

Seramun SpotSight[®] scan


Release Version 3

Software to capture, analyze and archive SeraSpot[®] spot immunoassays



SP-SCAN-A



In vitro diagnostic medical device 



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In vitro diagnostic medical device



Unique device identifier



Manufacturer



Article number

Abbreviations:

ASTM	American Society for Testing and Materials
CSV	Comma Separated Values (file type)
DLL	DLL file (Dynamic-Link Library)
D.O.B.	Date of Birth
IP	Internet Protocol
LIMS	Laboratory Information Management System
OS	PC Operating System
TCP	Transmission Control Protocol

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NOTE

The document contains phrases in cursive writing, that directly reference labels from user interface elements.

1 Indented Use

Seramun SpotSight® scan is an IVD software for acquisition, automatic evaluation and archiving of SeraSpot® spot immunoassays by a laboratory professional user in a laboratory environment.

The product is used in combination with the device Seramun SpotSight® plate mono, Seramun SpotSight® strip or Seramun SpotSight® well for image acquisition of arrays and the kits of the SeraSpot® product line.

The product must not be used with tests other than the SeraSpot® spot immunoassays, in the near patient setting and by lay persons.

2 Operating Principle

2.1 Methodology SeraSpot® Tests

SeraSpot® tests are immunoassays in a spot pattern in wells of 96-well microtiter plates (spot immunoassay). The tests allow the simultaneous detection of several different parameters in fluids (e.g. serum or plasma). These are bound by specific capture molecules printed as spots (dots in the nanoliter range) on the bottom of wells of 96-well microtiter plates. The bound parameters are detected by detection molecules. The arrangement of spots within the spot pattern is determined by a specific layout, which allows the exact assignment of spots to parameters.

Besides parameter spots each spot pattern contains control spots to ensure proper test validity and allow for an automatic software analysis of the developed test.

The bound capture molecules bind parameters from the sample. After incubation and wash steps bound antibodies are detected by horseradish peroxidase (HRP)-labeled antibodies against human antibodies by a substrate reaction with hydrogen peroxide and 3,3',5,5'-tetramethylbenzidine (TMB). Blue spots indicate the formation of immune complexes. Spots range from pale to dark blue and are visible by eye.

Following removal of excess substrate, spot patterns can be digitized as images and evaluated.

2.2 Evaluation Method SeraSpot®

Seramun SpotSight® scan uses Seramun SpotSight® plate mono, Seramun SpotSight® strip or Seramun SpotSight® well devices to capture images of a properly processed SeraSpot® test.

These images are used to analyze the color intensity of individual spots. Results can be presented in different forms (see also section 7.5):

- (1) Evaluation by cut-off – results are displayed as ratio between the measured color intensities of the parameter spots and control spots divided by the measured color intensity of the cut-off spot.
- (2) Evaluation by reference curve – if spot patterns contain reference spots a reference curve is calculated. The results for parameter and control spots are displayed as test specific units (Units) as calculated by the reference curve. Each well contains its own set of reference spots.

Based on defined evaluation rules a sample is determined as 'positive', 'borderline' or 'negative'.

If results of control spots deviate to a defined extent from defaults (see Instructions for Use of respective SeraSpot® tests), samples are flagged 'n.a.' ((result) not available, see section 7.5.3).

3 Restrictions to Application

The software Seramun SpotSight® scan is designated to be installed and used on a PC with Microsoft Windows OS (tested on Windows 10).

Seramun SpotSight® scan runs only, if the included hardware key is connected to the PC via an USB port. In devices delivered without PC, the hardware key is integrated into the device and therefore part of the device.

Seramun Diagnostica cannot rule out that third party software installed on the same PC may impair the correct functioning of Seramun SpotSight® scan.

All serious incidents occurring in relation with Seramun SpotSight® scan must be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient are located.

4 Components

Seramun SpotSight® scan is delivered pre-installed on a PC or delivered as software setup file for installation on a designated PC. To run the software a hardware key included in the delivery or integrated into the device is needed. Seramun SpotSight® plate mono, Seramun SpotSight® strip or Seramun SpotSight® well devices are not part of Seramun SpotSight® scan.

5 Setup File

5.1 New Installation

If Seramun SpotSight® scan is delivered as setup file, the software must be installed on the designated PC using the setup file. The setup file is device specific. Each device is delivered with the corresponding setup file.

- SpotSightscanSetup[Version number-digits]plate.exe
- SpotSightscanSetup[Version number-digits]strip.exe
- SpotSightscanSetup[Version number-digits]well.exe

To install start the executable setup file and follow the instructions on the screen.

Warning: If a setup file is executed on a PC, that already contains an installation of Seramun SpotSight® scan, the existing installation is overwritten by a new installation. All client specific settings, device specific settings and the Order archive are deleted. If the setup file detects an existing installation, the user is warned prior to overwriting the existing installation. Two different device types cannot be used on the same PC. However, a second device of the same type may be added by simply starting the software without executing a setup file.

5.2 Update

Setup files with the word 'Update' in the file name can be executed only if the correct existing installation of the software is available on the PC. In this case an update of the existing installation is performed. All client specific settings, device specific settings and the order archive remain unchanged.

6 Starting and Terminating

6.1 Seramun SpotSight® plate mono or Seramun SpotSight® strip

Warning: Seramun SpotSight® scan version 3.4.5 cannot connect to Seramun SpotSight® strip devices. Users of Seramun SpotSight® strip must use version 3.3.x or 3.5.x.

6.1.1 Turn on Device / Start Software

First boot the PC connected to the device. Before Seramun SpotSight® scan can be started the device must be switched on and complete the automatic initialization process (see Instructions for Use of Seramun SpotSight® plate or Seramun SpotSight® strip device-). Please strictly follow this sequence.

During initialization, all symbols on the device front plate are shortly lit up. The initialization process is finished after one (Seramun SpotSight® strip) or two (Seramun SpotSight® plate mono) signal tones.

When the software starts and connects to the device all symbols light up again including one or two signal tones.

The device is now ready for use.

6.1.2 Close Software / Turn off Device

First shut down the software Seramun SpotSight® scan (button Exit or title bar button: close window).

If the tray of the device is in loading position still (device is open), it will be retracted automatically, and the device will be closed.

After shutting down the device, the PC may be switched off.

6.2 Seramun SpotSight® well

6.2.1 Connect Device / Start Software

First boot the PC connected to the device. Before Seramun SpotSight® scan can be started the device must be connected to the PC via the USB cable included.

When starting the software, the device is automatically connected to the software, initialized, and immediately ready for use. Please follow the instruction shown to remove the well holder during the last step of the initialization.

6.2.2 Close Software / Disconnect Device

First shut down Seramun SpotSight® scan (button Exit or title bar button: close window). Then the device can be disconnected, and the PC may be switched off.

7 Application Seramun SpotSight® scan

7.1 Page Login

When starting the software, the page Login opens (Figure 1). To use the software a valid username and password are required. If an invalid username or password is entered 4 times, the software shuts down automatically. To change or add a new user see section 7.8. In a new installation of the software the following users are predefined:

- Username: **std** / Password: **pw** (default user)
- Username: **admin** / Password: **seraspot** (access to additional software options, user management, test importing and editing of results)

Username and password can be submitted by pressing the Enter key or by clicking the *Login* button. The *Exit* button cancels the login and closes the software.

A connection to the device used is only established after a successful login (see also section 6).

The user admin is preferably used by the administrator to create new users in the user management. The predefined users should be deleted once new users are set up.

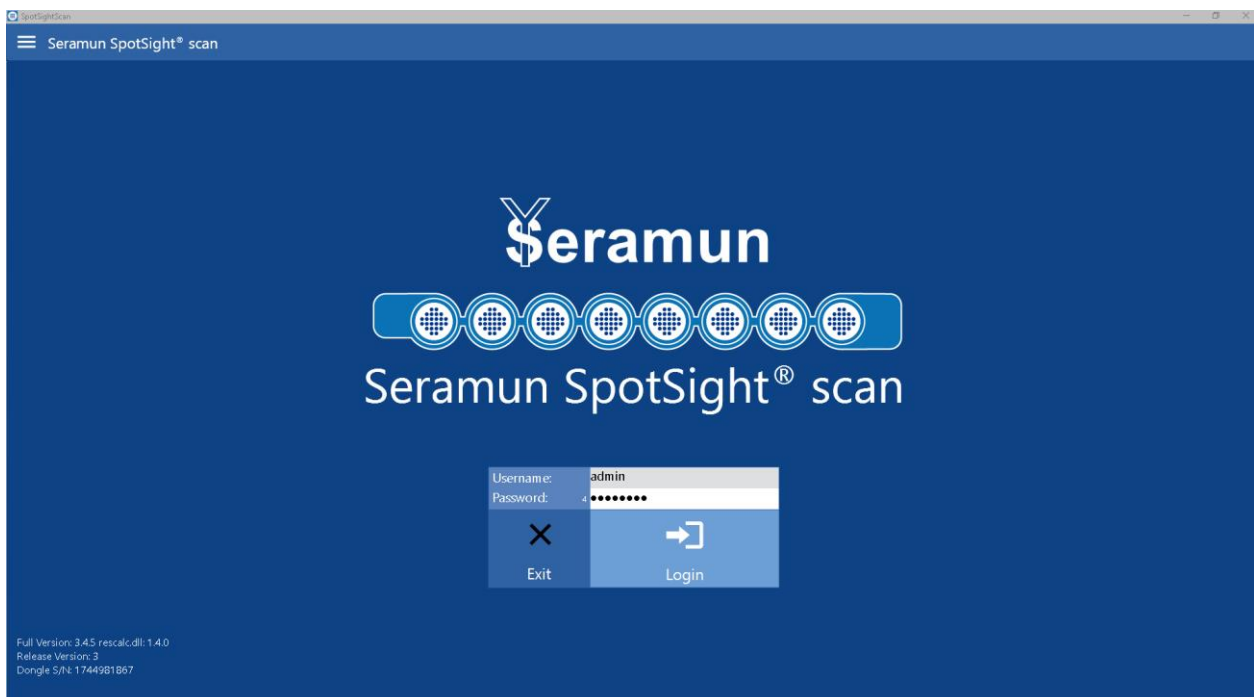


Figure 1: Page Login

7.2 Page Start

After a successful login, the software opens page Start (Figure 2). With a mouse-click on one of the three buttons in the center of the page the three main functions of the software can be accessed:

1. *Orders* – enter or import of new orders / samples
2. *Scan* – image acquisition and evaluation of SeraSpot® tests
3. *Archive* – access to archived results



Figure 2: Page Start

At the top of the software user interface a permanently visible function bar allows access to diverse options and the three main functions of the software.

The function bar contains from left to right:

1. options menu (three horizontal lines) – Note: selected options are not visible for all users (see section 7.8)
 - a. *Language* – switch user interface language
 - b. *User* – user management (see section 7.8)
 - c. *Options* – different options of the software (see section 7.9)
 - d. *About* – general information about software Seramun SpotSight® scan
 - e. *Import Test* – import new SeraSpot® test definition
2. software name (Seramun SpotSight® scan)
3. username of currently logged in user
4. name and serial number of connected device
5. *Orders* – opens page Orders
6. *Scan* – opens page Scan
7. *Archive* – opens page Archive
8. *Logout* – logs out current user and shows page Login
9. *Exit* – closes software

7.3 Orders

Page *Orders* (Figure 3) is used to enter or import orders in order to run a selected test.

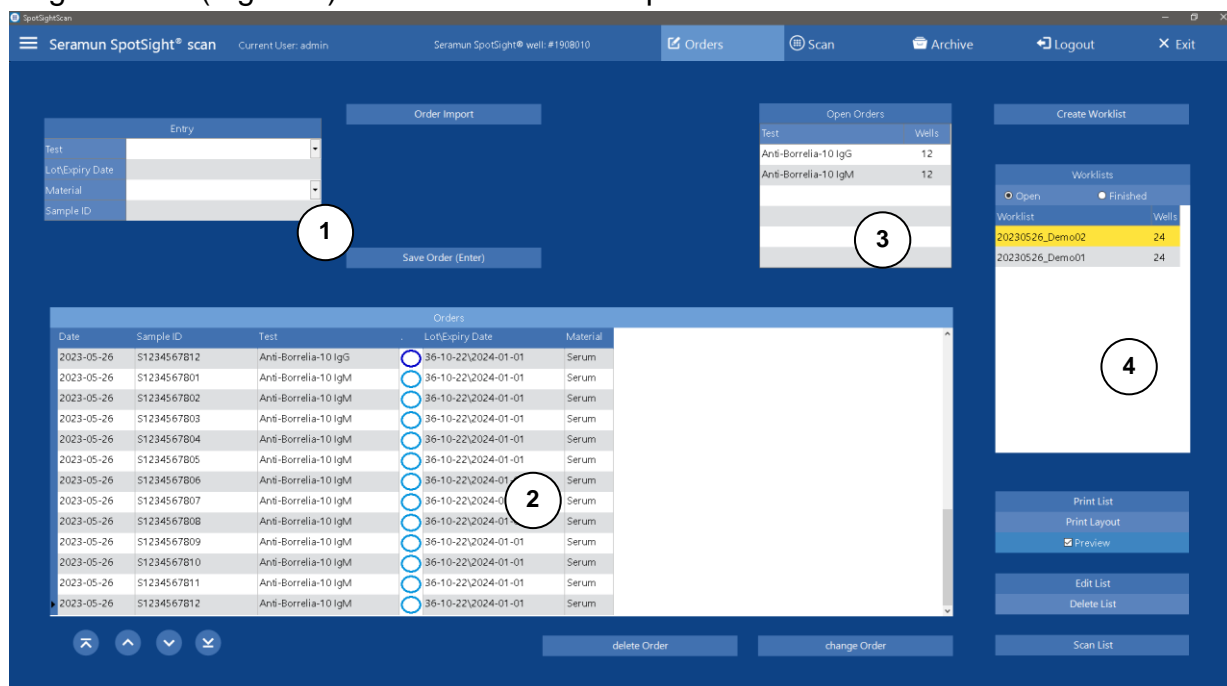


Figure 3: Page Orders

In version 3.4.5, the following SeraSpot® tests are predefined (information in brackets specifies the abbreviated test name and color coding):

- detection of IgG or IgM antibodies to *Borrelia burgdorferi* sensu lato
 - Anti-Borrelia-10 IgG (BOR G, dark blue)
 - Anti-Borrelia-10 IgM (BOR M, light blue)
- detection of IgG or IgA antibodies to *Yersinia enterocolitica*
 - Anti-Yersinia-6 IgG (YER G, dark brown)
 - Anti-Yersinia-6 IgA (YER A, light brown)
- detection of IgG or IgM antibodies to *Treponema pallidum*
 - Anti-Treponema-4 IgG (TREP G, black)
 - Anti-Treponema-4 IgM (TREP M, white)
- detection of IgG or IgM antibodies to Parvovirus B19
 - Anti-Parvovirus-6 IgG (PARV G, dark purple)
 - Anti-Parvovirus-5 IgM (PARV M, light purple)
- detection of IgG or IgM antibodies to Epstein-Barr Virus (EBV)
 - Anti-EBV-4 IgG (EBV G, red)
 - Anti-EBV-3 IgM (EBV M, orange)
- detection of IgG or IgA antibodies to *Helicobacter pylori*
 - Anti-Helicobacter-6 IgG (HELICO G, green)
 - Anti-Helicobacter-6 IgA (HELICO A, light green)
- detection of 12 nuclear and cytoplasmic autoantibodies
 - ANA-12 IgG (ANA12 G, purple)
- detection of autoantibodies present in autoimmune liver diseases
 - HepAk-7 IgG (HEPAK G, green)
- detection of autoantibodies present in systemic vasculitis
 - Vaskulitis-3 IgG (VASK G, red)
- detection of 17 nuclear and cytoplasmic autoantibodies
 - ANA-17 IgG (ANA17 G, dark purple)

7.3.1 Orders input

Entry of new orders (samples) can be made in three different ways.

7.3.1.1 Manual Mode, direct input into software using the given input fields

The input fields (see Figure 3 ①) allow the entry of the following order data:

- *Test* – select test to be used
- *Lot\Expiry Date* – input lot number and expiry date of the test in a defined input mask: 00-00-00\yyyy-MM-dd; when selecting a test, the last lot\expiry date are filled in automatically
- *Material* – select sample type (Serum, Plasma, CSF)
- *Sample ID* – enter sample identification number (max. 18 characters)

Additionally, the entry of patient data is possible. From software version 3.2.1 onwards the entry of patient data is deactivated by default.

- *Last Name* (max. 30 characters)
- *First Name* (max. 30 characters)
- *D.O.B. (Date of Birth)* (OS date format)

After entering all required fields, the order must be saved. Switching to another function of the software without saving, discards the current entries.

- *Save Order* or Enter key – save newly entered order

7.3.1.2 Manual Mode, import of externally generated files

- *Order Import* – shows dialog to open file, can be used to import orders / samples from CSV formatted files with a defined layout

The imported list needs to contain at least a sample ID and the requested test separated by a semicolon with a new line for every order. Optionally, these lists may contain the lot\expiry date, material, last name, first name and date of birth. The field for lot\expiry date must follow a defined format: 00-00-00\yyyy-MM-dd. If lot\expiry date is missing, the software queries those on import. If the field material is missing, the software automatically fills in Serum. From software version 3.2.1 onwards the import of patient data is deactivated by default.

- Sample ID;Test
or
- Sample ID;Test;Lot\Expiry Date;Material;Last Name;First Name;D.O.B.(MM/dd/yyyy)

Example:


- EXS0123;Anti-Borrelia-10 IgG;23-01-19\2021-06-27

7.3.1.3 Automated Mode, import of externally generated files from ELISA processors

The import format can be adjusted to the specific needs of a LIMS or to the output of automated ELISA processors. This requires the activation of Automated Mode.

For activation and to select an ELISA processor type, see section 7.9.2. Please contact your distributor for additional information.

7.3.2 Orders table

- Main table order (Figure 3 ②) – shows all open orders that are not part of a worklist yet
 - buttons  under the main table are used for navigation: first entry / previous entry / next entry / last entry
 - Delete Order – deletes all selected orders completely (selection by using arrow keys and shift key)
 - Edit Order – allows for editing and changing existing orders within the input fields (see Figure 3 ①), complete edits by clicking *Save Order* (cancel edits by exiting the input fields)
- *Open Orders* (Figure 3 ③) – shows tests and count of all open orders that have not been included in a worklist yet

Open orders are not discarded if the software is restarted.

7.3.3 Broken microtiter plate strips / single wells

Incomplete / broken microtiter plate strips shall be placed starting at position A of the microtiter plate always (Figure 6) (microtiter plate layout see section 7.3.5). To ensure correct positioning of the array, all wells are marked with a black line on the bottom at the 1 o'clock position (30°), which allows the software to rotate an image into the correct orientation prior to analyzing the spot pattern (rotation correction, Figure 4).

If the rotation correction is incorrect or missing, i.e. the black line cannot be found at the 1 o'clock position (30°), the software shows an error message (see section 7.5.3).



Figure 4: Symbolic illustration of a developed well with well marking for rotation correction (1 o'clock position / 30°)

7.3.4 Worklists

Open orders can only be processed if collected into a worklist (see Figure 3 ④).

- *Create Worklist* – collects all open orders into a worklist

A dialog is shown, asking for the worklist to be named. Each new worklist must be named differently. The software prevents a name to be given twice (open or completed lists).

A worklist may contain a maximum of 96 orders / samples (equals one microtiter plate). Additional orders remain open and are added to the next worklist created.

- *Worklists – Open / Finished* – depending on the selected option either all open (not yet imaged) or all imaged worklists are displayed
- *Print List* – printout of the selected worklist (sample well allocation) (Figure 5)
- *Print Layout* – printout of a symbolic illustration of the microtiter plate including color coding of the test – the arrangement of color-coded wells / strips of the microtiter plate that will be processed, has to match the illustration (Figure 6); each cell contains from top to bottom:
 - color coding of the test
 - well number
 - SeraSpot® test (abbreviations see section 7.3)
 - Sample ID
- *Preview* – opens a preview before printing (see section 8)
- *Scan List* – opens the selected worklist in the page Scan (see section 7.4).
- *Edit List* – the selected worklist is dismissed and all orders are shown as open orders again – **Warning: cannot be undone if used with a completed list – orders may be re-added to a worklist, but results are discarded.**
- *Delete List* – deletes the selected worklist and all orders within the list permanently – **Warning: cannot be undone. Completed lists may be deleted as well, subsequently results are removed from the archive.**

No.	Well	Sample ID	Test	Patient Name
01	A01	S1234567801	Anti-Borrelia-10 IgG	,
02	B01	S1234567802	Anti-Borrelia-10 IgG	,
03	C01	S1234567803	Anti-Borrelia-10 IgG	,
04	D01	S1234567804	Anti-Borrelia-10 IgG	,
05	E01	S1234567805	Anti-Borrelia-10 IgG	,
06	F01	S1234567806	Anti-Borrelia-10 IgG	,
07	G01	S1234567807	Anti-Borrelia-10 IgG	,
08	H01	S1234567808	Anti-Borrelia-10 IgG	,
09	A02	S1234567809	Anti-Borrelia-10 IgG	,
10	B02	S1234567810	Anti-Borrelia-10 IgG	,
11	C02	S1234567811	Anti-Borrelia-10 IgG	,
12	D02	S1234567812	Anti-Borrelia-10 IgG	,
13	A03	S1234567801	Anti-Borrelia-10 IgM	,
14	B03	S1234567802	Anti-Borrelia-10 IgM	,
15	C03	S1234567803	Anti-Borrelia-10 IgM	,
16	D03	S1234567804	Anti-Borrelia-10 IgM	,
17	E03	S1234567805	Anti-Borrelia-10 IgM	,
18	F03	S1234567806	Anti-Borrelia-10 IgM	,
19	G03	S1234567807	Anti-Borrelia-10 IgM	,
20	H03	S1234567808	Anti-Borrelia-10 IgM	,
21	A04	S1234567809	Anti-Borrelia-10 IgM	,
22	B04	S1234567810	Anti-Borrelia-10 IgM	,
23	C04	S1234567811	Anti-Borrelia-10 IgM	,
24	D04	S1234567812	Anti-Borrelia-10 IgM	,

Figure 5: Example of worklist

Seramun SeraSpot® Worklist: 20230526_Demo01 Full Version: 3.4.5 rescale.dll: 1.4.0 2023-05-26

	01	02	03	04	05	06	07	08	09	10	11	12
A	01 BOR G S1234567801	09 BOR G S1234567809	13 BOR M S1234567801	21 BOR M S1234567809								
B	02 BOR G S1234567802	10 BOR G S1234567810	14 BOR M S1234567802	22 BOR M S1234567810								
C	03 BOR G S1234567803	11 BOR G S1234567811	15 BOR M S1234567803	23 BOR M S1234567811								
D	04 BOR G S1234567804	12 BOR G S1234567812	16 BOR M S1234567804	24 BOR M S1234567812								
E	05 BOR G S1234567805		17 BOR M S1234567805									
F	06 BOR G S1234567806		18 BOR M S1234567806									
G	07 BOR G S1234567807		19 BOR M S1234567807									
H	08 BOR G S1234567808		20 BOR M S1234567808									

Figure 6: Example of microtiter plate layout

7.3.5 Different tests in one worklist

Orders for different tests can be collected into one worklist. In this case orders / samples within the list are automatically resorted for better processing.

1. Order / samples for the same test are collected and grouped on the microtiter plate.
2. Each new test is arranged on a new microtiter plate strip. (This can be deactivated in Options, see section 7.9.3)
3. Test groups are put into the following order on the microtiter plate (independent of their entry order):
 1. Anti-Borrelia-10 IgG
 2. Anti-Borrelia-10 IgM
 3. Anti-Yersinia-6 IgG
 4. Anti-Yersinia-6 IgA
 5. Anti-Treponema-4 IgG
 6. Anti-Treponema-4 IgM
 7. Anti-Parvovirus-6 IgG
 8. Anti-Parvovirus-5 IgM
 9. Anti-EBV-4 IgG
 10. Anti-EBV-3 IgM
 11. Anti-Helicobacter-6 IgG
 12. Anti-Helicobacter-6 IgA
 13. ANA-12 IgG
 14. HepAk-7 IgG
 15. Vaskulitis-3 IgG
 16. ANA-17 IgG
4. Within one group orders / samples are arranged according to their entry order, on each strip from well A to H (Figure 6).

If *Automated Mode* is activated (see section 7.9.2) the sample well allocation is taken from the output of the automated ELISA processor. Orders are not resorted.

7.4 Scan

Page Scan (Figure 7) is used to image, analyze, and create reports for worklists containing SeraSpot® tests.

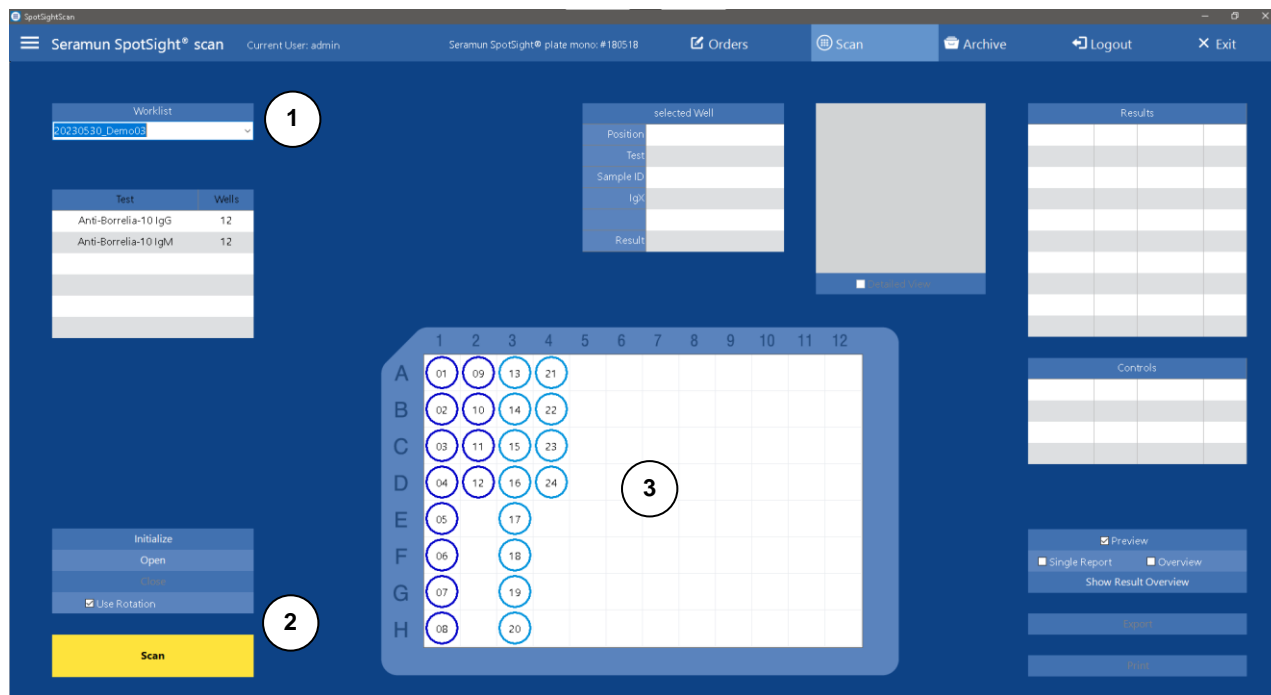


Figure 7: Page Scan (Seramun SpotSight® plate mono)

7.4.1 Select Worklist

- *Select Worklist* – (Figure 7 ①) select an open worklist for imaging

The table below shows the tests contained in the worklist and the corresponding number of orders. The overview in the center of the page (Figure 7 ③) represents the microtiter plate and shows the arrangement of tests by displaying their color coding (colored rings). The arrangement must be identical with the actual arrangement of the test on the microtiter plate to be imaged.

7.4.2 Imaging Process / Device Control

On the bottom left control buttons to operate the device are displayed (Figure 7 ②).

- *Scan* – moves the microtiter plate / strip tray into loading position, asks the user to insert a microtiter plate / strip and starts imaging; when the imaging process is completed the tray is moved back to the loading position and the user is requested to remove the microtiter plate / strip. After confirming the removal, the device will be closed automatically.
- *Cancel* – during imaging the button *Scan* is changed to *Cancel* and may be used to terminate the process. The selected list remains open, so it can be imaged again.

- *Scan Again* – after canceling or completing an imaging process the button *Scan* is switched to *Scan Again* and may be used to image the current microtiter plate / worklist again. Note: previous images and results will be overwritten!
- *Use Rotation* – allows for the activation or deactivation of the rotation correction based on the well marking (black line at 1 o'clock position (30°) Figure 4); it is possible, that in rare cases the rotation correction does not perform properly (see section 7.3.3). In this case the rotation correction can be deactivated, provided that broken strips have the correct orientation and there are no single wells in the plate frame

Only Seramun SpotSight® plate mono and Seramun SpotSight® strip:

- *Initialize* - re-initializes the device in case problems occur
- *Open* – brings the microtiter plate / strip tray of the device into loading position
- *Close* – closes the device

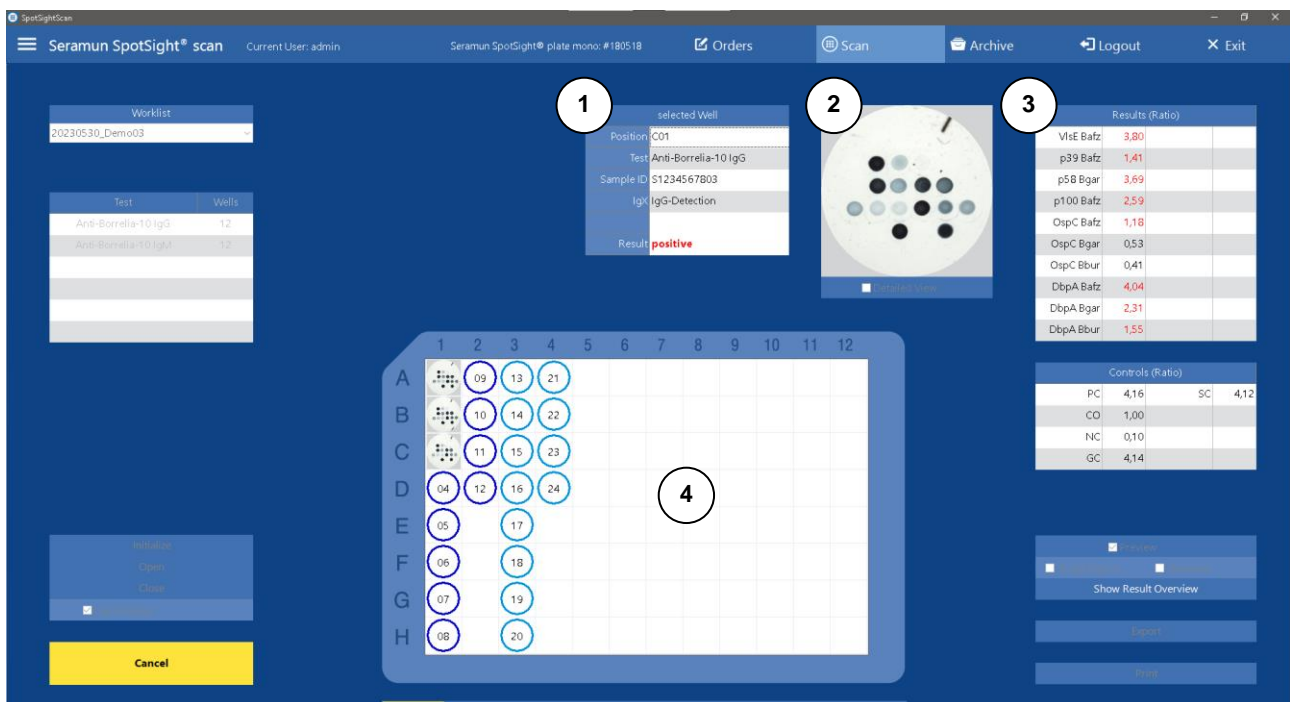


Figure 8: Page Scan during imaging (Seramun SpotSight® plate mono)

During imaging the software shows the last imaged well with results (see Figure 8 ①②③) in schematic illustration of the microtiter plate imaged wells are shown as thumbnails (Figure 8 ④). Below the schematic illustration of the microtiter plate a progress bar is displayed, showing the progress of the imaging process.

7.4.3 Imaging Process Errors

If errors occur during imaging, no thumbnails appear in the corresponding positions in the schematic illustration of the microtiter plate. Orders that cause these errors are automatically reset to 'open' and are relisted on the page Orders. When the imaging process is completed, an error dialog lists all orders that were not analyzed (Sample IDs, well positions).

7.4.4 Specifics Imaging Process Seramun SpotSight® strip

When using Seramun SpotSight® strip the selected strip is shown on the left of the schematic illustration of the microtiter plate (Figure 9). During imaging, thumbnails of imaged wells are initially shown there. After imaging of a strip, thumbnails are moved to the schematic illustration of the microtiter plate, and the next strip is automatically selected for imaging.

- *Select Strip* – select strip to be imaged
- *Strip # Scan* – button *Scan* is labeled with the number of the selected strip (# is placeholder for strip number). As any strip may be selected for imaging again, there is no function *Scan Again*.

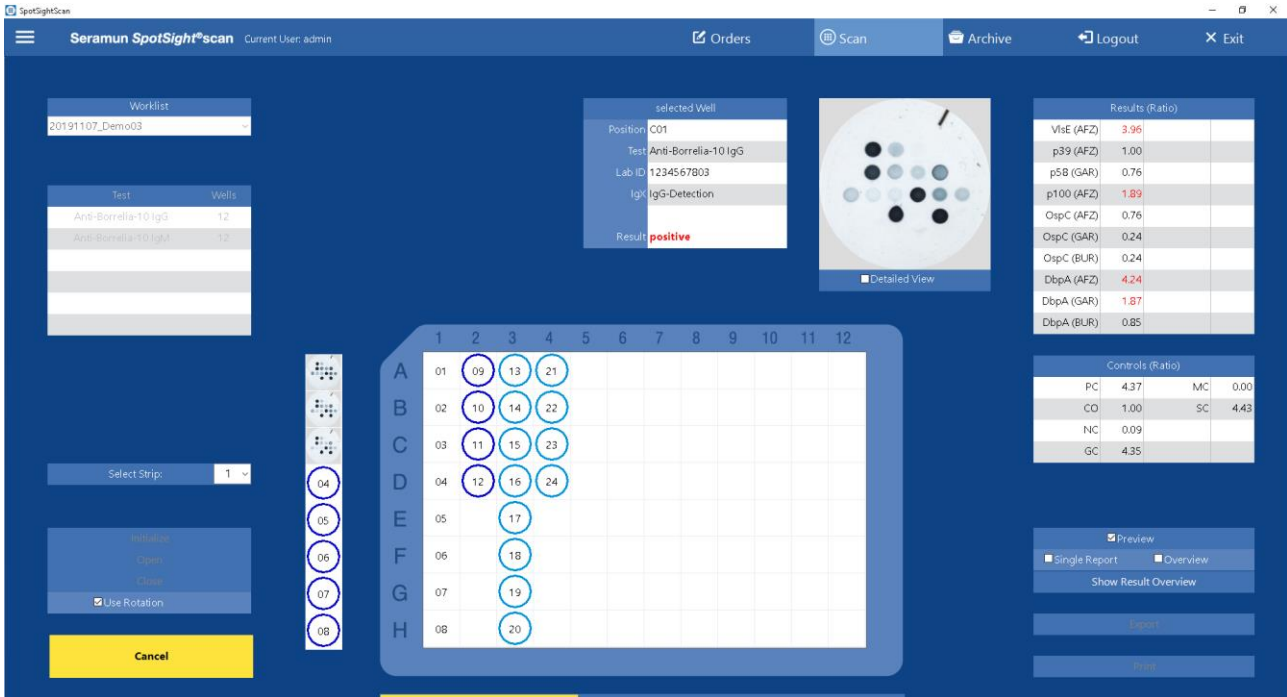


Figure 9: Page Scan for Seramun SpotSight® strip

7.4.5 Specifics Imaging Process Seramun SpotSight® well

When using Seramun SpotSight® well the selected strip is shown on the left of the schematic illustration of the microtiter plate (see Figure 10). During imaging thumbnails of imaged wells are initially shown there. After imaging of a strip, thumbnails are moved to the schematic illustration of the microtiter plate, and the next strip is automatically selected for imaging.

On the right of the symbolic strip illustration the current well holder position is shown (yellow A to H or '-', when outside of valid position).

An arrow (↓ ↑) under the symbolic strip illustration shows the necessary direction of well holder movement. A cross (✘) is shown if the well holder should not be moved.

Under *Select Strip* a label shows the current well holder position. During imaging the label also shows the next position, the well holder must be moved to.

- *Select Strip* – select strip to be imaged
- *Strip # Scan* – button Scan is labeled with the number of the selected strip (# is placeholder for strip number). As any strip may be selected for imaging again, there is no function *Scan Again*.

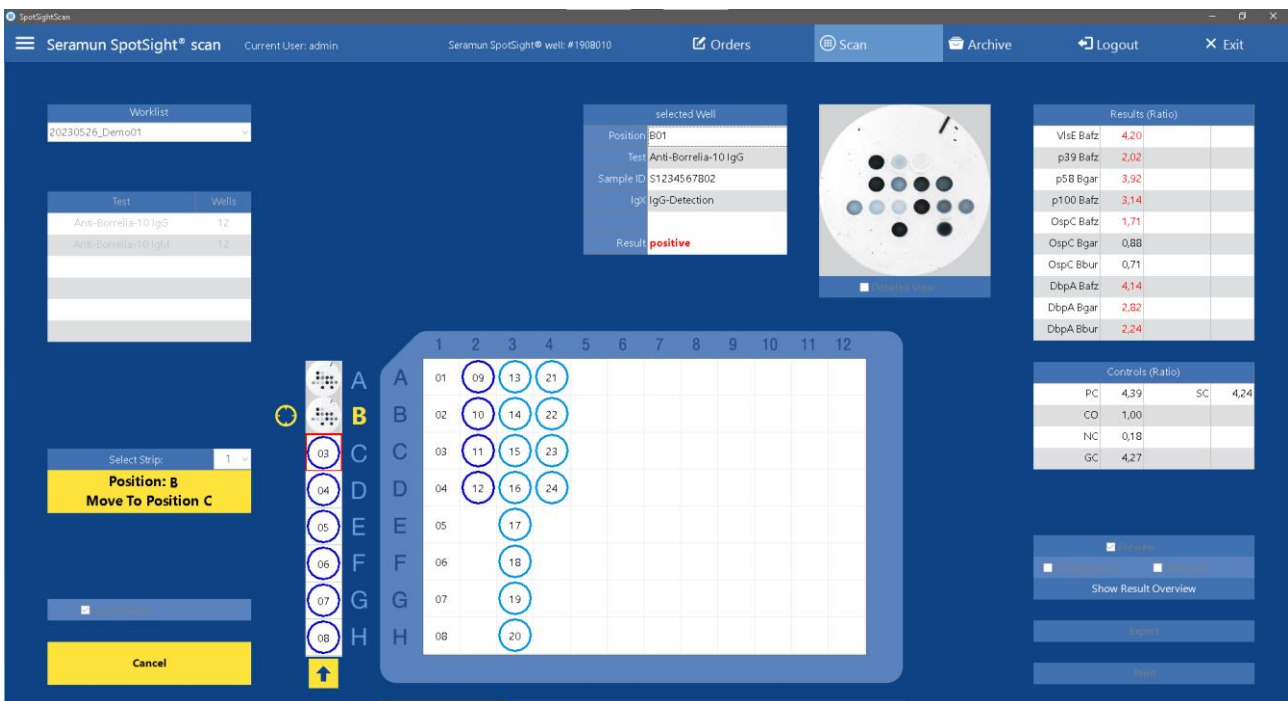


Figure 10: Page Scan for Seramun SpotSight® well

7.4.6 Result Overview

After imaging, thumbnails in the schematic illustration of the microtiter plate are replaced by a result overview (Figure 11 ④). The results of each well are displayed as follows:

- SeraSpot® test (abbreviation, see section 7.3)
- Test result (see section 7.5)
- Sample ID

The font color reflects the test result.

- *positive* = red font
- *borderline* = blue font
- *negative* = green font

Wells that cannot be evaluated (see section 7.5.3) are displayed with a red background.

- *n.a.* = not available, white font on red background

The result overview can be hidden or shown, allowing to look at the thumbnail view again. The button label changes accordingly:

- *Hide Result Overview / Show Result Overview* – switches between result overview and thumbnail view (Figure 11 ⑤)

The screenshot shows the Seramun SpotSight software interface. The top navigation bar includes 'Seramun SpotSight® scan', 'Current User: admin', 'Seramun SpotSight® plate mono: #180518', 'Orders', 'Scan', 'Archive', 'Logout', and 'Exit'. The main interface is divided into several sections:

- Worklist:** Shows a dropdown menu with '20230530_Demo03' and a table with columns 'Test' and 'Wells'.
- Test Table:** A table with columns 'Test' and 'Wells' showing 'Anti-Borrelia-10 IgG' and 'Anti-Borrelia-10 IgM' both with '12' wells.
- Well Table:** A grid showing test results for wells A-H and 1-5. Results are color-coded: red for positive, blue for borderline, and green for negative.
- Well Selection Panel (1):** A panel showing details for the selected well (A01), including 'Test: Anti-Borrelia-10 IgG', 'Sample ID: S1234567801', and 'IgG: IgG-Detection'. The result is 'positive'.
- Detailed View (2):** An enlarged image of the selected well (A01) showing a dark spot.
- Results Table (3):** A table showing 'Results (Ratio)' for various tests: VisE Bafz (3.87), p39 Bafz (1.89), p58 Bgar (3.51), p100 Bafz (3.21), OspC Bafz (1.75), OspC Bgar (0.92), OspC Bbur (0.72), DbpA Bafz (3.85), DbpA Bgar (2.89), and DbpA Bbur (2.28).
- Controls Table (4):** A table showing 'Controls (Ratio)' for PC (4.02), CO (1.00), NC (0.15), and GC (3.94).
- Buttons (5):** A panel with buttons for 'Preview', 'Single Report', 'Overview', 'Hide Result Overview', 'Export', and 'Print'.

Figure 11: Result Overview and Detailed View after imaging

7.4.7 Results Output

By clicking a thumbnail or a result box in the overview (Figure 8 ④; Figure 11 ④) a well can be selected. The properties of the well are shown in the well table (Figure 11 ①), an enlarged image is shown (Figure 11 ②) and the table on the right displays the corresponding results (Figure 11 ③).

Well table – *selected Well*

- *Position* – position of well in microtiter plate
- *Test* – SeraSpot® test
- *Sample ID* – Sample ID
- *IgX* – SeraSpot® test conjugate isotype (if part of test definition)
- *Result* – SeraSpot® test evaluation

Selecting *Detailed View* (Figure 11 ② below) opens an enlarged and labeled well image.

- *Detailed View* – opens a separate window, showing an enlarged well image with labels showing parameter and control names and their respective results (Figure 11 ⑥)

For SeraSpot® tests that are evaluated via reference curve, the corresponding reference curve is shown.

Results may be exported or printed using the buttons displayed on the bottom right (Figure 11 ⑤).

- *Hide Result Overview / Show Result Overview* – switches between result overview and thumbnail view (activates / deactivates the print option *Overview* at the same time (see next bullet point))
- *Print* – issues a batch report (eight wells per page)
 - *Preview* – opens a preview before printing (see section 8)
 - *Single Report* – prints detailed report (one well per page)
 - *Overview* – prints result overview (see section 7.4.6)
- *Export* – saves results in a CSV file; the exported list contains test, Sample ID, and results.

The format of the export may be adjusted to the specific needs of a LIMS. Please contact your distributor for additional information.

All images and results recorded by Seramun SpotSight® scan are saved within a database.

Warning: Leaving page Scan resets all results shown on the screen. To access the results of imaged worklists for export or print use page Archive (see section 7.6). The result overview can only be accessed in page Scan and not via page Archive.

7.4.8 Context Menu after Imaging

A right-click on a thumbnail opens a list with additional functions. These functions are only accessible if the thumbnails are shown.

- *Reset* – the results of the selected order are deleted; the status is reset to 'open' and the order is listed in the page Orders – **Warning: cannot be undone**
- *Delete* – the selected order including results are deleted from the database – **Warning: cannot be undone**
- *Comment* – adds a comment to the selected order or edits an existing comment
 - comment is assigned to the order and saved in the database of the software
 - comment may contain a maximum of 255 characters
 - comment may be edited by opening the comment function with the same order (i.e., also in the archive, see section 7.6)
 - the comment may be deleted by editing and saving an empty comment instead
 - batch report (eight wells per page) shows a note with the corresponding order, that a comment is available
 - single report (one well per page) is printed including comment
- *Edit* – results of single parameters may be edited (see section 7.7 for further details); this option can only be accessed by users with corresponding user rights (see section 7.8)
- *Save Image* – saves the selected well image as an external JPG file (automatically generated file name: test_SampleID.jpg)
- *Scan Single Well* – images the selected well again. **Warning:** the existing well image and results are replaced by the new image and results

7.5 Interpretation of Results

7.5.1 Evaluation by Cut-off (Ratio)

If the spot pattern contains the control spots listed below, results are displayed as intensity ratios (see Figure 12: A, A.1, A.2). This pattern of control spots is applied in SeraSpot® tests for infectious diseases.

Control Spots

- PC – Positive control
- NC – Negative control
- CO – Cut-off control
- GC – optional IgG conjugate control
- MC – optional IgM conjugate control
- AC – optional IgA conjugate control
- SC – Serum control

The result for a specific parameter or control spot is calculated by dividing the measured color intensity of the parameter spot by the measured color intensity of the cut-off spot (ratio). A ratio greater than 1.00 represents a positive result. A ratio less than or equal to 1.00 represents a negative result. Single positive results are highlighted red. The result of the cut-off is always determined at 1.00. Table 1 shows the evaluations for the color intensities possible.

If test specific rules regarding single parameter spots are available the sample is evaluated 'positive', 'negative' or 'borderline'. Note: depending on the test, ratios of 1.00 for individual parameters may be assessed as 'borderline' or 'positive' (see Instructions for Use of the respective test).

Table 1: Evaluations of single parameter spots when using the cut-off and ratio evaluation

Color intensity of spots	Software result (Ratio)	Evaluation
parameter > CO	parameter ratio > 1.00	parameter positive
parameter ≤ CO	parameter ratio ≤ 1.00	parameter negative

For possible evaluation errors see section 7.5.3.

7.5.2 Evaluation by Reference Curve (Units)

If the spot pattern contains not only the control spots described in section 7.5.1, but three additional reference spots, a reference curve is calculated and results are displayed as units (Units) based on the reference curve (see Figure 12: B, B.1). This pattern of control spots is applied in SeraSpot® tests for autoimmune diseases. Units of the results are test specific.

Control Spots

- PC – Positive control
- NC – Negative control
- CO – Cut-off control
- R3 – Reference 3
- R2 – Reference 2
- R1 – Reference 1
- SC – Serum control

Spots NC, CO, R3, R2 and R1 are used to calculate a 4-parameter curve (regression). The reference curve is used to calculate results from color intensities in form of units (Units). For a correlation between reference spot and unit count, see Instructions for Use of the respective test.

If measured values exceed the measuring range of the reference curve, the software highlights these results.

- 'XXX*' – values between reference spot with highest unit count and highest unit count times 1.5 are determined by extrapolation and are therefore estimates only, labeled with '*', example: '351*'.
• '>max' – values above the reference spot with highest unit count times 1.5 or above asymptote of curve are labeled '>max'

If evaluation of such parameters is required, sample must be diluted to such an extent that the relevant parameter spot shows a color intensity within the measuring range of the reference spots (intensity lower than reference spot with highest unit count).

Table 2 shows evaluations for the color intensities possible.

If test specific rules regarding the single parameter spots are available, the sample is evaluated 'positive', 'negative' or 'borderline'.

Table 2: Evaluations of single parameter spots using the evaluation by reference curve and units

Color intensity of spots	Software result	Evaluation
parameter > CO	parameter > CO	parameter positive
parameter >> CO	'>max'	parameter positive
parameter ≤ CO	parameter ≤ CO	parameter negative

Single results evaluated as positive are highlighted in red.

For possible evaluation errors see section 7.5.3.

If a reference curve cannot be calculated using the reference spots given, the single parameter results are displayed as ratios (see section 7.5.1). The overall evaluation is marked as 'n.a.' still (not available) (see section 7.5.3).

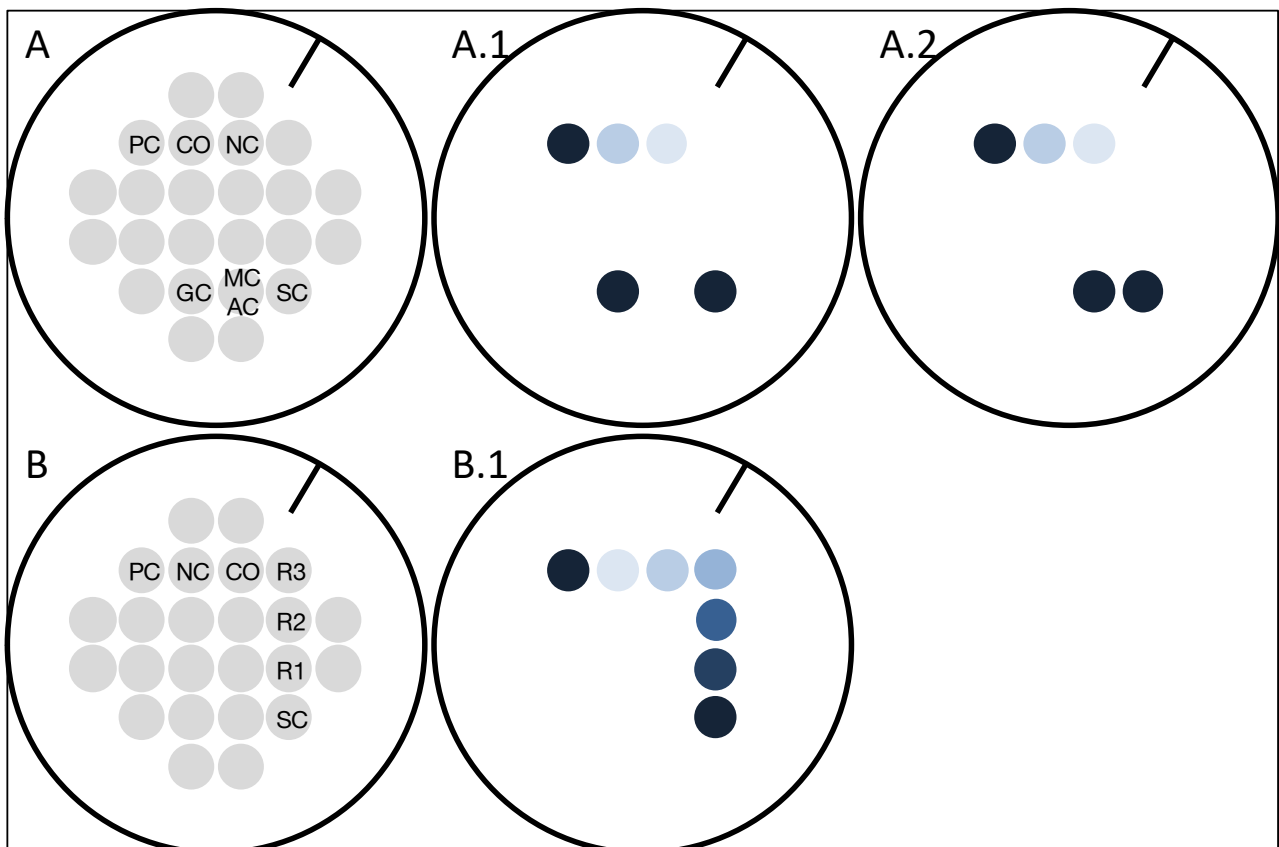


Figure 12: Patterns of control spots of SeraSpot® tests for
(A) infectious diseases: symbolic illustration of a developed well with IgG conjugate (negative sample) (A.1) and IgM or IgA conjugate (negative sample) (A.2);
(B) autoimmune diseases: symbolic illustration of a developed well with IgG conjugate (negative sample) (B.1)

7.5.3 Evaluation Errors

Each spot pattern contains several control spots (see sections 7.5.1 and 7.5.2). Seramun SpotSight® scan uses the color intensity of these spots to check the validity and plausibility of test results. If the evaluation of these control spots shows an error the evaluation is marked as 'n.a.' (not available) and the error cause is shown. Table 3 lists all possible errors or irregularities possible for the control spot values including their descriptions. When more than one error occurs, only the one with the highest priority is displayed.

Table 3: Error messages displayed by SpotSight® scan instead of an evaluation result.

Error category	Priority	Error message	Error description
controls not valid	1	'n.a. CO<=min'	CO ≤ minimum (RAW)
	2	'n.a. CO<=NC'	CO ≤ NC
	3	'n.a. PC<=CO'	PC ≤ CO
	4	'n.a. CO>max'	CO > maximum (RAW)
	5	'n.a. PC<min'	PC < minimum (RAW)
	6	'n.a. SC<=CO'	SC ≤ CO
	7	'n.a. PC<2xCO'	PC < 2 (ratio)
	8	'n.a. SC<2xCO'	SC < 2 (ratio)
	9	'n.a. GC<2xCO'	GC < 2 (ratio)
	9	'n.a. MC<2xCO'	MC < 2 (ratio)
	9	'n.a. AC<2xCO'	AC < 2 (ratio)
no curve	10	'n.a. no curve'	evaluation by reference curve only: software cannot calculate a curve based on the reference spots output of single results as ratio

Values labeled with RAW are checked before conversion to ratios or units.

In the result overview 'n.a.' is not displayed but the short error description only. Corresponding cells in the grid are highlighted red (see section 7.4.6).

In all cases the well image should be checked visually for plausibility!

For possible error causes contact your distributor.

7.6 Archive

Page Archive (Figure 13) may be used to review, print, and export results of completed orders.

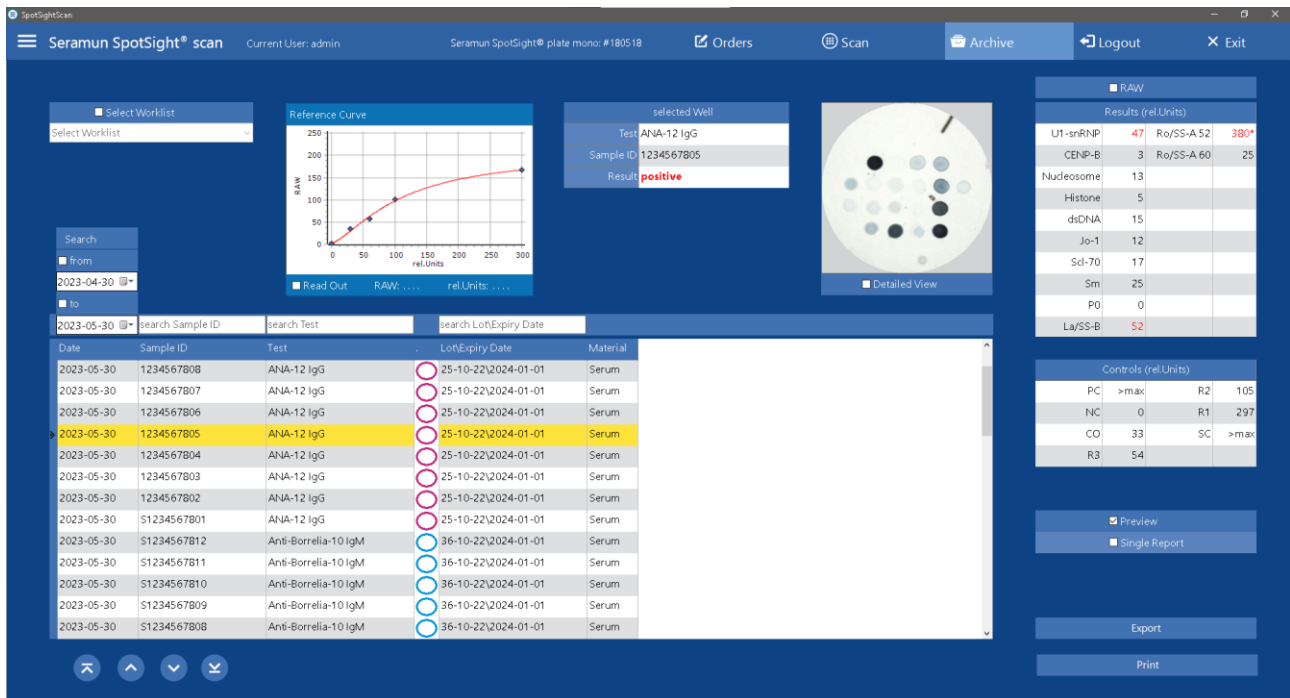



Figure 13: Page Archive

The table shows all completed orders. When selecting a row, the corresponding image and results are displayed.

The buttons  under the main table are used for navigation: first entry / previous entry / next entry / last entry.

- *Select Worklist* – shows orders contained within the selected worklist, only active if checkbox is selected

For SeraSpot® tests that are evaluated via reference curve, the corresponding reference curve is shown.

Above the table a lineup of search fields is displayed, that can be used to search for orders within the table. Search phrases may contain a part of the desired word or number only (except *from / to*).

- *from / to* – shows orders only imaged after or/and before the selected dates, active if corresponding checkbox is selected only
- *search Sample ID* – search for sample IDs
- *search Test* – search for SeraSpot® test name
- *search Lot* – search for a specific lot

By clicking the arrow keys and the shift key several orders may be selected at the same time for printing or exporting.

From software version 3.2.1 onwards the search for patient data is deactivated by default.

- *Print* – issues a batch report (eight wells per page)
 - *Preview* – opens a preview before printing (see section 8)
 - *Single Report* – detailed report of one well per page
- *Select All* - visible only if a worklist is selected, marks complete worklist for exporting or printing
- *Export* – saves results in a CSV file, the exported list contains information on test, Sample ID and results

The format of the export can be adjusted to the specific needs of a LIMS. Contact your distributor for additional information.

The archive allows to display, print, or export results of selected orders as RAW values. The results are shown as raw color intensities (minus background) without conversion to ratios or units (see section 7.5).

- *RAW* – displays, prints, exports single results as raw color intensities (automatically deactivated when leaving the archive)

A right mouse-click on a selected row (Order) opens a list with additional functions.

- *Reset* – results of the selected order are deleted; the status is reset to 'open', and the order is listed in the page Orders – **Warning: cannot be undone**
- *Delete* – the selected order including results are deleted from the database – **Warning: cannot be undone**
- *Comment* – adds a comment to the selected order or edits an existing comment
 - comment is assigned to the order and saved in the database of the software
 - comment may contain a maximum of 255 characters
 - comment may be edited by opening the comment function with the same order
 - the comment may be deleted by editing and saving an empty comment instead
 - the batch report (eight wells per page) shows a note with the corresponding order, that a comment is available
 - single report (one well per page) is printed including comment
- *Edit* – results of single parameters may be edited (see section 7.7 for further details), this option can only be accessed by users with corresponding user rights (see section 7.8)
- *Save Image* – saves the well image of the selected order as an external JPG file (automatically generated file name: test_SampleID.jpg)

Selecting Detailed View below the well image opens an enlarged and labeled well image.

- *Detailed View* – opens a separate window, showing an enlarged well image with labels showing parameter and control names and their respective results

Edited single parameter results are marked as edited in software and reports. The export contains edited results without markings, though. Original values may be accessed when opening the edit dialog again (*old*).

- Marking in software – the edited value is shown only, the value is highlighted yellow – example: **1.01** (red font because value of ratio > 1.00)
- Marking in reports – the edited value is shown in a bold italic font, the report contains username and date of the edit – example: ***1.01*** (red font because value of ratio > 1.00)
- Export – edited results only are exported, no markings

Under the following conditions the software prevents an edit:

- Order was not evaluated and marked by the software with 'n.a.' (see section 7.5.3)
- Evaluation by reference curve: single results with values above the reference spot with highest unit count times 1.5 or above the curve asymptote ('>max') can't be edited (see section 7.5.2)
- Activating the RAW option on page Archive deactivates editing (see section 7.6)

7.8 User Management

On page User users may be changed, deleted, or added (see Figure 15). The page may be accessed via options menu (3 horizontal lines, top left). The menu entry *User* and the page are visible only for authorized users. In a new installation of the software the following users are predefined:

- *User: admin* (access to user management and editing of results)
- *User: std* (default user)

The table on the left lists all existing users with username and password. The fields in the center are used to change existing users or to create new users. The following fields are displayed and adjustable:

- *User* – username
- *Password* – password
- *Edit Results* – user is allowed to edit results of single parameters after imaging or from the archive (see section 7.7). This authorization includes the following permissions:
 - authorization to edit results
 - access to user management
 - access to options
 - access to test import
- *User Management* – user management is shown and accessible in order to add, delete, and change users. Authorization includes the following permissions:
 - access to user management (**exception**: no permission to grant or change authorization to edit results)
 - access to options
 - access to test import

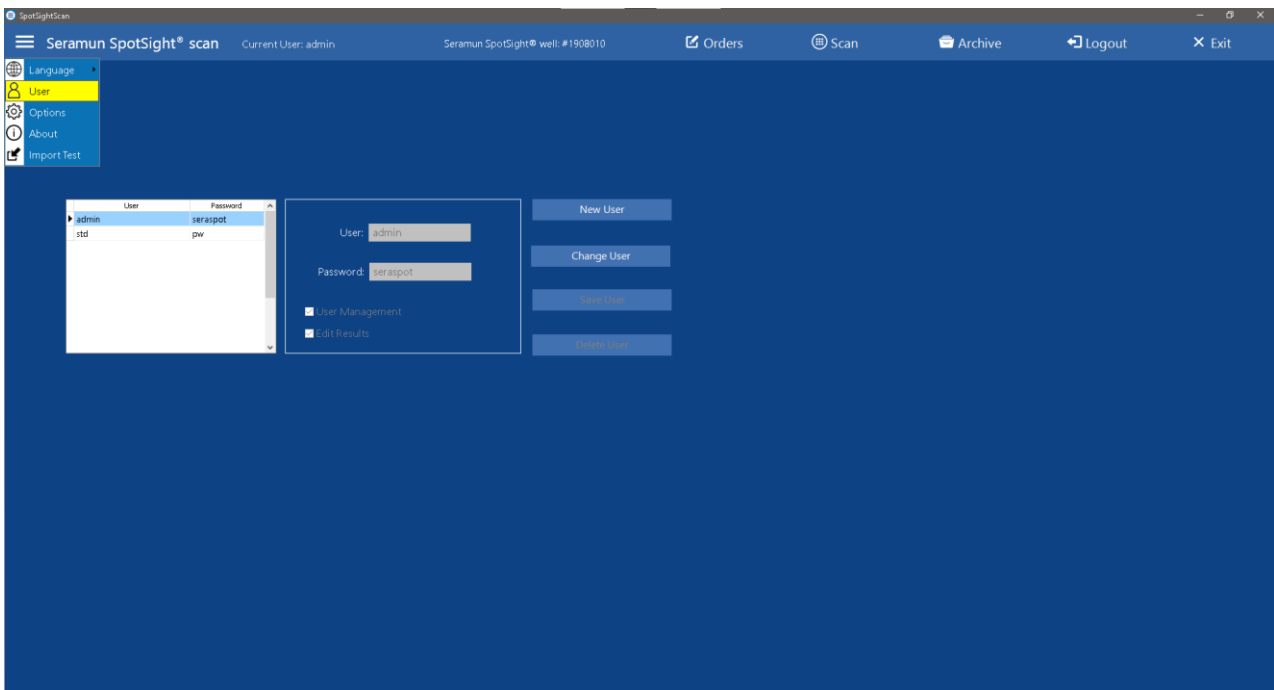


Figure 15: Page User

On the right the following buttons for user management are available:

- *New User* – creates a new user and allows to cancel the creation of a new user (label changes to *Cancel*); the fields in the center are used for the entry of a new user profile
- *Change User* – allows to change the properties of an existing user selected in the table on the left and to cancel and reset changes (label changes to *Cancel*); the user that is logged in cannot remove his access to the *User Management*
- *Save User* – saves the properties of a new or changed user
- *Delete User* – deletes the user selected from the table on the left, the user that is logged in cannot delete himself

The user admin is preferably used by the administrator to create new users in the user management. The predefined users should be deleted once new users are set up.

7.9 Options

Page Options is used to adjust different settings of Seramun SpotSight® scan. The page can be accessed via options menu (three horizontal lines, top left).

The menu entry and page *Options* is only visible for authorized users (see section 7.8).

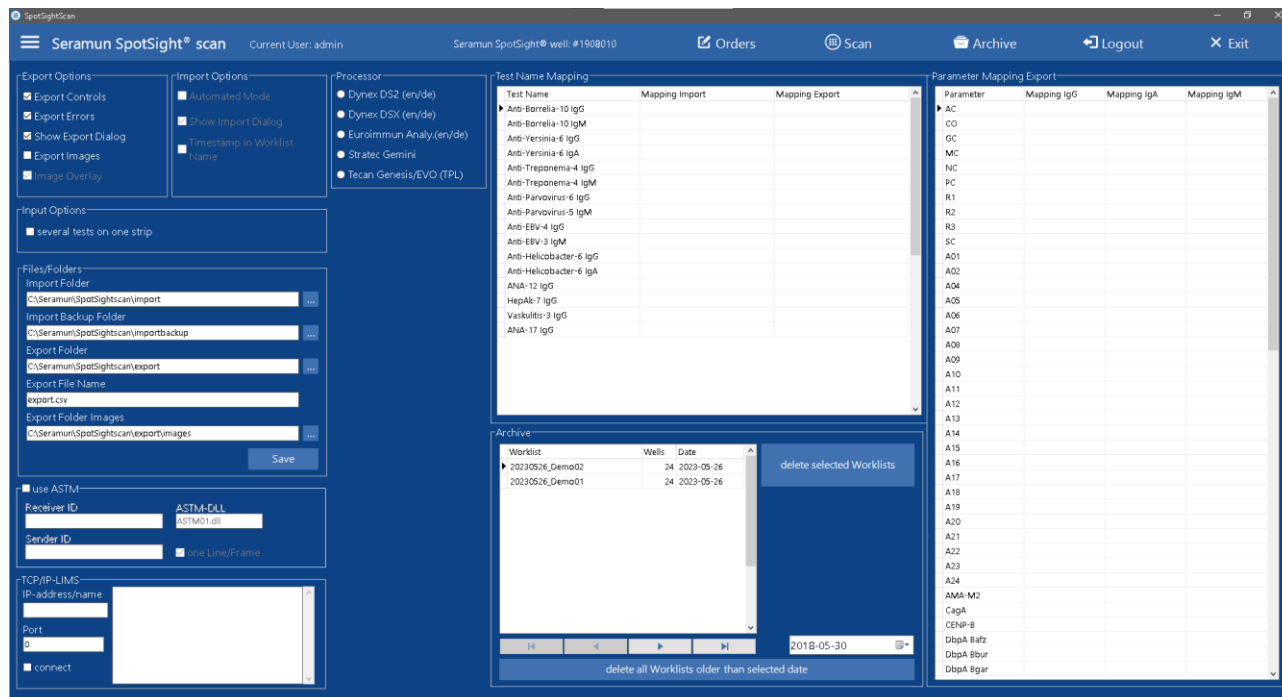


Figure 16: Page Options

7.9.1 Export Options

- *Export Controls* – result-values from single parameter spots are exported as well as result-values from control spots
- *Export Errors* – orders not evaluated by the software are exported ('n.a.', see section 7.5.3)
- *Show Export Dialog* – shows and hides the 'Save As' dialog when exporting results. If the dialog is hidden, the software automatically exports a file with a defined name into an export folder (see section 7.9.4)
- *Export Images* – in addition to the results in form of a CSV file (see section 7.4.7), the software saves well images in a specified folder (see section 7.9.4)
- *Image Overlay* – inserts a permanent overlay to the exported well images (file name, rectangles around parameters, parameter labels including results)

7.9.2 Import Options / Processor

- *Automated Mode* – the sample-well allocation is taken from the output of an automated ELISA processor. Orders are not resorted (see section 7.3.5). Worklist (see section 7.3.4) is marked with '@_' in front of the name. If the automated processor does not export lot\expiry date the software requires this information upon import. After import orders are automatically added to a worklist, that cannot be edited. Interface elements for manual order entry are hidden.
- *Show Import Dialog* – shows or hides dialog 'Open' when importing orders. If dialog is hidden, the user is asked for a worklist name. Software checks for and opens the corresponding import file automatically (see 7.9.4 for Import Folder).
- *Timestamp in Worklist Name* – if a worklist is created, a timestamp is automatically added to the worklist name. This can be useful in context with *Automated Mode* and deactivated option *Show Import Dialog*. It allows to repeatedly import files with the identical names.
- *Processor* – this option defines the automated ELISA processor orders are imported from in the automated mode. The processors listed are dependent on import applications stored in a specific folder. By default, Seramun SpotSight® scan is delivered with the following import applications:
 - Dynex DS2 (en/de)
 - Dynex DSX (en/de)
 - Euroimmun Analyzer (en/de)
 - Stratec Gemini
 - Tecan Genesis/EVO (TPL)

Please contact your distributor for additional information.

7.9.3 Input Options

- *several tests on one strip* – if a worklist contains more than one test, the software does not allocate tests on a new microtiter plate strip, when arranging orders and switching to a different test.

7.9.4 Files/Folders

- *Import Folder* – source folder for import files
- *Import Backup Folder* – backup folder for import files (import transfers import file into this folder)
- *Export Folder* – target folder export files
- *Export File Name* – export file name (and file name extension)
- *Export Folder Images* – target folder for export well images
- *Save* – saves all file and folder settings after a change

7.9.5 Test Name Mapping

To allow the use of laboratory specific test names in import and export files, test names used in the software can be mapped to user-definable descriptions.

- *Test* – name of SeraSpot® test in Seramun SpotSight® scan
- *Mapping Import* – test name used during import, i.e. name of SeraSpot® test on automated ELISA processor
- *Mapping Export* – test name used during export, i.e. name of SeraSpot® test in LIMS

7.9.6 Parameter Mapping Export

To allow the use of laboratory specific parameter names in export files, parameter names used in the software can be mapped to user-definable descriptions for each isotype.

- *Parameter* – name of parameter (single parameters und controls) in Seramun SpotSight® scan. Note: all controls and select parameters are present in different tests
- *Mapping IgG* – name of parameter during export in IgG tests
- *Mapping IgA* – name of parameter during export in IgA tests
- *Mapping IgM* – name of parameter during export in IgM tests

7.9.7 Archive

The table shows all worklists saved in the archive with name, well count and date. The interface elements allow to permanently delete worklists to remove them from the archive.

Warning: deletion cannot be undone; worklists including orders / results are deleted permanently.

- column *Worklist* – worklist name
- column *Wells* – worklist well count
- column *Date* – worklist date
- navigation buttons – navigation through list (first, previous, next, last element)
- *delete selected Worklists* – deletes all worklists selected in table
- date selector – (see next item)
- *delete all Worklists older than selected date* – deletes all worklists older than the date selected in the date selector

7.9.8 ASTM

Results may be exported following the ASTM protocol (ASTM Standard E 1394). The format of the export can be adjusted to the specific needs of a LIMS. In this case Seramun SpotSight® scan acts as client, the LIMS acts as server.

- *use ASTM* – instead of exporting a CSV file the software sends results in ASTM format to a LIMS
- *Receiver ID* – identification or name of the receiver within the LIMS
- *Sender ID* – identification or name of sender (Seramun SpotSight® scan)
- *ASTM-DLL* – input for DLL file which defines the High-Level ASTM format, the given DLL file must be located in the files folder of Seramun SpotSight® scan
- *one Line/Frame* – the ASTM format sends one line per frame only

Please contact your distributor for additional information.

7.9.9 TCP/IP LIMS

The following options only apply if results are exported by ASTM protocol.

- *IP-address/name* – IP address or network name of the receiver within the LIMS
- *Port* – port that should be used at the receiver
- *connect* – checks if a connection to the receiver can be established; before each export Seramun SpotSight® scan automatically reopens the connection to the receiver

8 Report Window

To show a preview before printing Seramun SpotSight® scan opens a separate report window (Figure 17).

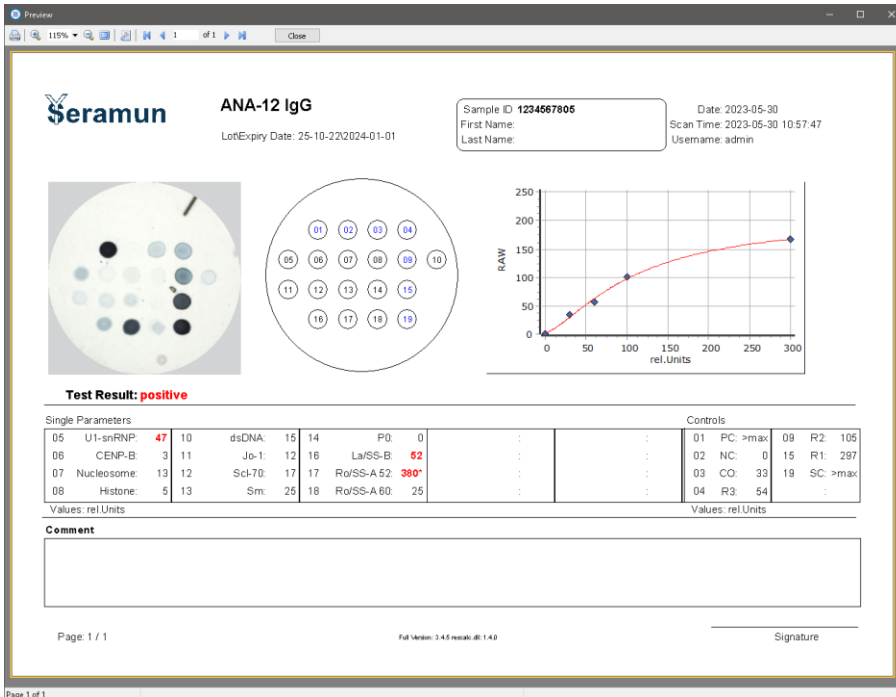

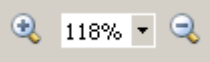



Figure 17: Report software showing a single report

Overview of the most important control elements:

-  – the button prints the report shown directly from the report window; to generate a PDF file, a suitable PDF printer has to be chosen (i.e. PDF Creator or Microsoft Print to PDF)
-  – control elements allowing for adjustments of the display size of the report (zoom) on the screen
-  – control elements allow for the navigation through different pages of a report
- *Close* – closes the report window (alternatively the title bar button may be used)

9 Change History

Section	Modifications
3 and 4	references added to Seramun SpotSight® well software setup file added as alternative to preinstallation notes removed on non-acceptability of USB hubs and other USB cables (moved into device manual) note added that hardware key may be integrated into device
5	section added about setup file and updates
6.1	note removed for desktop shortcut Seramun SpotSight® plate mono and Seramun SpotSight® strip description merged into one section
6.2	start / stop description added for Seramun SpotSight® well
7.1	passwords of predefined users added device type references removed note added on deleting predefined default users
7.2	name and serial number of device added
7.3.1.3	checkbox description removed (checkbox moved into Options) description of Automated Mode adjusted
7.3.5	note on option for several tests on one strip added Automated Mode references 7.9.2 description of Automated Mode adjusted
7.4	changes to generalize for Seramun SpotSight® well Initialize, Open, Close specific for Seramun SpotSight® plate mono and Seramun SpotSight® strip
7.4.5	section added for Seramun SpotSight® well
7.5.2	section generalized and references on rel.Units removed specific evaluation (one antigen positive) removed and replaced by generalized evaluation (test specific)
7.6	note for reference curve generalized Sample ID search cannot contain several phrases anymore
7.8	note about deleting predefined default users added
7.9.2	section renamed to Import Options / Processor Show Import Dialog added Timestamp in Worklist Name added added dynamic reading of automated methods Euroimmun Analyzer added to default automated methods
7.9.3	section Input Options added
7.9.7	section added for deleting worklists in the archive
Short Instructions	section modified to include Seramun SpotSight® well

Seramun SpotSight® scan Release Version 3 Short Instructions

1 – Start

- Start PC
- Seramun SpotSight® plate mono / Seramun SpotSight® strip:
Switch on device / wait for initialization to finish;
Seramun SpotSight® well: connect device to PC
- Start software
- page **Login** – login with username and password

2 – Order_Entry

=> switch to page **Orders**

- **Direct input** (top left)
 - select **Test**
 - enter **Lot\Expiry Date**
 - select **Material**
 - enter **Sample ID**
 - confirm with **Save Order** or by pressing **Enter key**
 - repeat input, until all orders are entered
- **Import prepared lists**
 - **Order Import** (top left) as alternative input option loads a prepared list of the format: [Sample ID];[Test];[Lot\Expiry Date]
- **Create a worklist**
 - **Create Worklist** (top right) – puts all open orders into a worklist
- **Output worklist with sample microtiter plate allocation**
 - select a worklist under **Open** and **Print Layout** for sample microtiter plate allocation; process SeraSpot® tests according to protocol

3 – Imaging Process & Evaluation

=> switch to page **Scan**

- **Select Worklist** (top left)
- Seramun SpotSight® strip / Seramun SpotSight® well: **Select Strip**
- Start imaging by clicking **Scan** (bottom left) – insert microtiter plate, strip or well holder, when asked and confirm by clicking **OK**
- Seramun SpotSight® well: follow instructions of software
- Seramun SpotSight® plate mono / Seramun SpotSight® strip: after imaging and upon request remove microtiter plate or strip. Confirm by clicking **OK**
- **Print** or **Export** results (bottom right)

4 – Output Old Results

=> switch to page **Archive**

- **Select Worklist** (top left), check **Select All** (bottom right) or select individual orders by using arrow keys and shift key
- **Print** or **Export** results (bottom right)

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