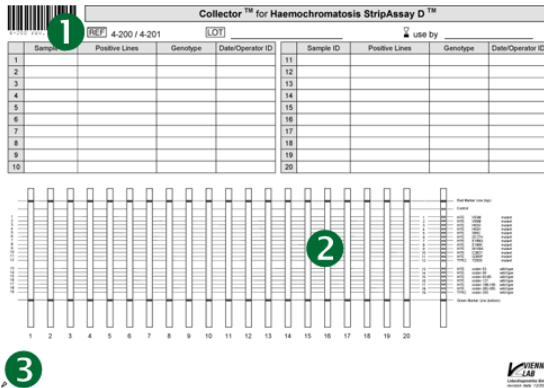
Make sure not to cover any marker or hybridization positions with the tape, as this might interfere with scanning. Also take care not to obscure the barcode (❶) area since otherwise the automatic detection of the assay type might not be possible.

Assay Setup

If it is not already displayed, switch to the Start / Acquisition screen. If another assay document is still open, start a new assay by clicking File->New (or File->New From Template if you want to reuse assay information stored in another assay document or template file).
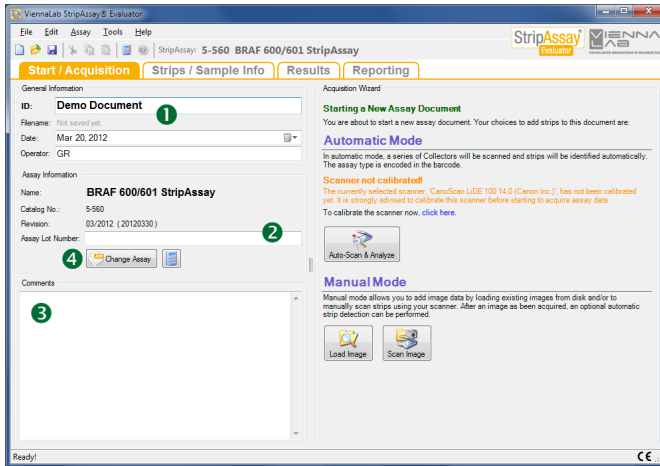
Before scanning of the strips some information about the assay should be recorded in the appropriate fields:

❶ Enter an assay ID. The program automatically suggests a name based on the current date and time. You might want to put an assay ID consistent with the policy of your lab here. Also, set the date of the assay, and enter an operator ID, i.e. a reference to the person who performed the analysis.

❷ Specify the lot number of the kit used.

❸ Enter any additional comments if desired.

Define the StripAssay® Type

When the strips are mounted on a *Collector™* with a barcode, this step is not necessary, as the assay type will be determined automatically.

When you plan to scan manually, or load a pre-existing image for analysis, the type of assay should be specified before starting with the image acquisition. To select a *StripAssay®* type, click the Change Assay button (❹), and select an assay type from the list (for more information on the StripAssay® Selector, see chapter 13).

Preparing to Scan

Place the *Collector™* onto the scan area of the scanner in such a way that the arrow in the lower left corner of the sheet (❸ in the image on the previous page) points towards the scanner's scan origin. The corner of the sheet should touch the corner of the scan surface. The scan origin usually is the front left or rear right corner of the scanner when the lid opens away from you.

Continue to chapter 6 for more details on the image acquisition process.

To empirically determine where the scan origin is located, simply place a Collector™ (or any other suitably marked piece of paper) into the scanner in one of the positions mentioned earlier. Then, perform a manual scan using StripAssay® Evaluator (or any other scanning software). The sheet is inserted correctly when the arrow (or marking) appears in the upper left corner of the scanned image.


IMPORTANT

Please make sure that the strips mounted on a *Collector™* (or any other support) are lying flat on the scanner's surface and that the lid is closed securely. Failure to ensure this might lead to uneven scan results and potential misinterpretation of assay results..

6. DATA ACQUISITION

After the necessary preparations have been completed (see chapter 5), the next step is to scan the strips (or to load an existing image). The Acquisition Wizard (❶) shown on the Start / Acquisition screen will guide you through the acquisition process. The options presented by the wizard will depend on the state of the current assay document.

> *The aquisition options will be limited, depending on whether images already exist in the current assay document, and how the first image was acquired. For example, if a Collector™ was scanned, the options are limited to scanning further Collectors™ of the same type.*
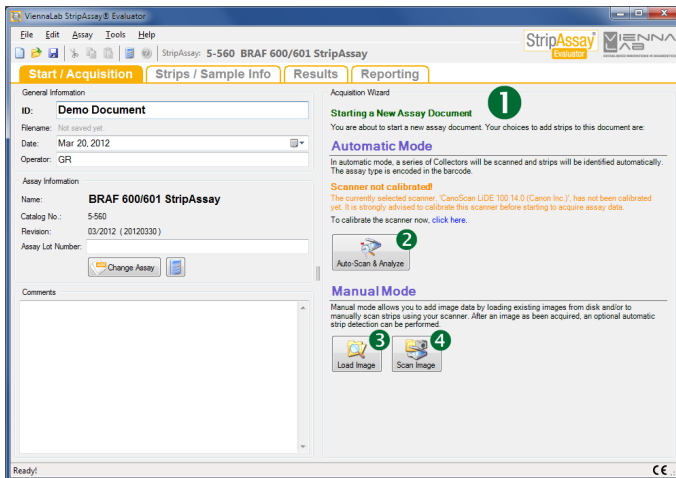

Two basic modes of operation are possible, Automatic Mode (Auto-Scan & Analyze, ❷) and Manual Mode (❸❹).The mode will be locked after the acquisition of the first image. For routine scanning of strips mounted on *Collectors™*, the automatic mode is most appropriate. In the manual mode, sheet images are obtained either by loading pre-existing images from disk (Load Image, ❸) or by scanning (Scan Image, ❹).

> The options to acquire images from a scanner (automatic or manual mode) is only available when a scanner has been chosen in Program Settings (see chapter 4).

Automatic Mode

Click on Auto Scan & Analyze to start automatic scanning and analysis of strips mounted on a *Collector™*. Follow the instructions of the wizard. Unless you have put a checkmark into Ignore Barcode (❶), the software will read the barcode from the *Collector™* to determine the type of assay. Otherwise, it will be assumed that a *Collector™* matching the current assay type has been placed into the scanner. Click the Auto-Scan & Analyze (❷) button to start the scanning process.
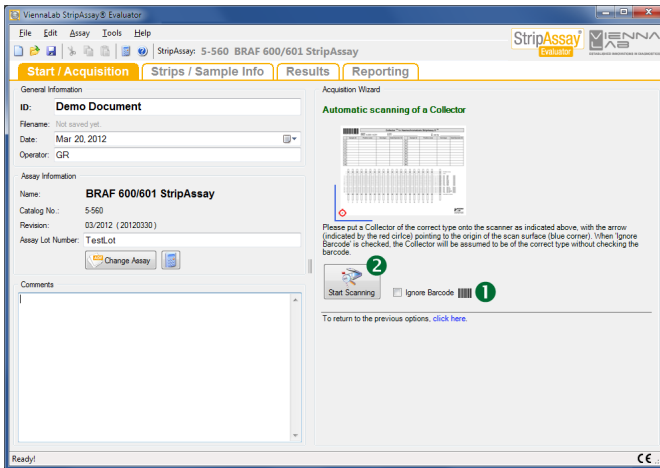

Before scanning Collectors™, it is important to calibrate your scanner (see chapter 4*).*

After the barcode has been correctly interpreted, the software will extract the area containing the strips and start the automatic detection process. If reading of the barcode failed, you will be prompted to set the type of assay manually. When scanning and detection are completed, you will be informed about the number of detected strips and presented with the option to either scan more sheets, or to continue to the Strips / Sample Info screen or to the Results screen.

Subsequent *Collectors™* in a multi-sheet assay must be of the same type, as different types of strips within one assay document are not allowed.

Manual Mode

Image acquisition in manual mode can be done by scanning images manually, using the interface provided by the scanner driver, or by loading existing images from disk. After loading or scanning a sheet, you will be prompted to enter some information about the sheet (❶) and whether to just add the sheet to the assay or to attempt automatic detection of strips (❷), to add the sheet without automatic detection (❸), or to not add the sheet (❹).
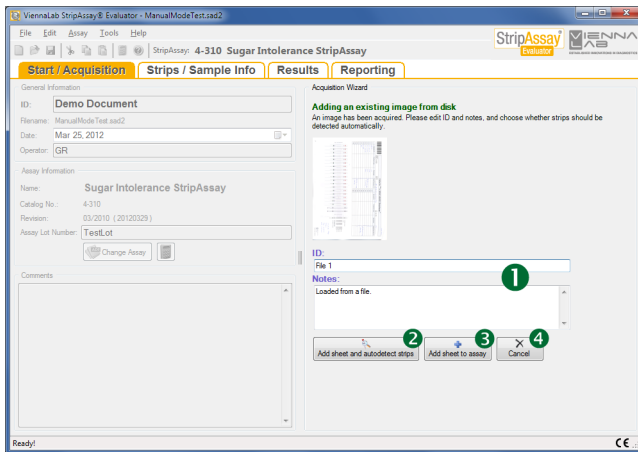
Automatic detection is only available for single-strip assays.

Some scanner drivers support a "full-auto" mode where no user intervention is required. Such a mode is not suitable for manual scanning from within *StripAssay® Evaluator*. Please set the scanner software to run in a mode that allows user intervention, i.e. the manual setting of scan parameters such as resolution, color depth, and image processing. Alternatively, you can scan images with your favorite scanning software and later import these images via Load Image.
For best results, a scan resolution of 300 dpi and a color depth of 24 bits per pixel is recommended. Also, disable any color correction or image processing options such as "unsharp mask".

StripAssay® Evaluator supports images in these formats: TIFF (*.tif), JPEG (*.jpg, *.jpeg), GIF (*.gif), Portable Network Graphics (*.png), and Windows Bitmap (*.bmp).

Removing Sheets

Sheets can be removed from an assay document via the Sheet->Delete menu on the Strips / Sample Info screen. See chapter 7 for more information.

7. MANIPULATING STRIPS

On the Strips / Sample Info screen you can verify the placement of strips after auto-detection. Furthermore, you can add, re-position, or delete strips manually on scanned images. Additionally, especially when using loaded or manually scanned images, you can perform a number of image manipulations such as rotating or cropping.
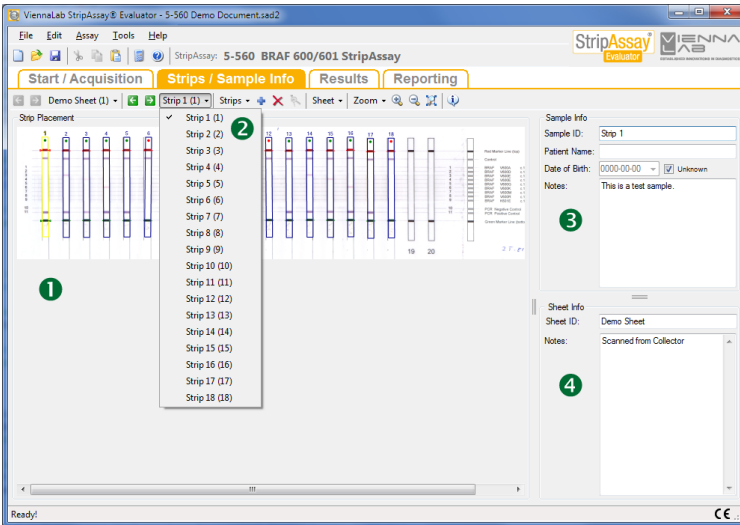
The main options on the Strips / Sample Info screen are:

❶ Manipulate strips: Re-position, add, or delete strips.

❷ Navigate between strips: Use the menu to jump directly to a specfic strip (a similar menu is available for sheets when there are two or more sheets in an assay document).

❸ Edit sample information: Change the default name of strips, add patient data (name, date of birth), as well as any comments and remarks.

❹ Edit sheet information: You can name sheets and add comments.

Toolbar Options
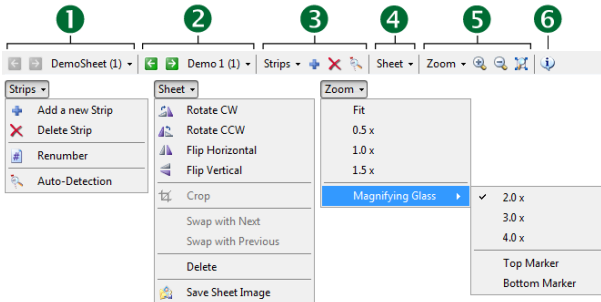
❶ **Navigate between sheets**. Either select a specific sheet from the menu, or use the arrow buttons to navigate to the previous (left) or next (right) sheet.

❷ **Navigate between strips**. Either select a specific strip from the menu, or use the arrow buttons to navigate to the previous (left) or next (right) sheet.

> *You can also use the PageUp and PageDown keys on your keyboard to navigate between sheets, and the < and > (left and right arrow) keys to navigate between strips.*

❸ **Add, delete, renumber, and detect strips**:

⊙ Click the Add a new Strip menu (or click the corresponding toolbar button) to add a new strip to the sheet. The frame for the new strip is initially displayed in the top left corner of the sheet area, and is labeled with the next available number.

If a *Collector™* was scanned, strips can only be added as long as unoccupied positions are available; when a new strip is added to a *Collector™*, the Strip Position dialog is displayed and you have to assign a position number.


Strips can also be added by pressing the A key. In this case, the new strip is added to the sheet at the position of the mouse cursor.

- ⊙ Click the Delete Strip menu (or click the corresponding toolbar button) to delete the currently selected strip. The remaining strips will be renumbered, starting with 1. In *Collector™* mode, no renumbering will occur when strips are deleted. The keyboard shortcut is Del.

- ⊙ Click the Renumber menu to swap the numbers of two strips (❶) or to renumber all strips on the sheet (❷). Numbering will start with 1 and proceed from top left to bottom right. This option is not available in *Collector™* mode.

Renumber Strips #

Swap
❶ Strip 1 (Test)
Strip 2 (Neg. Control)   Swap

Automatic
❷ # Auto-Renumber all Strips

✖ Close

- ⊙ Click the Auto-Detection menu (or the corresponding toolbar button) to attempt an automatic detection of strips. This will remove any strips already present on the sheet. This option is not available in *Collector™* mode or for multi-strip assays.
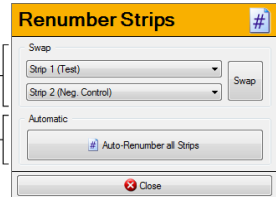
❹ **Manipulate sheets**:

- ⊙ Rotate sheets clockwise (CW) or counterclockwise (CCW). Existing strips will be rotated with the sheet.

- ⊙ Flip (mirror) sheets horizontally or vertically. Existing strips will be transformed accordingly.

- ⊙ Crop sheets. First, draw a cropping rectangle (❶) on the sheet (hold down the left mousebutton while moving the mouse). Then, press the Crop menu item (❷) to remove everything but the marked area.
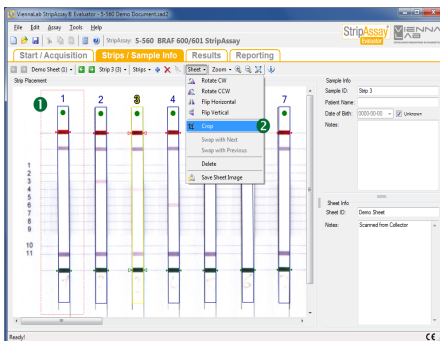

All strips on the sheet will be removed! This cannot be undone.

⊙ Swap the current sheet with the previous or next.

⊙ Delete the current sheet.

> All strips on the sheet will be removed! This cannot be undone.

⊙ Save the current sheet as an image file. You will be prompted to choose a save location and file name. The image can be saved in the TIFF, JPEG, or BMP format.

❺ **Adjust the zoom**. You can adjust the magnification/ reduction with which the sheet image is displayed zoom controls on the toolbar, or select a predefined magnification from the zoom menu. The Magnifying Glass settings allow control of display of a "magnifying glass" while dragging the top or bottom marker hotspots (see image below). When checked, top or bottom marker magnifiers are always displayed, otherwise they are only visible when hotspots (see below) are dragged with the right mousebutton.
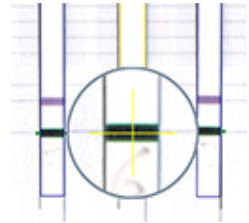
❻ **Toggle display of the sample info area**. Click the toolbar button to show or hide the sample and sheet info area on the right side of the Strips / Sample Info screen.

Positioning Strips

To position strips, first select the strip to be manipulated (either by clicking on it or by selecting it from the strip selection menu). The active strip and its number will be highlighted with a yellow frame (❶). When the mouse is moved over the selected strip, the cursor will change to a hand. The strip can now be moved on the sheet by dragging it while holding down the left mousebutton (for example, the hotspot marked ❸). Two special hotspots exist on a strip, top (❷) and bottom (❹) markers, marked by triangles pointing towards the strip outline. When the mouse is positioned in these hotspots, a crosshair cursor is displayed. Dragging the topmarker will move the strip (equivalent to dragging with the hand cursor), unless the top marker magnifier is enabled (see above) or dragging is done with the right mousebutton. In these cases, the region around the marker is magnified,

facilitating propper positioning of a strip (see above). Dragging the bottom marker hotspot will result in the rotation of the strip and, within certain limits, the adjustment of the strip's length.

Strips can be easily positioned with the help of keyboard shortcuts. Pressing T will move the active strip's top marker hotspot to the position of the mouse cursor. B will move the bottom maker (if the mouse is in a valid distance from the top position). Pressing A adds a new strip at the current mouse position.

8. EDITING SAMPLE INFORMATION

Sample information, including sample id (❶), patient name (❷) and date of birth (❸), as well as additional notes (❹), can be conveniently edited for each strip in the assay using the corresponding fields found on these screens:

- ⊙ Strips / Sample Info (see chapter 7),
- ⊙ Results (see chapter 9), and
- ⊙ Reporting (see chapter 10).

The example shown is from the Results screen.

Any changes to the sample information apply in real-time (i.e. the selection menus will be updated immediately).

The sample info panels on the Results and Reporting screens additionally allow to set whether a strip should be included in the detailed and/or summary reports (❺). See chapter 10 for more details on reporting.
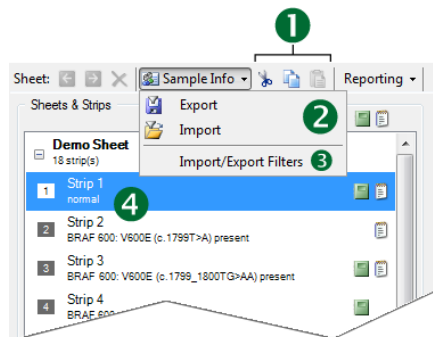
Importing/Exporting Sample Information

On the Reporting screen, additional options to manipulate sample information, including importing and exporting, can be found:

❶ The sample information (id, patient name and date of birth, and notes) of the active strip (❹) can be cut, copied, or pasted.

❷ Clicking the Export or Import menu items, sample info data can be exported or imported, respectively. See below for a detailed description of the data format of the build-in import/export filter.

❸ To choose how sample info data is handled, click the Import/Export Filters menu item. This will pop up the Program Settings dialog where you can select the filters (see chapter 4).

Basic Import/Export Filter – Specification

The built-in standard filter for sample information reads and writes a simple tab-delimited text file with six columns. Empty lines and lines starting with "#" are ignored.

|	
1	Sheet Number
2	Strip Number
3	Sample (Strip) ID
4	Patient Name
5	Patient Date of Birth
6	Comments / Notes

Sheets and strips have to be numbered consecutively, beginning with 1.

Example (Export):

```
# SheetNo StripNo SampleID  PatientID        Date of Birth  Notes

# Sheet -1- Test Sheet #1

1        1       Strip 1  Neg. Control                      water as PCR template
1        2       JD123    John Doe         1972-12-09
1        3       Strip 3                                    high background
1        4       Strip 4  Synthetic Sample
1        5       Strip 5
1        6       Strip 6
```

9. RESULTS

The Results screen shows detailed information about individual strips. You should view and validate each result before including a strip in a report.
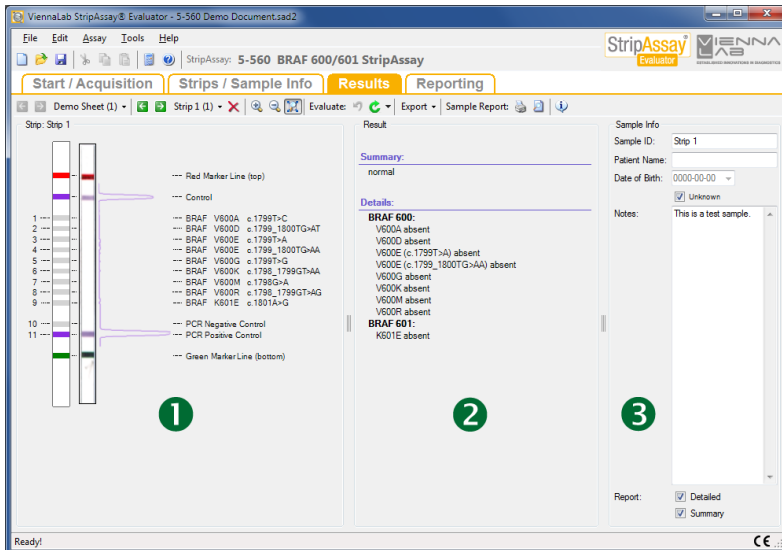
The screen is divided in three panels:

❶ The strip panel, where individual strips are shown in detail, with a schematic representation of the strip on the left side, labels on the far right, and – aligned with the schematic drawing– the scanned image of the strip and a curve roughly corresponding to staining intensities in the middle.

❷ The result panel, where the interpretation of the strip's pattern (negative/ positive positions) is shown as summary and detail results. Any warning or error messages are also shown here.

When positions, or related groups of positions, fail to evaluate (e.g. when corresponding mutant and wild-type positions are both negative), the respective positions will be marked with an exclamation mark in a yellow triangle. Inspect these positions carefully and, if warranted, correct one of the positions involved. Any changes will be reflected in the result immediately (see below for information on how to modify positions).

❸ The sample information panel, which can be used to enter additional information, such as the id of the sample/patient the strip is corresponding to. See chapter 8 for more information on editing sample information.

> *Once the interpretation of the strip has been validated by a responsible person, include the strip in one or both of the report types by checking the corresponding checkboxes.*

Editing the Strip Pattern

Based on staining intensities and other criteria (e.g. peak shape), the software determines whether a specific position on the strip should be regarded as positive or negative. The result of this assessment is presented by blue (positive) and light gray (negative) positions in the schematic drawing of the strip.

> You, the user, can override the decisions made by the software. However, whenever modifications are made by the user that differ from the automatic evaluation, the strip will be marked as "user-modified". This is indicated in the results panel and on all reports. Modified positions are highlighted (orange frame) in the strip schematic.

> *To undo/reset any user modifications, press either the* Remove user modifications *button or the* Re-evaluate strip *button on the toolbar (see below).*

To change the state (positive or negative) of a position, do this:

⊙ Move the mouse cursor over the respective position (the cursor will change to a hand symbol).

⊙ Click the position with the left mousebutton to mark it as positive.

⊙ Click the position with the right mousebutton to mark it as negative.

Moving the cursor over positions while holding a mousebutton pressed will mark all positions moved over. The changes will be reflected in the results immediately.

Toolbar Options
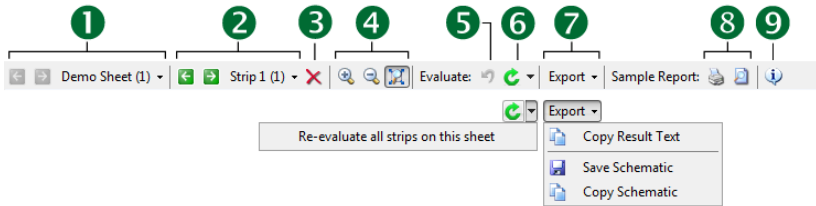
❶ Navigate between sheets by clicking the left/right arrow buttons, or by selecting a sheet from the dropdown menu. Keyboard shortcuts: PageUp, PageDown.

❷ Navigate between strips on a sheet by clicking the left/right arrow buttons, or by selecting a strip from the dropdown menu. Keyboard shortcuts: <, >.

❸ Delete the current strip. Keyboard shortcut: Del.

❹ Zoom the strip view (in, out, and fitting the available space).

❺ Remove user modifications.

❻ Re-evaluate the strip. The dropdown menu gives the option to re-evaluate all strips on the current sheet.

❼ Export the results:
- ⊙ Copy Result Text will copy the results to the clipboard in text form.
- ⊙ Save Schematic will save the content of the strip view as Metafile (EMF, vector graphics) or TIFF (pixel graphics) file.
- ⊙ Copy Schematic will copy the content of the strip view to the clipboard (Metafile format).

❽ Print or preview a detailed report for this strip (see chapter 10 for more details on reporting).

❾ Toggle the display of the sample information panel (see chapter 8 for more details on managing sample information).

10. REPORTING

The Reporting screen summarizes the results of all strips and lets you print and export detailed and summary reports. Additionally, it provides enhanced sample information management tools (see chapter 8 for more information on this aspect).
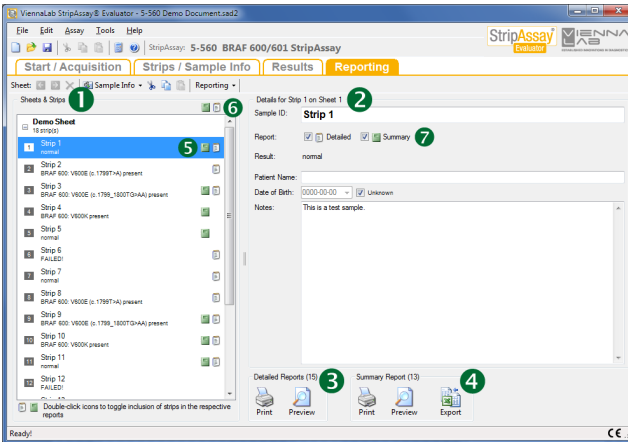
The main elements of the Reporting screen are:

❶ The Sheets & Strips panel lists all strips, ordered by sheets. Left-click a sheet or strip entry to select it. Panel ❷ will update accordingly. Right-clicking will show a popup menu (see below).

❷ The Details panel shows detailed information for the selected sheet or strip.

❸ The Detailed Reports panel lets you print and preview detailed reports. The number of strips that are marked for inclusion in this type of reporting is indicated.

❹ The Summary Report panel lets you print, preview, as well as export summary reports. The number of strips that are marked for inclusion in this type of reporting is indicated.

Strips marked for inclusion in a summary report will be exported when clicking the Export button. For more detailed information on data export, please see chapter 11.

Inclusion or exclusion of individual strips in the respective report types (detailed, summary) is controlled via the detailed and summary report icons (❺ ❻ ❼).

To toggle between inclusion and exclusion, either double-click the respective icons for each strip in the list (❺), or double click the icons above the list to include or exclude all strips (❻). Alternatively, the corresponding checkboxes can be set in the Details view for each strip (❼).

Inclusion/exclusion of strips for reporting can also be set on the Results screen (see chapter 9).

Context Menu
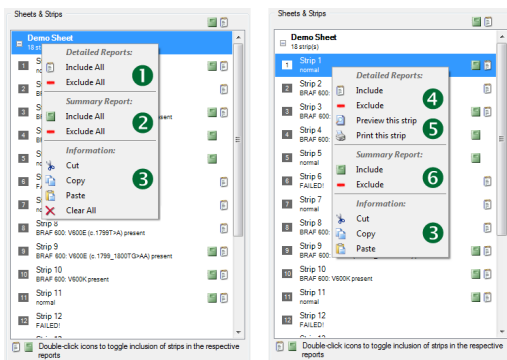
Depending on whether the list entry for a sheet or strip is right-clicked, a corresponding context menu will pop up, with these options:

❶ Include or exclude all strips on the selected sheet in/from detailed reporting.

❷ Include or exclude all strips on the selected sheet in/from summary reporting (results data exporting).

❸ Cut, copy, paste sample information. See chapter 8 for more details on sample info management.

❹ Include or exclude the selected strip in/from detailed reporting.

❺ Print or preview a detailed report for the selected strip.

❻ Include or exclude the selected strip in/from summary reporting (results data exporting).

Reporting Toolbar
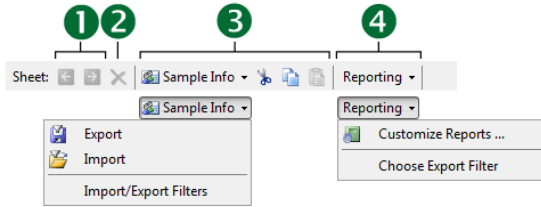
❶ Navigate between sheets.

❷ Clear the sample info for all strips on the currently selected sheet.

❸ Sample info management options. Please see chapter 8 for more information on this topic.

❹ Here, you can customize certain aspects of printed detailed and summary reports (see below). Choose Export Filter will open the Program Settings dialog (see also chapter 4) where an export filter can be selected that will be used when the Export button is clicked (see chapter 11 for more information on data export).

Previewing Reports

The Print Preview dialog displays reports as they would appear on paper. Using the toolbar, the reports can be printed (❶), the zoom level can be changed (❷), and multi-page reports can be navigated (❸).

Paper size and orientation can be set in the Page Setup dialog, accessible via the File menu.
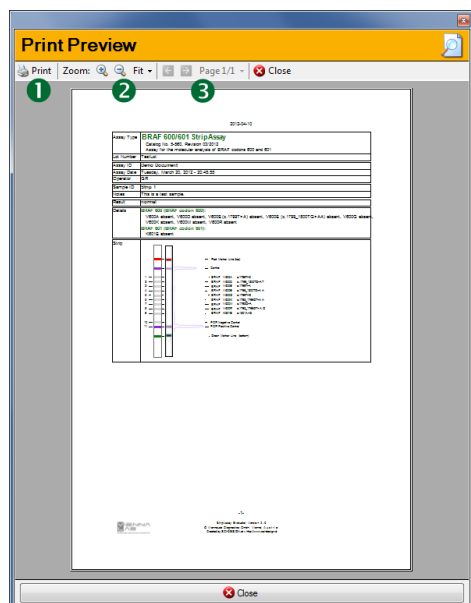
Customizing Report Styles

The Report Settings dialog allows to customize the way reports are printed.
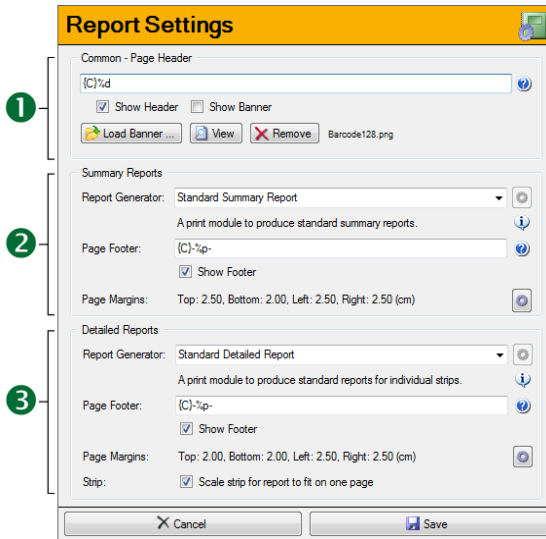
❶ In the Common - Page Header panel, a header line can be entered which will be printed at the top of each report (detailed and summary) if the Show Header checkbox is checked. If desired, a graphical banner can be loaded with the Load Banner button. It will be displayed at the top of each printed page if the Show Banner checkbox is checked. The banner image will be stretched across the full width of the page, so it should be designed accordingly.

❷ In the Summary Reports panel, the report generation engine can be selected that is used to generate the summary reports. A page footer line can be specified which will be printed at the bottom of each page if the Show Footer checkbox is checked. The page margins can also be set specifically for this report type.

❸ In the Detailed Reports panel, the report generation engine can be selected that is used to generate the summary reports. A page footer line can be specified which will be printed at the bottom of each page if the Show Footer checkbox is checked. The page margins can also be set specifically for this report type.

Formatting Parameters

A set of formatting parameters and placeholders can be used in the header and footer lines of reports.

Alignment of text portions can be achieved with the modifiers {L} (left), {C} (center), and {R} (right). These cause subsequent text to be aligned accordingly (left alignment is the default if no alignment is specified).

The aligment modifiers must occur in the order L C R and each can appear only once.

Usable placeholders are:

- ⊙ %d — current date.
- ⊙ %t — current time.
- ⊙ %p — page number within an individual report.

The placeholders can be used anywhere in a header or footer line and will be substituted with the respective values at the time of printing.

Example:

{L}Institution{C}-%p-{R}%d

This will result in a line of text with "Institution" printed at the left, the page number between dashes in the middle, and the current date at the right.

11. DATA EXPORT

Various data can be exported from StripAssay® Evaluator in different contexts:

Assay Results

To export genotype results (and sample info data), go to the Reporting screen and follow these steps (see also chapter 10):

- ⊙ Optionally, first select a results export filter in the Program Settings dialog (accessible via the Tools menu or from the Reporting screen toolbar).

- ⊙ Next, mark the strips to be exported for inclusion in the summary report.

- ⊙ Finally, click the Export button.

Using the default Basic Results Exporter, this will result in a text file containing general assay information as well as sheet/strip data in a tab-delimited format that can be opened with programs such as Microsoft Excel.

At the top of the file, basic assay information is written in a two-column format, followed by condensed strip results (6 columns: SampleID, PatientID, PatientDOB, Notes, Results Summary, Profile). In subsequent columns (the number depends on the specific assay type), the detailed results for each result group are written. The final two columns are Warnings and Errors.

Results of a Single Strip

The result of a single strip can be copied to the clipboard as plain text using the Copy Result Text menu item in the Export menu on the Results screen. See also chapter 9.

Strip Images and Schematics

An individual strip as presented on the Results screen can be exported either to the clipboard in the Windows Metafile format, or saved to disk (Windows Metafile or TIFF) directly from the Results screen using the options in the Export toolbar menu. See also chapter 9.

Sheet Images

Scanned sheets can be saved as TIFF, JPEG, or BMP images from the Strips / Sample Info screen. Browse to the sheet to be saved and click Save Sheet Image in the Sheet toolbar menu. See also chapter 7.

12. STRIP CALCULATOR

The Strip Calculator provides a means to evaluate patterns on strips without having to scan a physical strip. It can be activated by clicking the Calculator button on the main toolbar, the Start / Acquisition screen, the StripAssay Selector dialog, or from the Tools menu.
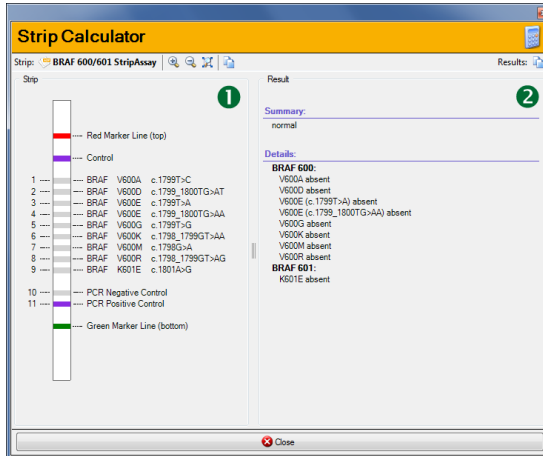
The window is divided into two panels, a schematic strip on the left (❶) and the corresponding result on the right side (❷).

Initially, all positions on the strip are set to their default states, corresponding to a typical normal result. To alter the state of a position, click it with the left mousebutton to make it positive, or with the right mousebutton to make it negative. Any changes in the Strip panel are immediately reflected in the Result panel.

Toolbar Options
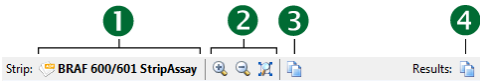
❶ Click the assay name to show the StripAssay Selector dialog (see chapter 13) in order to select a different assay type.

❷ Use the zoom controls to adjust the display of the strip.

❸ Click to copy the strip schematic shown in the Strip panel to the clipboard (Windows Metafile format).

❹ Click to copy the text in the Result panel to the clipboard.

# 13. STRIPASSAY SELECTOR

The StripAssay Selector dialog is used to:

- ⊙ Display the list of installed assay definitions.
- ⊙ Select an assay type to work with.
- ⊙ Manage assay definition files.
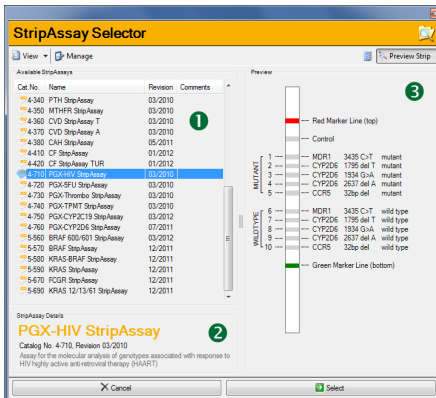
The dialog consists of three panels, that show the list of available assay definitions (❶), details about the currently highlighted assay definition (❷), and a preview of the strip(s) defined in the currently highlighted assay definition (❸).

Toolbar Options

❶ Use the View menu to control how the available assay definitions are displayed (as detailed list or simple icons) and sorted (by name or catalog number).

❷ Click the Manage button to toggle management mode on or off (see below).

❸ Click the Calculator button to display the Strip Calculator window pre-loaded with the currently highlighted assay definition.

❹ Click the Preview Strip button to toggle the display of the Preview panel.
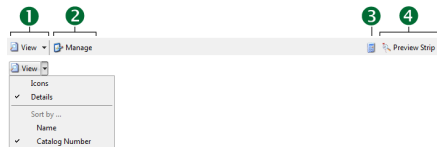
Assay Definition Management
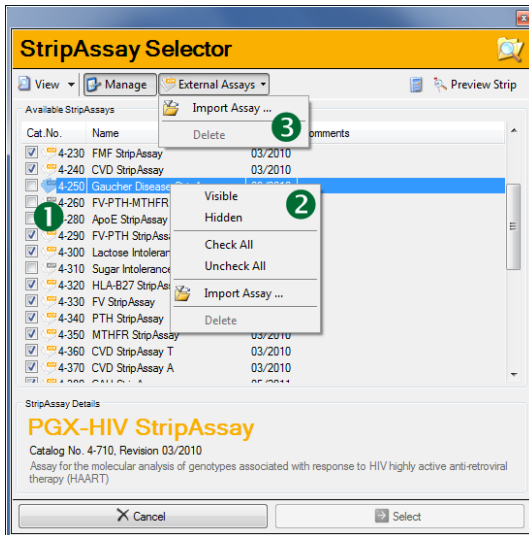
Use the management mode to choose which assay definition are displayed in regular mode by checking (displayed) or unchecking (hidden) the corresponding checkbox (❶), or by using the popup menu (❷) that opens when an assay definition is right-clicked.

The External Assays menu (❸) allows you to import additional assay definitions. Only imported ("external"), but not built-in assay definitions can be deleted.

14. SOFTWARE DEINSTALLATION

To uninstall *StripAssay® Evaluator* from your computer, start the uninstall program that was installed with the software. You can find it at Start->All Programs->StripAssay Evaluator->Uninstall.

Alternatively, go to Start->Control Panel->Add or Remove Programs. Locate the entry for *StripAssay® Evaluator* and click on Remove.
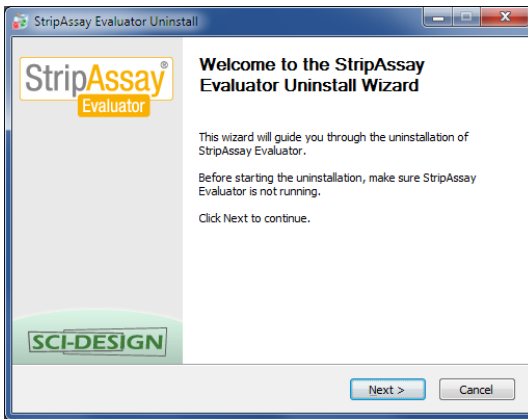
Follow the instructions presented by the uninstall program.

15. TROUBLESHOOTING & SUPPORT

Software/Hardware-related Problems

⊙ **Software Installation**

  ⊙ StripAssay® Evaluator must be installed using an administrator account. If you cannot run the installer with administrator privileges, please contact your system administrator.

  ⊙ If your system does not currently have the Microsoft .NET Framework 2.0 installed, and the language of your installation of Windows is not listed in the language selection dialog that appears when you first run the installation program, it is advisable to download and install a version of the Microsoft .NET Framework 2.0 matching your language version of Windows rather than to install one of the version included on the installer CD. Microsoft .NET Framework 2.0 can be downloaded directly from Microsoft (go to http://www.microsoft.com and search for "Framework 2.0 Redistributable").

⊙ **No assay definitions available**

  ⊙ Open the StripAssay Selector dialog, activate management mode, and check whether maybe all assay definition have been hidden (see chapter 13).

  ⊙ Re-install *StripAssay® Evaluator* and make sure that at least one assay definitions is checked for installation.

⊙ **Import/Export does not work** (buttons are disabled)

  ⊙ Open the Program Settings and/or Report Settings dialogs and verify that plugins are selected. If no plugins are available, please re-install StripAssay® Evaluator.

⊙ **Scanning does not work**

  ⊙ Open the Program Settings dialog and verify that the Scanner section shows the name of a scanner that is installed on the system and that this scanner is connected to the computer and turned on.

- ⊙ Install an updated version of the scanner driver. The scanner driver must provide a TWAIN-compatible interface.
- ⊙ Make sure the scanner driver does not operate in a "Full-Auto" or "Wizard" mode. Set it to "Advanced" or "Professional" mode (please consult the documentation of your scanner).

If you cannot solve the problem by yourself, please follow these steps:

- ⊙ Record the problem and the steps leading to the problem as detailed as possible.
- ⊙ If StripAssay® Evaluator displayed an error message, record it with all details (make a screenshot and copy/paste additional information.

With the gathered information, please contact the technical support department of ViennaLab Diagnostics GmbH by email (techhelp@viennalab.com).

Analysis-related Problems

In case of problems with the interpretation of a strip, submit a Problem Report, accessible via the Help menu (if this menu items is not available, please contact your local ViennaLab distributor or ViennaLab Diagnostics GmbH directly).

Please follow these steps:

❶ Enter your details (name, email address, lab name).

❷ Give a detailed description of what the problem is.

❸ Optionally, check to include the currently open assay document.

❹ Click the Send Email button.

> Sending a problem report requires that a MAPI-enabled email program such as Microsoft Outlook or Outlook Express is installed on the computer running *StripAssay® Evaluator*, and that an active internet connection is available!

16. MENU / TOOLBAR REFERENCE

File Menu
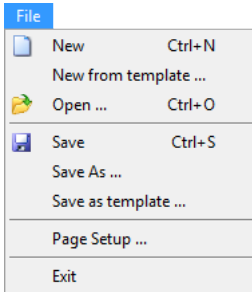
New – Starts a new assay.

New from template ... – Starts a new assay based on settings/information contained in an assay template (.sat2) or assay document (.sad2) file.

Open ... – Opens a previously saved assay document file (extension .sad2).
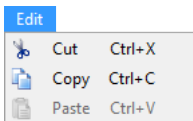
Save – Saves an assay document to disk.

Save As ... – Saves an assay document file (.sad2) to disk under a new name.

Save as template ... – Saves the current assay setup information into an assay template file (.sat2).

Page Setup ... – Opens the Page Setup dialog.

Exit – Quits *StripAssay® Evaluator*.

Edit Menu

Cut – Copies the selected text into the clipboard and removes it.

Copy – Copies the selected text into the clipboard.

Paste – Pastes text from the clipboard into the active textbox.

Assay Menu
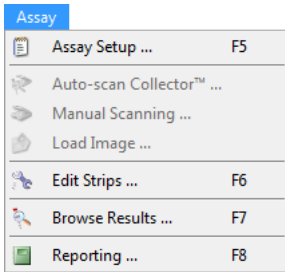
Assay Setup ... – Shows the Start / Acquisition screen. See chapter 5 for more information.

Auto-scan Collector™ ... – Shows the Start / Acquisition screen and initiates automatic scanning of a *Collector™*. See chapter 6 for more information.

Manual Scanning ... – Shows the Start / Acquisition screen and initiates manual scanning of a sheet. See chapter 6 for more information.
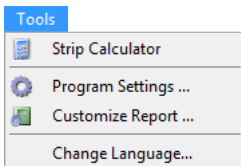
Load Image ... – Shows the Start / Acquisition screen and loads an image from disk. See chapter 6 for more information.

Edit Strips ... – Shows the Strips / Sample Info screen. See chapter 7 for more information.

Browse Results ... – Shows the Results screen. See chapter 9 for more details.

Reporting – Shows the Reporting screen. See chapter 10 for more information.

Tools Menu


Strip Calculator – Opens the Strip Calculator window. See chapter 12 for more information.

Program Settings ... – Displays the Program Settings dialog. See chapter 4 for more information.

Customize Report … – Displays the Report Settings dialog. See chapter 10 for more information.

Change Language – Shows the Change Language dialog. Changes will take effect after a restart of the software.

Help Menu
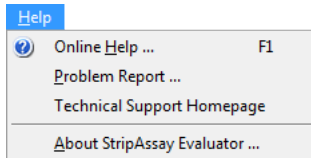
Online Help … – Displays the online help.

Problem Report … – Opens the Problem Report dialog. See chapter 15 for details. This menu may be unavailable.

Technical Support Homepage – Opens a browser window. This menu may be unavailable.

About StripAssay Evaluator … – Displays the splash screen with program version information.

Main Navigation Bar

See chapter 3 for an overview on navigating the software.

❶ Shows the Start / Acquisition screen. See chapter 5 and chapter 6 for more information.

❷ Shows the Strips / Sample Info screen. See chapter 7 for more information.

❸ Shows the Results screen. See chapter 9 for more information.

❹ Shows the Reporting screen. See chapter 10 for more information.

Main Toolbar

❶ Starts a new assay document, loads an existing assay document, or saves the assay document.

❷ Cut / Copy / Paste text from/into textboxes.

❸ Opens the Strip Calculator window. See chapter 12 for more information.

❹ Shows the online help.

❺ Shows the catalog number and name of the currently active assay type.

Strips / Sample Info Toolbar

See chapter 7 for a detailed description of the toolbar buttons.
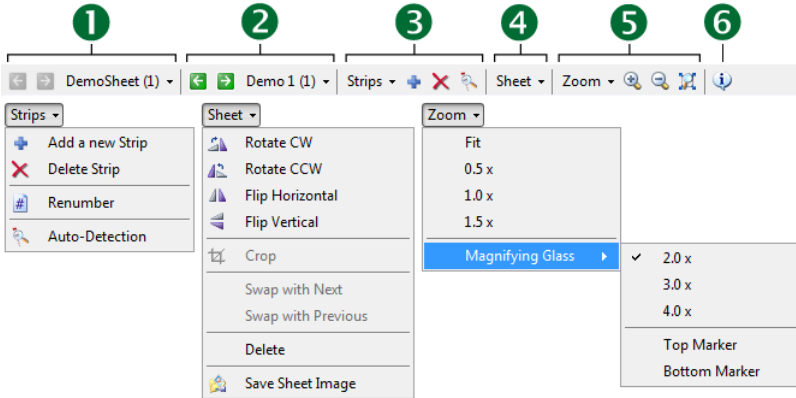
❶ Navigate sheets.

❷ Navigate strips.

❸ Add addtional strips, delete strips, renumber strips, or start the automatic detection of strips.

❹ Manipulate sheets.

❺ Sets the zoom level of the sheet display and controls the behavior of the magnifying glass during strip adjustment.

❻ Shows or hides the sample information panel.
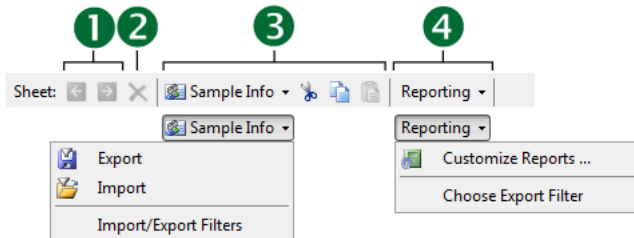
Results Toolbar

See chapter 9 for a detailed description of the toolbar buttons.
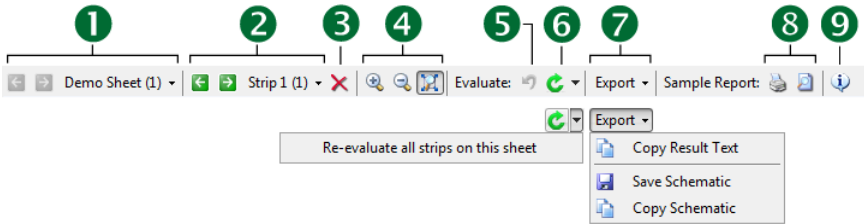
❶ Navigate sheets.

❷ Navigate strips.

❸ Deletes the currently active strip.

❹ Controls the display (zoom level) of the strip image and schematic.

❺ Removes any user modifications from the current strip.

❻ Re-evaluates the current strip or all strips on the current sheets.

❼ Copies the current result text or strip image (including the schematic) to the clipboard and/or saves the currently displayed strip to a Windows Metafile.

❽ Prints (previews) the detailed report for the current strip. See chapter 10 for more information on reporting.

❾ Shows or hides the sample information panel.

Reporting Toolbar

See chapter 10 for a detailed description of the toolbar buttons.

❶ Navigate sheets.

❷ Clear all sample information from all strips on the selected sheet.

❸ Advanced sample editing controls. See chapter 8 for more information on managing sample information.

❹ Shows the Report Settings dialog (see chapter 10) or the Program Settings dialog (see chapter 4 and chapter 11).
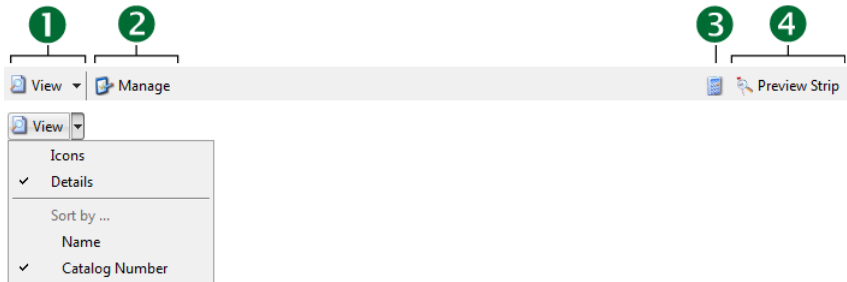
Strip Calculator Toolbar

See chapter 12 for a detailed description of the toolbar buttons.
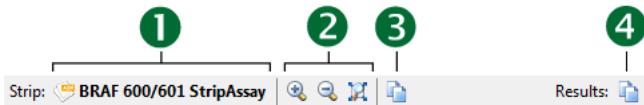
❶ Click to select a different assay type.

❷ Controls the display (zoom level) of the strip schematic.

❸ Copies the currently displayed strip schematic to the clipboard.

❹ Copies the currently displayed result text to the clipboard.

StripAssay Selector Toolbar

See chapter 13 for a detailed description of the toolbar buttons.

❶ Set the display style and sort order of assay definitions.

❷ Turns management mode on or off.

❸ Opens the Strip Calculator window with the currently selected assay type preloaded.

❹ Shows or hides the strip preview.

Print Preview Toolbar

See chapter 10 for additional information on reporting.
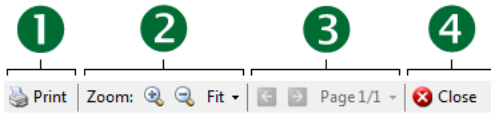
❶ Prints the report.

❷ Controls the zoom level.

❸ Navigates the pages of the report.

❹ Closes the Print Preview dialog.