

Biotest SSP Typing

Typing Software

Version 1.1



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Installation and Preparation

1. Introduction

The software Biotest SSP typing enables depicting, evaluating and saving patients' typing results from reaction patterns. This manual is a brief instruction on the installation and use of the typing software.

2. Minimum system requirements

- Operating system Windows 98/NT/2000 or Windows XP.
- IBM-compatible PC with at least Pentium processor / 90 MHz / 32 MB RAM.
- A minimum of 15 MB free hard disk storage space, CD drive
- Graphics resolution at least 256 colours, 640x480 pixel, preferably: True Colour

3. Update of an existing version

To update a previously installed version of SSP 1.1, install the new version and then adopt data of the previous version.

Should the uninstalling of an existing SSP software version not be necessary, please copy the files \cfg, \date and \archive from the installation directory of the SSP software into a temporary directory. Uninstall the old version of the program with the software tool from the Windows system control and then install the new version.

Subsequently transfer the data from the temporary directory into the newly created subdirectory \cfg, \date and \archive.

Please note that the two new language files ENGLISH.LNG and GERMAN.LNG must not be overwritten by old files from the temporary directory!

4. Adoption of typing data from an installed software version

After installing the new software, you should adopt data from older installations. Because the software does not include a data adopting feature, all data must be copied with the operating system's explorer. Please proceed as follows:

1. Open the explorer of your system
2. Copy the files from the directory \cfg from the old installation directory of the SSP software into the directory \cfg of the new installation directory.

Please note that the two new language files ENGLISH.LNG and GERMAN.LNG must not be overwritten by old files from the temporary directory!

3. Copy the files of the directory \data and \archive from the old installation directory of the SSP software into the directory \data and \archive of the new installation directory.

5. Instructions for installation

Log into your system as administrator. Place the CD in the CD drive of your computer. Should the installation not start automatically (AutoPlay of the CD) start the program by selecting Setup.exe from the CD.

The installation program is dialogue based. The standard subdirectory is C:\ProgramFiles\Biotest\SSPxxxx\ (xxxx = recent version number)

Click on the yellow box in the start window and initiate the installation.

By clicking on „next“ the following windows will appear subsequently:

1. Welcome screen
2. License agreement
Select " I accept the terms in the license agreement"
3. Manufacturer's notes on the installation structure
4. PC user and organization
5. Proposed target files
"Change" – select other directory
In this screen changes can be selected or confirmed by clicking on "OK".
It is not recommended to install a new version in the same directory where a previous version was installed because possibly not all data will be overwritten.
6. Pathway suggestion
Single user version: Use the automatically suggested pathway
Multi user version: Network pathway can be selected
7. Opportunity to check the pathway before definitive installation
Confirm by clicking on „install“
8. Installation
9. Confirmation of successful installation
Confirm by clicking on „finish“

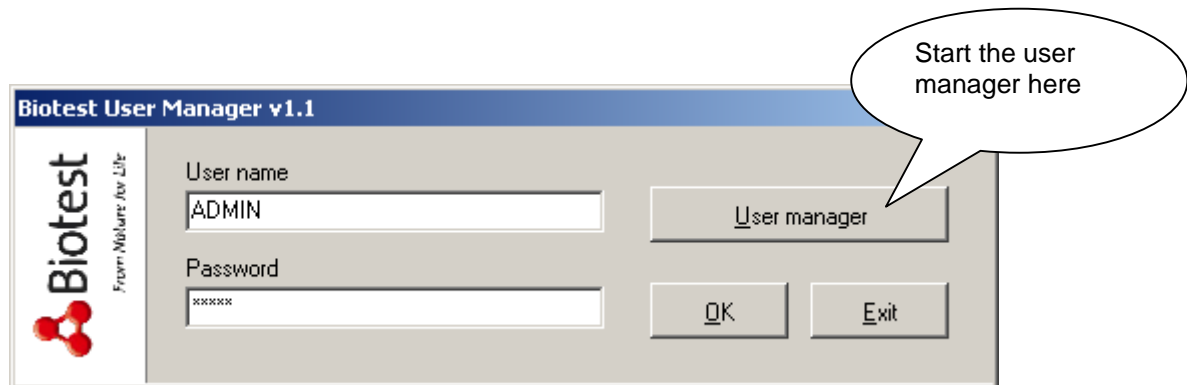
After successful installation, the software should appear on your desktop window and be listed in programs-start menu as „Biotest HLA-SSP typing v1.1“ .

For the network operation a joint file path can be configured on all work stations on the network. All users save their data on the joint network drive. The software will automatically ensure that there is an unambiguous allocation of file names. It is also possible to install a joint archiving path on the network. This path would need to be set up in the INI file of each work station.

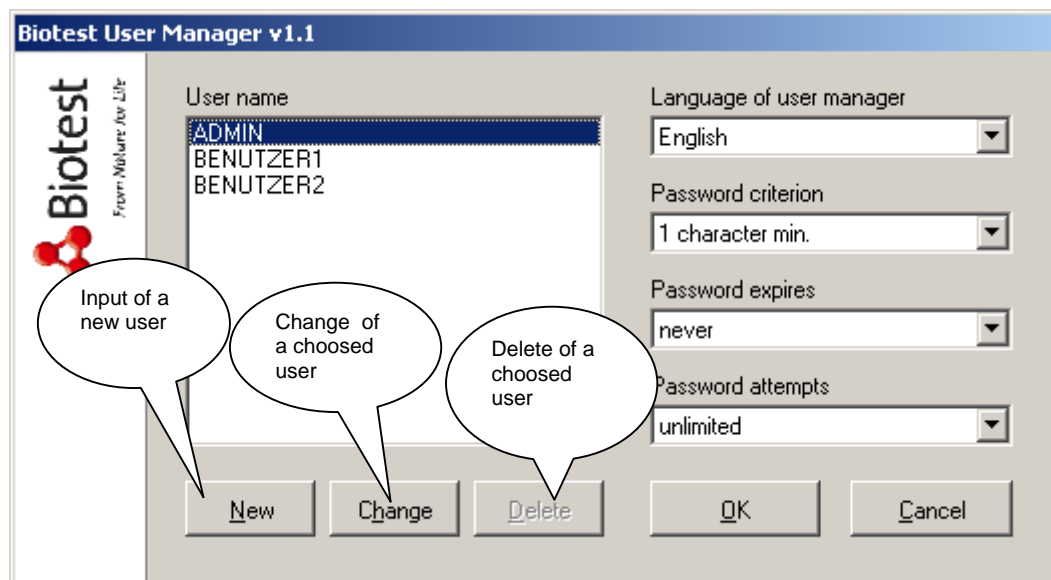
If the software is changed from a single user version to a multi user version, it is important that files from the folders "Data" and "Archive" do not have identical file names to avoid overwriting. By archiving data, the current time is added to the file name and overwriting is thus impossible.

6. Setting up the user manager and user registration

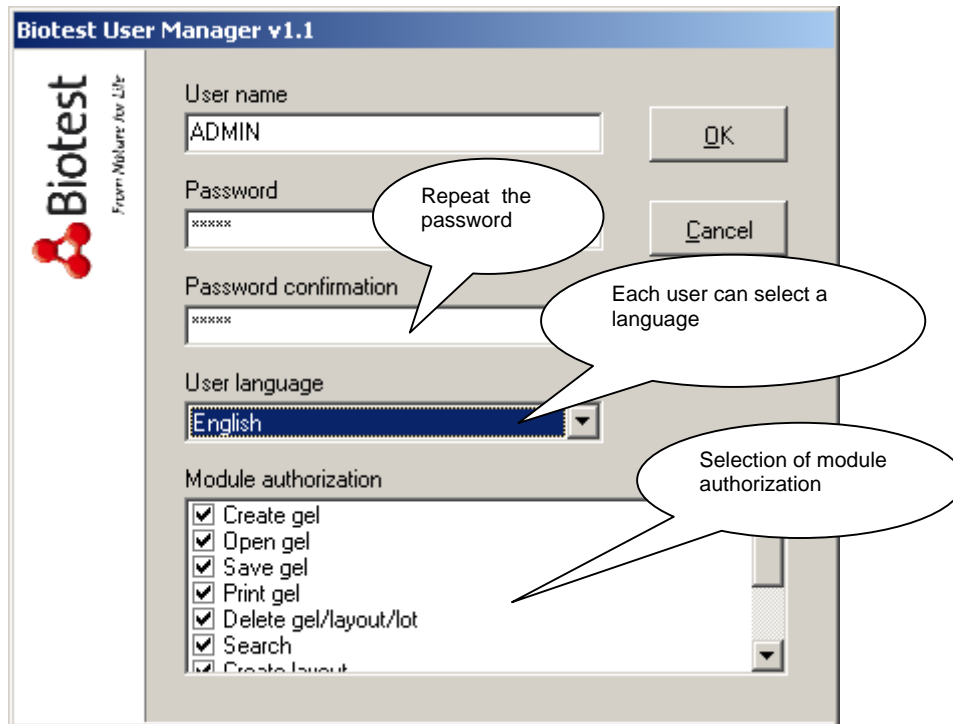
For your first registration please use the user name „ADMIN“ and the password „ADMIN“



The user manager can only be started with the user name „ADMIN“. The password for „ADMIN“ can be altered by the ADMIN user in the user manager.



To set up a new user, click on „New“.



Once a user was set up by the administrator, he/she can change the password after proper registration.

When working with the user manager, the following notes may appear on your screen:

Shall the user be deleted?

Appears if deleting a user is selected.

Password does not meet required criteria:

The selected password does not meet the requirements set by the administrator

Password not confirmed!

The password repetition is incorrect.

User name already exists!

The selected user name already exists

Password expired! Please enter new password.

Appears if the password expired due to the criteria set by the administrator

More than 3 incorrect attempts. Please contact system administrator.

The system administrator allowed for only three attempts to enter the correct password. That number was exceeded.

No user language selected.

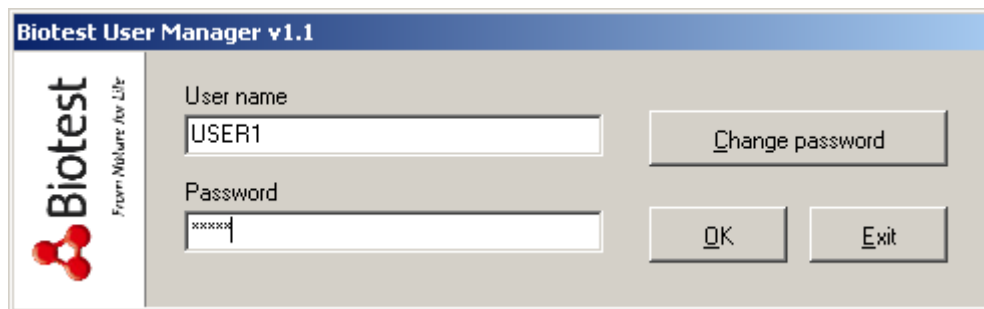
Each user needs to enter his language selection.

Working with the Software

Start the program

Start the program by double-clicking on the program symbol „Biotest HLA-SSP typing v1.1“. Alternatively, the software can be started by selecting it from the computer start menu „Start/Program/Biotest/ Biotest HLA-SSP typing v1.1“.

To log on, please enter user name and password.



The screenshot shows a dialog box titled "Biotest User Manager v1.1". On the left side, there is a logo for "Biotest" with the tagline "From Molecules to Life" and a red molecular structure icon. The main area of the dialog contains two input fields: "User name" with the text "USER1" and "Password" with masked characters "xxxxxx". To the right of the "User name" field is a button labeled "Change password". Below the "Password" field are two buttons: "OK" and "Exit".

Confirm with „OK“.


To log off a user during a working session or to select a different user during the program, please select the function "Extras – Change user" and "Extras – logoff user" or the buttons

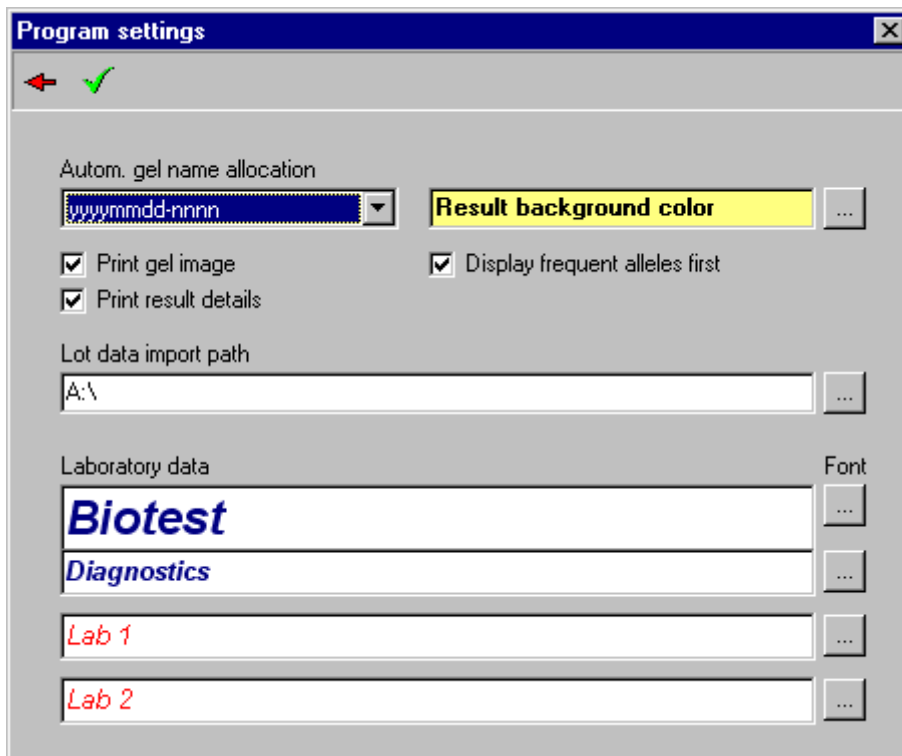


1. Language selection

After successful registration or in the demo version the start screen of SSP typing software will be in English. Language selection can be done in the user manager. Either German or English can be selected as program language.

2. Program Settings

When selecting “Extra – Options” or by clicking on the button  the following dialogue menu appears:



Program settings

← ✓

Autom. gel name allocation
yyymmdd-nnnn **Result background color** ...

Print gel image Display frequent alleles first
 Print result details

Lot data import path
A:\ ...

Laboratory data **Font**

Biotest ...
Diagnostics ...
Lab 1 ...
Lab 2 ...

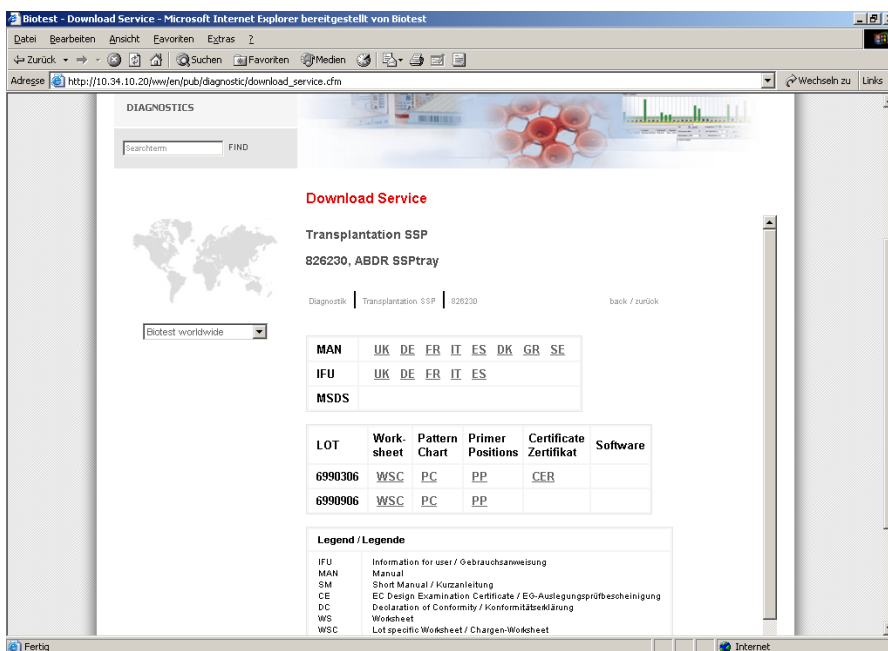
Please select your options for the result protocol and for the path of the lot data import.

3. Import of Lot Data


The lot-specific software updates are provided in the internet as ZIP files and have to be downloaded from there. You find the download service on <http://www.biotest.com> in the menu item diagnostics.

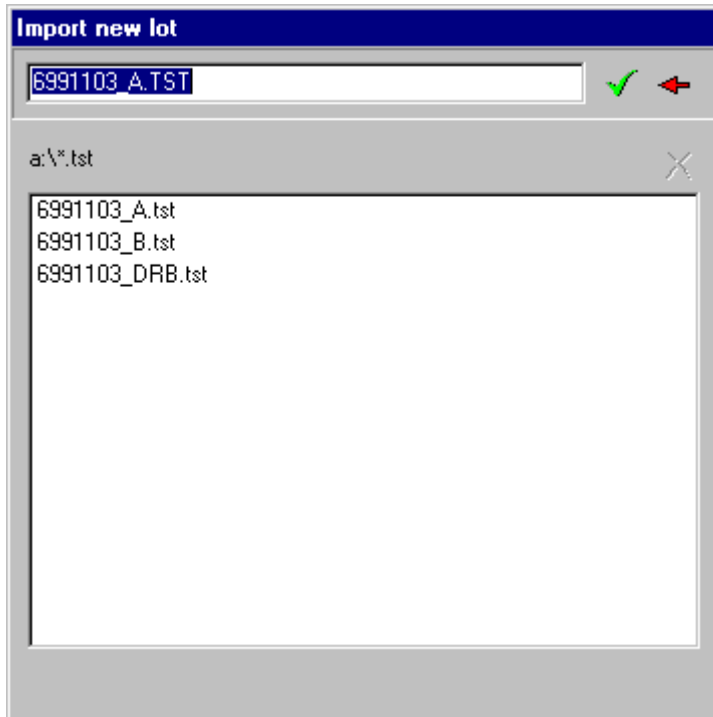


Select your country and enter the download area. Here, all product information like user manuals, worksheets, reaction pattern charts and lot-specific software updates is provided. Select the appropriate product and the corresponding lot.

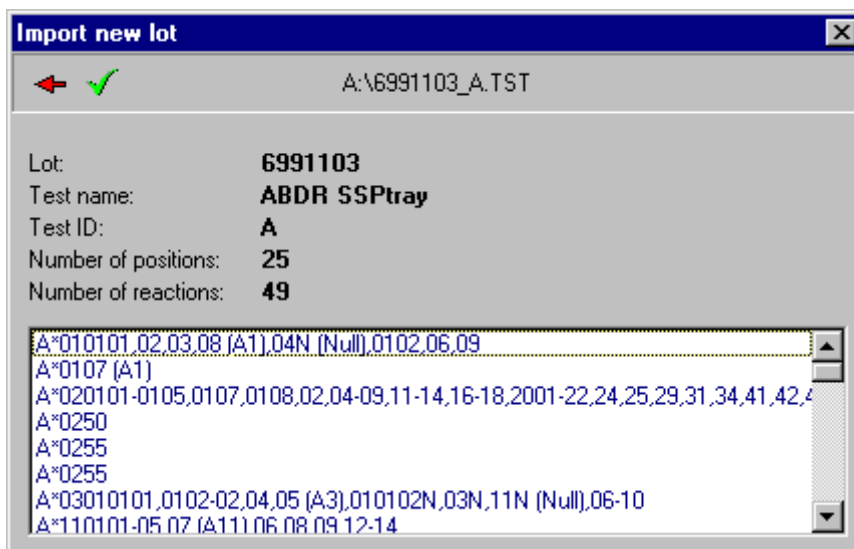


Start the download by clicking on the corresponding ZIP file in the "Software" column of the table. Save the ZIP file in a designated folder on your PC. The path to this folder should be defined as the lot data import path in the software (see chapter 2).

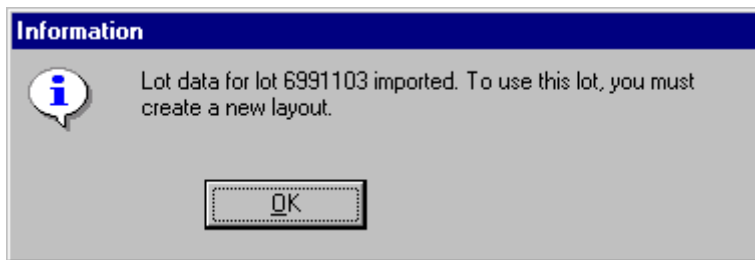
Import data by selecting „Extra – Import new lot“ or start importing new data by clicking on the button .



Select test by clicking on it.




Confirm by clicking on .



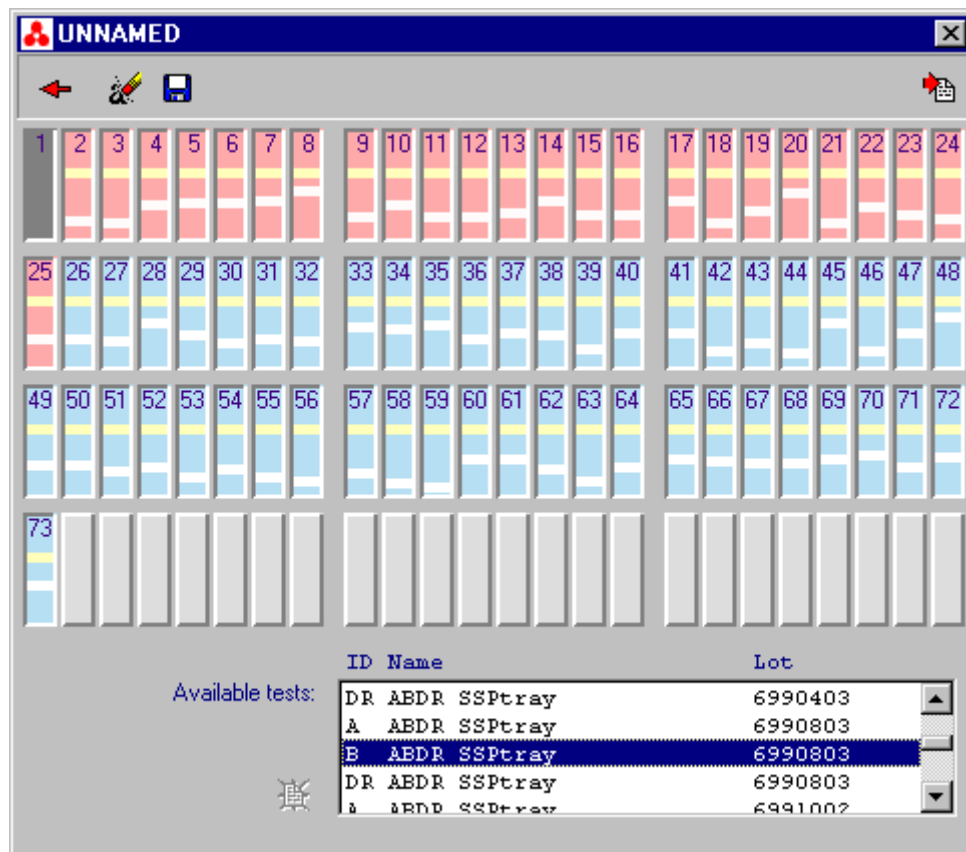
Confirm with „OK“.


Note: For combination test ABDR SSPtray and ABC SSPtray each gene loci must be selected individually!

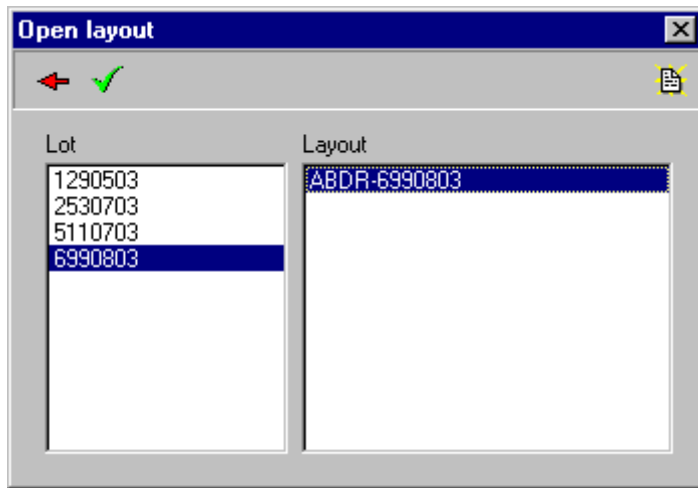
4. Design New Layout

By selecting "Layout – new design" or by clicking on the button , the layout creator is started. With this feature new tray layouts can be defined by double-clicking on a test from a list of available tests. For an ABDR test, first double click on "A", then on "B" and finally "DR" of the resp. kit lot.

Store your layout by selecting "save" and entering a design name. It is recommended to use the test name together with the lot number as layout name, for example "ABDR6990803" Of course, designs may also be deleted if desired.



With „Layout-Open “ or by clicking on the button , stored layouts can be selected.




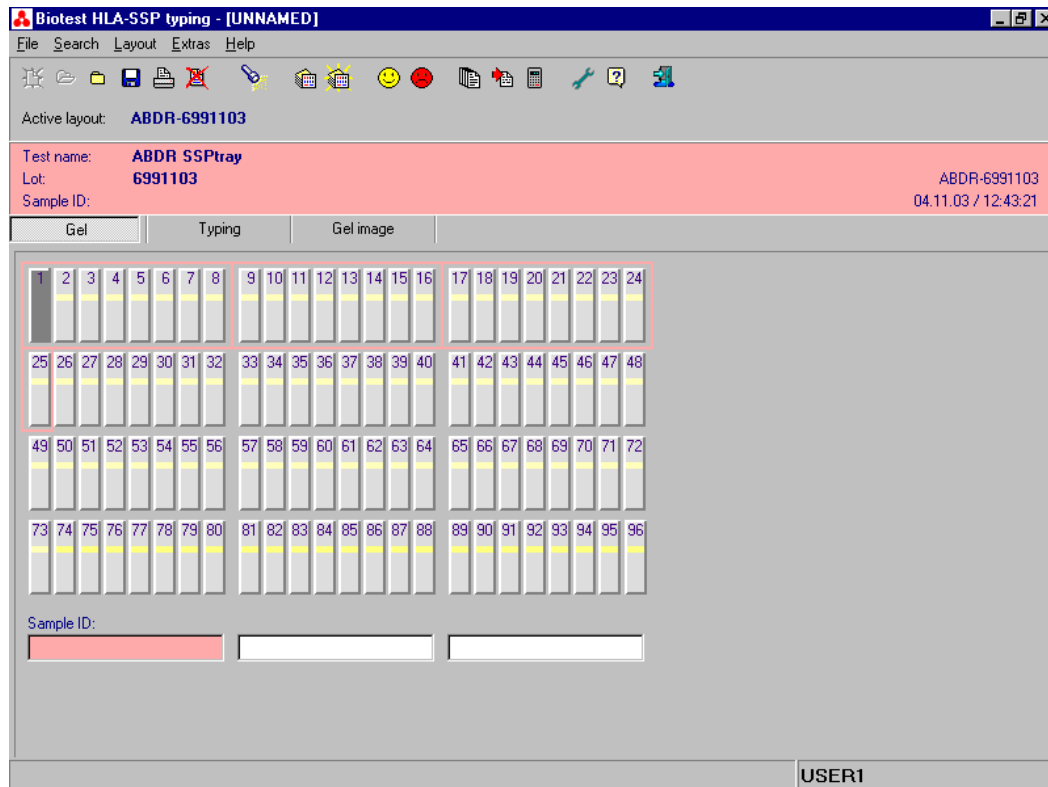
Confirm by clicking on .

The active layout will be displayed in the headline of the SSP typing software.

Evaluation

1. Input Amplification Patterns

By clicking on the button  or by selecting "File - New" an empty gel picture with the selected layout will be shown.



For each typing, the appropriate sample ID must be entered.

By clicking on the respective gel pocket with the left mouse button, amplification patterns from the electrophoresis gel are transferred to the software. Renewed clicking on the gel pocket cancels the activation.

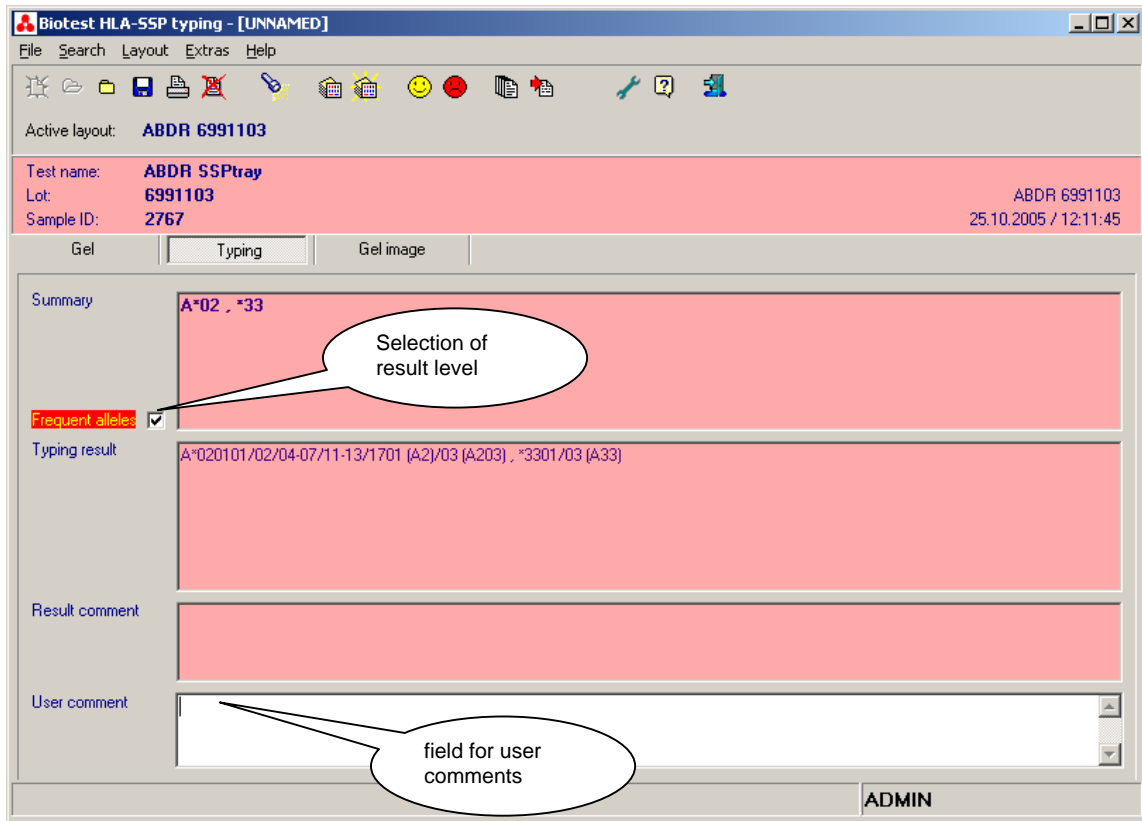
By selecting the gel position with the right mouse button additional comments on the amplification pattern can be entered.

The screenshot shows the 'Biotest HLA-SSP typing - [UNNAMED]' software window. The interface includes a menu bar (File, Search, Layout, Extras, Help), a toolbar with various icons, and a status bar at the bottom showing 'USER1'. The main area is divided into 'Gel', 'Typing', and 'Gel image' tabs. The 'Gel' tab is active, displaying a grid of 96 gel lanes (numbered 1-96) arranged in four rows of 24. A context menu is open over lane 23, with options: 'Control band missing', 'Control band exists', 'Weak band correctly positive' (highlighted), and 'Weak band false positive'. Three callouts are present: 'Marking of positive reactions' points to lane 23; 'Enter additional comments' points to the context menu; 'Enter sample ID' points to the '2767' entry in the 'Sample ID' field at the bottom. The 'Sample ID' field contains three entries: '2767', '2767', and '2767'. The top right of the window shows 'ABDR-6991103' and '04.11.03 / 12:43:21'. The 'Active layout' is 'ABDR-6991103'. The 'Test name' is 'ABDR SSPtray', 'Lot' is '6991103', and 'Sample ID' is '2767'.

2. Typing

After entering all reactions on the gel, selecting „Typing“ will activate the display for the active sample or the active test.

The colour highlighted data fields can not be altered. Comments by the user can be entered under “User comment”.



Two result levels are available with different information content. They are selected by activating or deactivating the field „Frequent alleles“:

- typing results considering **only frequent** allele combinations
- typing results considering **all** allele combinations.

„Frequent alleles“ is based on two criteria:

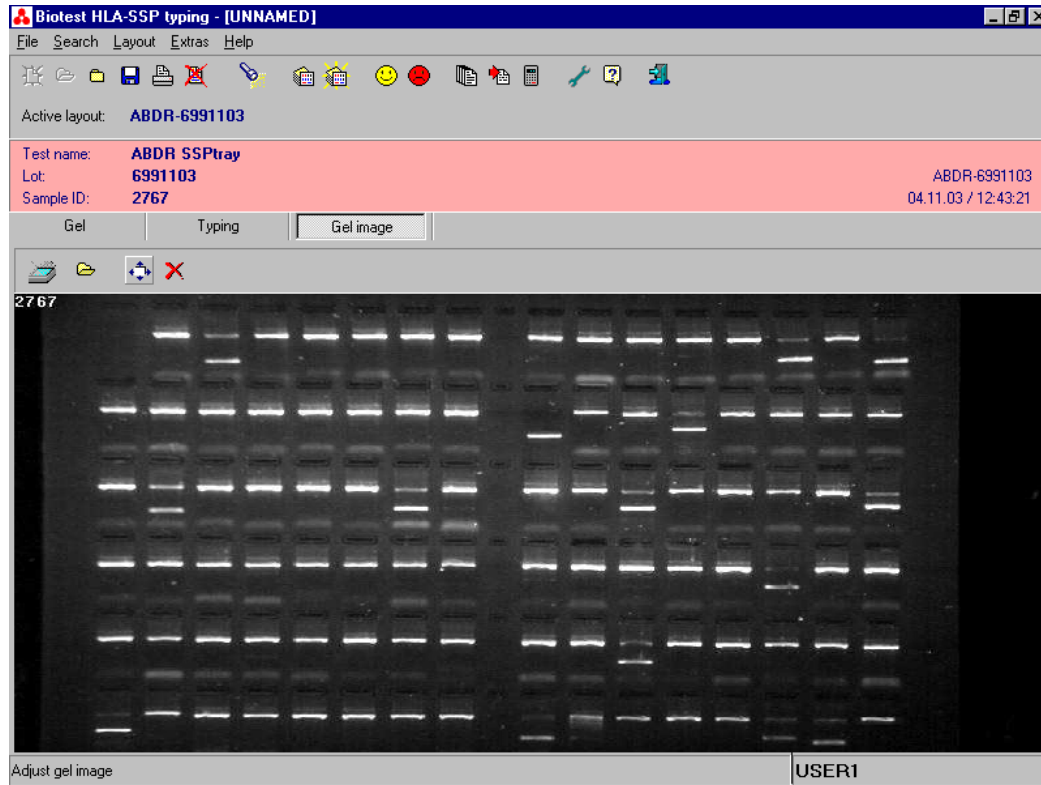
1. Alleles described in the resp. literature as having a frequency higher than 1:1000 (>1‰) (Ref. 1 - 12).
2. Alleles required to be detected in a high resolution system according to the EFI accreditation program.

Notes:

- **False positive or false negative reactions are not displayed.**
- **Missing control bands should be documented in the gel image with a right mouse button click. The software will automatically regard missing control bands as “negative”. The user is obligated to verify whether a positive result of the missing amplification would result in different typing result. In such a case the typing must be repeated. Generally, if more than one control band are missing, the typing should be repeated.**

3. Gel Image


The option „Gel image“ enables digitally integrating the image of an evaluated gel into a result by importing a respective file or scanning it. For a file import the formats "BMP", "IMG", "JPG" and "JPEG" are supported



The size of the picture will automatically adjust to the available space in the print-out.



Result Management

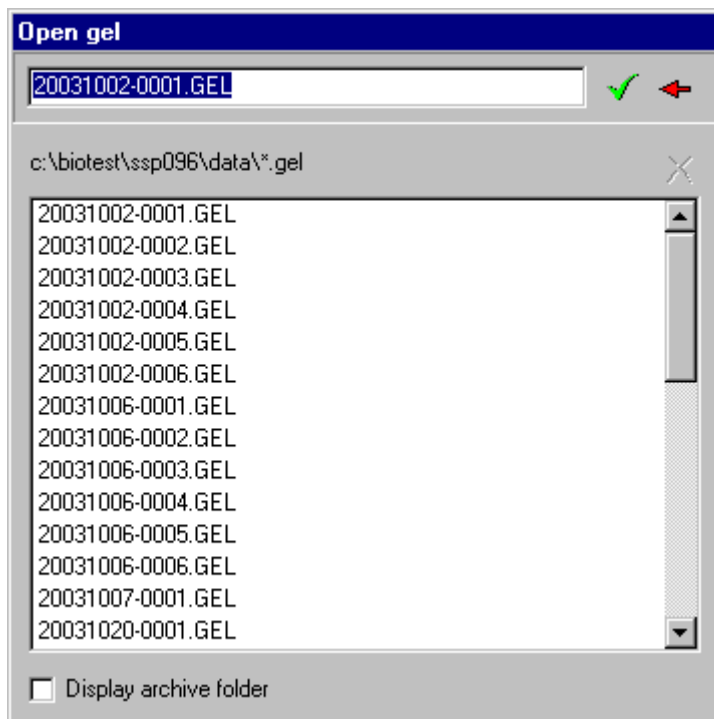
1. Save Results

After all data were entered, the gel can be saved by clicking on the button  or by selecting „File - save“ and entering a file name.
The result is saved under yyyy/mm/dd-xxxx.


Note: In order to avoid data manipulation, saved data can no longer be altered. Therefore please make sure that all relevant data were entered prior to saving!


2. Open Results


To open a saved gel, select „File-Open“ or click on the button . A dialogue window will appear on your screen where a previously saved gel can be selected. Confirm your selection with . The archive can be accessed from this menu as well.



3. Delete Results

By selecting „open gel“ saved results can be deleted. Select the result to be deleted and click on the button .

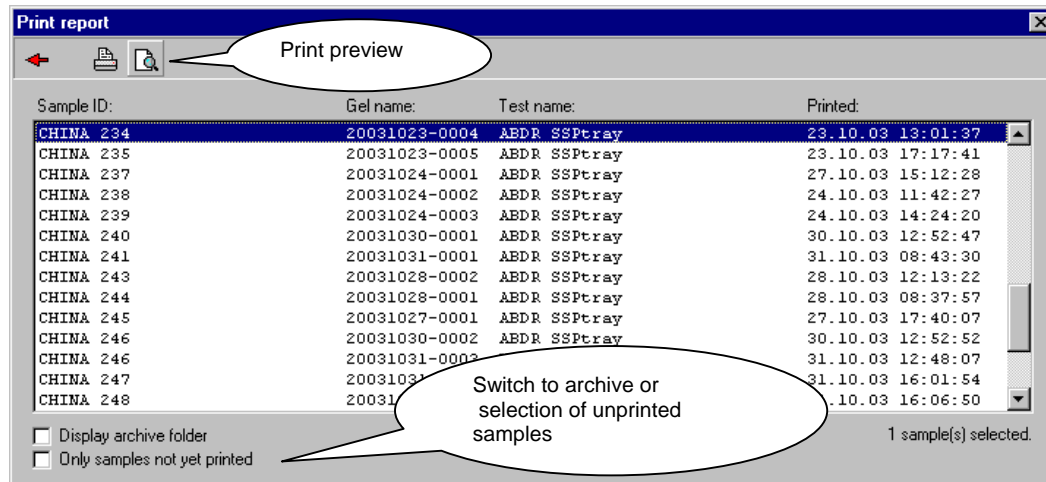
Alternatively the result may be opened and deleted by selecting „File - Delete“ or clicking on the button .

A gel image displayed on your screen can be closed by selecting “File – Close” or by clicking on the button . It is not possible to have more than one gel open on your screen.

Report

To print results select „File – Print“ or click on the button .

A list will appear on your screen including sample IDs, test names and gel names as well as date of the last print-out of the respective test results.



It is possible to access the archive file or list unprinted results **only**.

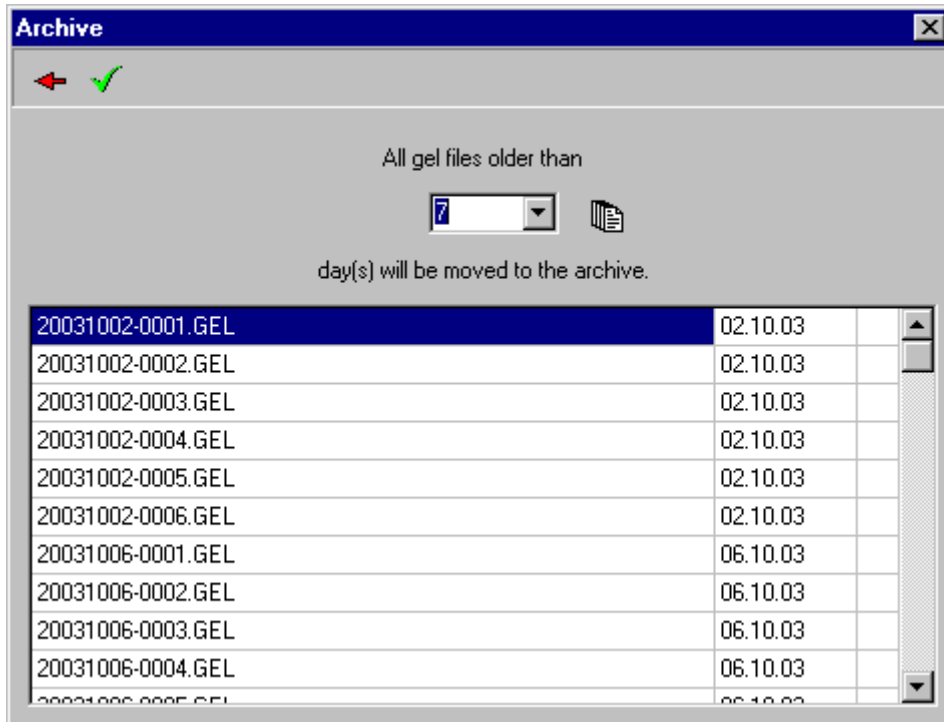
Select the sample to be printed by clicking on it.



By pressing the "STRG" button it is possible to select a number of samples for printing.

The count character in the typing report may be changed manually in file SSP.INI. If there is a need to change the default count character please add a line to the "Options" section "Countchar=<char>" (w/o the quotation marks where <char> is the new count character).

Archive function


By selecting „Extra - Archive“ data can be transferred from the working data base to the archive.



Select how old data for archiving shall be. Activate the button  to display the respective files. Start archiving with  and confirm with „yes“.

By selecting “File - Open”, “File - Print”, or „Search“ data from the archive can be re-opened.

Search function

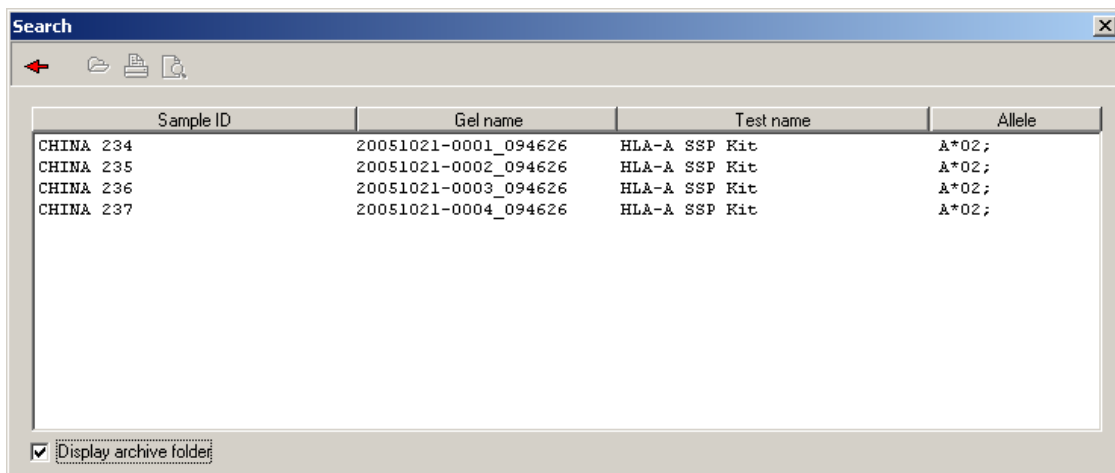
The search function is started by „Search – Start“ or by clicking on the button .

An empty search window will be displayed. By clicking on “Sample ID”, “Test name”, Gel name” or “Allele” the test results will be listed.

Tests are selected by clicking on them.


Alternatively, tests can be searched with any desired search phrase (incremental search).

By pressing the "STRG" button it is possible to select a number of samples.



The screenshot shows a window titled "Search" with a table of results. The table has four columns: Sample ID, Gel name, Test name, and Allele. There are four rows of data. At the bottom left of the window, there is a checkbox labeled "Display archive folder" which is checked.

Sample ID	Gel name	Test name	Allele
CHINA 234	20051021-0001_094626	HLA-A SSP Kit	A*02;
CHINA 235	20051021-0002_094626	HLA-A SSP Kit	A*02;
CHINA 236	20051021-0003_094626	HLA-A SSP Kit	A*02;
CHINA 237	20051021-0004_094626	HLA-A SSP Kit	A*02;

Confirm your selection and start the search with .

The displayed search results can be opened or printed. A search may also be performed in archived files.

References

1. M. Bunce et al., Tissue Antigens 48, 100-111 (1996)
2. V. K. N. Cereb and S. Y. Yang, Tissue Antigens 50, 74-76 (1997)
3. V.K. Prasad et al., Blood 93, 399-409 (1999)
4. D. Middleton et al., Human Immunology 61, 1048-1052 (2000)
5. F. Williams et al., Human Immunology 62, 645-650 (2001)
6. K.C. Cao et al., Human Immunology 62, 1009-1030 (2001)
7. C.K. Hurley et al., Tissue Antigens 50, 401-418 (1997)
8. D.M. Sintasath et al., Human Immunology 60, 1001-1010 (1999)
9. T.F. Tang et al., Human Immunology 61, 820-827(2000)
10. M.M. Collins et al., Tissue Antigens 55, 48-52 (2000)
11. T.F. Tang et al., Human Immunology 63, 221-228 (2002)
12. D. S. Chen et al., Human Immunology 63, 665-672 (2002)

For further questions please contact phone +49-06103-801-9201, 801-807 or 801-765.

Disclaimer: Two independent interpretations of primary reactions are recommended according to the relevant tissue typing guidelines. Biotest HLA typing software should not be used as a tool to generate definitive results without verifying correctness but is designed to assist manual interpretation by qualified personnel.

Enclosure

Biotest License Agreement

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