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Instruction for use

Seraline®scan

[**REF**] LIA-00

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Software for evaluation of
Seraline® Immunoassays

REF	Catalogue-No	LOT	Lot-No.
⚠	Notice advices	◢	Manufacturer
📖 i	Consult Instructions for use		

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 from the performer. The use of automatic methods for objectivization of measurement increases. The *Seraline*®scan software enables the automatic evaluation and documentation of *Seraline*® Immunoassays.

Intended use

Seraline®scan is Software for automatic interpretation of *Seraline*® Immunoassays.

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 analysed by use of a commercially available flatbed scanner. 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, the result will be determined positive for the respective band; quotients of < 1 will be determined negative. In case of predefined evaluation criteria the evaluation report will include an overall result defined positive, negative or equivocal.

Scope of service

- IvD-registered *Seraline*®scan software with hardware key (dongle)
- Instructions for use
- Short manual
- Supply of software updates by the website of Seramun Diagnostica GmbH (www.seramun.com)

System requirements

- PC with 2,0 GHz and 2 GB RAM or more
- 100 MB free disk space
- operating system: minimum Windows XP, Windows 7, (32 /64-bit version)
- Flatbed scanner, minimum 300dpi, recommended CanoScan Lide 200 or 210 , connected to an USB-Hub with electric power supply to guarantee reproducible results
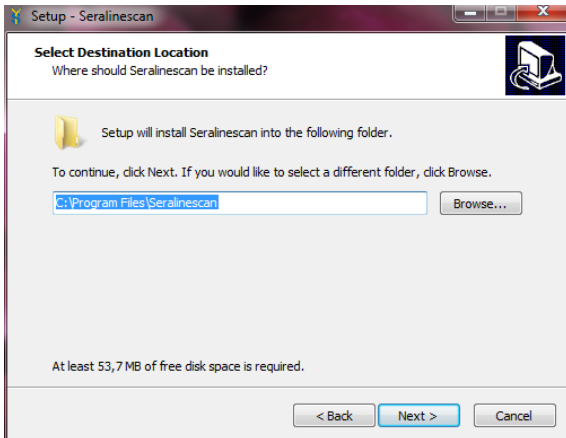
Installation and deinstallation

The installation includes the installation and start-up of the *Seraline*®scan software.
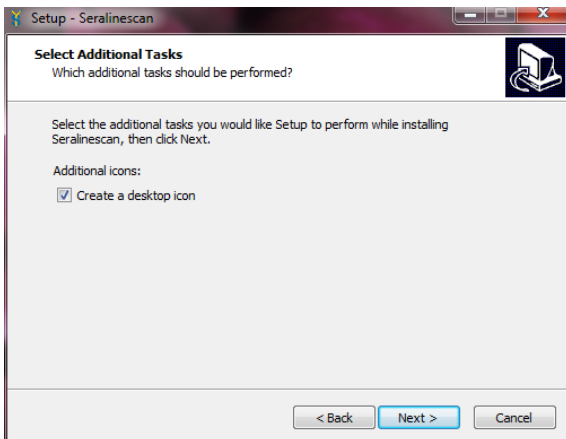
Software installation
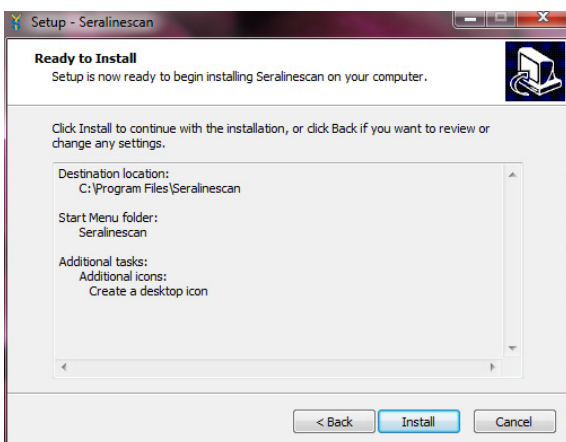Administrator rights to the PC are necessary.

Implementation
– Start SERALinesetup.exe (from CD/ USB-drive /Website).
– Follow the Install Wizard.
– Select installation folder.
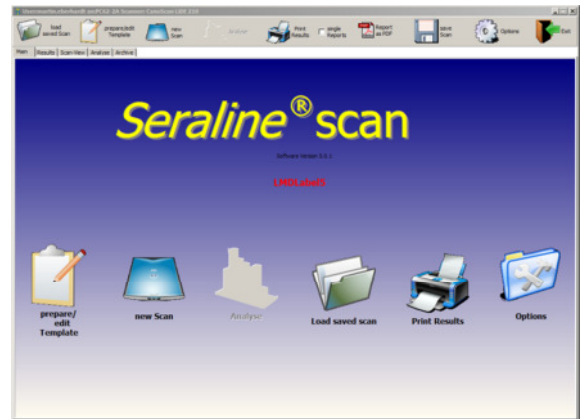

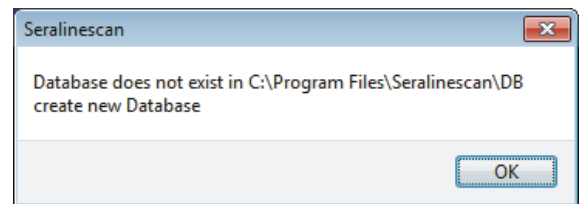– Desktop-symbol is optional but recommended.

– Start installation.

– ⚠ **Insert the dongle into the USB-port on PC or into the server by using of multi user licenses.**

– Start *Seraline*®scan.

– Confirm database initialization after first installation.

Software deinstallation
For deinstalling of the software administrator rights to the PC are necessary.

Implementation
– The deinstallation-routine is in the start-folder „Seralinescan" at the menu point "remove Seralinescan"
– Follow the deinstallation routine
– Remove database manually

In case of error message during installation or deinstallation of the *Seraline*®scan software contact Seramun Diagnostica GmbH.

Initial startup

⚠ **For initial startup of the *Seraline*®scan software some options have to be checked or modified.**

Options

1. Select **Options**.

2. Select **show dialog** and close Options.

3. Select **new Scan**.

4. Options scanner software:
   • **resolution:**   300dpi
   • **mode:**   color
   • **automatic picture correction:**   all disable
   Close dialog.

5. Disable **show dialog** under Options (see 1.).

Function test

1. Select **prepare** /**edit Template**.

2. Select and print **Test Template**.

3. Select **new Scan**.

   Confirm the message „Cut-Off not found on Row 18". All positions have to be stated OK.

   If the **Test Template** was evaluated successfully, the *Seraline*®scan software in combination with the used hardware components are ready to use.

   ⚠ **In case a hardware component (e.g. scanner or printer) was changed repeat this procedure.**

Prepare Template

Strips of tests with integrated conjugate controls (e.g. *Seraline*® Anti-Yersinia IgG/ *Seraline*® Anti-Yersinia IgA) developed with different conjugates can be fixed and evaluated on the same template. The *Seraline*® scan software identifies conjugate controls and evaluates strips accordingly.

Implementation

1. Select **prepare** / **edit Template**.

2. Enter patient data.
ID:	*strip number*
Lab-ID:	*Laboratory identification number*
Name:	*Last Name*
First Name:	*First Name*
D.o.B.:	*Date of birth*

3. Select test **select Template**.
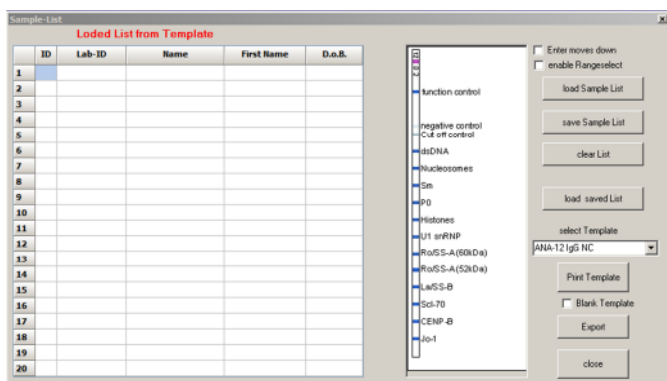
4. Select **Print Template**.
   *Insert Lot. No. p.r.n.*

Working hints for templates

⚠ **The combination of strips from different *Seraline*® tests or the use of strips of other producers is not possible.**

The bands of *Seraline*® tests will be correctly identified and matched if the following advices are considered.

- When using the templates supplied with the kit, pay attention to the correct test selection.
- Fix the test strips in the middle of the designed area. Please note that the function control of the strip should be on top of the marked function control of the Template.

- Do neither write nor stick transparent tape on the following areas on the template:
  - bold black line in the back of the area designed for fixing the strips
  - barcode
  - banding patterns

  Do not use any other marks in these areas
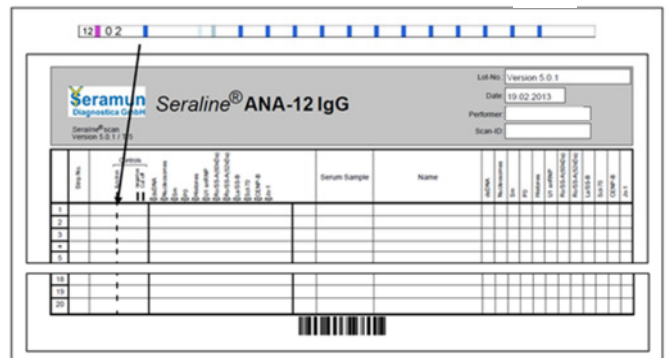
⚠ **By using of supplied Templates (without barcode) from the test kit the test selection starts after the scanning process.**

Scanning of Template

⚠ **Place the Template with the fixed strips on the scanner. Please note the positioning hints of the scanner (positioning corner or arrow). The scanner surface should be tidy.**

1. Select **new Scan**.

2. If barcode cannot identified, enter the Scan-ID manually (**Input**).

   Select **select**, if the supplied Template was used and choose the right test template.

3. Select the orientation of the Template.

Processing

The results are shown as table report and can be further handled.

Output of data

Select **Print Results** to get an overview report of all fixed strips with short patient information's. Select **single Reports** before **Print Results** to get the detailed patient reports.

Select **save Scan** to archive the scanned picture.

Every strip analyses will be archived if **use Archive** (Options) was selected.

Processing of data

It is possible to edit patient information after the scanning process by use of **prepare** / **edit Template**.

For a deep single strip analyze select the tab **Analyse**.

The Analysis Tab offers following possibilities:
- Densitogram of selected strip.
- Optimize the first band distance (variation of the band-distances in relation to the positive control) / interband distance (variation of the distances between bands) in case of misinterpretations (e.g. inaccurately fixed strips).

  The first band / interband distance can be modified by directly typing the desired number or by using the arrows under the sign.

These settings will disappear in the next scan or after restart of the software.

Options

The following Software parameter can modify under Options:

- **Software Version**
  Release information of the Software

- **Dongle**
  Number of the hardlock

- **Update function (enable/ disable)**
  Automatic update checkup at initialization

- **Show Analysis Page (enable/ disable)**
  Activation of detailed Analysis
  (see processing of data)

- **Show scan (enable/ disable)**
  Activation of scan picture

- **Use last Scan (enable/ disable)**
  Last scan load at initialization

- **Show Mainbuttons (enable/ disable)**
  Activation of Mainbuttons on initial page

- **Scan + process (enable/ disable)**
  Activation of automatic analyze after scanning

- **Print color (enable/ disable)**
  Optimizes color print

- **Report Values (enable/ disable)**
  Results as Qualitative ("+" or "-") or quantitative (Values)

- **Use archive**
  Automatic archiving of results

- **Back color- and Text color**
  Definition of back and text color

- **Scanner**
  Selection of scanner and scanning parameters

- **Language**
  Selection of software language

- **Import methode**
  Import function for new Seraline® Testmethods

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	
	c_1	c_2	c_1	c_2	c_1	c_2	c_1	c_2
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 Canoscan Lide 200 / 210 (Scanner 1).

	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%

Limitations of the procedure

The Seraline®scan software is exclusively designed for the interpretation of Seraline® tests. Teststrips from other manufacturers cannot be interpreted with the Seraline®scan software.

The Seraline®scan software can not compensate 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.

Common advice and precautions

The Seraline®scan software is classified as class A – No injury or damage of health is possible (DIN EN 62304:2006).

⚠ **This software is only for detection of Seraline® Immunoassays and should be performed by trained technical laboratory staff only.**

The test instructions have to be followed strictly.

We do not offer any guarantee for errors resulting from incorrect handling of the Seraline®scan software.