



Seraline[®] scan

Release Version 6





Software for image capture and analysis of *Seraline[®]* tests

 LIA-00  *In-vitro*-diagnostic medical device 



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Symbols:

	Catalogue-No.
	<i>In-vitro</i> -diagnostic medical device
	manufactured by
	Note – helpful information

Abbreviations:

CSF	cerebrospinal fluid
CSV	comma separated values (file type)
DPI	dots per inch
LIMS	laboratory information management system
PC	personal computer

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1 Introduction

The use of Line Immunoassays (LIA) for detection of antibodies to different antigens or auto antigens in human serum samples is well established in laboratory diagnosis. The visual result evaluation is time-consuming, and the results can depend on the performer. The use of automatic methods for objectivization of measurement increases. The *Seraline*[®] scan software enables the automatic evaluation and documentation of *Seraline*[®] tests.

1.1 Intended Use

Seraline[®] scan is software for acquisition, automatic interpretation and archiving of *Seraline*[®] tests.

1.2 Common Advice and Precautions

The *Seraline*[®] scan software is classified as class A – No injury or damage of health is possible (DIN EN 62304). This software is only for detection of *Seraline*[®] tests and should be performed by trained technical laboratory staff only. The test instructions have to be followed strictly. Seramun does not offer any guarantee for errors resulting from incorrect handling of the *Seraline*[®] scan software.

1.3 Functional Principle

The strips are developed and dried according to the corresponding test instructions for use and fixed on the template printed with the *Seraline*[®] scan software. The fixed strips are detected and analyzed by use of a commercially available flatbed scanner (see section 3).

As an alternative the software can analyze single strip images of an automatic Line Immunoassay processor, read in from a predefined folder (see section 4).

The measured intensities of the specific antigen bands are divided by the intensity of the cut-off band present on every single strip. If the quotient from specific band intensity and cut-off band intensity is ≥ 1.0 , the result will be determined positive for the respective band; quotients of < 1.0 will be determined negative.

By using predefined evaluation criteria, the result will include an overall evaluation according to the instructions for use of the corresponding *Seraline*[®] test.

1.4 Limitations of the Procedure

The *Seraline*[®] scan software is exclusively designed for the interpretation of *Seraline*[®] tests. Test strips from other manufacturers cannot be interpreted with the *Seraline*[®] scan software.

The *Seraline*[®] scan software can not compensate the human eye. Plausibility checks should be done regularly. Bands with intensities near cut-off band intensity may give different results in different scans. Diffuse strips (sprinkle or high background) must be controlled visually and checked for plausibility.

Generally, results near cut-off should be checked and evaluated in context with the complete banding patterns by trained technical laboratory staff.

2 Basic Instructions

2.1 Scope of Service

- IVD-registered *Seraline*[®] scan software
- hardware key (dongle) for use of software
- Instructions for Use

2.2 System Requirements

- PC with 2.0 GHz and 2 GB RAM or more
- 100 MB free disk space
- operating system: Microsoft Windows 10
- Flatbed scanner, minimum 300 DPI, recommended Canon CanoScan LiDE 220, connected to an USB-Hub with electric power supply to guarantee reproducible results
- Printer to print Templates on A4 paper.
- alternative: automatic Line Immunoassay processor, able to generate single strip images into a predefined PC folder (minimum 300 DPI)


2.3 Installation

The software is installed using the setup file *SeralinescanSetup600.exe* and requires admin rights on the designated PC.

The setup detects the language of the Windows operating system and suggests a language for the installation, selected from three possible languages (English, German, Chinese). The language selection only applies to the installation process. The language selection for use of the software is later adjusted in Options.

Its recommended to keep the standard settings of the setup. The following settings could be changed:

- Installation folder (standard = C:\Seralinescan6)
- optionally create a desktop icon (standard = create)

 Before use of the software make sure to connect the delivered hardware key (dongle) to the used PC.

2.4 Deinstallation

The software can be removed by using the start menu entry *Seraline*[®] scan/Uninstall *Seraline*[®] scan.

2.5 Initial Setup

2.5.1 Flatbed Scanner

To use the software with a flatbed scanner, the according scanner has to be selected in Options (see section 7).

If the software used to scan a Template for the first time after installation, the scan dialog of the scanner manufacturer will be shown. The setting in the scan dialog of the scanner manufacturer must be adjusted as follows:

- Resolution = 300 DPI
- Mode = Color / Scan Full Plate
- deactivate all automatic image corrections



Subsequently the scanner dialog can be hidden in Options (see section 7).

To check the correct function of the used printer and scanner, please print (see section 3.2) and scan (see section 3.4) the Test Template. If all 18 entries of the Test Template are evaluated with "Test OK", the system can be used to analyze *Seraline*[®] tests with *Seraline*[®] scan. If the scanner, printer, or PC (new installation) of the system setup changes, please repeat the process.



2.5.2 Single Strip Images Automatic Processor


After installation, the software is set to use a flatbed scanner. To analyze single strip images from an automated processor the device type used by the software has to be changed in Options (see section 7).

Before loading single strip images, an automatic processor has to be defined in Options (see section 7). As an example, the software comes preinstalled with the following processor:

- Name = Auto1
- DPI = 530
- Image Type = bmp
- Folder = C:\Seralinescan6\SavedScans

3 Instructions Flatbed Scanner

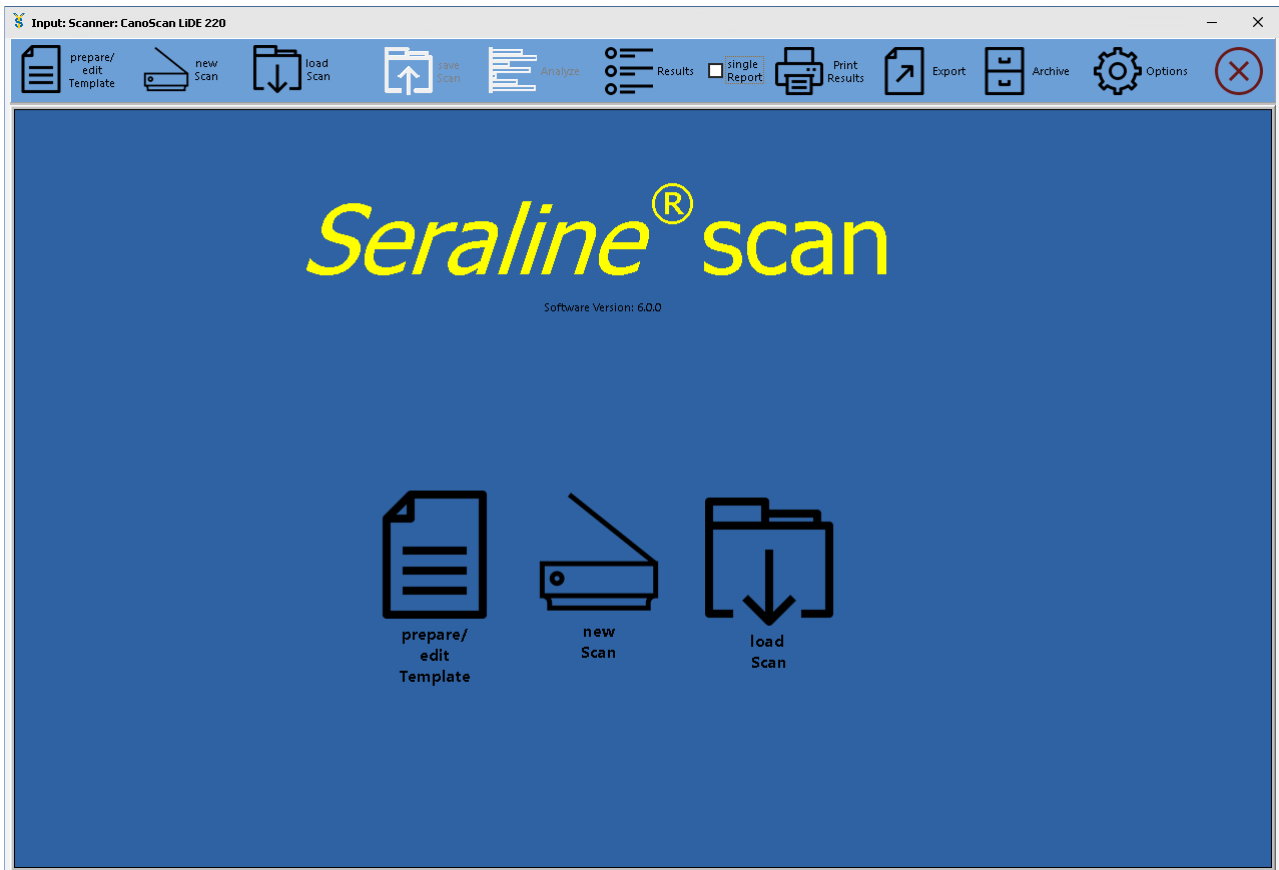
To analyze *Seraline*[®] test strips with a flatbed scanner a sample list must be created and printed in form of a Template. The dried *Seraline*[®] test strips are then glued to designated positions on the Template and scanned with a flatbed scanner.

 Attention, the Template inside the test kit is only indented for use with visual result evaluation and cannot be used to analyze test strips with the software.

The procedure of analyzing *Seraline*[®] test strips with a flatbed scanner is as follows:

- (1) **prepare / edit Template** – enter sample data (Sample List)
(section 3.2)
- (2) **Sample List / Print Template** – print Template based on sample list
(section 3.2)
- (3) attach dried *Seraline*[®] test strips to Template
(section 3.3)
- (4) **new Scan** – scan Template with *Seraline*[®] test strips
(section 3.4)
- (5) **Analyze** – analyze the currently scanned or loaded Template (happens automatically if Scan+Analyze is activated in Options)
- (6) **Results** – display analysis results (Analyze switches to Results automatically)
- (7) **Print Results** – print a batch report with one sample per row (appr. 20 samples per page)
single Report: print a single report with one sample per page
- (8) and / or **Export** – export results as CSV file

3.1 Start Page / Button Bar



prepare / edit Template – enter sample date (optional patient data) and print Template

new Scan – scan Template with *Seraline*[®] test strips

load Scan – load a previously saved image file of a scanned template with test strips

save Scan – save the currently scanned Template as an image file

Analyze – analyze the currently scanned or loaded Template (happens automatically if Scan+Analyze is activated in Options, see section 7)

Results – display analysis results (Analyze switches to Results automatically)

Print Results – print a batch report with one sample per row (appr. 20 samples per page)

- **single Report:** print a single report with one sample per page

Export – export results as CSV file, please contact Seramun to inquire details about the structure of the CSV file, i.e. to export results to a LIMS

Archive – access to all scanned *Seraline*[®] test strips including results

Options – access to options and settings of software (see section 7)

Exit – close software

3.2 Prepare Template (Sample List)

Sample List

Main Menu

use Patient Data Enter moves down Import Orders Clear List Print Test Template Close

use CSF Sort by Test Print Template Template Description:

Number of Samples: 20 Anti-Borrelia-8 IgM

ID	SampleID	Test	Lot
1	SampleID01	Anti-Borrelia-8 IgM	40-10-19
2	SampleID02	Anti-Borrelia-8 IgM	40-10-19
3	SampleID03	Anti-Borrelia-8 IgM	40-10-19
4	SampleID04	Anti-Borrelia-8 IgM	40-10-19
5			
6	SampleID05	Anti-Borrelia-8 IgM	40-10-19
7	SampleID06	Anti-Borrelia-8 IgM	40-10-19
8	SampleID07	Anti-Borrelia-8 IgM	40-10-19
9	SampleID08	Anti-Borrelia-8 IgM	40-10-19
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

function control
IgG conjugate control
IgM negative control
Cut off control
p100
VteE
p58
p41
p39
OspA
OspC
p18

To create a sample list at least a SampleID must be entered and a *Seraline*[®] test must be selected. Optionally the lot of the *Seraline*[®] test and a test strip number (ID) can be entered.

If use Patient Data is activated, the software also allows to enter patient data (last name, first name, date of birth, gender). If use CSF is activated a sample can be designated as CSF.

Different *Seraline*[®] test can be mixed on one Template. As long as 2 different *Seraline*[®] tests only differ in their isotype, samples will remain in their designated spot (row numbers in the sample list table equal row numbers on the Template). If 2 different *Seraline*[®] test differ in more than just their isotype or at least 3 *Seraline*[®] test are on one Template, then the samples will be automatically resorted and grouped by *Seraline*[®] test. Empty rows will be removed.

- **ID:** enter test strip number
- **SampleID:** enter sample identification number
- **Test:** select *Seraline*[®] test
- **Lot:** enter lot of *Seraline*[®] test
- **Name:** enter patient last name
- **First Name:** enter patient first name
- **D.O.B.:** enter patient date of birth
- **CSF:** set checkbox for CSF samples
- **Gender:** select patient gender

The software saves the last used lot for each *Seraline*[®] test. If a test is selected again the software automatically fills in the last used lot of the selected *Seraline*[®] test.

If the cursor is put into the first SampleID cell and Enter moves down is activated, the SampleID can be read into the sample list table via barcode reader. Please first select the appropriate *Seraline*[®] test with the selection above the table.

Number of Samples – set count of samples to be entered (default = 20), if the sample count does not fit on one Template, they will be spread across multiple Templates

***Seraline*[®] test selection** – if a *Seraline*[®] test is selected above the table, the selected *Seraline*[®] test will be automatically applied to each newly entered SampleID

Print Template – prints the sample list on a Template and creates a sequential ScanID, which uniquely identifies the sample list

use Patient Data – activate use of patient data (last name, first name, date of birth, gender) (standard with new installation = deactivated)

use CSF – activate column with checkbox for CSF samples

Enter moves down – use of Enter key moves cursor to the next row and not to the next column of the table

Sort by Test – entered samples will be resorted and grouped by *Seraline*[®] test, empty rows in the sample list will be removed

Import Orders – import sample data from CSV file with a defined format, please contact Seramun to inquire details about the structure of the CSV file

Clear List – delete all sample list entries and Template Description

Print Test Template – prints a Test Template with artificial strips and lines to test the used system setup (scanner, printer, see section 2.5.1)


Template Description – adds an optional description line to the printed template and printed batch report, can also be used with Test Template

Close – close the Sample List

Main Menu – partly additional actions:

- **Clear List:** delete all sample list entries
- **Import Order:** import sample data from CSV file with a defined format
- **Load List by ScanID:** load an available sample list into the sample table by entering the ScanID
- **Show Unused Templates:** show table with not yet scanned ScanIDs

3.3 Hint for Working with Templates




Seraline[®]

Seraline[®] scan Software Version: 6.0.0

Date: 5/15/2020
Operator: erik.hoechel
ScanID: 0000001

StripID	FC	SampleID	CSF	Test	Lot-No.	Name
1	8 0	SampleID01		Anti-Borrelia-8 IgG	40-10-19	
2		SampleID02		Anti-Borrelia-8 IgG	40-10-19	
3		SampleID03		Anti-Borrelia-8 IgG	40-10-19	
4		SampleID04		Anti-Borrelia-8 IgG	40-10-19	
5						
6		SampleID05		Anti-Borrelia-8 IgM	40-10-19	
7		SampleID06		Anti-Borrelia-8 IgM	40-10-19	
8		SampleID07		Anti-Borrelia-8 IgM	40-10-19	
9		SampleID08		Anti-Borrelia-8 IgM	40-10-19	
10						
11						
12						
13						
14	8 0.3					
15						
16						
17						
18						
19						
20						



i Attention, the Template inside the test kit is only indented for use visual result evaluation and cannot be used to analyze test strips with the software.

For safe use of the printed Template with the software, keep the following directions in mind:

- the printer has to position the Template straight on the sheet of paper (edges of printed Template and paper edges are parallel)
- the printer must not scale the Template, but print the Template in its original size (on A4 paper)

Fix the test strips in the middle of the designed areas on the printed Template. Please note that the function control of the strip must line up with the marked function control on the Template (see figure above).

The barcode at the bottom edge of the Template is used by the software to identify the ScanID of the Sample List. Please do not paste over the barcode or damage in any other way.

3.4 Scanning of Template

i To scan the Seraline[®] test strips position the Template on the scanner. Note that most scanners mark the corner for alignment with an arrow. Please position the Template straight in the scanner without skewing. Rotation by 180° however is not a problem. Please regularly clean the scanning surface of the scanner.

If the software does not recognize the barcode, the ScanID can be manually entered into the appearing dialog box. The software will then ask, where the head of the Template is positioned (left, top, right).

4 Instructions Single Strip Images Automatic Processor

Seraline[®] scan can analyze single strip images of an automatic Line Immunoassay processor. To use this mode of the software the device type has to be changed in Options and a corresponding device (processor) must be defined (see section 7).

The images are read from a folder predefined in Options. The following requirements have to be met:

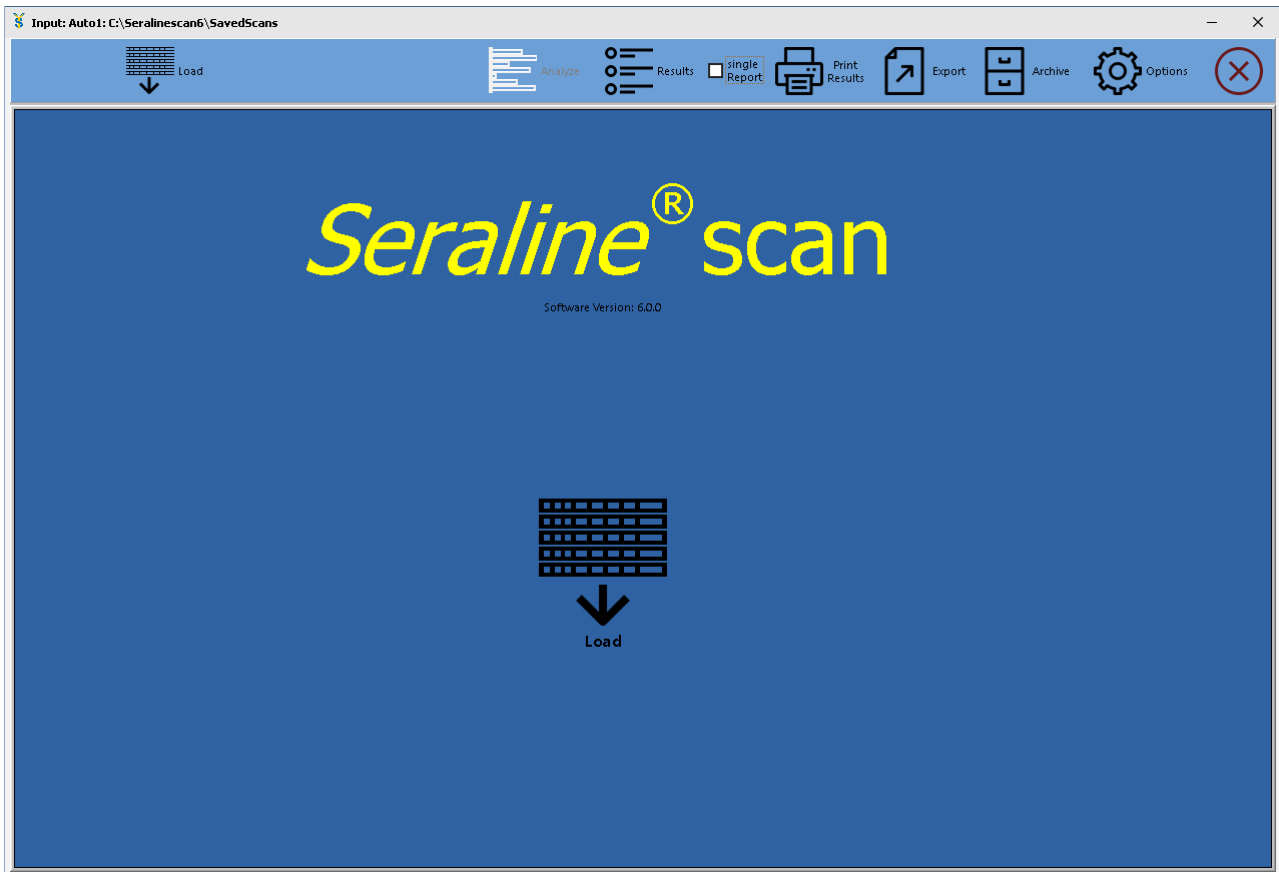
- one image contains one strip
- the images have a pixel density of at least 300 DPI
- the image background on which the strip is positioned is dark or black
- device name, DPI, image type, and image folder are correctly defined in Options
- the image file name has the following structure:
[scan date(yyyymmdd)]_[*Seraline*[®] test name]_[SampleID].[image type file extension]
Example: 20180702_ANA-12 G_LabID01.bmp

Distinct differences between images of different processors might make it necessary, to perform adjustments to the software. Please contact Seramun in these cases. However, a correct image analysis always depends on specific image qualities and can therefore not be guaranteed by Seramun. The usage of each new processor type must be validated by the user himself.

The process of analyzing *Seraline*[®] single test strip images is as follows:

- (1) the automated processor takes an individual image of each strip and puts all images into a predefined, shared folder, the images file names have the correct structure
- (2) **Load** – load single strip images from redefined folder, select images to be imported (see section 4.2)
- (3) **Analyze** – analyze the selected strips and switch to Results
- (4) **Results** – display analysis results (Analyze switches to Results automatically)
- (5) **Print Results** – print a batch report with one sample per row (appr. 20 samples per page)
single Report: print a single report with one sample per page
- (6) and / or **Export** – export results as CSV file
- (7) after successful analysis, please delete all single strip images from the predefined folder

4.1 Start Page / Button Bar



Load – load single strip images from redefined folder, opens new software page to select images to be imported, this software page can also be used to adjust the *Seraline*[®] scan test and enter the lot of test strips (see section 4.2)

Analyze – analyze the selected strips and switch to Results

Results – display analysis results (Analyze switches to Results automatically)

Print Results – print a batch report with one sample per row (appr. 20 samples per page)

- **single Report:** print a single report with one sample per page

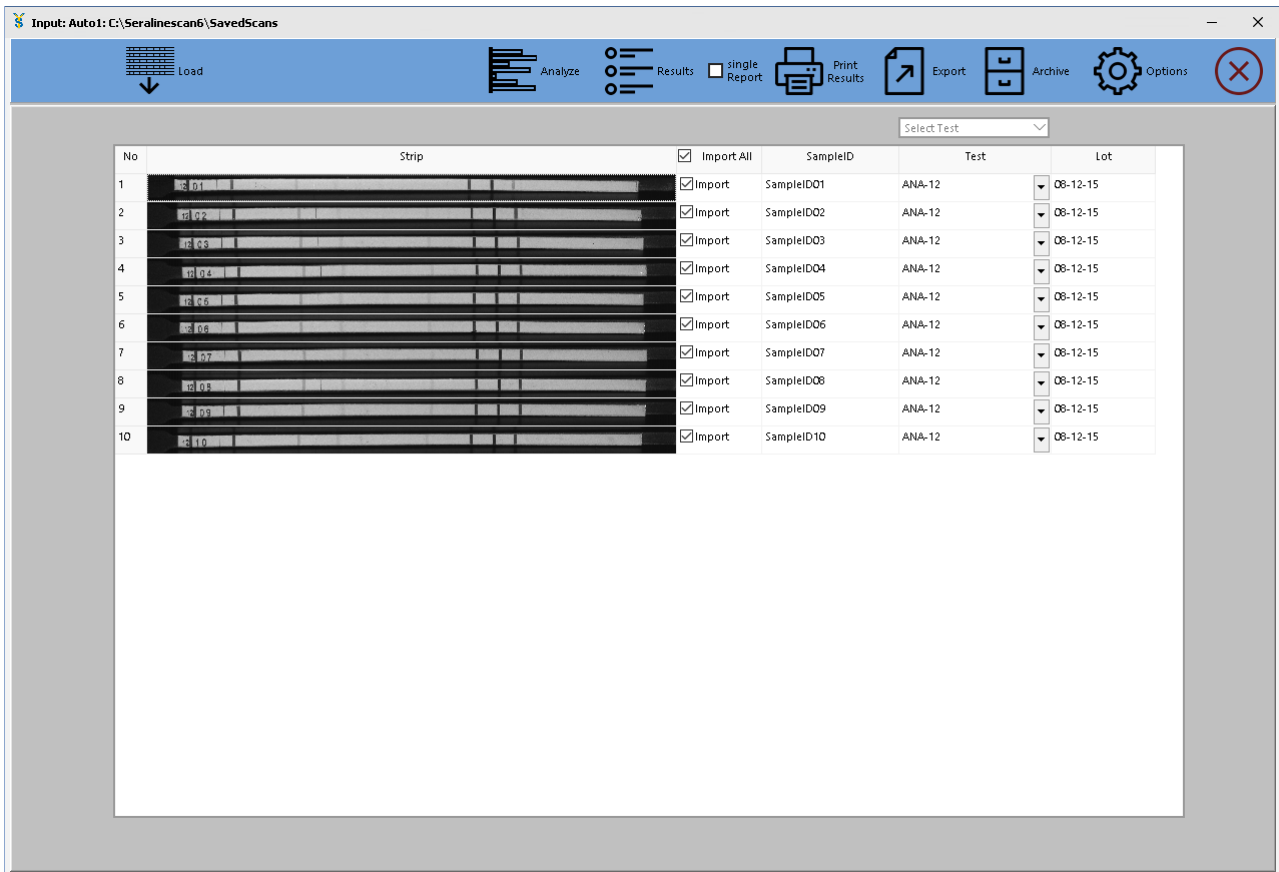
Export – export results as CSV file, please contact Seramun to inquire details about the structure of the CSV file, i.e. to export results to a LIMS

Archive – access to all scanned *Seraline*[®] test strips including results

Options – access to options and settings of software (see section 7)

Exit – close software

4.2 Read Images from Folder



Strip – displays the single strip images read from the folder

Import – select all single strip images you want to import and analyze

- **Import All:** selects all rows

SampleID – SampleID read from image file name

Test – *Seraline*[®] test read from image file name, the selected test can be changed for each row

- **Select Test:** change *Seraline*[®] test for all rows

Lot – enter lot of *Seraline*[®] test

The software saves the last used lot for each *Seraline*[®] test. If a test is selected again the software automatically fills in the last used lot of the selected *Seraline*[®] test.

To analyze the selected images click the Analyze button in the Button Bar. When the analysis is finished the software will switch to Results.

5 Evaluation Errors

Each *Seraline*® test strip does not only contain parameters for analysis, but also controls, which the software uses to determine the validity and plausibility of the test evaluation. If the analysis of the controls shows an error, the test evaluation is replaced with an error message.

The following table shows possible error messages and the configuration of measured control intensities causing the error message. If more than one error is detected, only the error message with the highest priority will be shown.

error priority	error message	error description
1	No Strip	no <i>Seraline</i> ® test strip was detected
2	n.a. FC<min	the FC (function control) is too small (RAW value of FC smaller than 50) error will only display if sample type is not CSF
3	n.a. CO<min	the CO (Cut-off) value is too low (RAW value of CO smaller than 15)
4	n.a. CO>max	the CO (Cut-off) value is too high (RAW value of CO greater than 105)
5	n.a. NC>CO	the NC (negative control) is bigger than the CO (Cut-off)
6	n.a. CC<min	the CC (conjugate control) corresponding to the test is too small (RAW value of CC smaller than 2/3 of CO (Cut-off) RAW value)
7	n.a. CC mix	the CC (conjugate control) not corresponding to the test but defined in the test is too big (RAW value of incorrect CC bigger than 2/3 of CO (Cut-off) RAW value and bigger than 90% of correct CC RAW value)

6 Archive

Date	ScanID	Test	Lot	SampleID	Result
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgG	40-10-19	SampleID01	positive
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgG	40-10-19	SampleID02	positive
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgG	40-10-19	SampleID03	positive
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgG	40-10-19	SampleID04	positive
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgM	40-10-19	SampleID05	positive
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgM	40-10-19	SampleID06	positive
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgM	40-10-19	SampleID07	positive
5/15/2020 10:39:37 AM	0000001	Anti-Borrelia-8 IgM	40-10-19	SampleID08	positive
5/15/2020 10:31:38 AM	0000002	ANA-12	08-12-15	SampleID01	positive
5/15/2020 10:31:38 AM	0000002	ANA-12	08-12-15	SampleID02	positive
5/15/2020 10:31:38 AM	0000002	ANA-12	08-12-15	SampleID03	positive
5/15/2020 10:31:39 AM	0000002	ANA-12	08-12-15	SampleID04	positive
5/15/2020 10:31:39 AM	0000002	ANA-12	08-12-15	SampleID05	positive
5/15/2020 10:31:39 AM	0000002	ANA-12	08-12-15	SampleID06	positive
5/15/2020 10:31:39 AM	0000002	ANA-12	08-12-15	SampleID07	positive
5/15/2020 10:31:39 AM	0000002	ANA-12	08-12-15	SampleID08	positive
5/15/2020 10:31:39 AM	0000002	ANA-12	08-12-15	SampleID09	positive
5/15/2020 10:31:39 AM	0000002	ANA-12	08-12-15	SampleID10	positive

	p100	VtE	p08	p41	p39	OpA	OpC	p18	Result
Index	5.4	5.4	5.4	5.6	5.6	5.6	5.4	5.5	positive
Evaluation	++	++	++	++	++	++	++	++	Strip OK

The archive gives access to all scanned *Seraline*[®] test strips. Different search fields can be used to filter the strips and results shown in the table.

Select Date – activating the checkbox will only show strips with a scan date younger or equal to the adjusted date

ScanID – filter strips to entered ScanID (leading zeros do not have to be entered)

Select Test – filter strips to selected *Seraline*[®] test

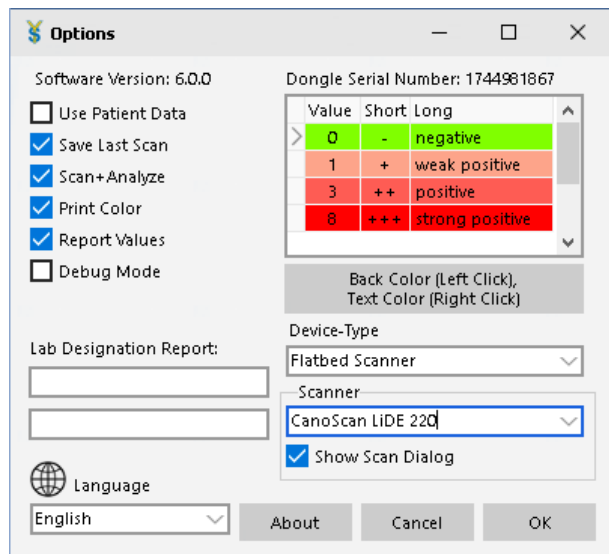
SampleID – filter strips to entered SampleID (entry must match complete SampleID)

Clear Filter – reset all search fields / filters

Below the table the image and results of the selected strip are shown

More than one row can be selected in the table by using the Strg and Shift button on the PC keyboard. Selected rows can be output by using Print Results and Output.

7 Options



display Software Version – shows current software version

display Dongle Serial Number – show serial number of hardware key

Use Patient Data – activate use of patient data (last name, first name, date of birth, gender) (standard with new installation = deactivated)

Save Last Scan – save the last scanned Template as an image file in the software folder (nachscan.bmp) (standard with new installation = activated)

Scan+Analyze – automatically analyze the scanned Template or loaded image file and switch to Results (standard with new installation = activated)

Print Color – highlight the values of different bands in color in the report (see Options/adjust Result Display) (standard with new installation = activated)

Report Values – show ratio values instead of Short Evaluation in Results and reports (see Options/adjust Result Display/Short) (standard with new installation = activated)

Debug Mode – the option gives access to additional analysis pages by displaying tabs, service personnel can use these pages to analyze problems occurring with the evaluation (standard with new installation = deactivated)

- **Tabs Flatbed Scanner:** Start, Results, Scan Image, Analysis, Archive
- **Tabs Auto-Processor:** Start, Results, Analysis Processor, Input Processor, Archive

Lab Designation Report (2 lines) – enter two additional lines (i.e. name of laboratory), printed in the head of the single report

Language – change the display language of the user interface (English, German, Chinese) (standard with new installation = English)

adjust Result Display – by adjusting 4 limits in the table (value = minimum ratio), the result display can be adjusted

- **Value:** limit ratio value (minimum)
- **Short:** single band result display if Report Values is deactivated
- **Long:** intensity legend in single report (only changed for current language)

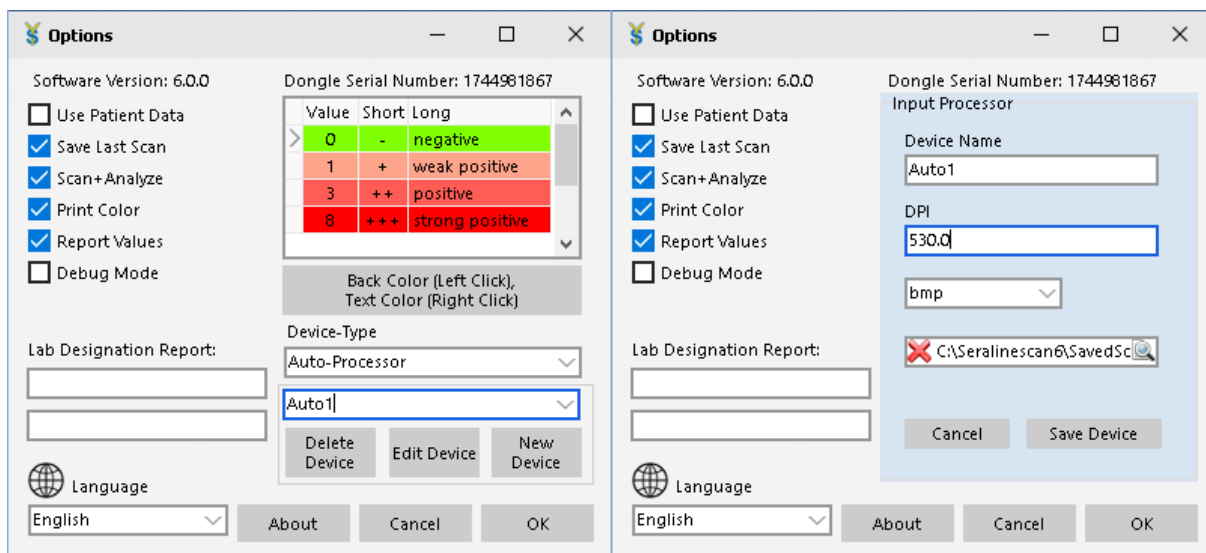
- **Button under table, left mouse click:** adjust the background color of single band results in the result display and reports (please first select the corresponding row in the table (> symbol in front of row))
- **Button under table, right mouse click:** adjust the font color of a single band result in the result display and reports (please first select the corresponding row in the table (> symbol in front of the row))

Device-Type – select device type: Flatbed Scanner or Auto-Processor (single strip images after automated processing) (standard with new installation = Flatbed Scanner)

Device-Type Flatbed Scanner/Scanner – select Flatbed Scanner to be used, if the Scanner appears more than once in the list, please select the entry, which shows a scan dialog, that allows all necessary adjustments to be made (see section 2.5.1)

Device-Type Flatbed Scanner/Show Scan Dialog – show the scan dialog of the scanner manufacturer with each new scan, has to be used at least once when setting up a new scanner, to make all necessary adjustments (see section 2.5.1) (standard with new installation = activated)

About – shows an 'About' window with software and manufacturer information



Device-Type Auto-Processor/Select Device – select a defined Auto-Processor (with new installation only Auto1 is predefined as an example, see section 2.5.2)

Device-Type Auto-Processor/Delete Device – delete selected Auto-Processor, note: if the device was already used to read and archive single strip images, the device cannot be deleted anymore)

Device-Type Auto-Processor/Edit Device – change setting of selected Auto-Processor

- **Device Name:** Auto-Processor name designated by user
- **DPI:** pixel density in DPI of images delivered by Auto-Processor
- **Image Type:** select image type delivered by Auto-Processor (image file name extension) (bmp, jpg, jpeg, png)
- **Image Folder:** shared folder from which to load strip images of the Auto-Processor

Device-Type Auto-Processor/New Device – create a new Auto-Processor (same settings as Edit Device)

8 Performance Characteristics

Compared analysis between visual detection and software assisted evaluation by *Seraline*[®] scan resulted in an agreement of more than 90%. Reproducibility was determined by measuring the band intensity of four different antigen bands in two different concentrations by 10-fold determination.

	antigen 1		antigen 2		antigen 3		antigen 4	
	C1	C2	C1	C2	C1	C2	C1	C2
Mean	17.5	20.9	93.1	149.9	279.9	290.0	73.2	215.1
Standard deviation	0.5	0.5	4.0	1.8	4.1	3.7	1.6	5.2
Coefficient of variation	2.9%	2.6%	4.3%	1.2%	1.5%	1.3%	2.2%	2.4%

The reproducibility of measurement values using different scanner types was determined by comparative evaluation on 4 different scanner types resulting in the recommendation for Canon Canoscan LiDE 220.

	scanner 1	scanner 2	scanner 3	scanner 4
	antigen 1	antigen 1	antigen 1	antigen 1
Mean	17.5	23.3	22.8	14.5
Standard deviation	0.5	2.0	3.0	1.1
Coefficient of variation	2.9%	8.4%	13.1%	7.7%

9 History of Changes

Section	Modifications
alle	Instructions for Use following the new format
alle	new division into main sections and sub sections moved position of some sections
2.5.2	new; Initial Setup / Single Strip Images Automatic Processor
3	new; Instructions Flatbed Scanner and procedure old section Processing removed and integrated into this section
3.1	new; Flatbed Scanner Start Page / Button Bar
4	new; Instructions Single Strip Images Automatic Processor and procedure old section Processing removed and integrated into this section
4.1	new; Automatic Processor Start Page / Button Bar
4.2	new; Automatic Processor Read Images from Folder
5	new; Evaluation Errors
6	new; Archive
7	Options removed: Update function, Show Main Buttons, Use Archive, Import Method removed: Show Analysis Page / Show scan -> instead added: Debug Mode removed: Use Last Scan -> instead added: Save Last Scan new: Use Patient Data new: Labor Designation Report new: Device-Type new: all Options Automatic Processor
9	new; History of Changes
10	Short Instructions for Flatbed Scanner integrated on back cover of Instructions for Use

10 Short Instructions *Seraline*[®] scan with flatbed scanner


1



- select *Seraline*[®] test
- enter lot
- enter SampleID
- enter test strip number (ID)
- optionally enter patient data
- ➔ print Template

2

attach dried *Seraline*[®] test strips to Template



Seraline[®]


Seraline[®] scanSoftware Version: 6.0.0

Date: 5/15/2020

Operator: erik.hoechel

ScanID: 0000001

	StripID	FC	SampleID	Test	Lot-No.	Name
1	1		SampleID01	Anti-Borrelia-8 IgG	40-10-19	
2	3		SampleID02	Anti-Borrelia-8 IgG	40-10-19	
3	5		SampleID03	Anti-Borrelia-8 IgG	40-10-19	
4	6		SampleID04	Anti-Borrelia-8 IgG	40-10-19	
5						
6	8		SampleID05	Anti-Borrelia-8 IgM	40-10-19	
7	10		SampleID06	Anti-Borrelia-8 IgM	40-10-19	
8	11		SampleID07	Anti-Borrelia-8 IgM	40-10-19	
9	12		SampleID08	Anti-Borrelia-8 IgM	40-10-19	
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						



3



- scan Template with test strips
- strips are analyzed automatically
- software switches to Results

4



- check or uncheck single report
- print results
- export results as CSV