EN

HISTO MATCH

CE IVD

Instructions for Use

Version: 18 / 2017

CHANGES TO THE LAST VERSION

Version	Date	Applies to	Description
14/2015	06/01/2015	HISTO MATCH V2.5	Improvements in the results display (differentiation CWD alleles) and in the reports, improvements in the inter-pretation algorithm
15/2015	01/07/2015	Not released	Implementation of the interpretation of the CWD high resolution kits (more than one well per test)
16/2015	10/10/2015	HISTO MATCH V2.6	Integration of the Xtend kits and the Null kits
17/2016	28/01/2016	HISTO MATCH V2.6.2	Filter for expired SSP kits, bug fixes
18/2017	12/01/2017	HISTO MATCH V2.6.5	Link / unlink Xtend tests, bug fixes

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1 INTRODUCTION

This document provides instructions for the installation and use of the HISTO MATCH Software. The HISTO MATCH Software is designed for the interpretation and data management of HLA typing results obtained with the HISTO SPOT® SSO system and HISTO TYPE SSP kits.

1.1 Limitations of the software

The HISTO MATCH software is designed to assist personnel experienced in HLA analysis by suggesting typing results. However, any clinical or diagnostic results must be carefully reviewed by a person qualified in HLA typing to assure correctness. This software may be used to aid in suggesting results, but should not be used as the sole method for determining reportable results. This software is meant as a laboratory aid, not as a source of definitive results.

2 PREREQUISITES

2.1 Hardware

The application will run on most modern personal computers, however, it is recommended that the computer has:

- minimum of 4 GB of RAM (8 GB recommended)
- A minimum video resolution of 1280 x 1024
- A 2Ghz Multi Core Processor
- Enough available hard drive space for the database (e.g. a 96 test worklist with results and images will occupy approximately 15 MB of space within the database)

2.2 Operating platform

The HISTO MATCH application is designed to run using the Microsoft .Net Framework 4.0, the Microsoft operating systems (both 32 and 64 bit, 64 bit systems are recommended) that support this framework are:

- Windows Vista
- Windows 7
- Windows 8 (requires SQL Server 2012 Express edition)
- Windows 10 (requires SQL Server 2012 Express edition)

The application requires a SQL server database to store data, results and images, Microsoft SQL Server 2008 Express edition is included with the installation, this is sufficient for a local installation or a network install of up to 10 client computers. For greater numbers of users or where data storage requirements are likely to exceed the 4 GB limit, a full version of SQL Server will be required.

The application can optionally use a local area network for communication with the MR.SPOT® Processor.

3 HISTO MATCH SOFTWARE STRUCTURE

3.1 Patients and samples

The HISTO MATCH application stores sample information, and optionally patient information associated with the sample.

3.2 Worklists for SSO

In order to perform an analysis a test must be created from the sample and added to a worklist. A worklist is a collection of tests to be processed together on the MR.SPOT®Processor. Each worklist can contain any combination of up to 96 tests from the HISTO SPOT®SSO range of products (with exception of combi strips).

3.3 SSP tests

To perform an SSP analysis a sample must be created and a test with the used lot has to be added. Double clicking on the test opens the interpretation screen. For detailed information refer to chapter 15 (Interpretation of HISTO TYPE SSP Tests).

3.4 Kits, lots and batches for SSO

A range of HISTO SPOT® SSO kits is stored within the database; each kit can have multiple lots:

- **Kit:** e.g. **HISTO SPOT® A**, defines the locus tested.
- **Lot:** e.g **A084**, **A085**, defines the layout and specificity of the probes that are contained in the kit. A single lot can contain many different batches.
- **Batch**: e.g. **A085-1, A085-2, A085-3**, defines how a probe reacts in comparison to control probes, and defines the manufacture and expiry date of the test strip. Single probes may be switched off in some batches within the same lot. This information can be found on the lot-specific CD supplied with the kits (Hit Tables – Excel file).

When creating a test for analysis only the kit name is required, batch information is supplied by barcode when the worklist is assembled on the processor.

3.5 Kits and lots for SSP

A range of HISTO TYPE SSP kits is stored within the database; each kit can have multiple lots:

- **Kit:** e.g. **HISTO TYPE A low**, defines the locus tested
- **Lot:** e.g. **145A1**, **146A2** defines a production lot with a specific set of primers

4. INSTALLATION AND DATABASE MANAGEMENT

4.1 HISTO MATCH installation

HISTO MATCH is provided on CD or as a download. To install the application insert the CD into your computer, the installer should start automatically. If the installer does not start, navigate to the CD drive, and run the setup.exe program to start the installer. There is no configuration required for the installation; all prerequisites (.NET Framework and SQL Server) will be installed automatically.

4.2 Database

HISTO MATCH uses SQL Server as a database server. SQL Server Express 2008 R2 is provided with the installation. With the 2008 R2 Express version database size is limited to 10GB.The server can be configured to run in “User Instance” mode, or in “Server” mode. The database can be located anywhere on your PC, but the folder should be accessible to all users, earlier versions of HISTO MATCH used the “C:\ExpediteDatabase” folder.

4.2.1 User Instance Mode

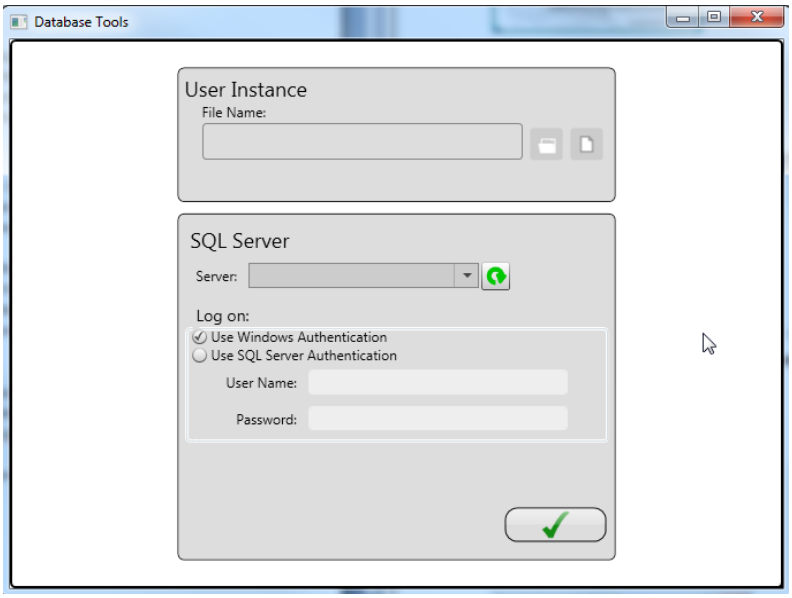
This mode allows the easy configuration and use of the database, and reduces the amount of resources required by the computer when HISTO MATCH is not running, but requires a little more time when HISTO MATCH is started to initialize. As the database files are not used when HISTO MATCH is not running, backup is simply a matter of copying the database files.

4.2.2 SQL SERVER Mode

This mode allows the database to be shared across a network, and as the program is running as a Server the database is available at all times, even if HISTO MATCH is not running. Use in this mode allows for faster database startup, but requires more resources.

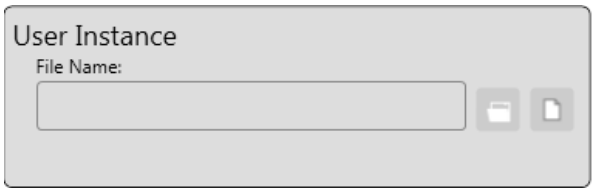
4.3 Initial database installation

When running HISTO MATCH for the first time, you will be presented with the “Database Tools” Window.



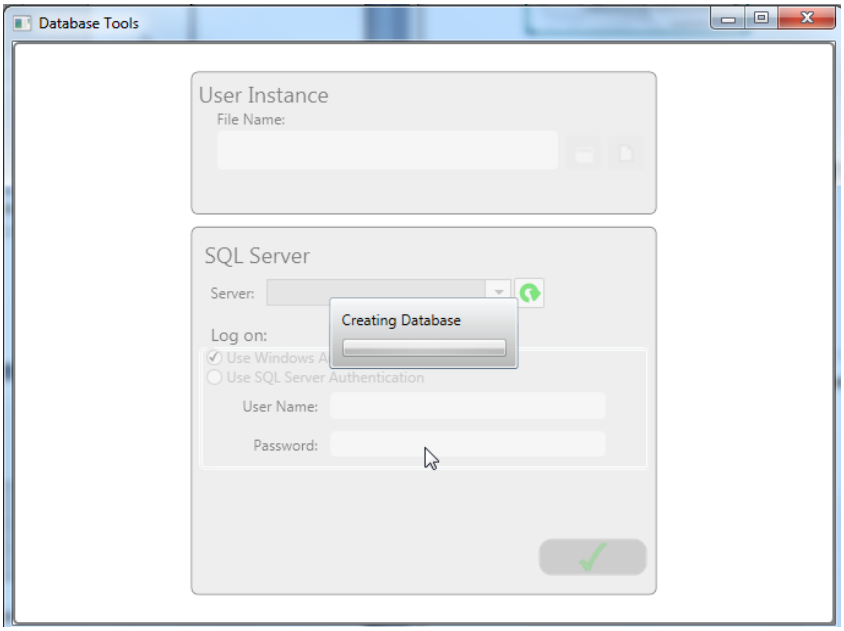
At this point you must decide if you wish to use “User Instance” or “SQL Server” modes, the default mode for Versions of HISTO MATCH before version 2, is “User Instance Mode”.

4.3.1 User Instance Mode



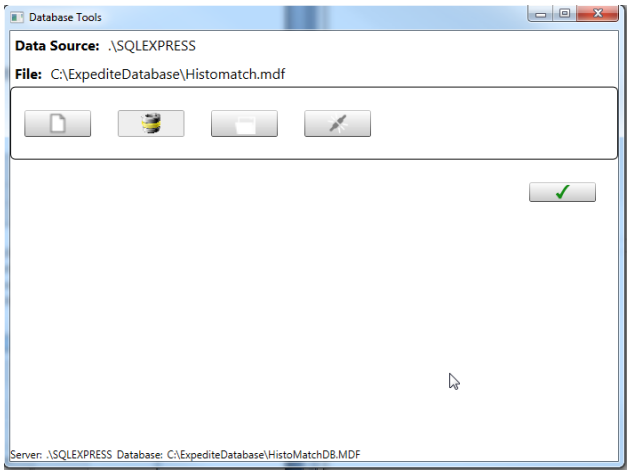
The two available options are,

- Open – to select an existing HISTO MATCH Database, choose this option if you have an existing database you want to use, select the file in the open file dialog.
- New - to create a new database. Choose a location and filename (do not use empty spaces in the file name) – do not choose an existing file to overwrite as this will fail. Ensure that all users have access to the folder you choose.



The Database will be created.

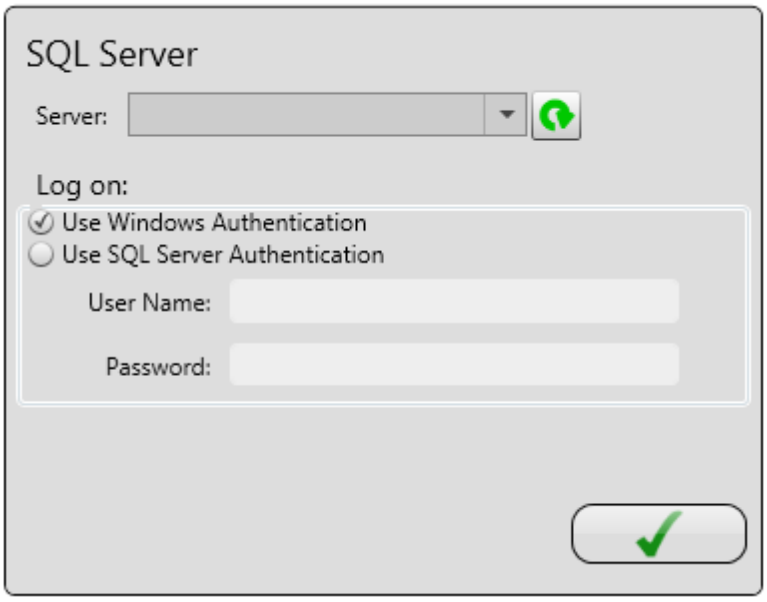
After Creating or Selecting a database file you will see the “User Instance” tools, click the “Green Check” to select the current database and return to HISTO MATCH.



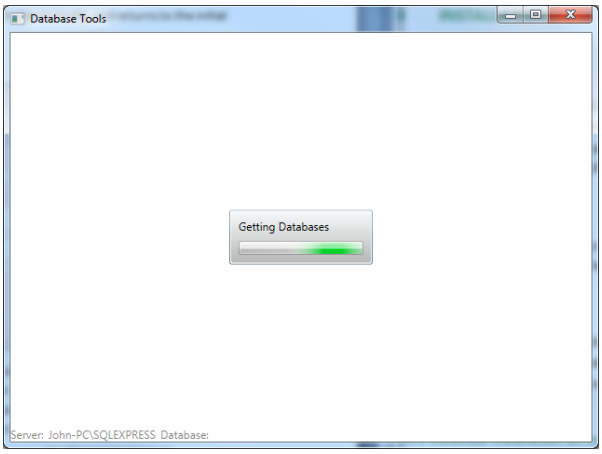
The available options are:

- **New** : Create a new database file.
- **Upgrade** : Upgrade a version 1.0 or 1.1 database to version 1.2 (HISTO MATCH 2.1 and higher).
- **Select** : Select an existing HISTO MATCH Database file.
- **Disconnect** : Disconnects from User Instance mode, and returns to the initial Database tool window.

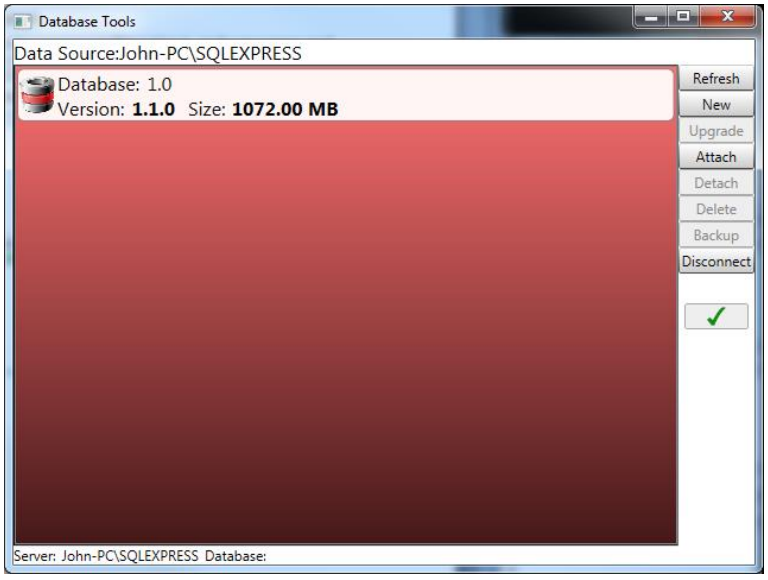
4.3.2 SQL Server Mode



Select a server from the drop down list, if the list is empty press the refresh button
To find available SQL Servers on the local network – this may take a few minutes to complete. You can also enter a server name manually if required.
Select the Authentication method, (depending on the server configuration), and user name and password if required. Select the connect button to attempt to connect.
If successful, the tool will attempt to find HISTO MATCH databases on the server.

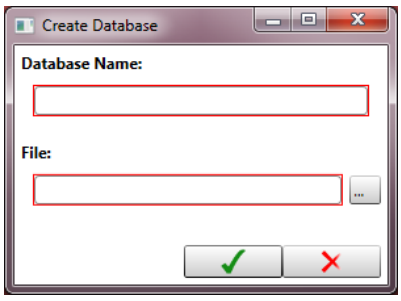


Any databases will be displayed in a list, and several options will be available.



- **Refresh** – refreshes the list of databases from the server
- **New** – create a new Database

  You will need to supply a unique database name, and enter a new file name, use the browse button to select the file, ensure the file is created in a location that all users have access to.



- **Upgrade** – this option is available if the selected database is a version 1.0 or 1.1 database, and can be upgraded to version 1.2 (HISTO MATCH 2.1 and higher)
- **Attach** – attach an existing database file to the server
- **Detach** – detaches the selected database from the server, the file can then be attached to a different server

- **Delete –** deletes the database from the server, and any associated files from the file system
- **Backup –** creates a backup of the selected database
- **Disconnect –** disconnects from the server, and returns you the initial Database Tools Window

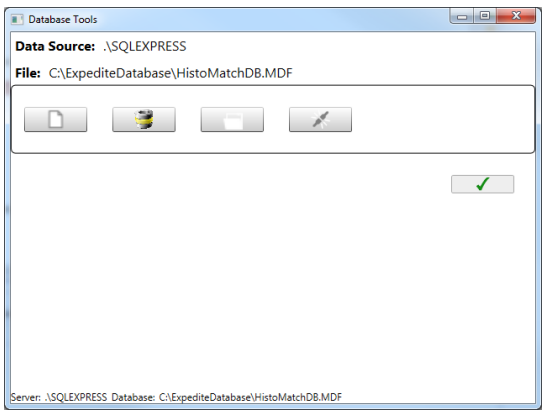
Selects the "selected" Database for use with HISTO MATCH and returns you to the HISTO MATCH program, this option is only available if you have a version 1.2 database selected in the list.

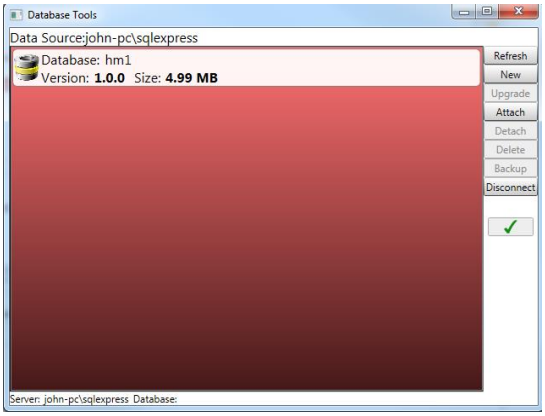
4.4 HISTO MATCH Upgrade

You should make a backup of your existing Database before performing this upgrade. Instructions for this can be found in the Instructions for Use, for the previous version.

Install HISTO MATCH from the supplied CD-ROM. It is recommended to uninstall the previous version. Any data you currently have will not be deleted. When running HISTO MATCH for the first time after an upgrade, you will be taken directly to the database Tools Window, the current database will be selected.

User Instance or Server mode



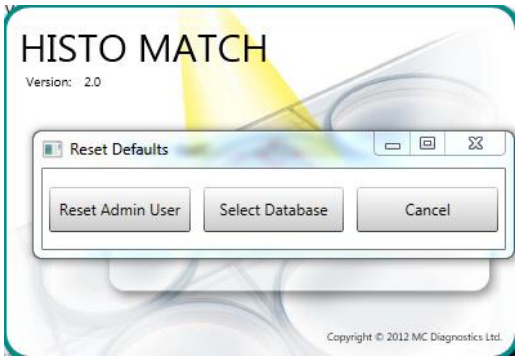


In either case you must upgrade the database before you can continue – this process will upgrade the database, and preserve your existing data. This is a one way process after it's complete it cannot be reversed.

4.5 Creating a New Database

If your database is becoming full, coming close to exceeding the 10GB limit, you can create a new blank database.

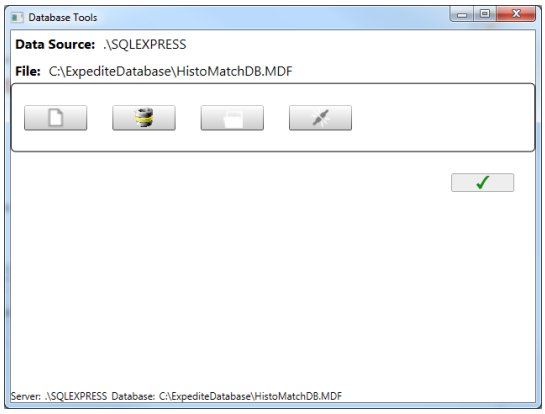
On starting HISTO MATCH press and hold down the "Ctrl" key before the HISTO MATCH splash screen is displayed, you will see the dialog box:



Choose the Select Database option.

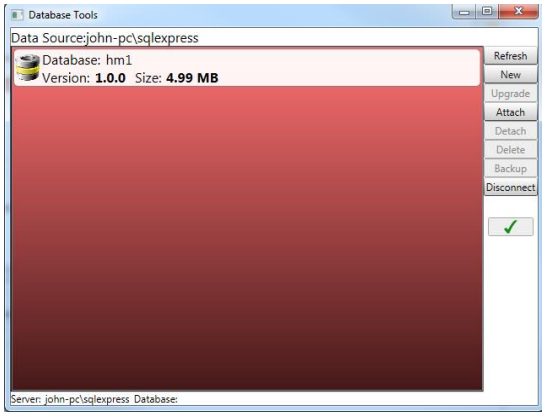
Depending on your configuration you will either see the User instance window or the SQL Server Window.

4.5.1 User Instance Mode

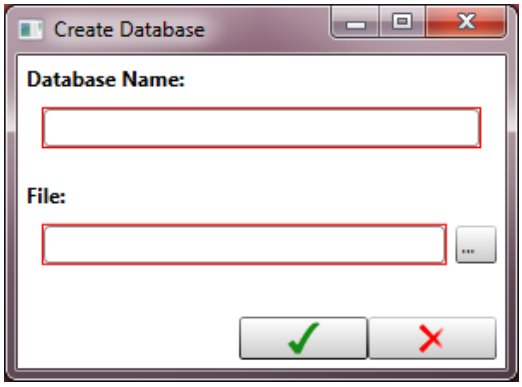


- Select New.
- In the Save file dialog box, select a new location and name (do not use empty spaces) for the database file.
- A new “empty” database will be created.
- Your existing Users, Kits, Installation Data, and Settings will be copied to the new database.
- Select to choose the new database and continue loading HISTO MATCH.

4.5.2 Server Mode



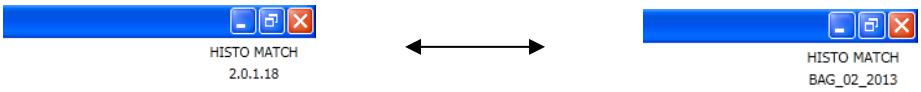
- Select New



- Enter a unique database name, the textbox will be outlined red if the database name is not unique or empty.
- In the file save dialog select a location and name for the new file.
- A new “empty” database will be created.
- Your existing Users, Kits, Installation Data, and Settings will be copied to the new database.
- Select to choose the new database and continue loading HISTO MATCH.

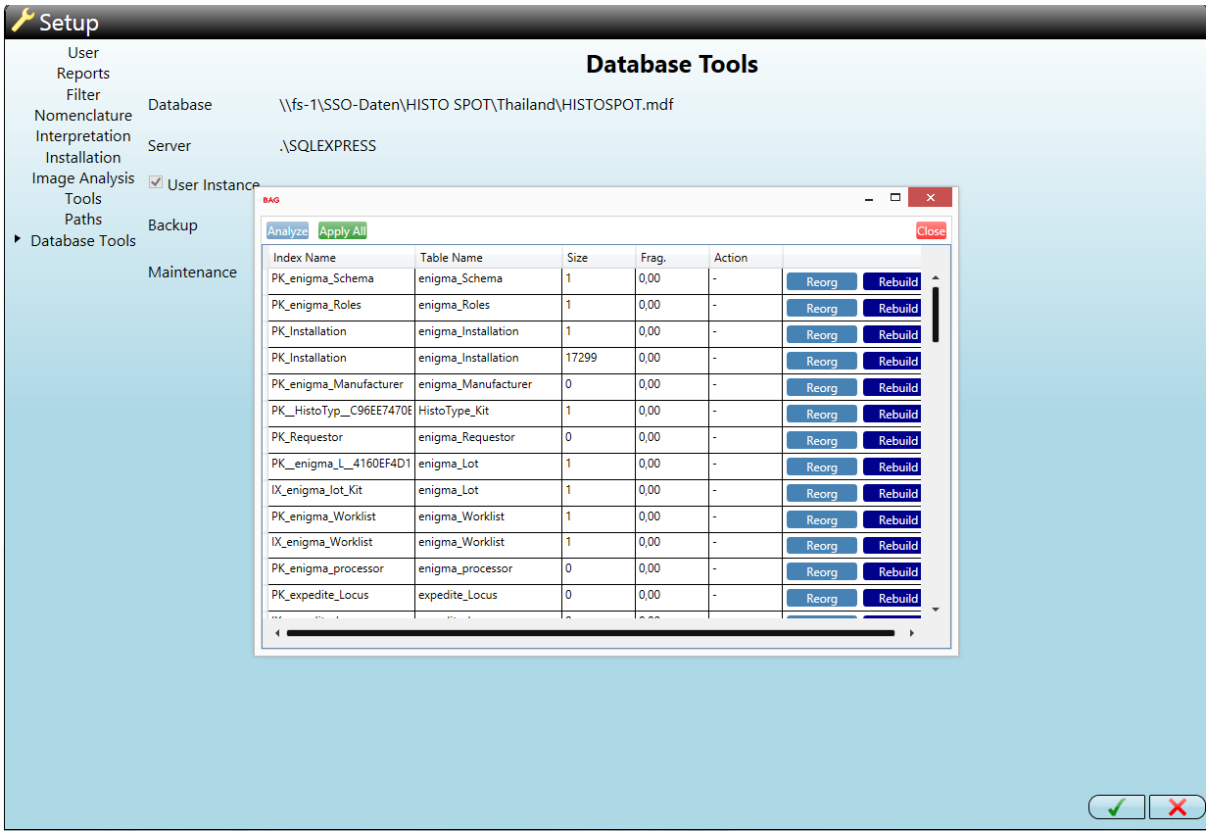
4.5.3 Displaying current database name

The name of the currently used database can be displayed in every screen by clicking on the HISTO MATCH version number in the upper right corner:



4.6 Database Maintenance Tools

While working with HISTO MATCH data is permanently saved, completed or changed in the database. The data is indexed and managed by the SQL database engine. The usage over time results into discrepancies between logical and physical order of data (fragmented index). Highly fragmented indexes may affect the performance of the database and the application (HISTO MATCH). The actions reorg or rebuild can help to improve the performance of the application.



Reorg: Recommended if index fragmentation is >5. The index is reorganized and data groups are sorted by its logical order (defragmentation)

Rebuild: Recommended if index fragmentation is >30. The index is deleted and rebuild. The data is sorted physically by its logical order. This requires exclusive access to the database. No other users are allowed to be logged in.

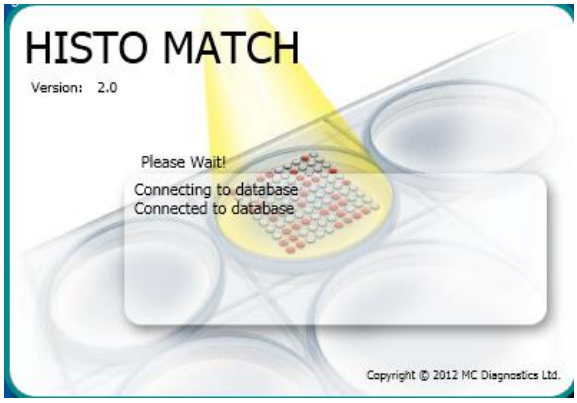
There are no recommendations depending on the size of the index. Nevertheless any action performed may only have measurable effect if the index size is >1000.

Analyze: Analyzes the database indices for fragmentation.

Apply All: Applies the recommended action for each index (the action column in the table).

5 STARTING THE HISTO MATCH SOFTWARE

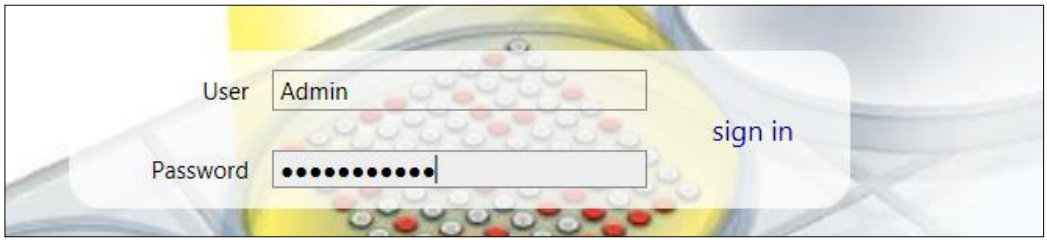
Installation of the application will place a shortcut on your computers desktop and a shortcut in the Windows Start menu. Double click either of the shortcuts to start the application. On start up, the application will attempt to connect to the local database; a splash screen will show the current progress.



6 INITIAL SOFTWARE SETUP

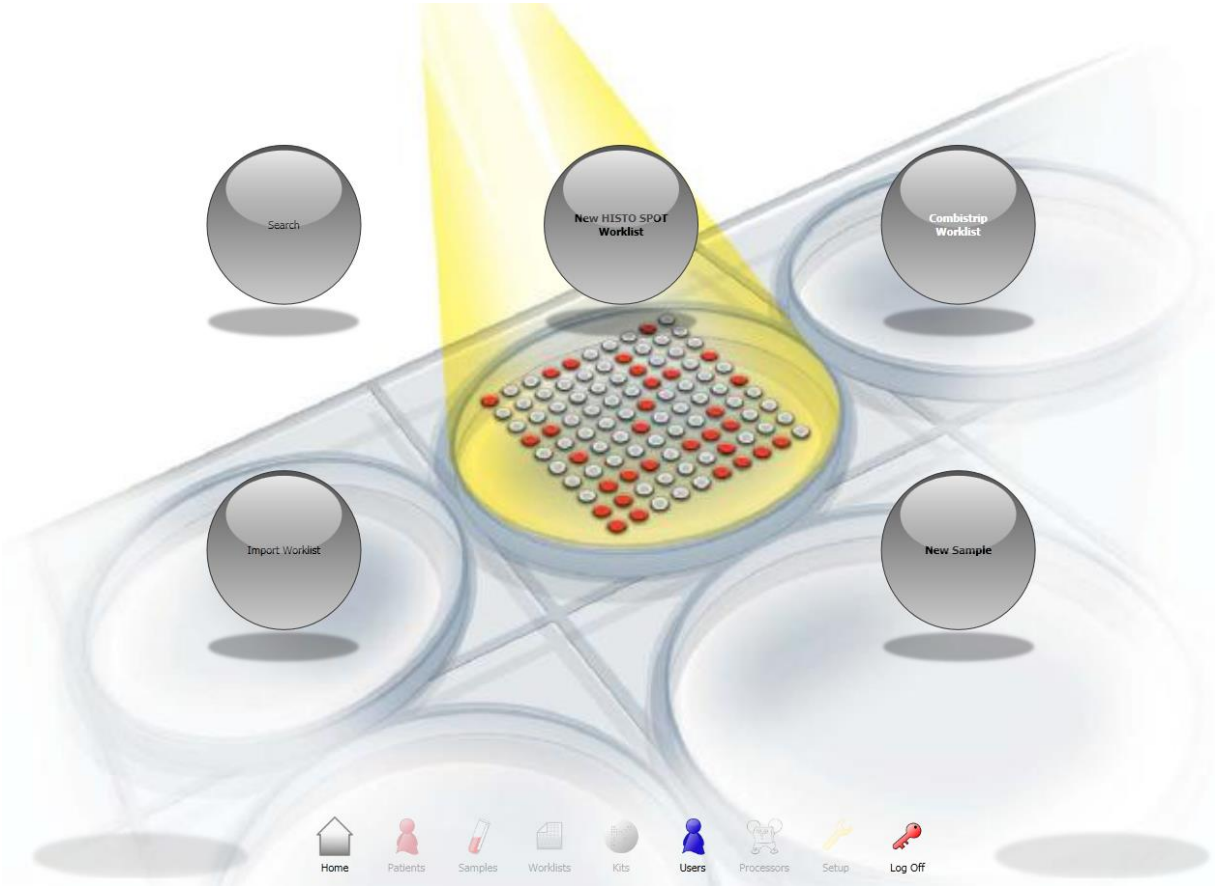
6.1 Login

The application is provided with a default administrator user, you will need to login with the username "**Admin**", and the password "**Password123**".



Press Enter or click "**sign in**".

The only function available to the Administrator user at this point is to edit the application "Users".



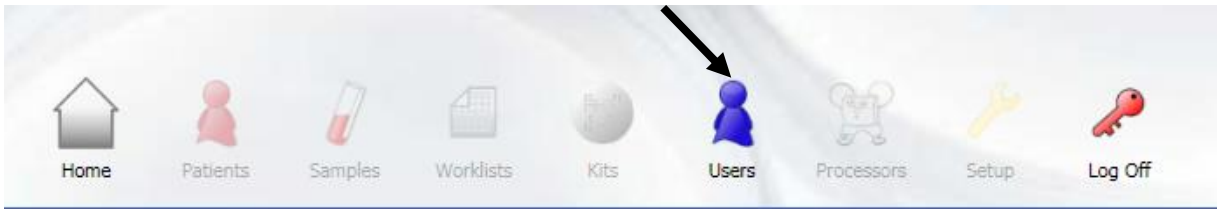
6.2 Add users and assign roles

The application defines 3 roles:

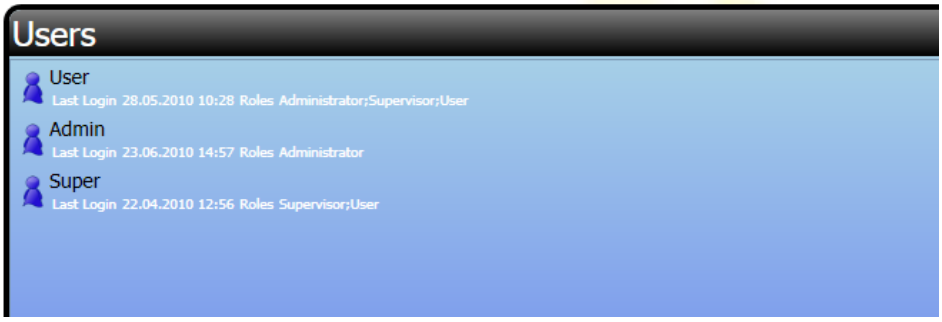
- **User:** Can perform most common tasks, adding samples and worklists, result analysis and allele assignment.
- **Supervisor:** Can authorize a result.
- **Administrator**: Can administer the software and users.

Each of the required roles should be assigned to the user, e.g. for a supervisor both the user role and supervisor role should be added.

1. Select the **Users** button.



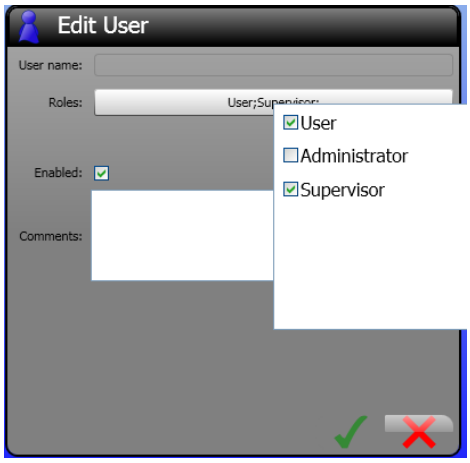
2. You will be shown a list of the current users.



3. Select the **Add** button.

4. Fill in the user details: **User Name** is the unique logon name for the user.

5. **Roles**: Select from the drop down list.

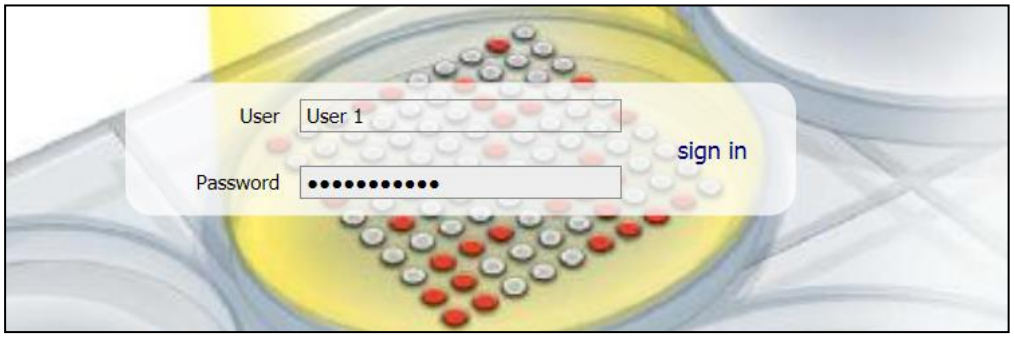


6. Select the **OK** button to save or **Cancel** to cancel adding the user.
7. The new user will be displayed in the user list.
8. Log off by selecting the **Log Off** button.

9. You can now logon using the new user, all new users have the password “Password123”.

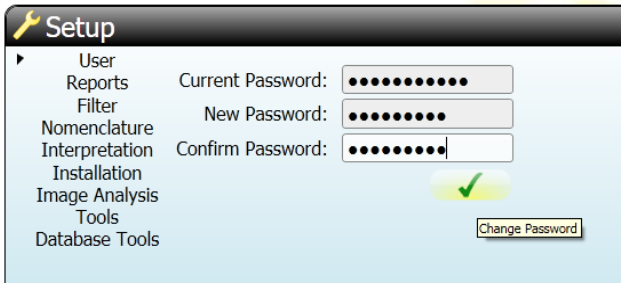
6.3 Changing the user password

1. Logon with your username and password.

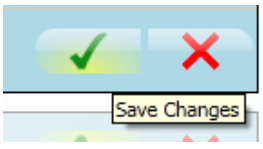


2. Choose **Setup**.

3. Enter your current password, new password, and confirm your new password.



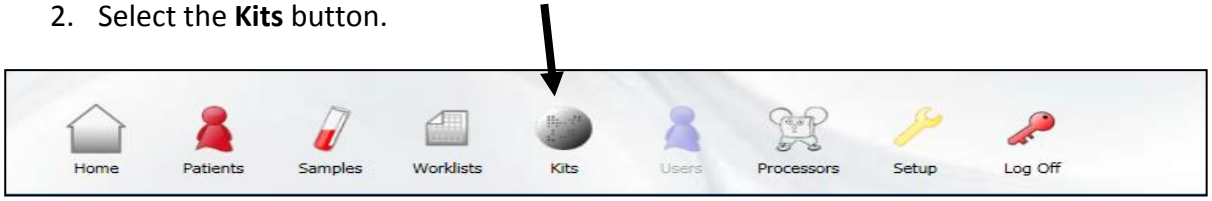
4. Select the **OK** button to change the password:
5. Choose **Save Changes** to return to the home screen.



6.4 Import, view and update kits

Kits and batches are distributed as XML files. A single file can contain many kits, lots and batches. The file contains the information that defines the probe layout and intensities required to interpret results.

1. Log in.
2. Select the **Kits** button.



There are no kits initially installed:

The following functions are available:

Import new batch.

Show **hit table** for selected batch.

Show **cut offs** for selected batch.

Generate older IMGT database hit table.

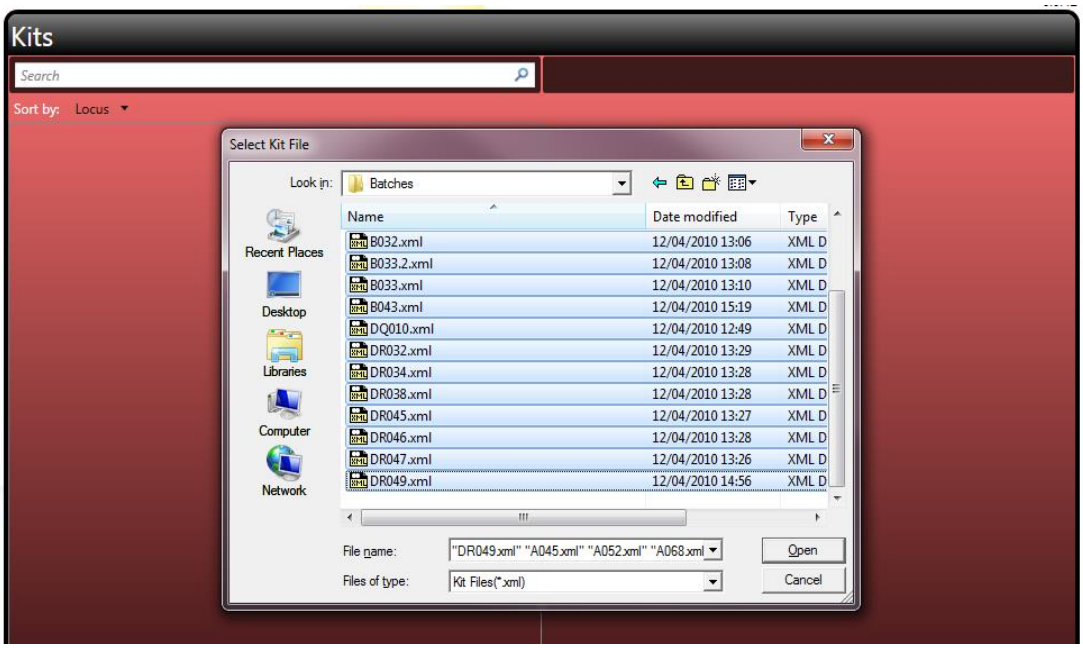
Show / hide expired batches.

Delete selected batch (only possible if batch is unused).

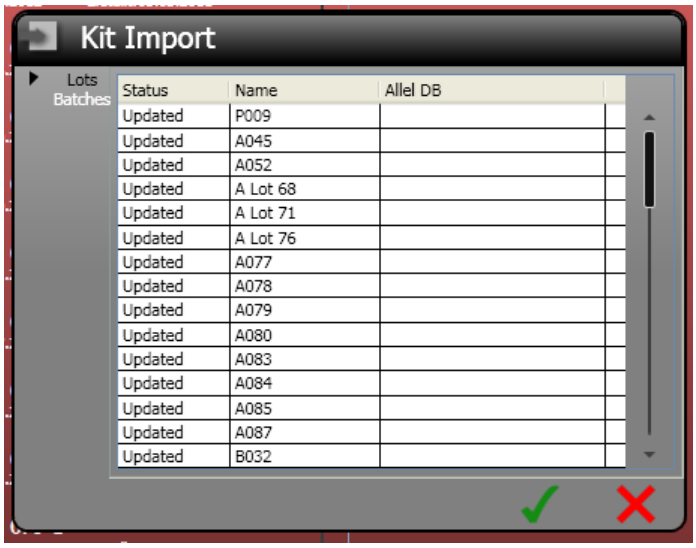
Update all batches to use latest allele database.

3. Choose the **Import** button.

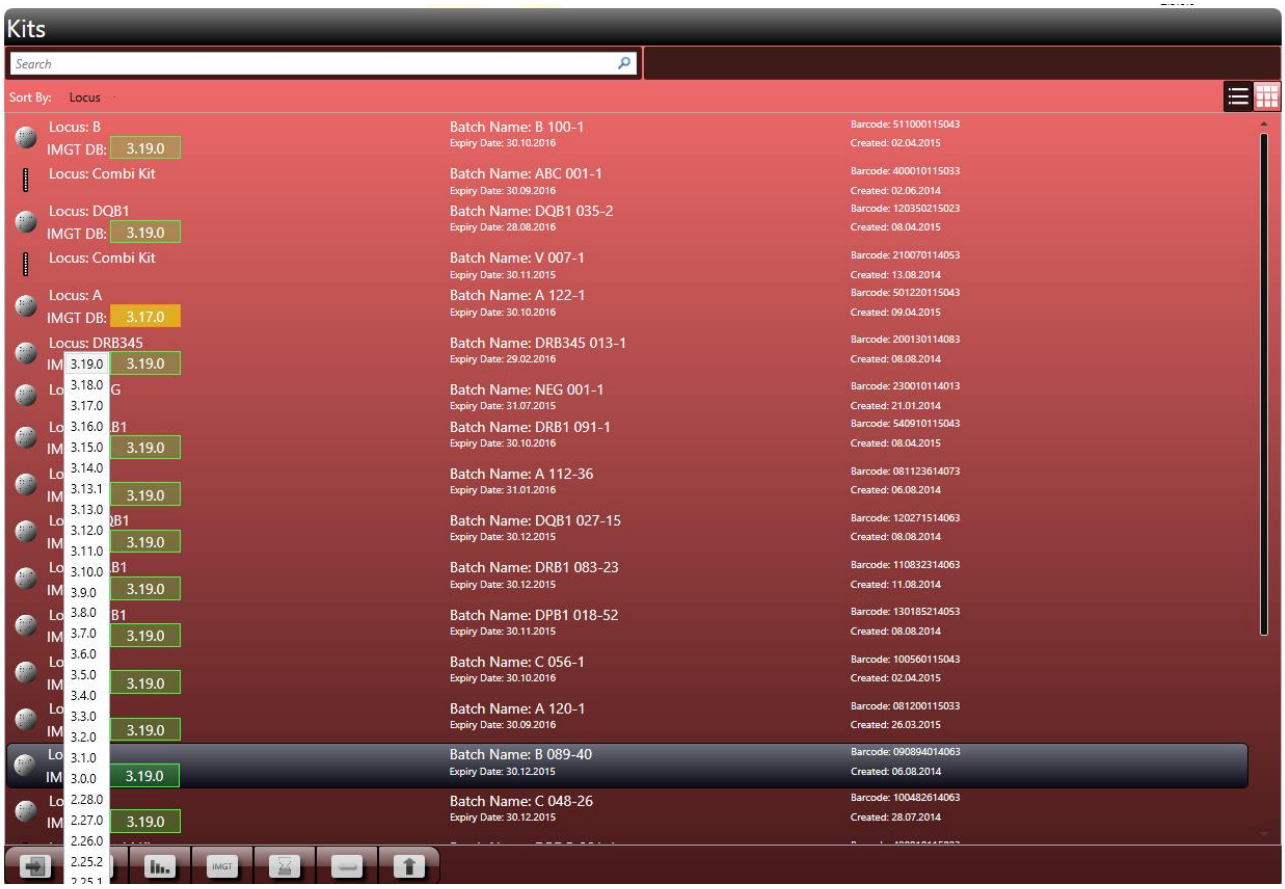
4. In the dialog box select one or many xml kit files to import, and choose **Open**.



5. The application will load the files, and show you the contents. This may take some time during which apparently nothing is happening. Please just wait until the batch files are displayed.



6. Choose **Save** to save the results to the database, or **Cancel** to cancel the import.
7. Once imported the kits are available to view in the kits screen. The database used for each batch is shown in green if the latest available update is used or in yellow if an older database is used. Clicking on the release number shows the list of older databases. It is possible to change the database by clicking on the release number. All batches that belong to one lot will be changed (e.g. B048-1 to B048-4).



SSO and SSP kits can be discriminated by the icon:

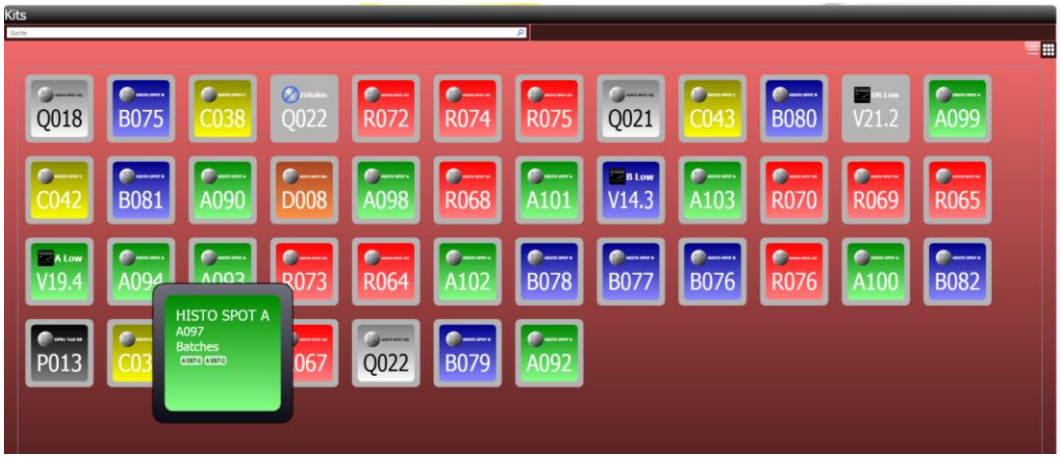
: HISTO SPOT® SSO kit

: Combistrips: HISTO SPOT® On-Call Typing kit, ABC CWD high res, ABDR CWD high res, DR/DQ CWD high res

: HISTO TYPE SSP kit

: HISTO SPOT® Coeliac Disease Kit

By clicking on the view icons in the upper right corner of the screen the view can be switched between the list view and the symbol view. In this view all available lots are shown. Clicking on the symbol shows all available batches for the respective lot.



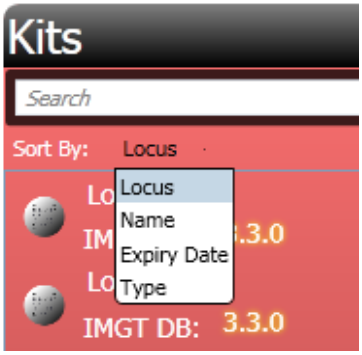
6.5 Finding batches

You can search for batches using the search toolbar.

Enter the search criteria into the search bar and press enter or click the button. Batches will be searched by name, batch/lot or locus. Batches that match the criteria will be displayed in the list below.

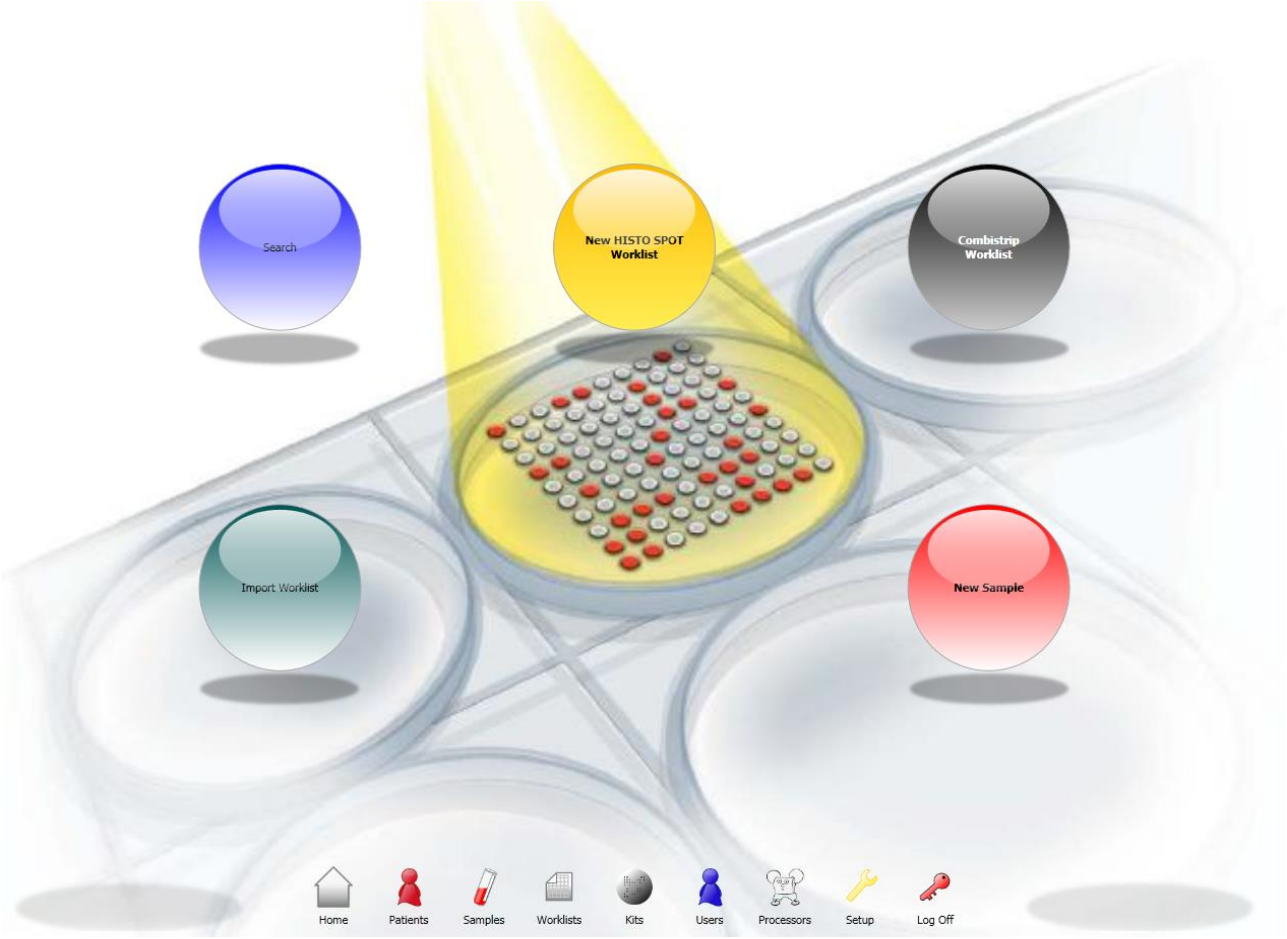
6.6 Sorting batches

You can sort the list of batches by clicking the **Sort by** field in the list.



You can reverse the sort direction by clicking the same field again.

7 THE HOME SCREEN



The home screen is the starting point in the software. It is accessible at most times by selecting the home button on the main menu.

The main functions of the home screen are

- **Search**: Provides access to the global search screen.
- **New HISTO SPOT Worklist**: Creates a new worklist.
- **Combistrip Worklist**: Creates a new worklist for a combi strip (HISTO SPOT® On-Call Typing kit, ABC CWD high res, ABDR CWD high res, DR/DQ CWD high res).
- **Import Worklist**: Imports an initial csv worklist or a processed worklist from MR.SPOT®.
- **New Sample**: Creates a new sample.

7.1 The main menu

The main menu is accessible from most screens within the software. The availability of the items depends upon the role of the current user. The menu provides access to the following functions.

Home: Returns the user to the home screen.

Patients: Takes the user to the browse patients screen.

Samples: Takes the user to the browse samples screen.

Worklists: Takes the user to the browse worklists screen.

Kits: Takes the user to the browse kits screen.

Users: Takes the user to the browse users screen.

Processors: Takes the user to the MR.SPOT® view.

Setup: Access to setup options.

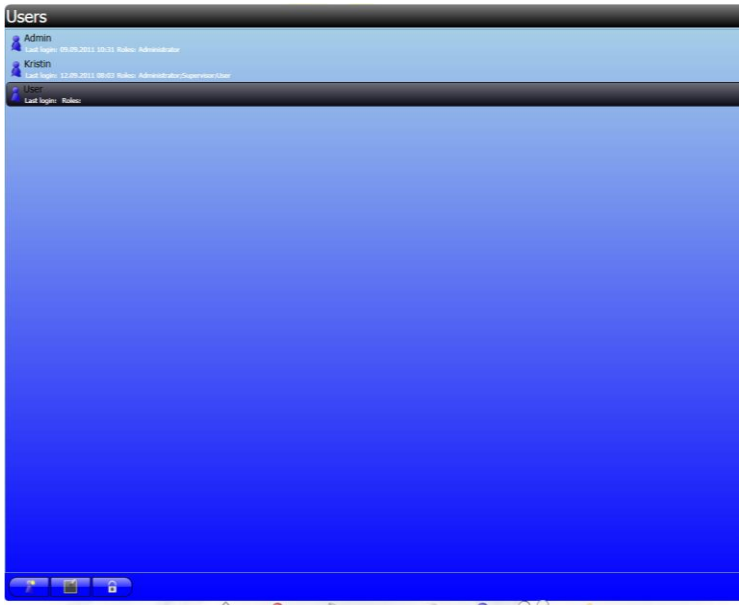
Log Off: Logs out the current user.

8 USER MANAGEMENT

The system requires users to be registered with a unique username and password. Users must also be assigned to one of the 3 roles defined by the system.

8.1 The browse users screen

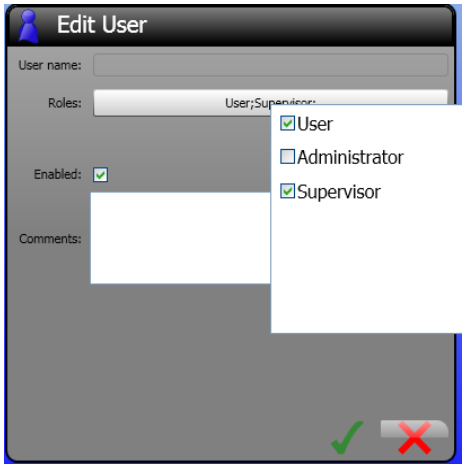
On showing this screen all users will be visible.



8.2 Adding a new user

1. Choose **Add**.

2. Fill in the **Edit User** dialog.



User Name: Unique Logon name for the user.

Roles: Select from user, supervisor, administrator.

Enabled: If cleared the user will not be able to logon.

Comments: Add comments about the user.

3. Select the **OK** or **Cancel** button.
4. The new user will be listed in the browse user screen.

8.3 Editing a user

An existing user can be edited. Editing is limited to changing user roles, enabling or disabling the user, or adding comments. To edit a user:

1. Select the user from the list, and choose **Edit**.

2. The user name is read only and cannot be changed, the other options can be edited.
3. Choose **OK** to save, or **Cancel** to abandon changes.

Note: The administrator user cannot be edited!

8.4 Reset a user password

If a user has forgotten their password, it can be reset by another user who belongs to the administrator role.

1. Select the user from the list.
2. Select the **Reset** button.

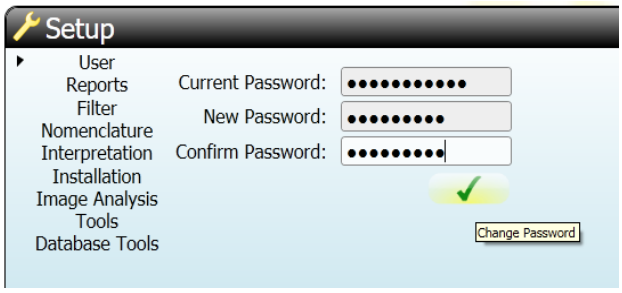
3. The user password will be reset to the default “Password123”.
4. The user should change the password at the next logon.

8.5 Deleting a user

It is **not** possible to delete a user, users should be disabled, using the edit user function, and not deleted.

8.6 Changing user password

The current user can change their password by choosing the **Setup** button from the main menu, the first page of the setup options allows the user to change their password.

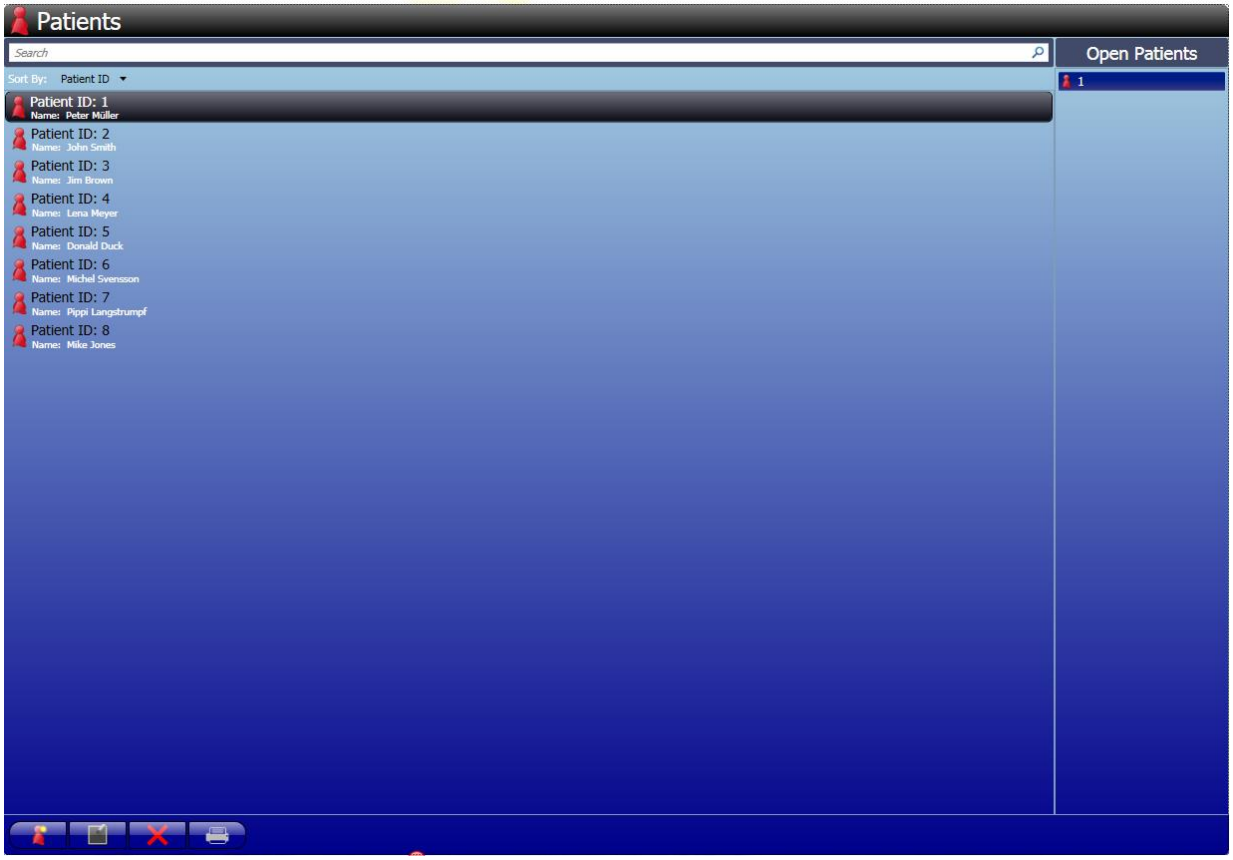


User passwords are case sensitive, i.e. “Password” is not the same as “password”, the **New Password** and **Confirm Password** text fields must match, to prevent errors during the password change. The user must press the **OK** button to change password.

9 PATIENT MANAGEMENT

Patients are optional on the HISTO MATCH system, it is not necessary to use patients to group samples or tests for analysis, but grouping in this way may be useful. Selecting the **Patients** button from the main menu will show the patients screen.

When this screen loads, all patients in the system will be displayed.



Create new patient.

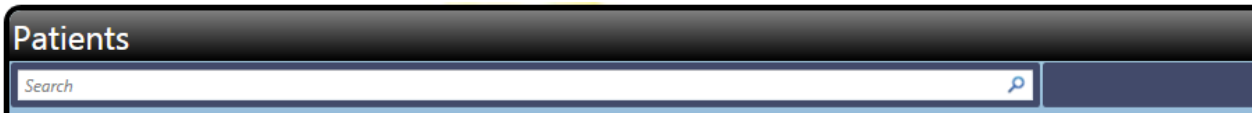
Edit selected patient.

Delete selected patient.

Create report for selected patient.

9.1 Finding patients

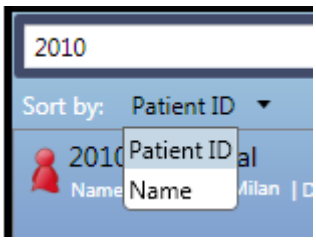
You can search for patients using the search toolbar:



Enter the search criteria into the search bar and press enter or click the button. Patients will be searched by name or ID, patients that match the criteria will be displayed in the list below.

9.2 Sorting

You can sort the list of patients by clicking the **Sort by** field in the list.



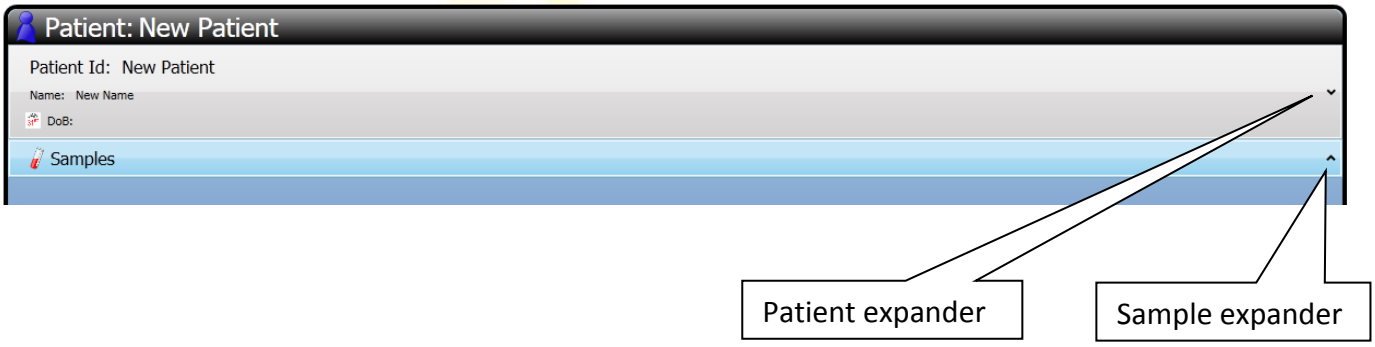
You can reverse the sort direction by clicking the same field again.

9.3 Adding a new patient

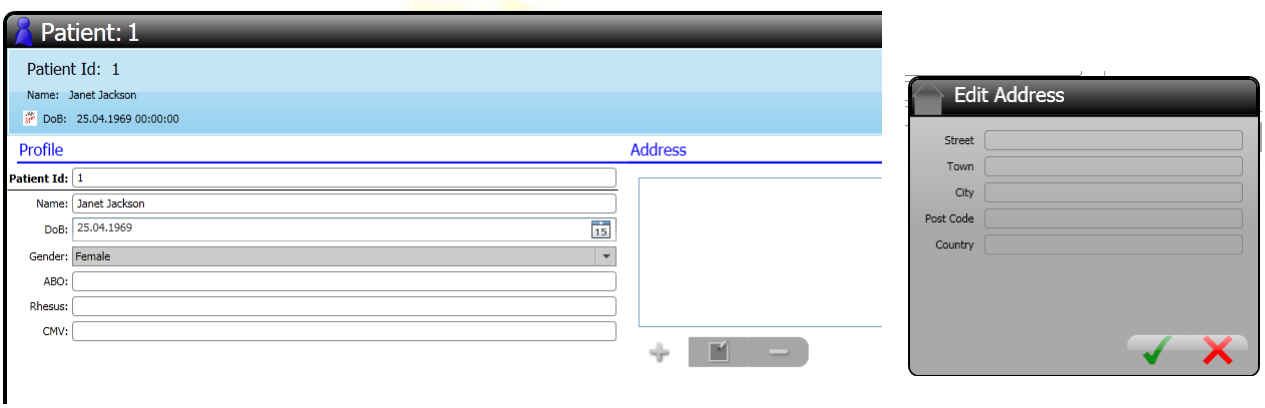
Patients can be imported from a text file along with sample information, see the sample management section for details. The method described here allows adding of a single patient, with multiple samples and tests.

1. Select the **Add** button.

2. The edit patient screen is displayed.



3. Select the patient expander to display the patient information (Clicking the control expands it to edit the fields. Clicking again will collapse it).

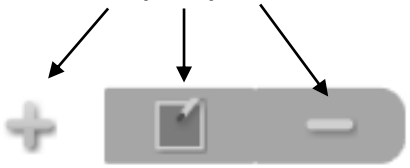


Patient ID: This is a **unique** Patient ID – **Required**.

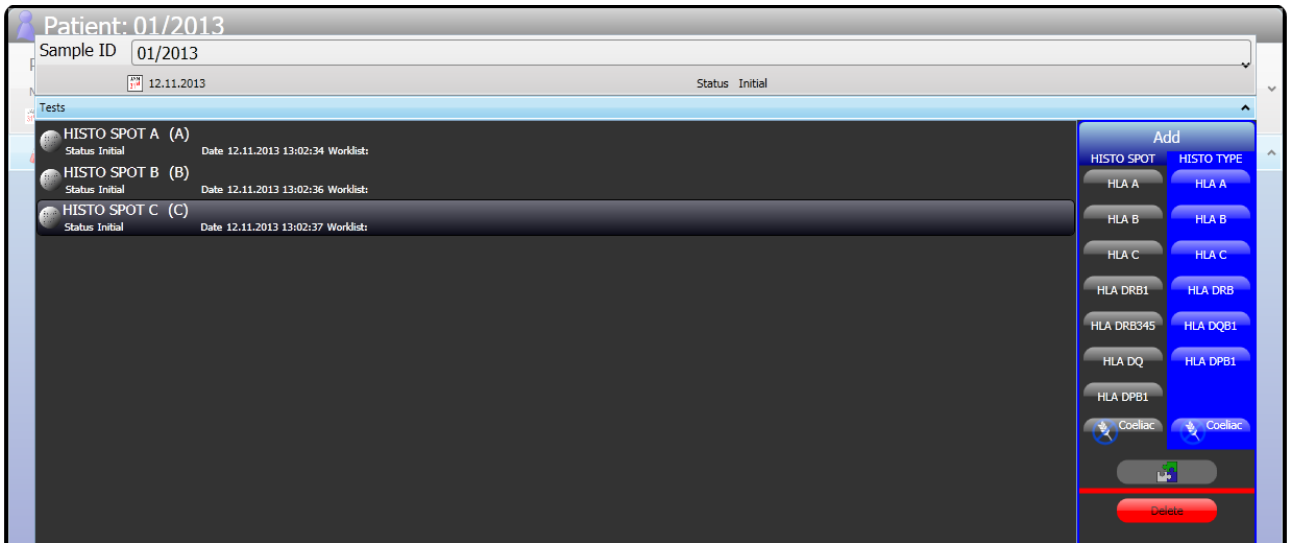
Name: The patient's name, (e.g. John Smith).

Date of Birth: Type a date into the field or choose the calendar to pick a date.

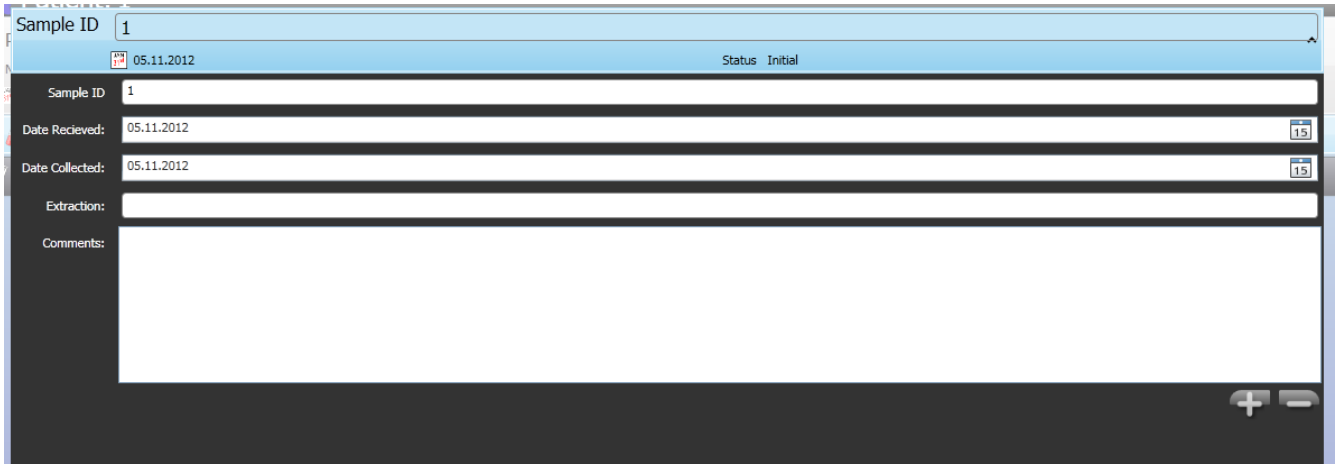
Address: Use the **Add/Edit/Delete** buttons to add an address to the patient.



4. Select the sample expander to add a sample. (Clicking the control expands it to edit the fields. Clicking again will collapse it.)
5. Choose **Add** to add a new sample.
   A sample window opens with a sample ID created identically to the patient ID (editable). In this window you can add HISTO SPOT or HISTO TYPE tests. You can add as many tests as you like. You can also delete a test by selecting the test and selecting the **Delete** button.
   When complete, click the **Save** button.

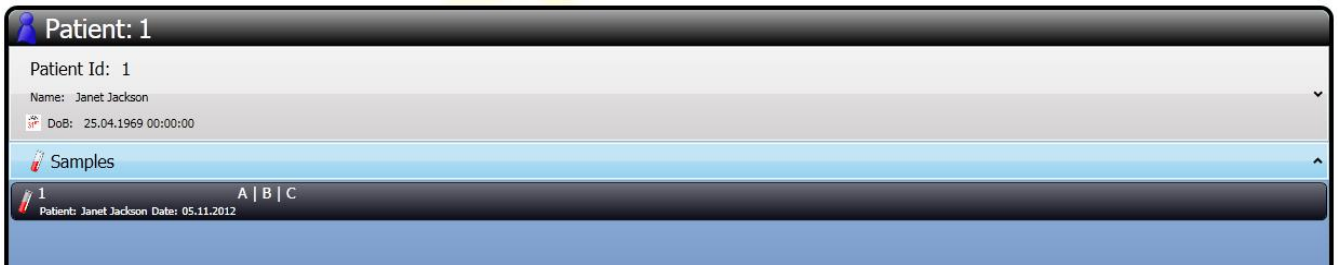


6. Select the sample expander to enter sample information.



Sample ID: Required unique ID for the sample.
Date received: Set to the current date, can be edited.
Extraction: Space to enter the DNA extraction method.
Comments: Use the **Add** Button to add comments.

7. The new sample will be listed in the sample list for the patient.



Along with the tests that were selected, you can modify the sample by clicking the **Edit** button or by double clicking the sample in the list.

8. Click **Save** to save patient and sample information to the database, or click **Close** to cancel changes.

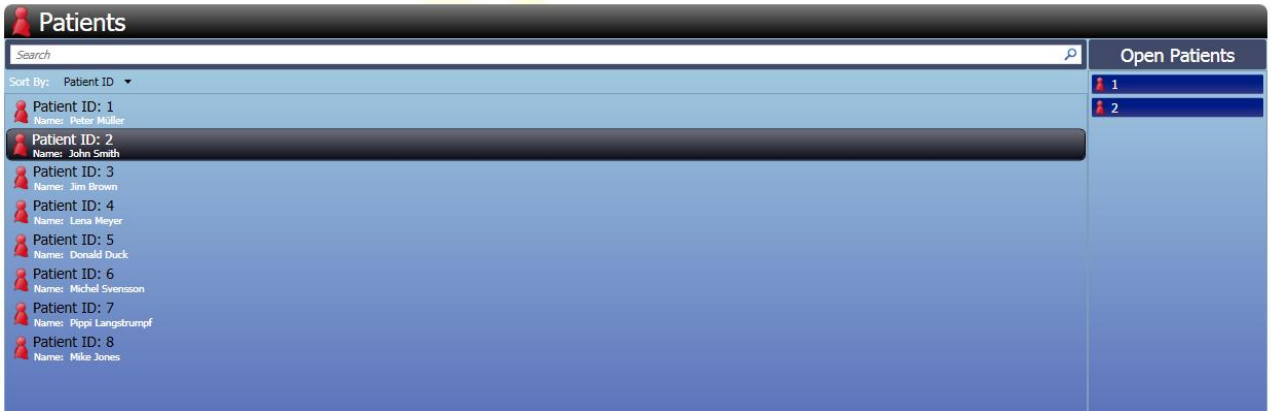
9.4 Editing an existing patient

To edit a patient that exists in the database:

1. Find the patient to edit using the search and sort functions.
2. Select the **Edit** button or double click the patient in the list.
3. The edit patient screen is displayed.
4. All fields are editable. Samples and tests can be added in the same way as for new patients.

When a patient is being added or edited, it is possible to navigate to other parts of the software, using the main menu at the bottom of the screen. This allows editing of multiple patients or

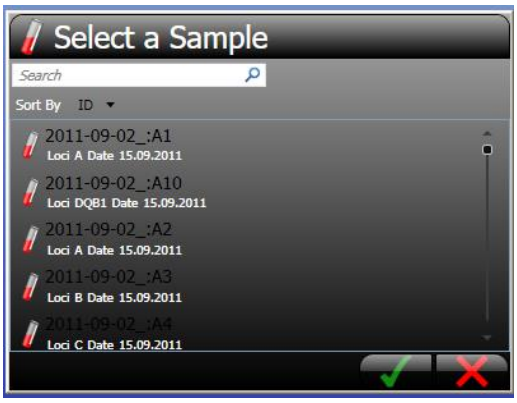
patients and other items simultaneously. Patients that are currently being edited will be displayed in the **Open Patient** list in the browse patient screen. To return to the patient being edited, double click the patient in the list.



9.5 Assigning existing samples

When you add or edit a patient you can assign existing samples from the database.

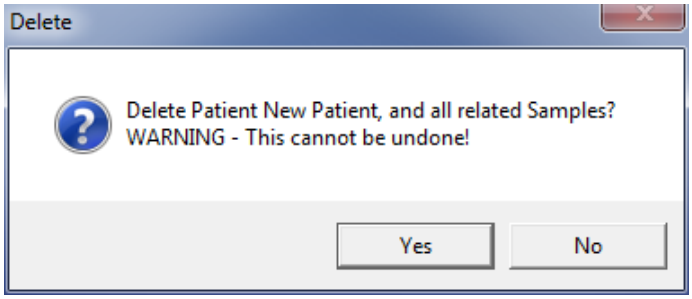
1. Select the patient you want to edit, choose **Edit** or double click the patient:
2. Click the **Select** button:



3. Select the sample from the list (only samples without patients are shown).
4. Choose **OK** .
5. The selected sample is added to the patient's samples.

9.6 Deleting patients

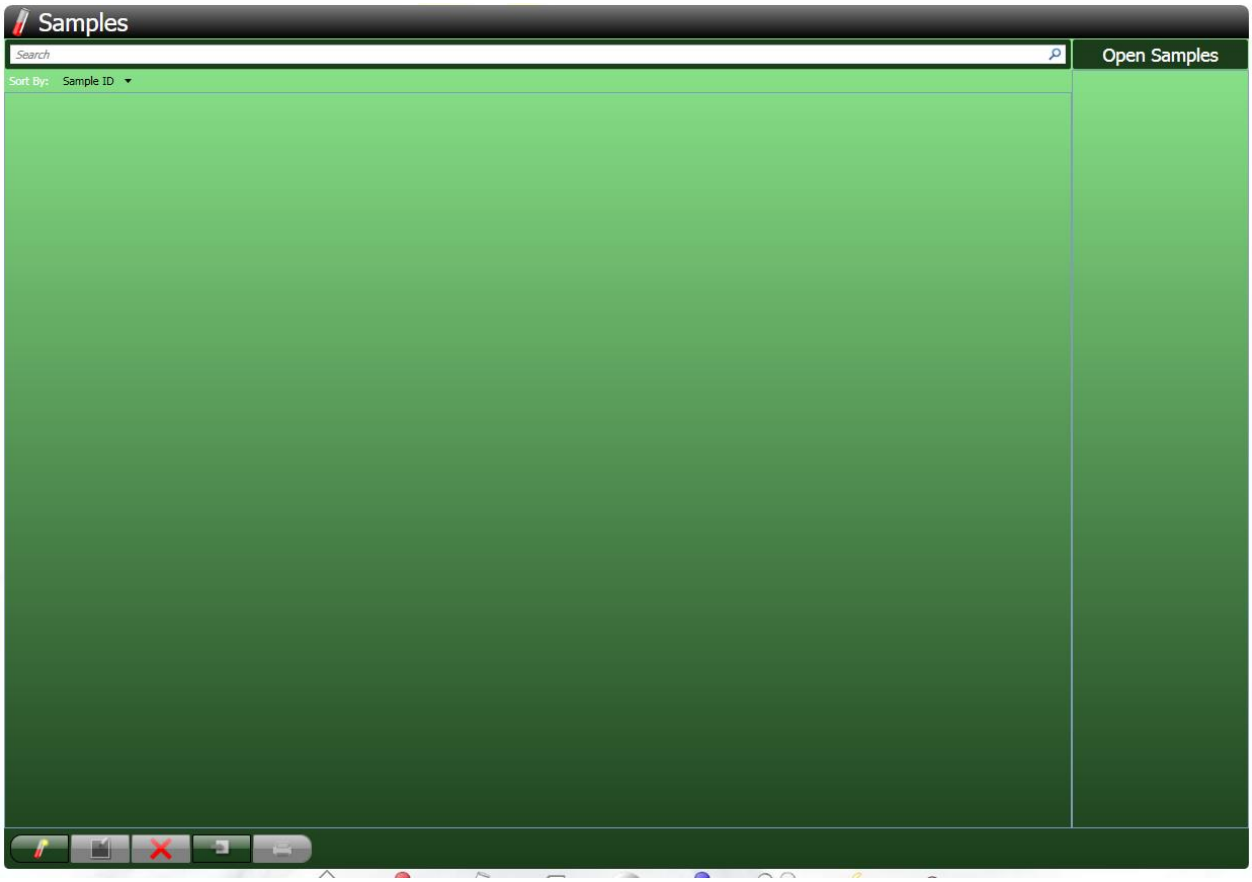
You can delete a patient from the system by selecting the patient from the browse patient screen and clicking the **Delete** button:



Click **Yes** to confirm that you want to delete the patient. All associated samples and tests will be deleted. **Deletion of the patient will fail if any tests are on a worklist**. Only members of the supervisor role can delete patients.

10 SAMPLE MANAGEMENT

HISTO MATCH uses samples to represent physical samples. Like physical samples many different tests can be performed on a single sample. Unlike physical samples these do not need to belong to patients. Selecting the **Samples** button from the main menu will display the browse samples screen. By default this screen will be empty when it is first opened.



Create a new sample (**Add**).

Edit selected sample (**Edit**).

Delete selected sampel (**Delete**).

Import samples from file (**Import**).

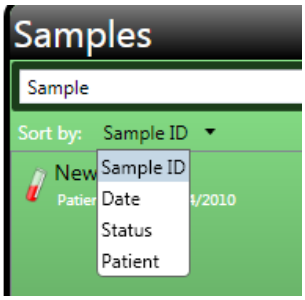
Create a report for selected sample (**Report**).

10.1 Finding samples

You can use the **Search** toolbar to locate samples:

Enter the search criteria into the search bar and press enter or click the button. Samples will be searched by Sample ID or by Patient name. Samples that match the criteria will be displayed in the list below.

10.2 Sorting

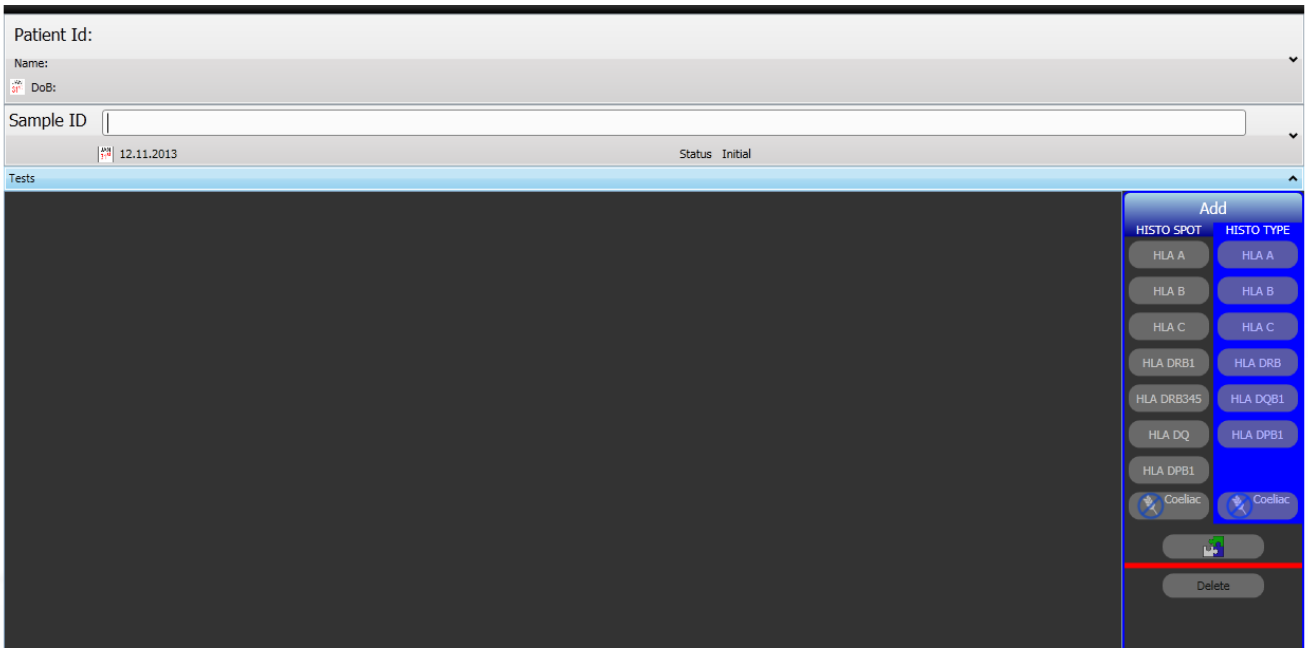


You can sort the list of samples by clicking the **Sort by** field in the list. You can reverse the sort by clicking the same field again.

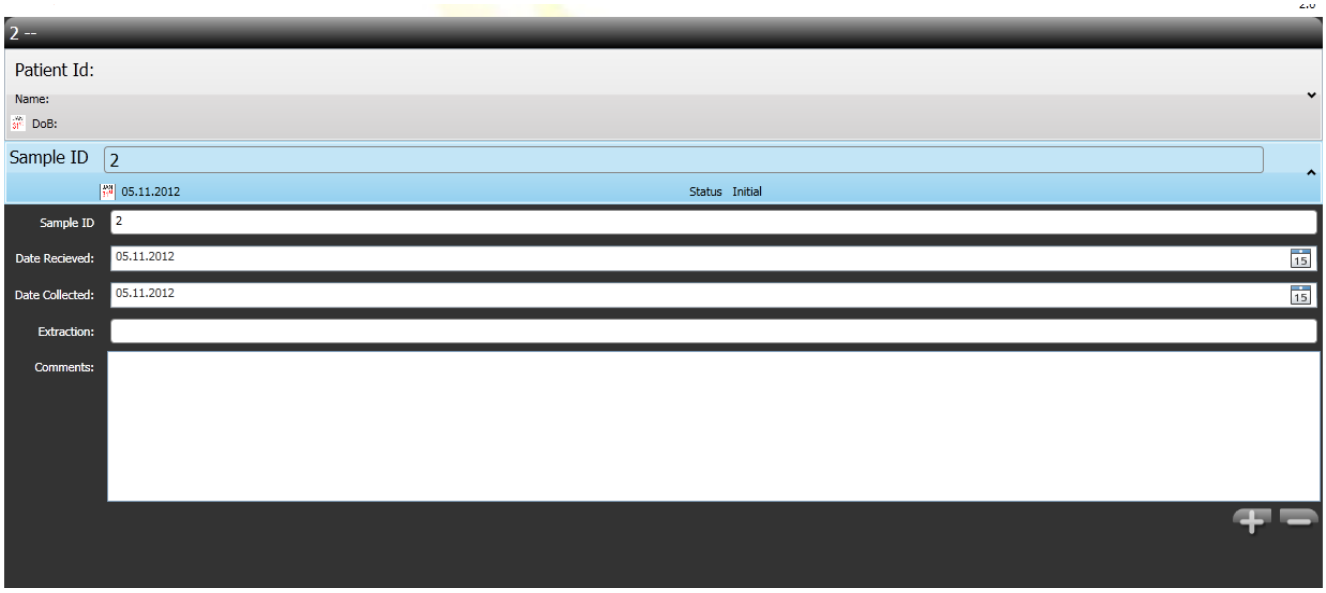
10.3 Adding a new sample

Samples can be imported from a text file (see below) or added individually as described here.

1. Select the **Add** button from the browse sample. You have to enter a sample ID before you add tests.



2. Select the sample expander to edit the sample information.



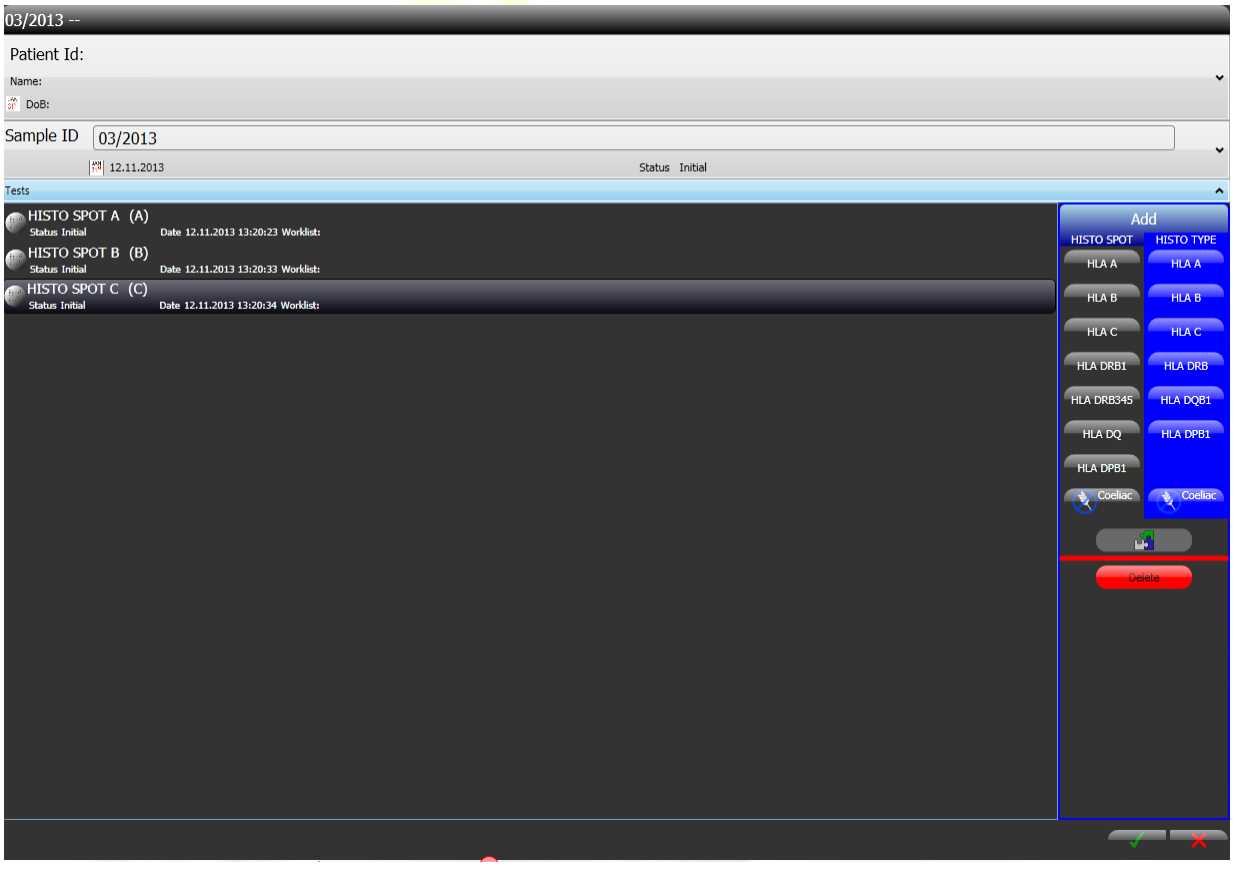
Sample ID: This is the unique Sample ID. You cannot click **Save** without an ID.

Date Received: Set to the current date, can be edited.

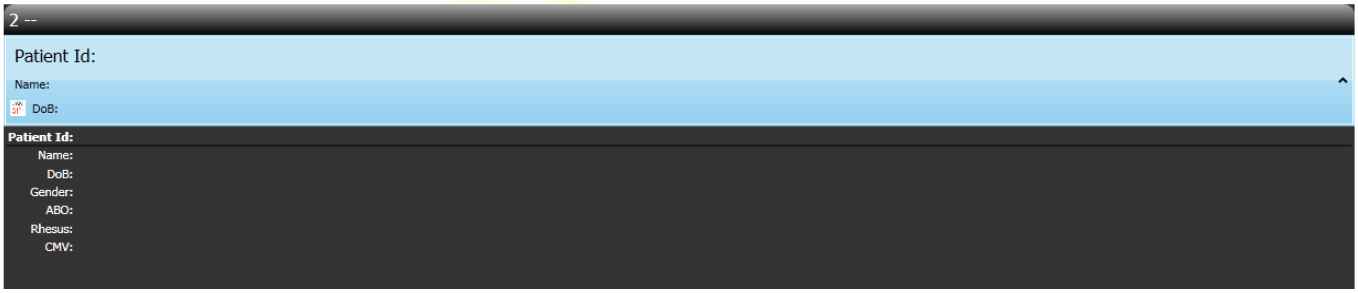
Extraction: Space to enter the DNA extraction method.

Comments: Use the **Add** button to add new comments.

3. Open the tests expander and add the tests for the sample.



4. You can view additional patient information by using the patient expander. Patient information can be entered using the patients screen.

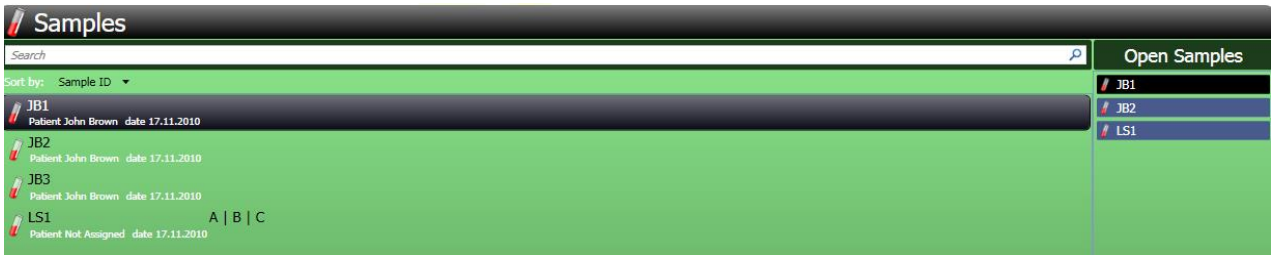


5. Choose **Save** to save changes or **Close** to abort.

10.4 Editing an existing sample

1. Locate the sample you want to edit using the search and sort functions in the browse samples screen.
2. Click the **Edit** button or double click the sample in the list.
3. The edit sample screen is displayed, all fields are editable.
4. The **sample ID** can be edited by a supervisor, but cannot be blank.
5. If a duplicate sample ID is found you will receive an error message.

When a sample is being added or edited, it is possible to navigate to other parts of the software, using the main menu at the bottom of the screen. This allows editing of multiple samples, or samples and other items simultaneously. Samples that are currently being edited will be displayed in the **Open Samples** list in the browse sample screen. To return to the sample being edited, double click the sample in the list.



10.5 Importing samples

To provide a quick method of adding patients, samples and tests you can import data from a text file.

10.5.1 Import file format

The text file should contain a list of records each record should be in one of two formats:

1) PatientID FirstName LastName DoB SampleID Locus
2) SampleID Locus

Each field should be separated by either a tab or a comma.

PatientID: This is the unique ID of the patient.

FirstName & LastName: The patient name.

DoB: The Patient's Date of Birth (must match to your local date format).

SampleID: The unique ID of the Sample.

Locus: The HLA locus to add a test. (e.g. A, HLA A, HLA-A accordingly B, C, DRB1, DRB345, DQB1, DPB1, COE for coeliac disease, Ax, Bx, Cx for Xtend kits, NULL for the Null Kit and NEG for the negative control).

The Patient ID should be unique, if an existing ID is found in the database then the name and DoB fields are compared, if they are identical the new record will be added to the patient, otherwise an error will be generated. The Sample ID should be unique, if an existing ID is found in the database the new test will be added to the existing sample in the database.

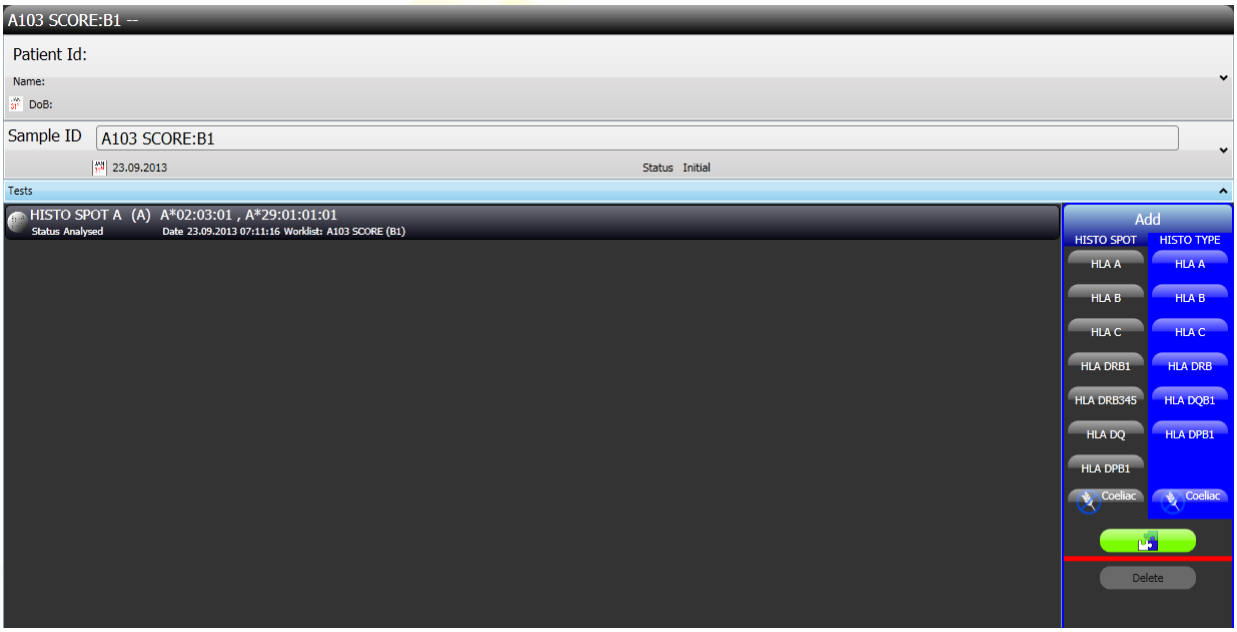
10.5.2 Importing the text file

1. On the browse sample screen choose **Import.**
2. Select the text file to import.
3. The imported samples will be displayed in the list.

The text file can also be imported directly from the "Create Worklist" screen (see chapter 11.4 Creating a new worklist). It is also possible to import worklists with defined positions for the samples and tests (see chapter 11.5 Importing an initial worklist).

10.6 Link from sample to results

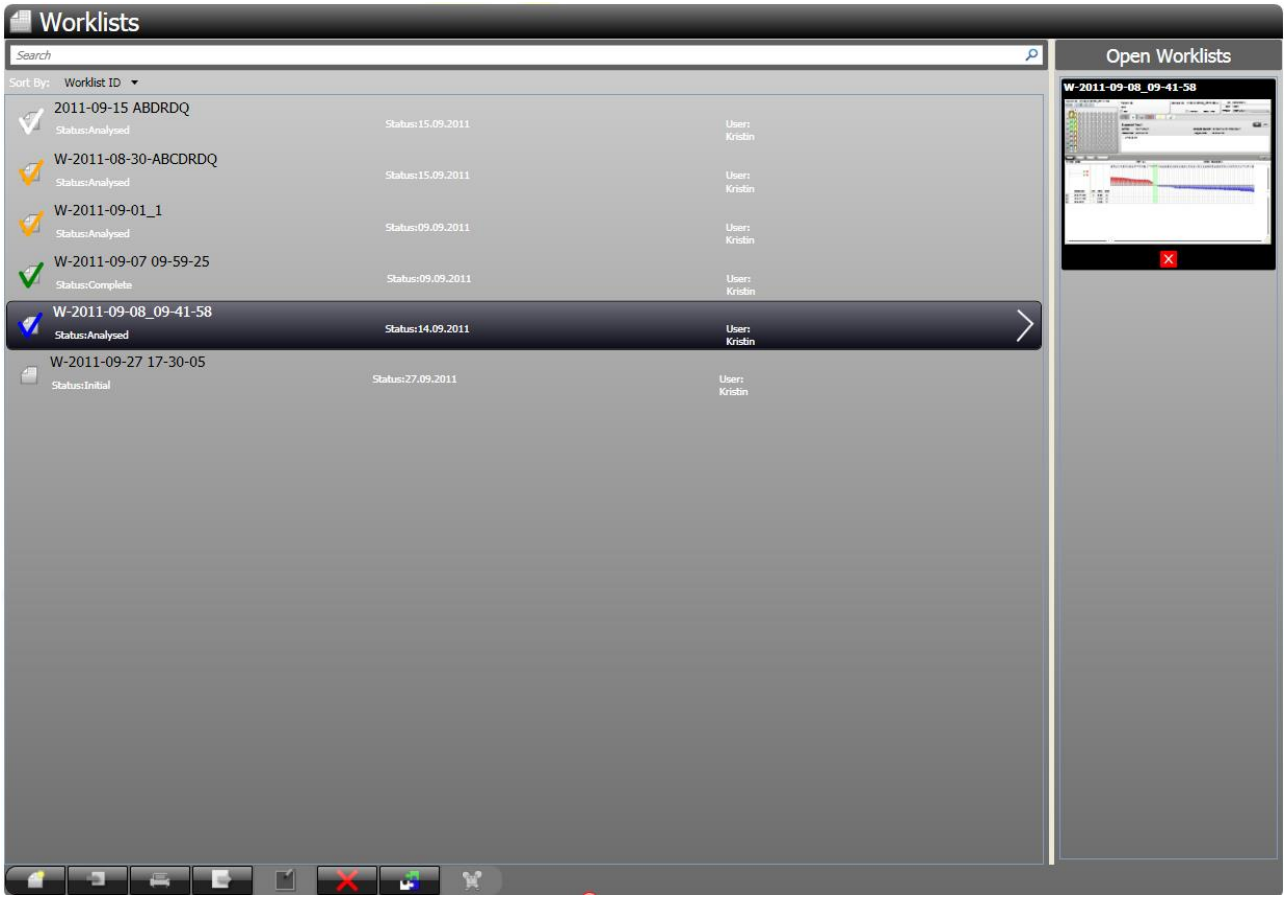
There is a direct link from samples / tests screen to the detailed results of a test: Navigate to the samples and open the tests sub screen. Then highlight the test you want to see and double click or press the green **Interpret** button:



The interpretation screen for this test will open (for details of the interpretation see chapter 14 Worklist Analysis Screen).

11 WORKLIST MANAGEMENT

HISTO MATCH collects tests to be analysed in a worklist, this can be up to 96 tests arranged in a 96 well format. Selecting the **Worklist** button from the main menu will display the browse worklist screen. When the screen is displayed, it will contain all worklists in the database.



Add new worklist (**Add**).

Import a worklist (**Import**).

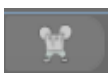
Create a report for the selected worklist (**Report**).

Export the selected worklist (**Export**).

Edit the layout of the selected worklist (**Edit**).

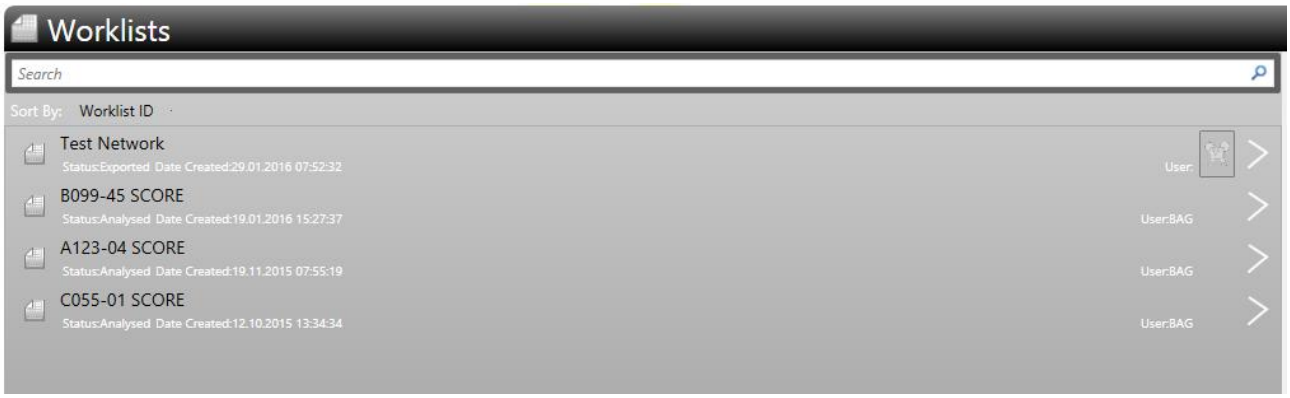
Delete the elected worklist (**Delete**).

Analyze the selected worklist (**Analyze**).



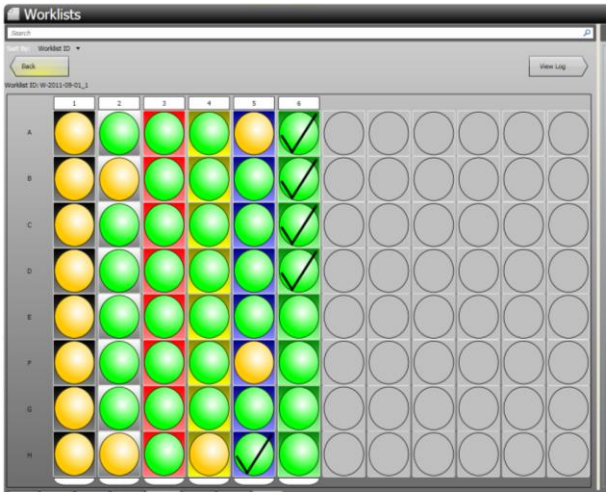
Send the selected worklist to MR.SPOT (**Send**).

If the MR.SPOT® processor is integrated in a network a flashing symbol indicates that the worklist is ready to be imported for interpretation. Pressing the symbol will start the import.



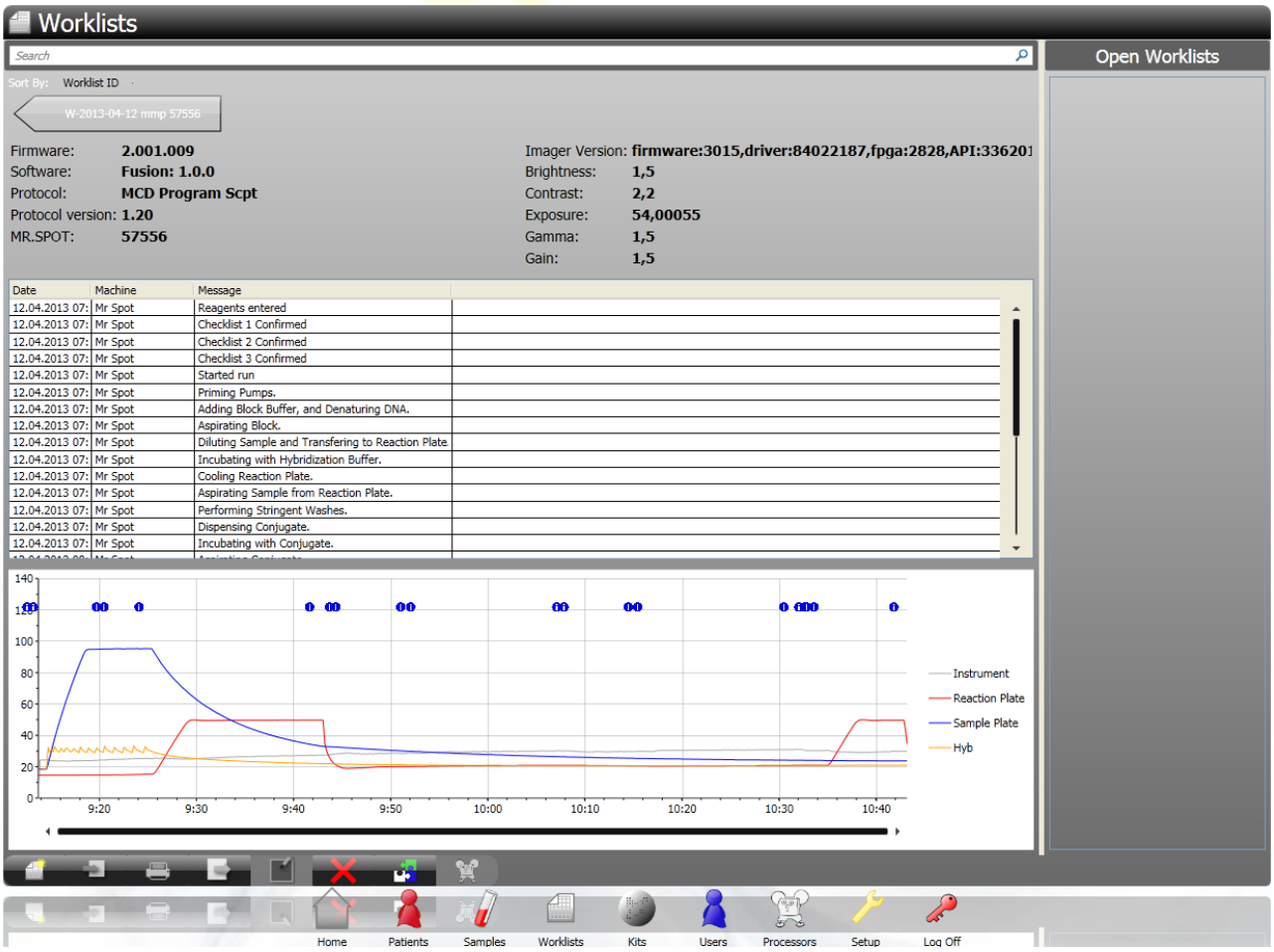
11.1 Worklist views and log data

Clicking on the arrow in the highlighted Worklist gives access to a detailed view of the plate layout:



The View Log arrow

opens the log data of the worklist, including a graph of the temperatures during the assay:

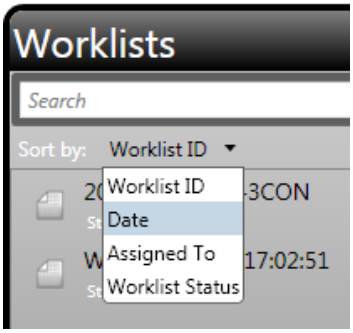

Worklists
Search
Sort By: Worklist ID
W-2013-04-12 mmp 57556
Firmware: 2.001.009
Software: Fusion: 1.0.0
Protocol: MCD Program Scpt
Protocol version: 1.20
MR.SPOT: 57556
Imager Version: firmware:3015,driver:84022187,fpga:2828,API:336201
Brightness: 1,5
Contrast: 2,2
Exposure: 54,00055
Gamma: 1,5
Gain: 1,5
Open Worklists
Date Machine Message
12.04.2013 07: Mr Spot Reagents entered
12.04.2013 07: Mr Spot Checklist 1 Confirmed
12.04.2013 07: Mr Spot Checklist 2 Confirmed
12.04.2013 07: Mr Spot Checklist 3 Confirmed
12.04.2013 07: Mr Spot Started run
12.04.2013 07: Mr Spot Priming Pumps.
12.04.2013 07: Mr Spot Adding Block Buffer, and Denaturing DNA.
12.04.2013 07: Mr Spot Aspirating Block.
12.04.2013 07: Mr Spot Diluting Sample and Transfering to Reaction Plate
12.04.2013 07: Mr Spot Incubating with Hybridization Buffer.
12.04.2013 07: Mr Spot Cooling Reaction Plate.
12.04.2013 07: Mr Spot Aspirating Sample from Reaction Plate.
12.04.2013 07: Mr Spot Performing Stringent Washes.
12.04.2013 07: Mr Spot Dispensing Conjugate.
12.04.2013 07: Mr Spot Incubating with Conjugate.
140
120
100
80
60
40
20
0
9:20
9:30
9:40
9:50
10:00
10:10
10:20
10:30
10:40
Instrument
Reaction Plate
Sample Plate
Hyb
Home
Patients
Samples
Worklists
Kits
Users
Processors
Setup
Log Off

11.2 Finding worklists

You can use the search toolbar to find worklists.

Enter the search criteria into the search bar and press enter or click the button. Worklists will be searched by Worklist ID. Worklists that match the criteria will be displayed in the list below.

11.3 Sorting worklists



You can sort the list of worklists by clicking the **Sort by** field in the list. You reverse the sort by clicking the same field again.

11.3.1 Worklist status

Worklists are assigned a status based on where they are in the workflow. The status can be one of:

Initial: The worklist has been created; tests may have been added to it.

Exported: The worklist is being analysed on MR.SPOT®processor.

Imported: The analysis data, and photographs, have been imported from MR.SPOT®.

Gridded: The images have been analyzed and a grid assigned to the images identifying the position of the probes in the image.

Analysing: HLA types are being assigned to the tests on the worklist.

Analysed: HLA types have been assigned to the tests on the worklist, and are ready for authorization.
The white tick mark indicates that some tests have already been analysed and approved by a technician:

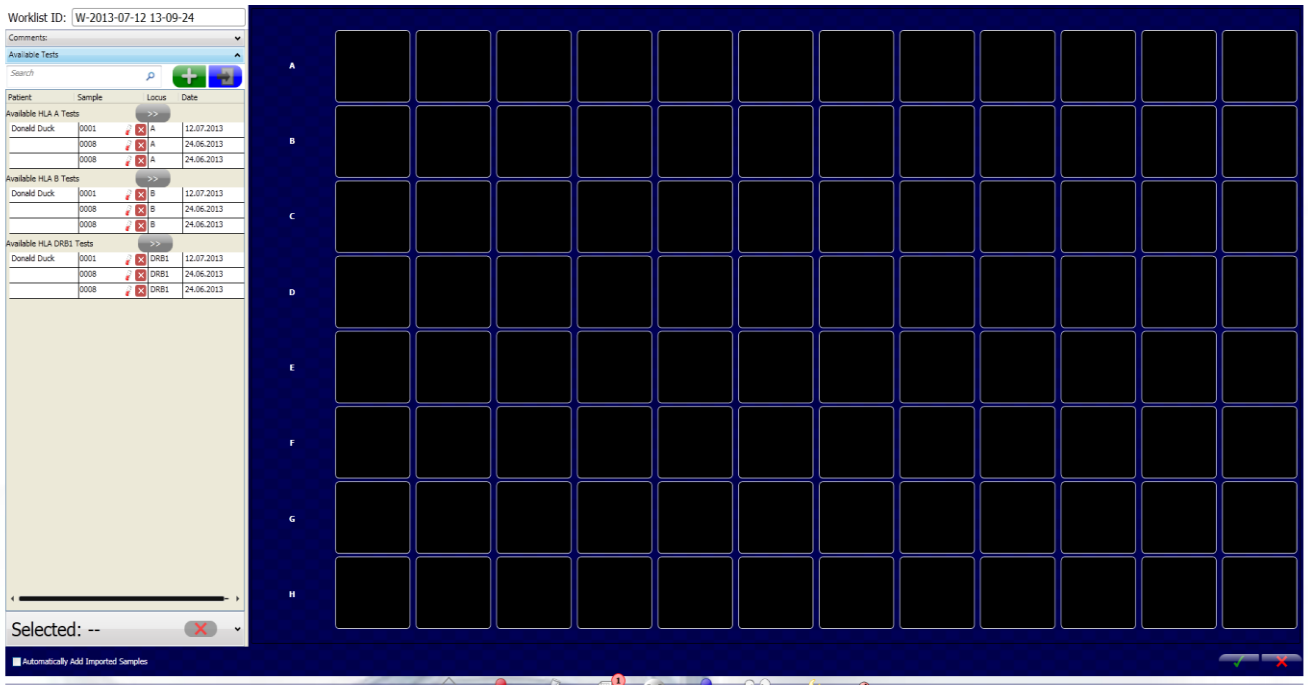
The blue tick mark indicates that all tests have already been analysed and approved by a technician:

The orange tick mark indicates that some tests have already been authorized:

Complete: All tests have been authorized, indicated by the green tick mark:

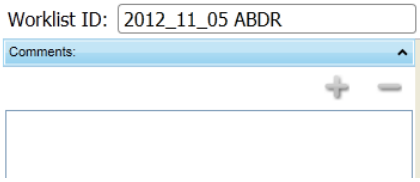
11.4 Creating a new worklist

Worklists can be created by clicking the **Add** button on the browse worklist screen. This will display the edit worklist screen.



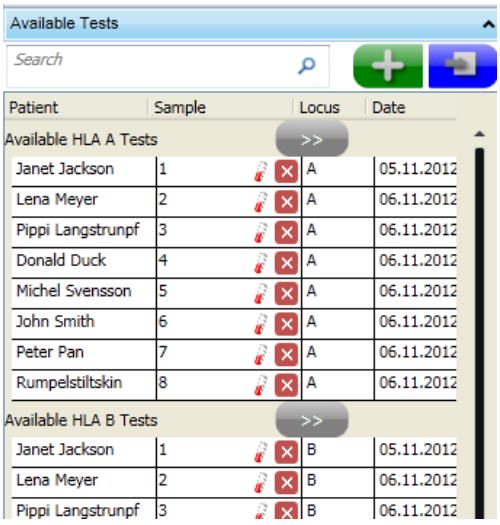
11.4.1 Worklist ID

This contains the Worklist ID. The default ID is created automatically by HISTO MATCH and should be changed according to requirements. The Worklist ID is unique.



Comments can be added by expanding the "Comments:" field and pressing the **Add** button.

11.4.2 Available tests



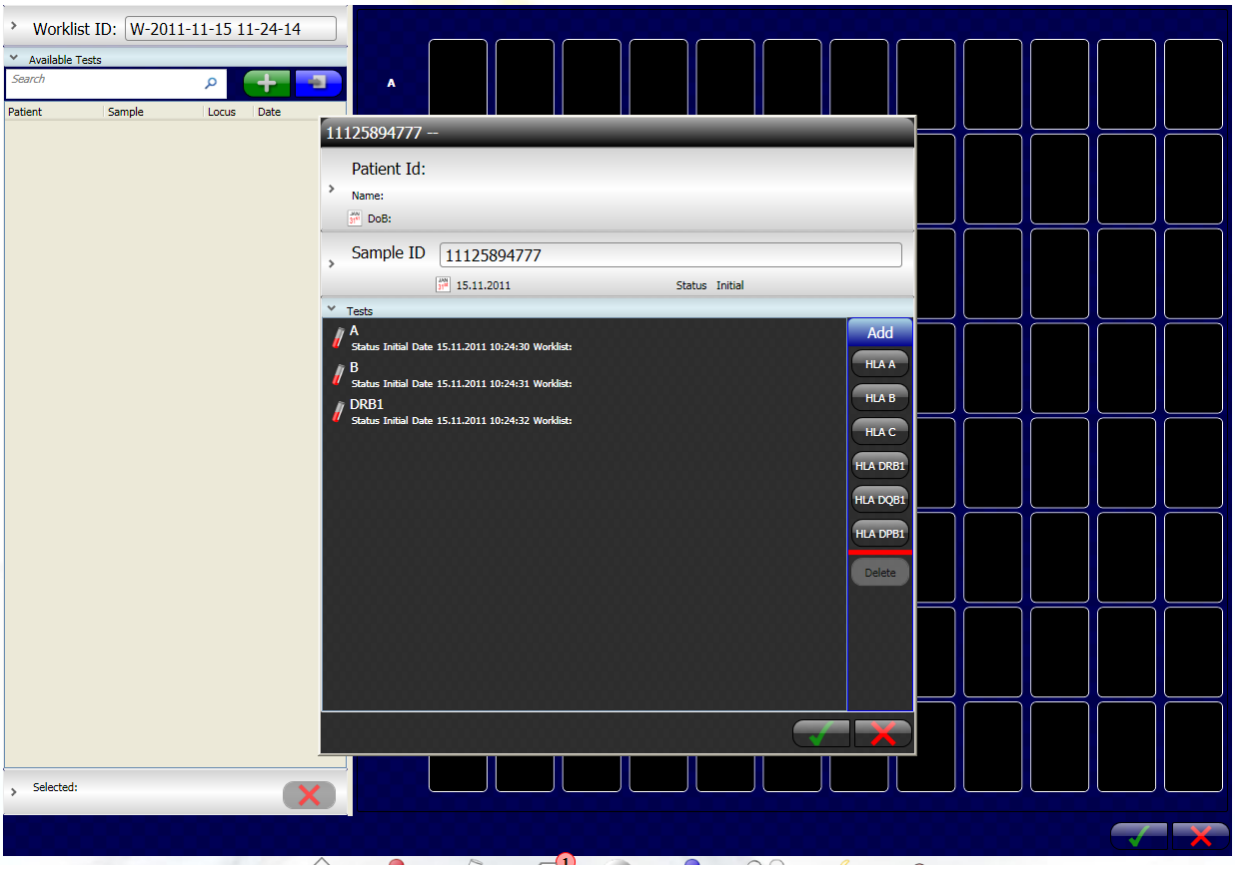
This control shows tests available to be placed onto the worklist, the **New** button will run the new sample dialog, and add any tests created to the list. The Import button will run the import samples function. The samples will be added to the list of available tests.

Clicking on will delete the test without further questions and clicking on will open the edit sample window where you can add or delete tests.

You can choose to add any new or imported samples directly to the worklist layout by checking the filed in the bottom left corner of the screen:

11.4.3 Adding samples with a barcode reader

When the screen to create a new worklist is open, you can add samples with a barcode reader. To do this read the barcode with the screen open. The window for new samples will open and the sample ID is added automatically. Now the tests you want to do can be added.



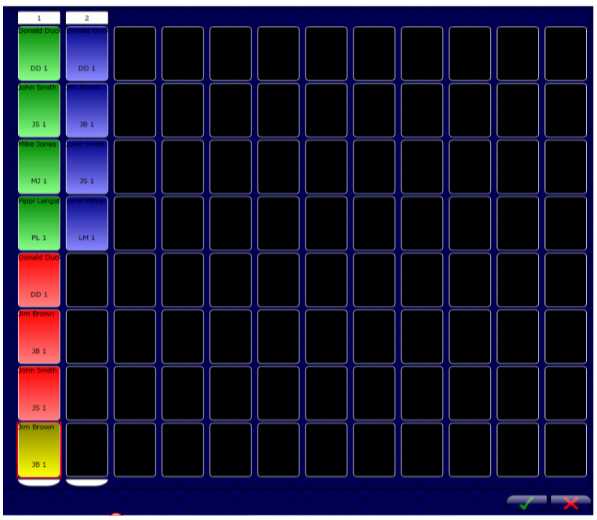
11.4.4 Editing the plate layout

This control shows the plate layout for the worklist. Empty wells are displayed as black space, coloured wells represent tests.
There are several methods to add tests to the plate layout:

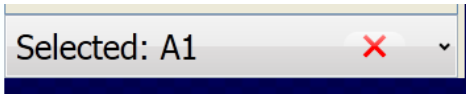
Double Clicking: Double clicking the test will add it to the next available well. HISTO MATCH will group tests of the same locus into a single strip.

Drag and Drop: One or more tests selected in the test list control can be dragged onto an empty position in the plate. The tests will be added to the sequence of positions following the drop target. This method allows the creation of mixed locus strips. You can also move tests within the plate, by dragging a test to a new empty location.

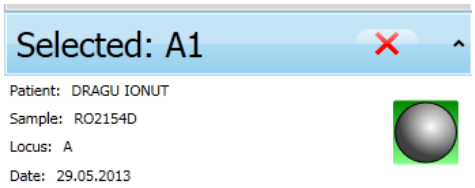
Locus Add: Clicking the button next to the locus name, will attempt to add all available tests for the specific locus. Tests will be added to strips of the same locus.



To delete tests from the plate layout, select the test on the plate by clicking it. The **Selected Test** control is activated:



This control can be expanded to show more information about the selected test.



Clicking the Remove button will remove the test from the worklist, tests removed from the worklist will be available in the available test list.

It is also possible to remove tests from the plate by **drag and drop** to the available tests list.

Clicking **Save** will save the worklist changes and open the send worklist to processor dialog (see 11.10 Send worklist to processor). **Cancel** will cancel any changes, and the view will be closed.

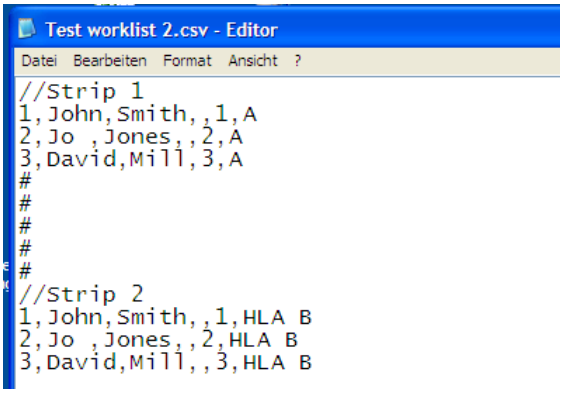
During worklist editing, the user can navigate away from the page, by selecting one of the available functions from the main menu.

The user can return to the screen by viewing the browse worklist screen. All open worklists will be listed in the **Open Worklist** list, double clicking the item in the list will return the user to the edit screen.

11.5 Importing an initial worklist

To provide a quick method to create worklists it is possible to import worklists from a text file (.csv). The text file should contain a list of records each record should be in one of two formats:

1) PatientID FirstName LastName DoB SampleID Locus
2) SampleID Locus



Each field should be separated by either a tab or a comma. For empty wells use "#". You can enter comments that are not imported by starting a line with "//". The filename will be the worklist name in HISTO MATCH.

A template file in Excel format is available from the HISTO SPOT Download Server (http://service.bag-healthcare.com/). This will transform an excel sheet to the correct .csv format. Access data are available from BAG Health Care GmbH or your local representative.

PatientID:	This is the unique ID of the patient.
FirstName & LastName:	The patient name.
DoB:	The Patient's Date of Birth (must match to your local date format).
SampleID:	The unique ID of the Sample.
Locus:	The HLA locus to add a test (e.g. A, HLA A, HLA-A accordingly B, C, DRB1, DRB345, DQB1, DPB1, COE, Ax, Bx, Cx for Xtend kits, NULL for the Null Kit and NEG for the negative control).

The text file can be imported using the import button from the home screen or the import button on the worklist screen.

In the file type box choose "CSV Worklist" and select the worklist file. After the import the edit worklist screen is shown.

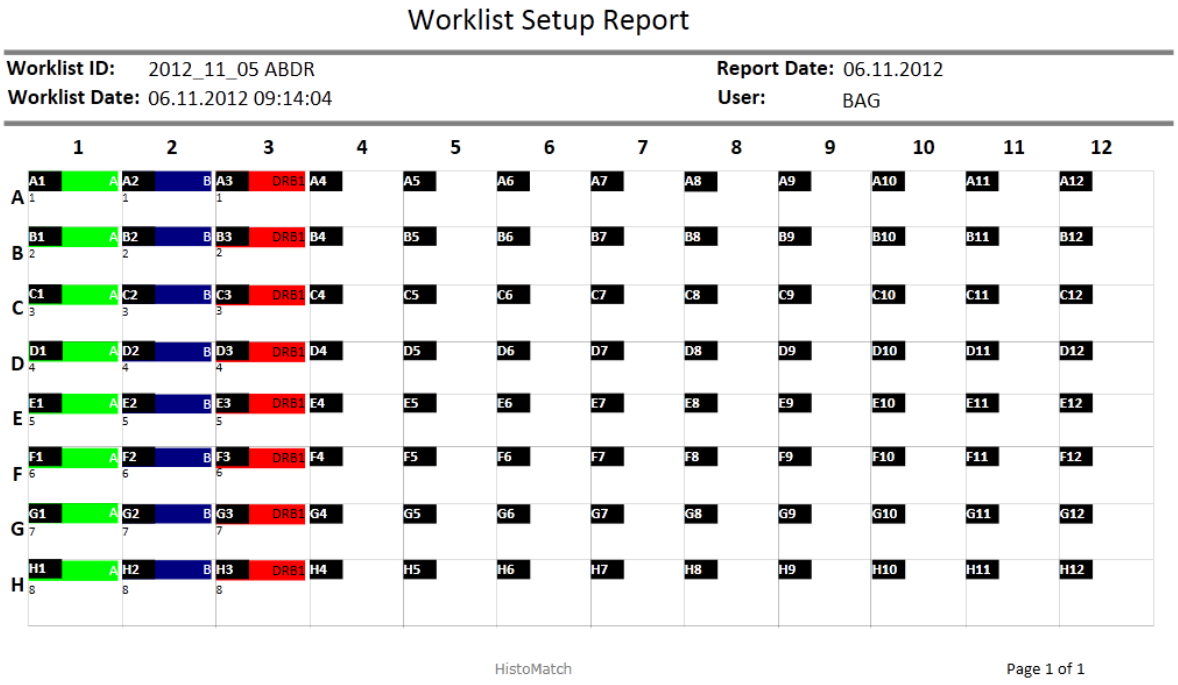
11.6 Editing an existing worklist

Worklists can only be edited, until they are exported, i.e. they have a worklist status of **Initial**, once exported the status will change to **Exported** and the worklist cannot be edited, except by a user with the role of an administrator.

To edit an existing worklist, locate the worklist using the search and sort functions on the browse worklist screen, then select the worklist and click the edit button or double click the worklist in the list.

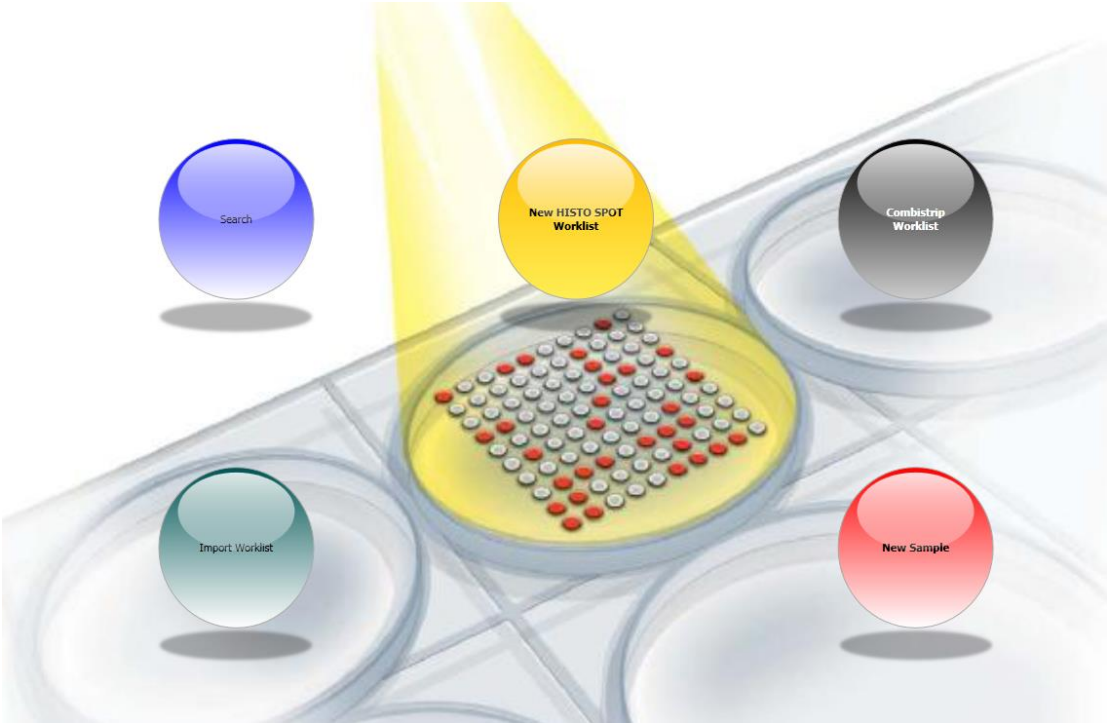
11.7 Worklist setup report

There are several report types, depending on the user setup preferences, and the worklist status. Worklist status **Initial** or **Exported**: HISTO MATCH will produce a **Worklist Setup Report**. This shows the position of each test on the worklist and is colour coded for the locus.



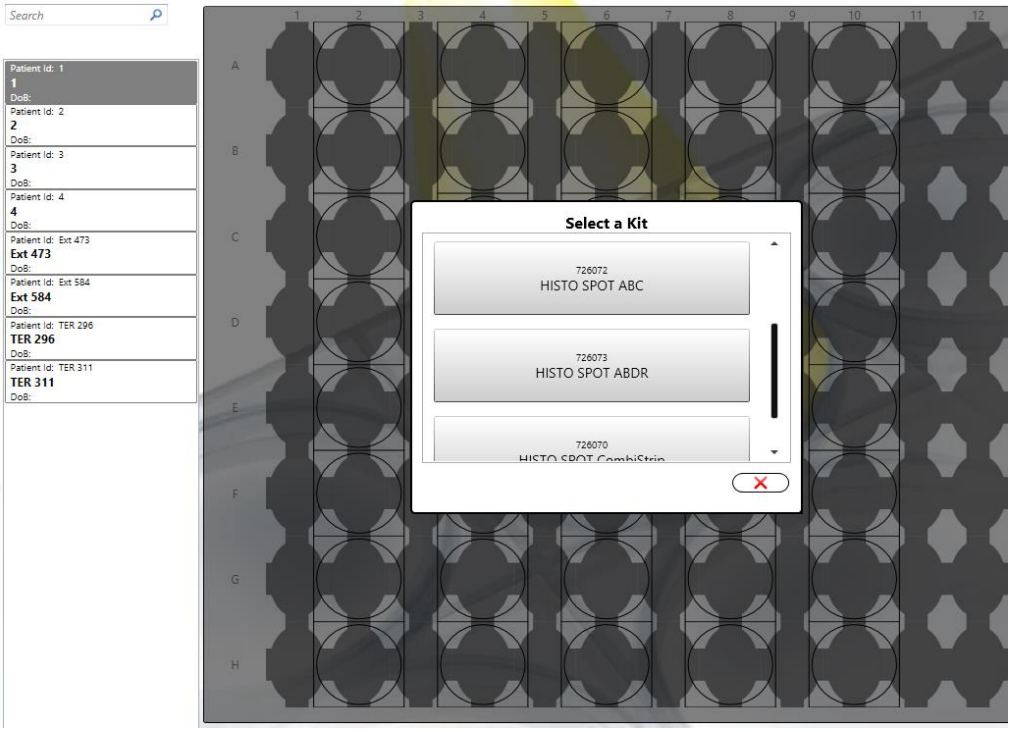
11.8 Creating a worklist for a combi strip (On-Call Typing kit, CWD high res kits)

From the home screen chose the button **Combistrip Worklist** :

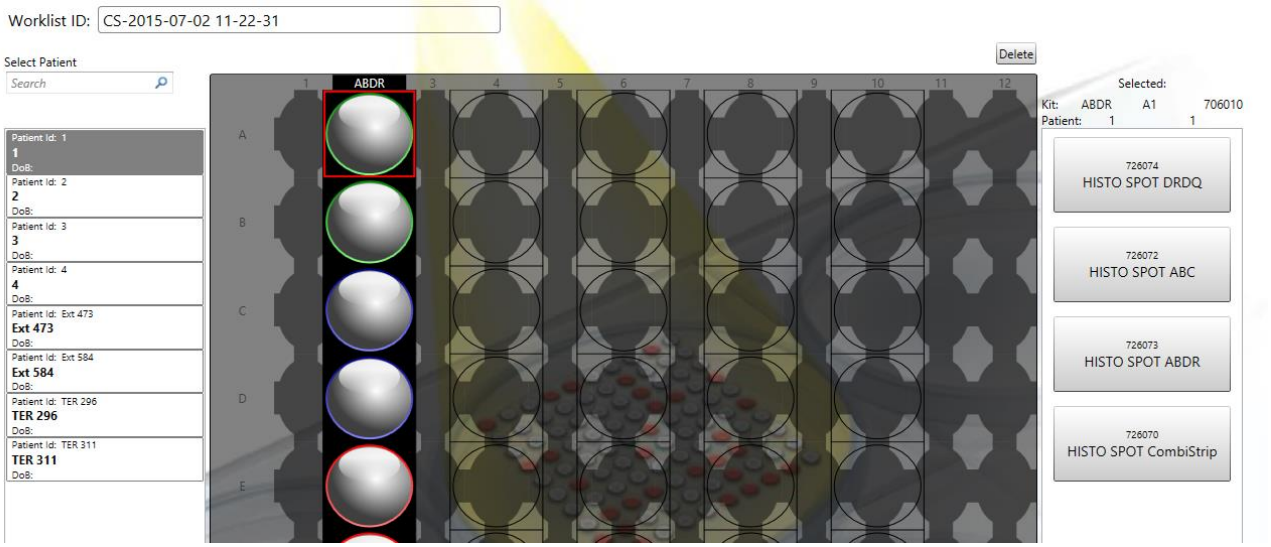


1. Create the Worklist ID. The default ID is created automatically by HISTO MATCH and can be changed according to requirements. The Worklist ID is unique.
2. Select and add a patient by using a) the **Search** function or b) by creating a new one:

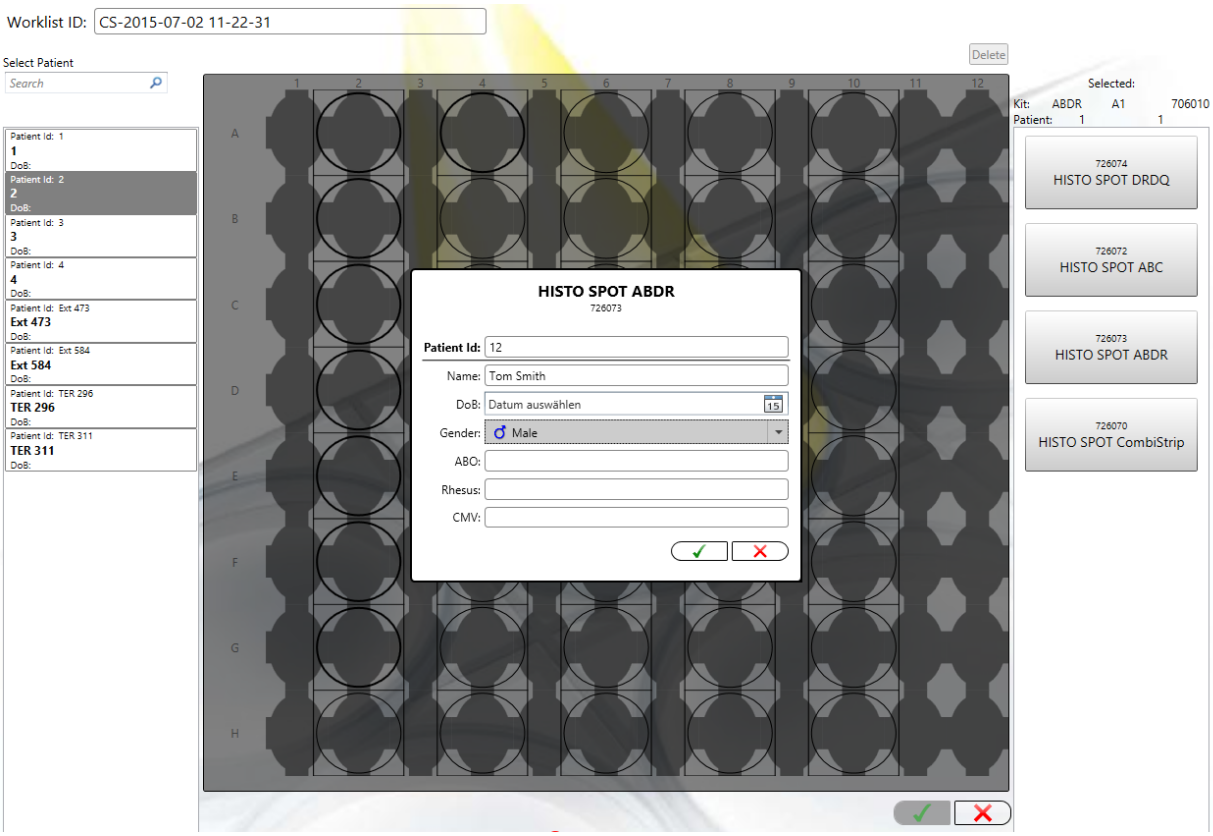
a. Place the cursor into the search field and press enter or the search button to show all available patients. You can also enter search criteria in this field to search for a specific patient. Double clicking on the patient opens a window to select the kit to be used. Select a kit with a double click and the test is added to the worklist.



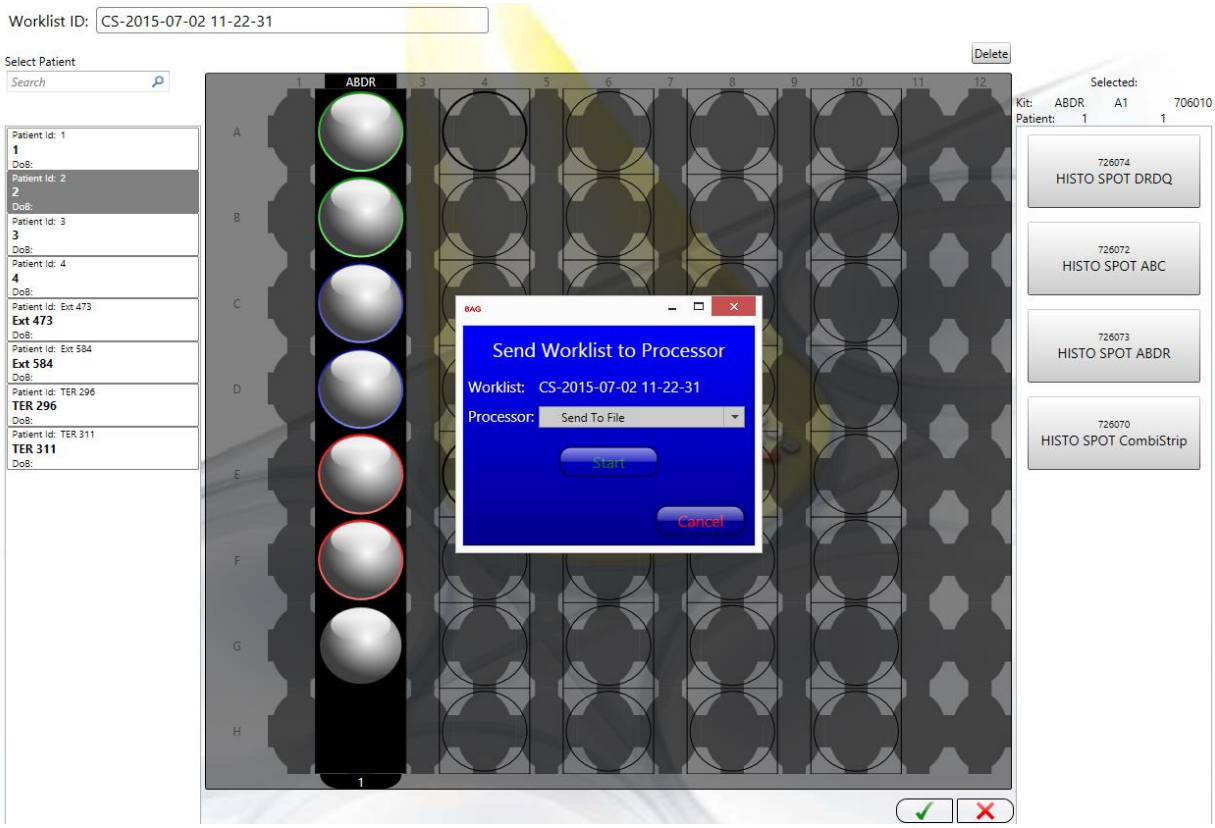
Patients can be removed again by marking them in the plate layout and pressing the **Delete** button in the upper right corner. Creating patients in the patient management is described in chapter 9 (9 Patient Management).



b. Press one of the kit buttons on the right side to create a new patient from this screen. Enter the patient data and press the **Save** button ✓. The test for the new patient is added to the worklist automatically.



3. Save the worklist by pressing the **Save** button ✓ below the plate layout. Then you have to send the worklist either directly to the processor or save it to a file for transfer via USB stick (see 11.10 Send worklist to processor). Cancelling this process will not send the worklist but save the worklist in the database.

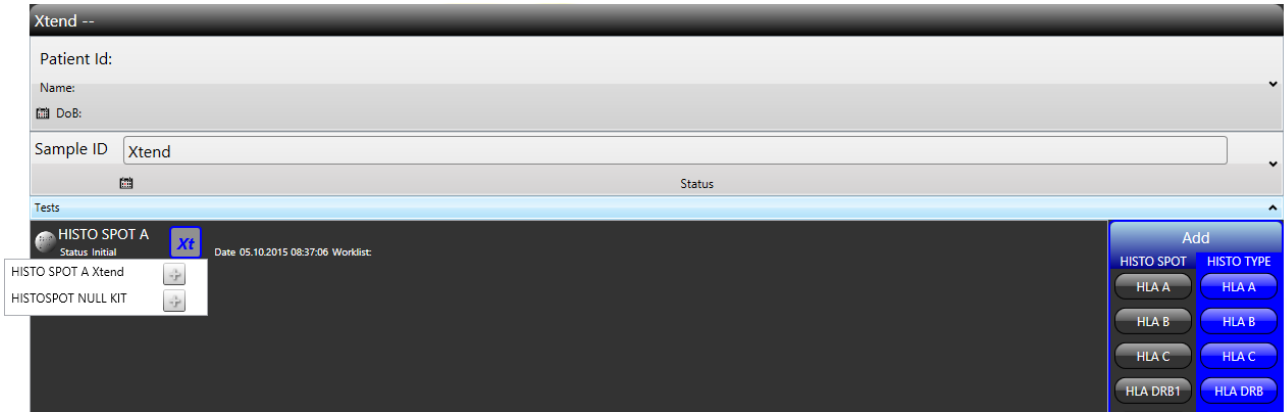


Press **Start.** You will then be asked to print a worklist setup report – press **Yes**.

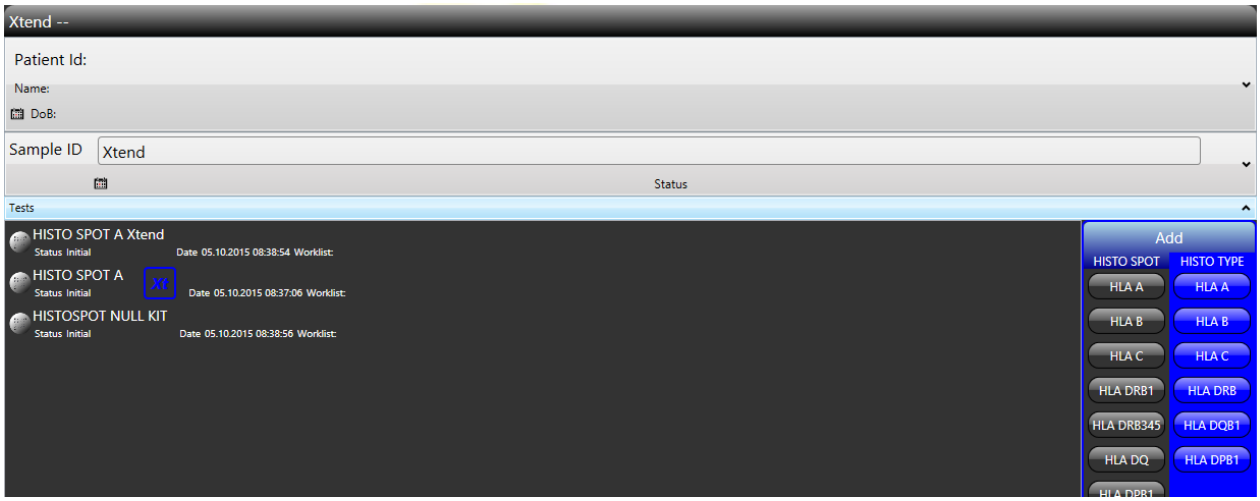
11.9 Create tests and worklists with Xtend and Null kits

11.9.1 Xtend and Null tests for initial testing

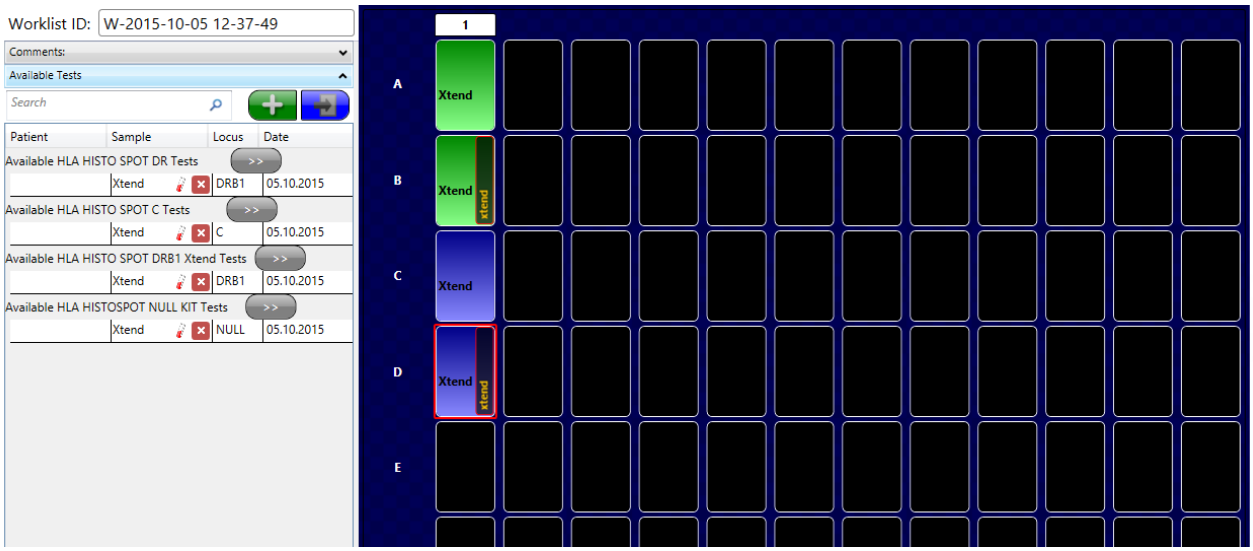
A complete high resolution test can be done from the beginning by adding a 4D test first and then an Xtend and /or Null test to a specific sample. Pressing the Xt button beside the regular 4D test opens a window to add an Xtend or a Null test with the "+" buttons.



The Xtend tests are then shown for the sample. Null tests will be linked to all class I test with the status initial for this sample ID.



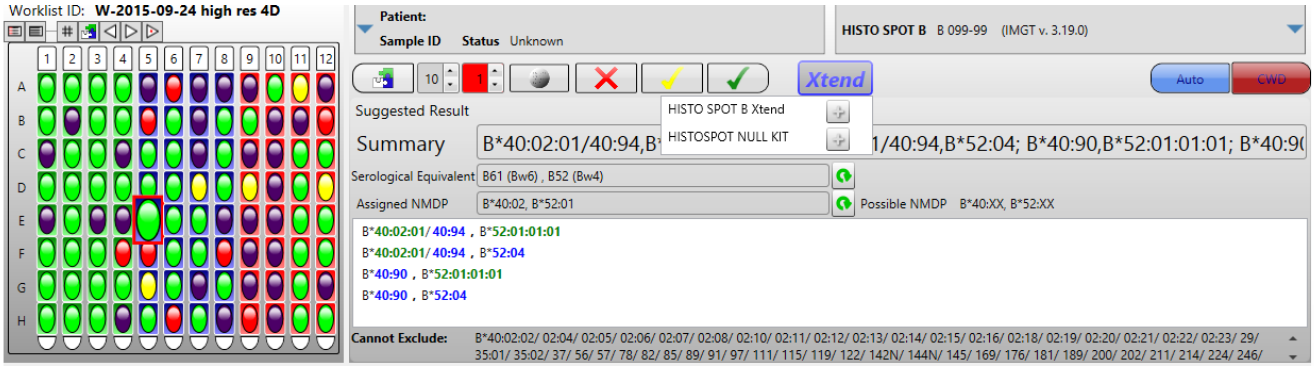
The Xtend tests can then be added to a new worklist as usual:



The tests and the respective hit tables will automatically be combined in the interpretation later on.

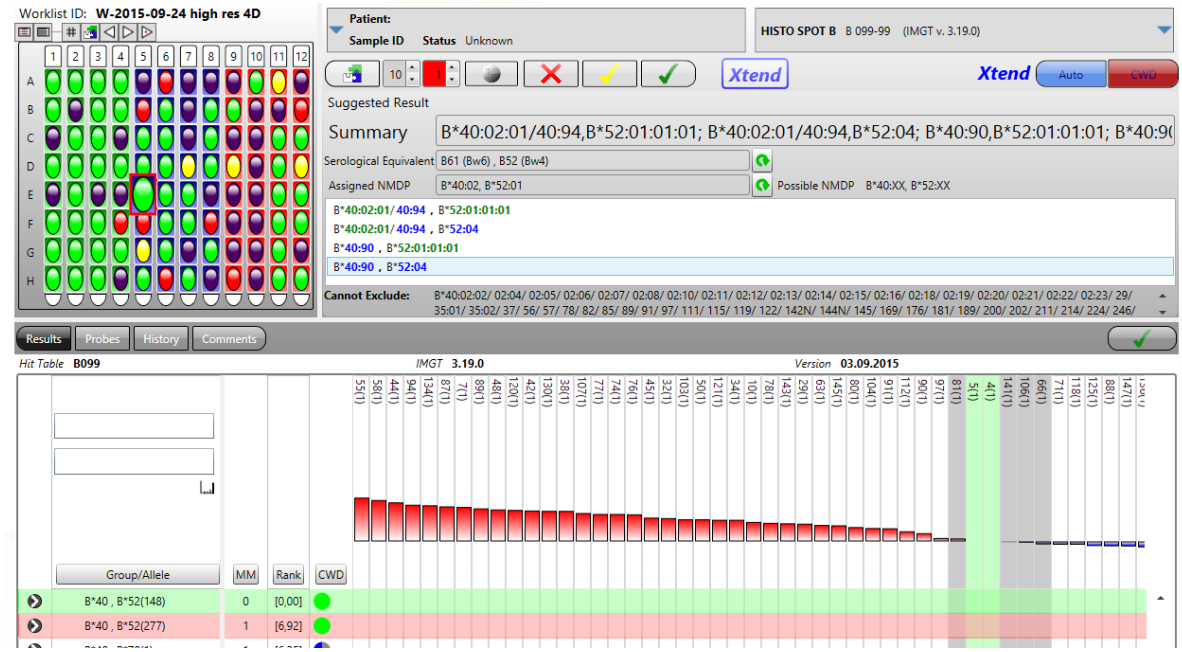
11.9.2 Adding Xtend and Null tests to already processed tests

Xtend and Null tests can be added to tests that are already interpreted from the interpretation screen. This 4D test is ambiguous with the CWD filter. An Xtend test can be added by pressing the Xtend button and then the “+” button:

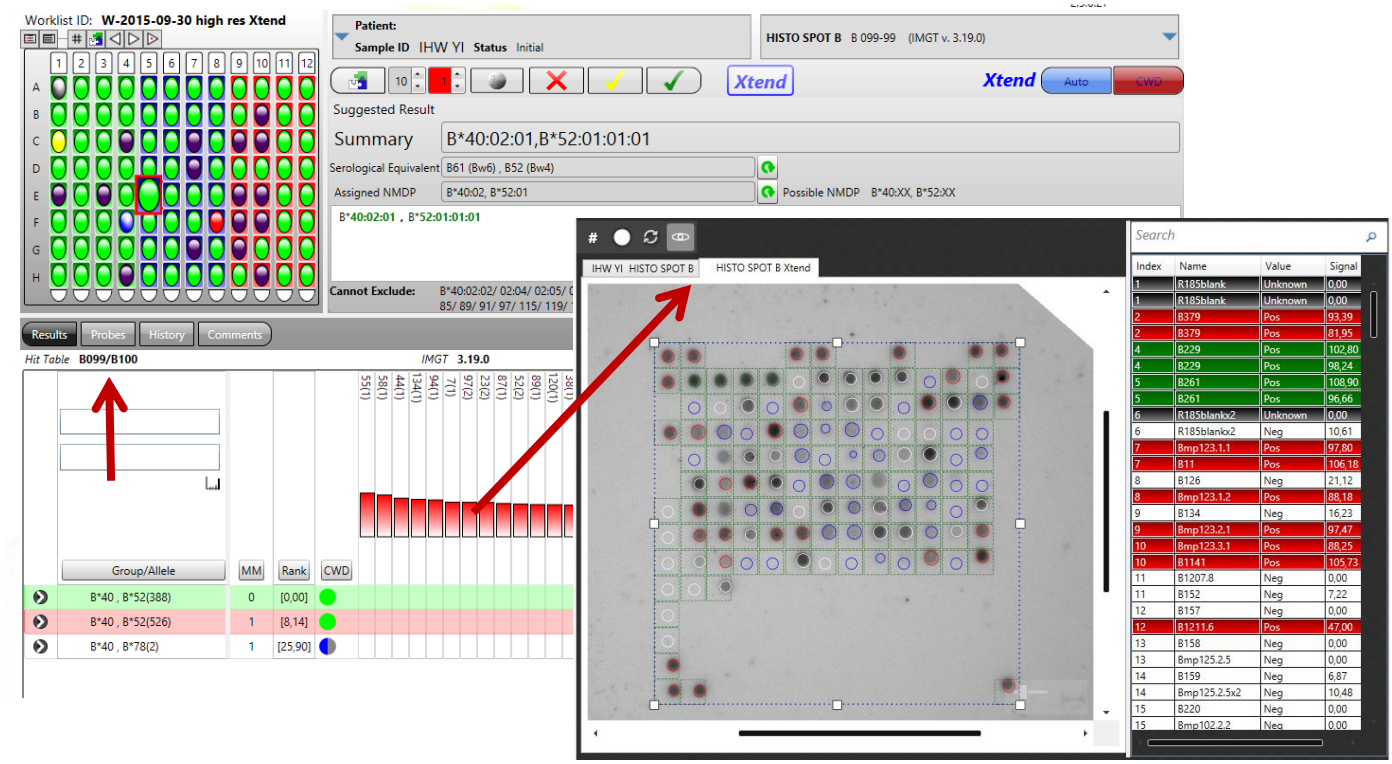


You have to confirm the “Complete” window by pressing “ok”.

For an extended test the blue Xtend symbol appears and the probe numbers in the histogram are complemented by a number in brackets to indicate that they are on the first (4D) well.



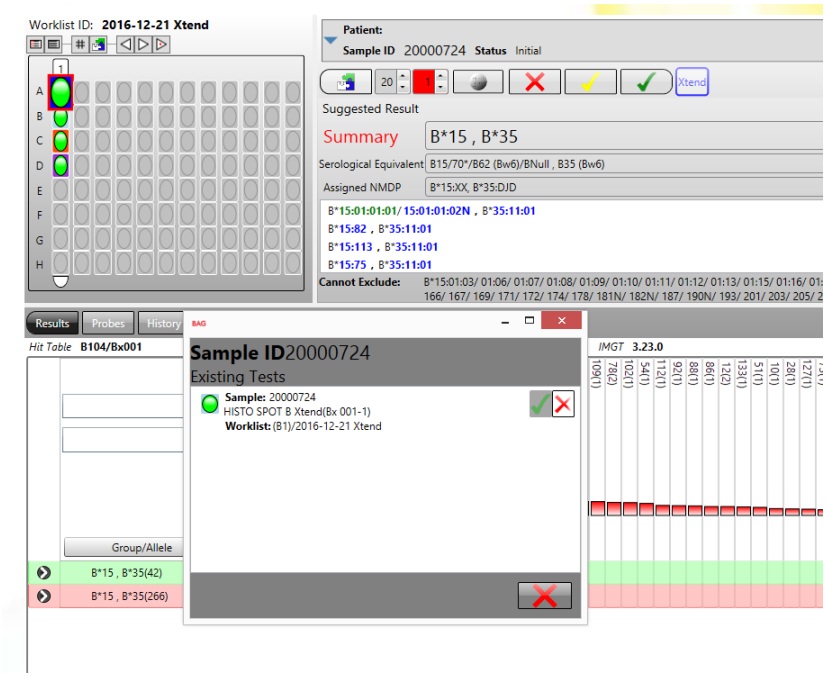
The Xtend and Null test created from the interpretation screen are displayed as “Available tests” in the screen to create a new worklist and can be added as shown in the previous chapter. After running the test and importing the worklist with the Xtend tests the tests are automatically combined. Both hit tables are displayed and both array images can be inspected. The result is now unambiguous with the CWD filter.



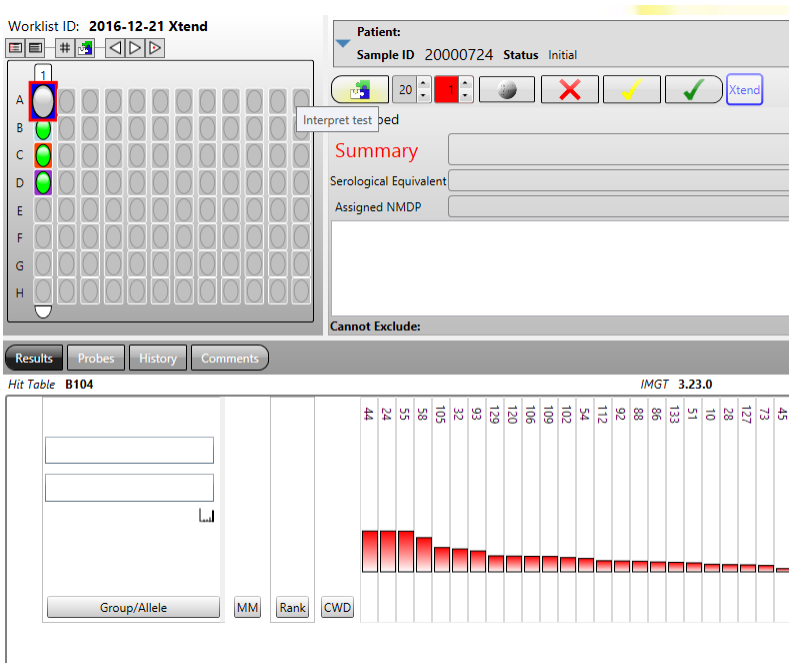
11.9.3 Link / unlink existing Xtend tests

If there are already Xtend tests for a given sample they can be shown by a right mouse click on the **Xtend** button

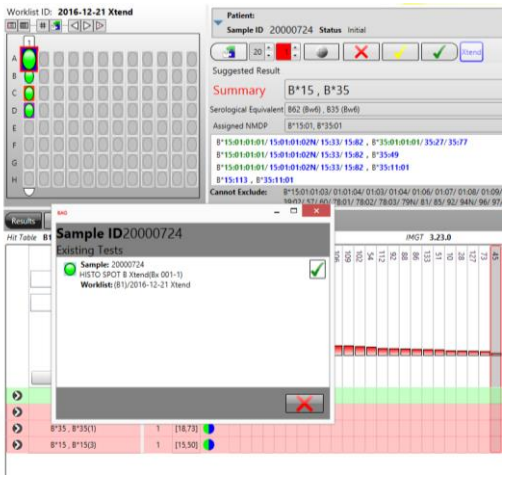
. By pressing the red cross in this window the Xtend test is unlinked from 4D test.



The 4D test can now be re-interpreted without the Xtend test by pressing the **Interpret** button:



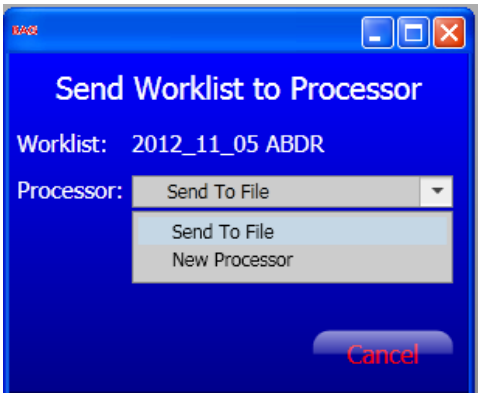
The Xtend test can be linked again by a right mouse click on the **Xtend** button and then pressing the green tick mark:

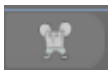


11.10 Send worklist to processor

Once a worklist has been created and all tests have been added, it can be sent to MR.SPOT® for processing. The worklist can be sent across a local area network directly to a MR.SPOT® processor, or by using a USB memory stick. The send worklist dialog is initiated by saving the worklist after it has been created or edited, cancelling this process will not send the worklist.

1. To send a worklist from the browse worklists screen, locate the worklist to send using the search and sort functions. Only worklists in the **Initial** state can be sent.



2. Select the Send button. 
3. In the dialog box shown, select either “Send to file” or select a MR.SPOT® processor (if available) from the list and select Start.

3a) **Send to file**:

i. Choose a location to save the file.
ii. Copy the file to a USB stick.
iii. Insert the USB stick into MR.SPOT®USB port.
iv. On MR.SPOT®choose **Worklist**.
v. Choose **Import**.
vi. The worklist is now available for processing.

3b) **Choose MR.SPOT®:**

i. Select a MR.SPOT® from the list.
ii. Choose **Start**.
iii. The worklist will be available on the MR.SPOT®.

4. After sending has completed, you will be prompted to print out a worklist layout report, choose **Yes** or **No**.
5. The worklist status will be updated to **Exported**.

11.11 Importing a processed worklist

11.11.1 Import via USB stick

After a worklist has been processed on the MR.SPOT®processor, it needs to be imported along with the well images. This can be done using a USB memory stick.

1. On the MR.SPOT®processor, export the worklist to the USB key.
2. The worklist file will be saved to the USB key along with a subfolder containing the well images.
3. Insert the USB key into the PC running HISTO MATCH.
4. On the home screen choose **Import** or choose **Import** on the browse worklist screen.
5. Select the worklist xml file, and choose **OK.**
6. The worklist will import, and the images will be saved to the database.
7. HISTO MATCH will automatically grid the images, interpret the results, and open the worklist analysis screen to review the results.

11.11.2 Import via network

A processed worklist can be imported directly over a network using the **Import Worklist** function on the processor's screen (see chapter 12.4) or from the worklist screen:

A MR.SPOT® icon in the list shows that the worklist is currently being processed, a flashing icon indicates that it is ready for import – clicking the Icon will import the worklist directly without having to go to the processor's screen.

11.12 Exporting a worklist

The export function is available to worklists that have been analyzed. There are four export formats available:

Text Export:

The results of the tests are saved to a text file. The text format is simply

Worklist Position or Sample ID Low Res result High Res Result

for each test on the worklist.

CSV Export:

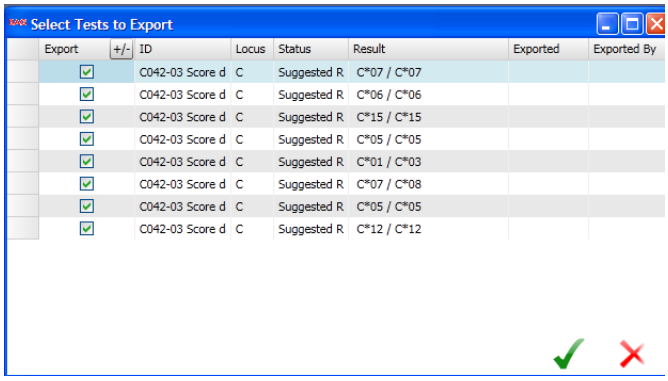
The result is also a text file with the test result given as NMDP code as well as user assigned results.

Technical Export Package:

Exports the worklist file (.xml) including some information on the analysis together with the folder of well images.

SCORE Export:

Exports the interpreted results to a file that can be imported to a full version of the SCORE™ Software. A whole worklist or single tests can be exported. Score typingkit files for the batches used are necessary to do this. They are available from the HISTO SPOT Download Server. This might be useful if typing results from different techniques should be combined. Please note that SCORE™ is not suitable for the interpretation of results obtained with the HISTO SPOT® system.



12 MR.SPOT® PROCESSOR

12.1 Processors screen

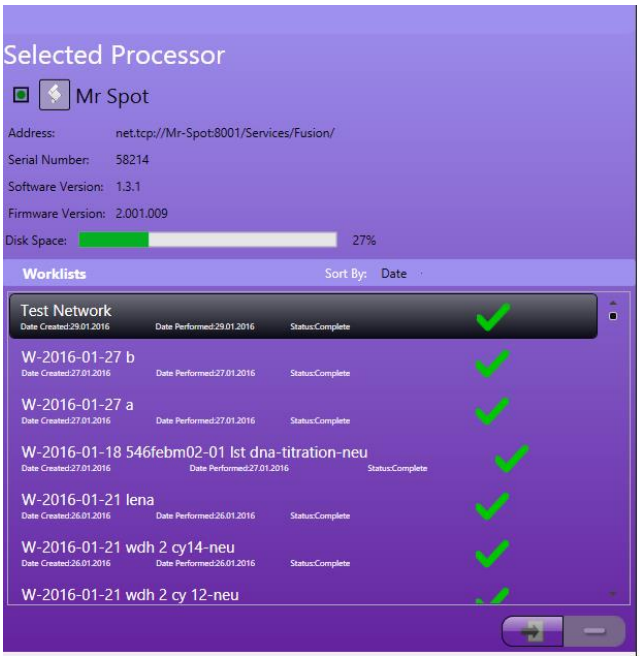
Selecting the **Processors** button from the main menu will show the processors screen.

This screen is made from 3 sub controls:

12.1.1 Processor list

This control displays the list of Processors currently installed, and provides functions to add and delete processors.

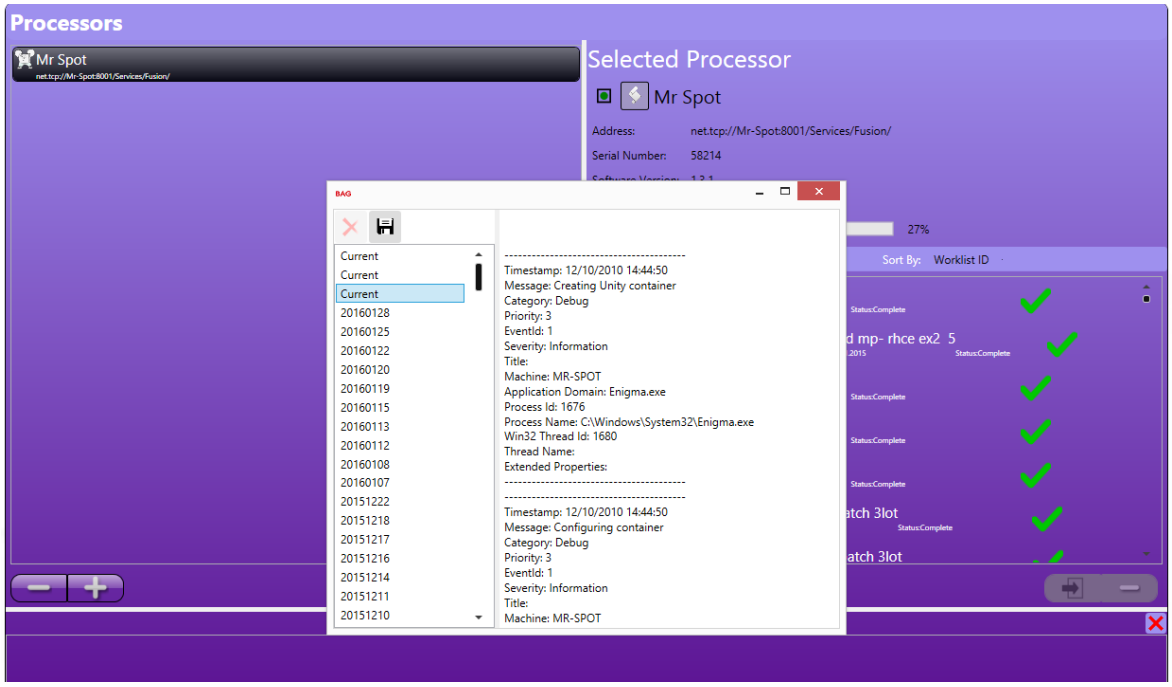
12.1.2 Selected processor



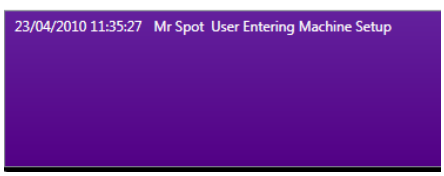
This control displays the currently selected processor in the list. It provides functions to import a worklist from the processor, and delete a worklist .

To reconnect to the processor click the reconnect button:

It is possible to download the log files from single session from the processor via the symbol.



12.1.3 Processor messages

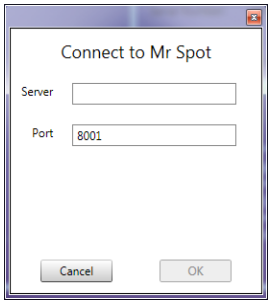


This control displays a list of messages from all connected processors.

12.2 Adding a new processor

This is the process for adding a processor that is connected to the local area network.

1. In the processor list, click the **Add** button.



2. In the server address, type the network name or IP address of the processor, by default the network name is Mr-Spot.
3. The Port should be left at 8001.
4. Choose **OK**.
5. The program will try to connect to the processor. If it succeeds the processor will be added to the list, if it fails you will be given the option to add to the list anyway.

12.3 Deleting a processor

Select the processor to delete from the list, click the **Delete** button. The processor will be removed from the list. You will not receive any further notifications from the processor.

12.4 Importing results from MR.SPOT®

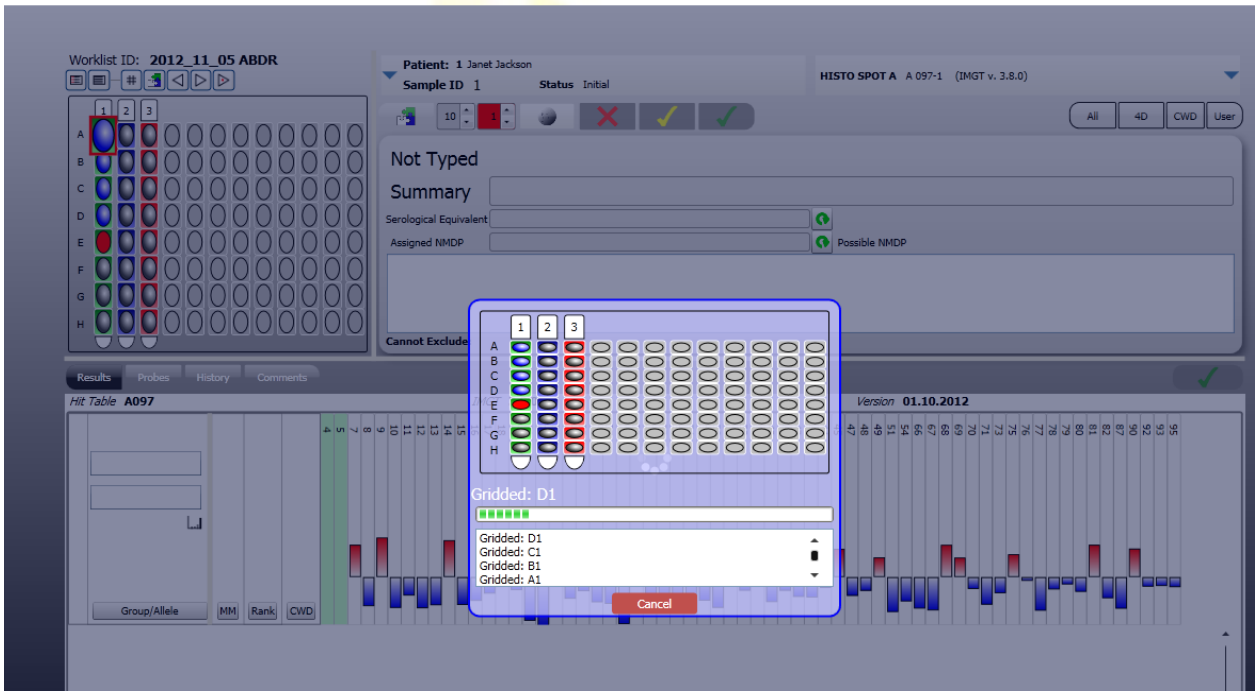
In the selected processor control, select the worklist you want to import, and click the **Import** button. The worklist will be imported into HISTO MATCH, and the images transferred to the database. You can now select the worklist in the browse worklist screen, and perform the image analysis and interpretation.

13 IMAGE ANALYSIS

HISTO MATCH performs the analysis of the well images automatically when a worklist is imported; the analysis consists of two stages: gridding where the grid size and position is identified, and spot measurement where each spot is measured and values are assigned for intensity and background.

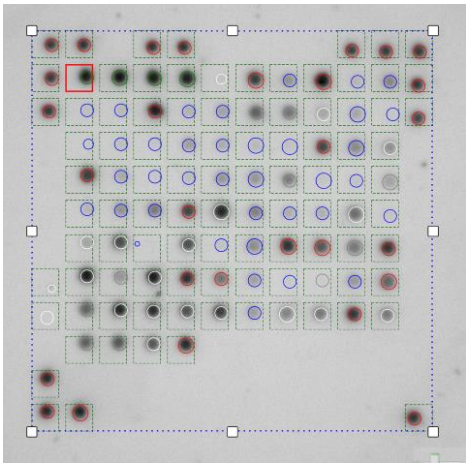
13.1 Automated gridding

When a worklist is imported, the images are automatically analysed.



This screen shows the gridding progress, as each well is gridded and measured. A red well means that it is currently analysed, blue means analysis is complete. It takes approximately 3 seconds to analyze each well. Once complete the screen will close, and interpretation of the data will start. Gridding can be cancelled by clicking the **Cancel** button. However, the current well will complete gridding before the screen closes. Automated gridding can be started at any time using the **Grid All** function in the worklist analysis screen.

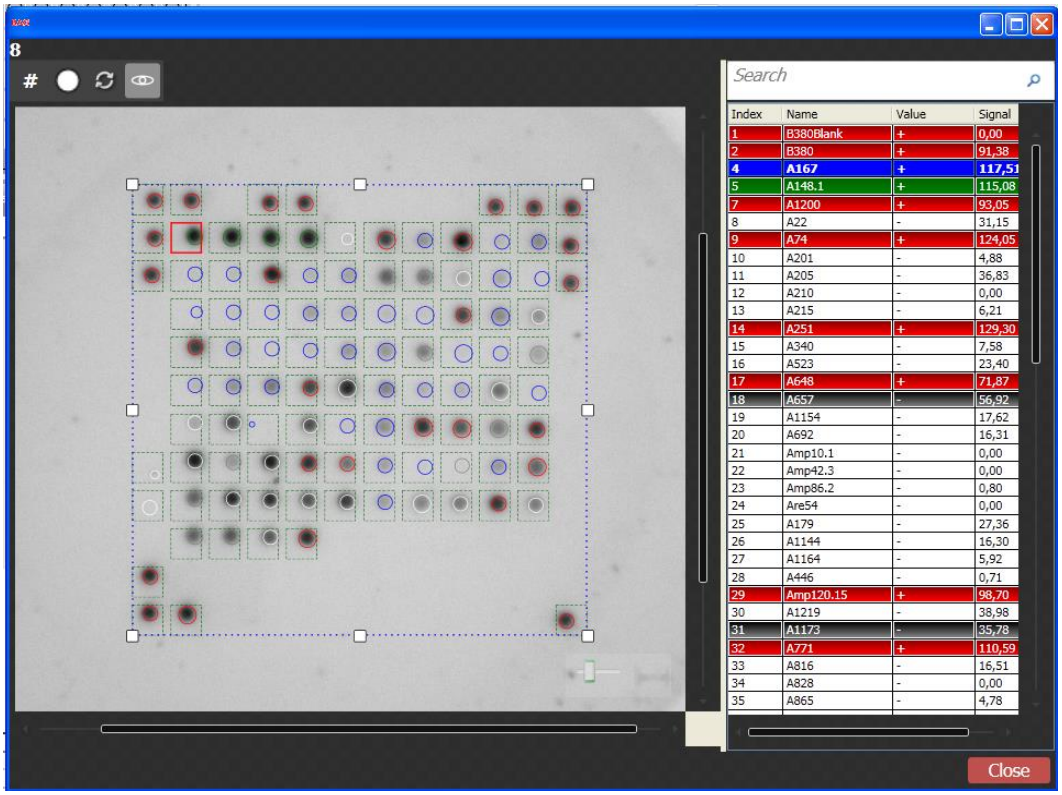
13.2 Manual gridding



Gridding can be performed manually, using the **View Array** function in the worklist analysis screen. The grid can be adjusted using the white drag handles. Each spot is allocated a region within the grid, the dotted outline in the image. The circle represents the detected spot, this can grow or shrink according to the size of the spot. The circle can be moved using the mouse, but is always contained within the dotted area.

13.3 Spot measurement

The value for each spot is measured, and background subtracted. Probes with multiple spots will be averaged.



Positive probes are shown with a red background in the list and a red circle in the image. Negative probes are shown with a white background in the list and with a blue circle in the image. Control probes are shown in green. Probes that were ignored during interpretation are shown black with a grey circle on the image. Inactive probes in the batch have a white circle on the image but are not discriminated in the probes list. Selecting the spot in the list will highlight the spot in the image.

The grid button will re-grid the image, find the spots and measure the values.

The measure spot button will attempt to find a spot and measure the values.

The image rotation button enables manual rotation of the image (see 13.4 Image rotation).

This button will show you the image without the grid.

13.4 Image rotation

When single tests are run on the MR.SPOT® processor, the wells will rotate in the reaction plate holder. Therefore, the image cannot be recognized by the software without correction of the image orientation.

13.4.1 Auto Rotate Images

By default the Auto Rotate function is switched off, e.g. the software will try to grid without any rotation. This setting should be kept if only whole strips are used, because sometimes the software rotates images that do not need to be rotated. For combistrips the Auto Rotate function is switched on automatically.

If switched on, the software will attempt to find the angle of rotation in the auto gridding step (directly after the import). It will then rotate the image and perform the gridding. The Auto Rotate function can be switched on in the **Setup** screen:

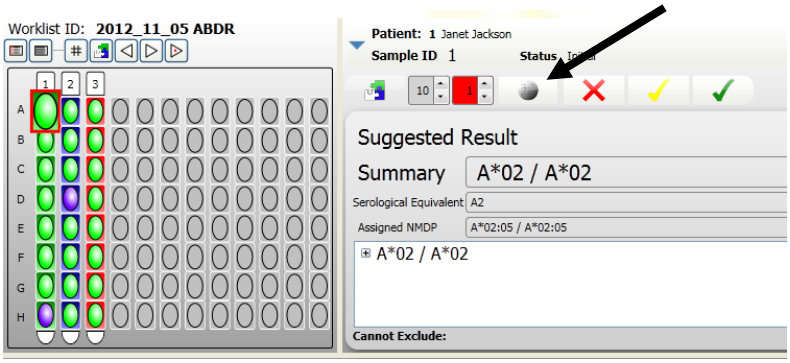
1. Choose **Setup** in the main menu.

2. Choose **Image Analysis**.
3. Activate **Auto Rotate Images**.

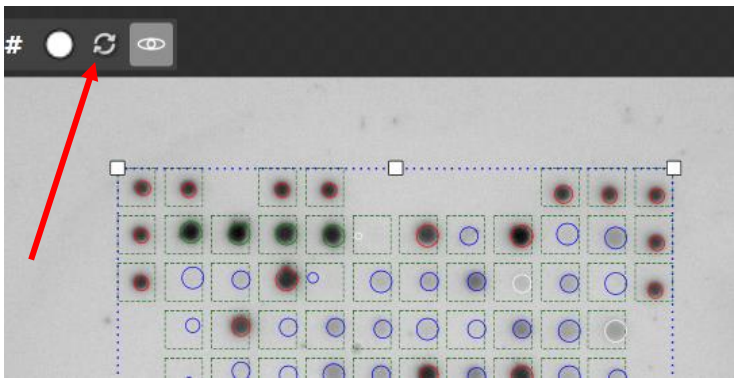
13.4.2 Manual image rotation

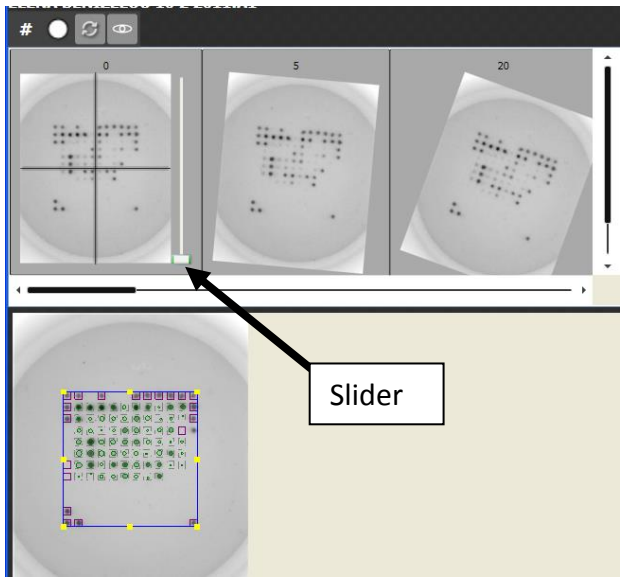
Images can be rotated manually in the **View Array** screen. This might be necessary if the Auto Rotate function is switched off or has failed to correct the orientation successfully.

1. Choose the **View Array** button in the worklist analysis screen.



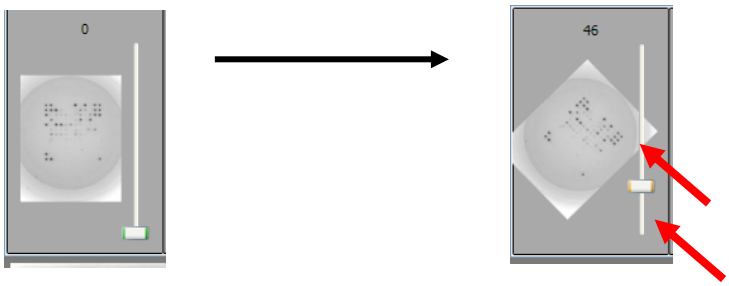
2. Choose the **image rotation** button in the View Array screen.





3. This view shows the best matching rotation detection results. Choose the image with the correct orientation. The spots should be in straight lines horizontally and vertically – the marker spots need not be in the correct orientation. If the correct orientation is not available in the list, the slider in first image allows manual rotation of the image.

Moving the slider up will rotate the image:



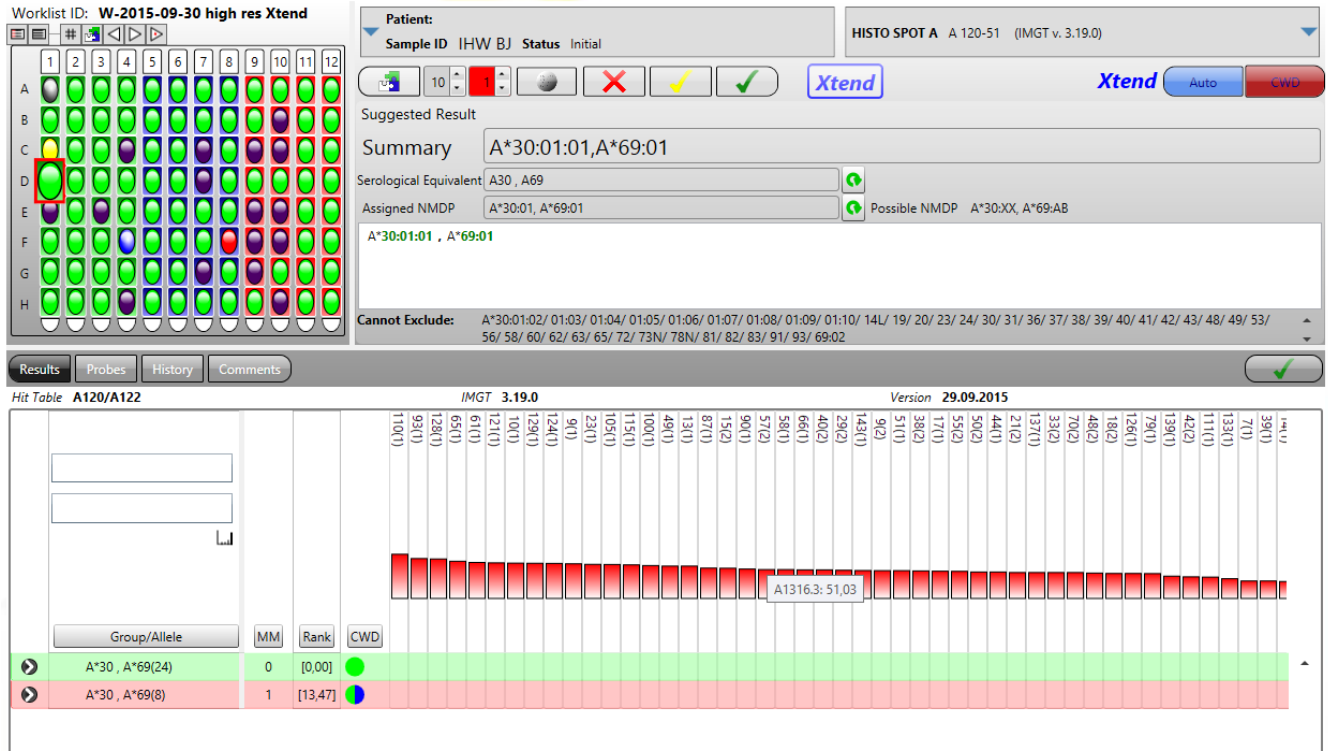
Fine tuning of the rotation is performed by clicking the left mouse button on the line above (+) or below (-) the slider. Each single click rotates the image by one degree in the respective direction.

Click in the centre of the rotated image to transfer it for interpretation. The software will automatically grid the image again. Close the window and re-interpret the test.

13.5 Reference values for failed control probes

The HISTO MATCH software is programmed to flag any test with a control intensity less than 10% higher than background and not to interpret that test. Individual tests containing control probe signals outside the 40 to 140 range, may be subject to false positive/false negative probe results and should be documented and checked before acceptance according to EFI standard v 6.1 section L7.1.

14 WORKLIST ANALYSIS SCREEN



14.1 Main toolbar

Plate view/List view toggle: Switches the worklist view.

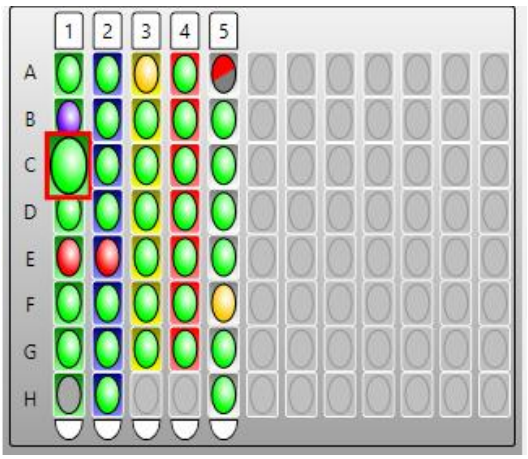
Grid All: Automatically grids all un-gridded tests.

Interpret All: Interpret all tests/ or interpret not typed tests.

Navigation buttons: Previous/Next/Next issue.

14.2 Plate view

This shows the status of each test in the plate:



Green: unambiguous common type

Purple: common haplotype or rare result

Yellow: ambiguous result (common or rare), not for DPB1

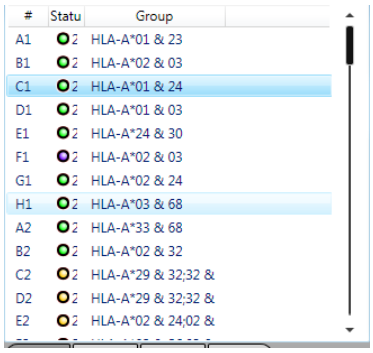
Red: no result

Grey: control probes have failed

Grey/red: control probes have failed for one of the loci in the DQB1 / DQA1 or coeliac disease kit

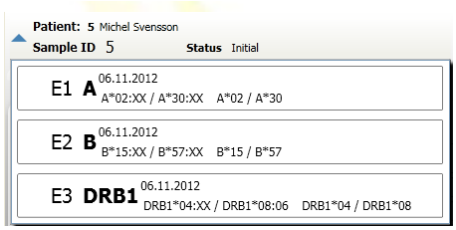
A check mark indicates the result has been technically approved or authorized. The user can navigate to each test by clicking the well. The background colour of each test indicates the locus.

The view can also be toggled with a list view if desired:

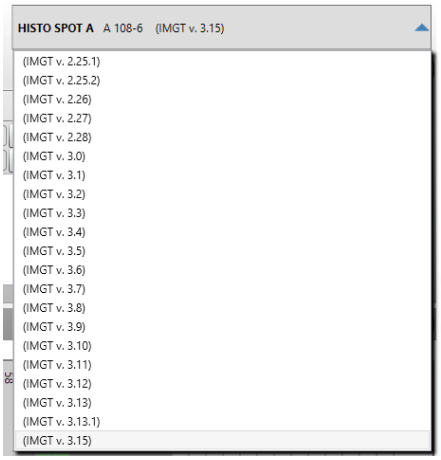


In this view the user can see the low resolution result of each test next to the test position and status indicator.

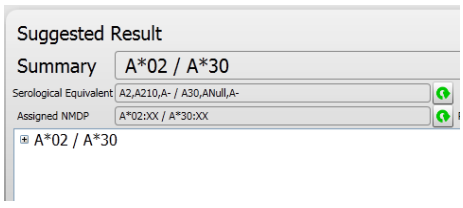
14.3 Test information



Patient and sample information for the currently selected test. Clicking on the expander shows all typing results of this sample.

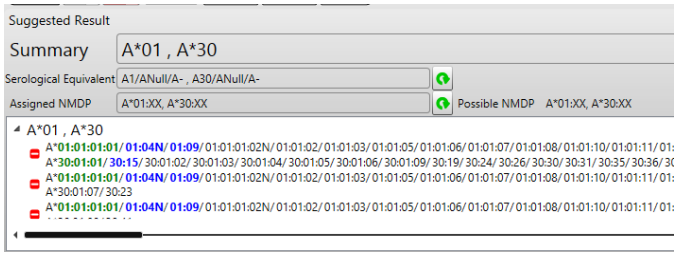


Kit and batch information for the currently selected test. Different hit tables can be selected by clicking on the expander .



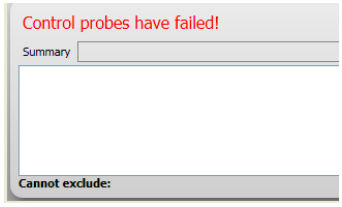
The suggested/authorized results for the test, this display groups the results by 2 digit group, the expanded allele name can be displayed by expanding the group.

Alternatively, filtered alleles are shown here (see 14.6.2 Common allele filters and 14.6.3 Display options for the summary field).



Once expanded, the alleles can be seen. Common alleles are displayed in green, well documented alleles in blue (according to the CWD 2.0.0 catalogue).

The " " button will remove this result from the suggested result.



If the controls probes are very weak, a warning is displayed. It is possible to try to interpret anyway with the **Interpret** button. This message will also be displayed for a contamination control without DNA.

14.4 Interpret controls

Interpret:

Performs Interpretation of the current results.

Max. number of probes to ignore:

Maximum number of probes that will be ignored, while trying to find a common result.
The default value is 10 and can be changed under "Setup-Interpretation".

Max. Number of mismatches allowed:

All results with the maximum number of mismatches indicated here will be shown.
The default value is 1 and can be changed under "Setup-Interpretation".

View Array:

Shows the image, and the grid overlay, allows the user to change the grid.

Delete:

Deletes the results for the selected test.

Approve:

Technical approval by a user.

Authorize:

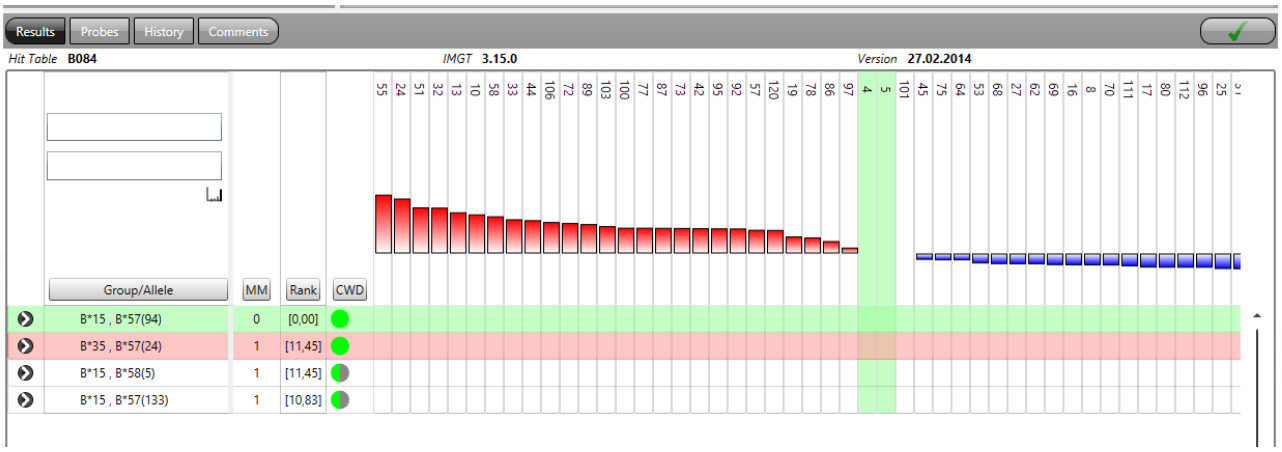
Authorizes/Un-Authorizes the current result. (Supervisor)

Add Xtend / Null test

Opens a window to add an Xtend or a Null test.
Only visible if the respective kit is available (batch file imported).
Right mouse click gives the option to link / unlink existing Xtend tests.

14.5 Results view

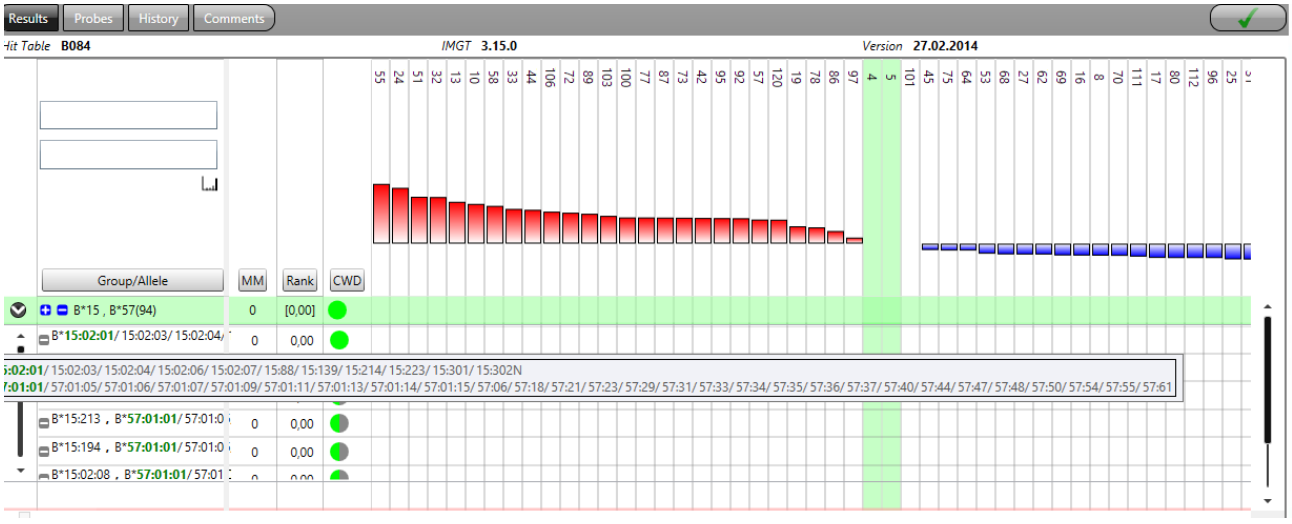
This view shows the results of the interpretation. The default view shows the possible 2 digit results, along with number of mismatches required to get the result.



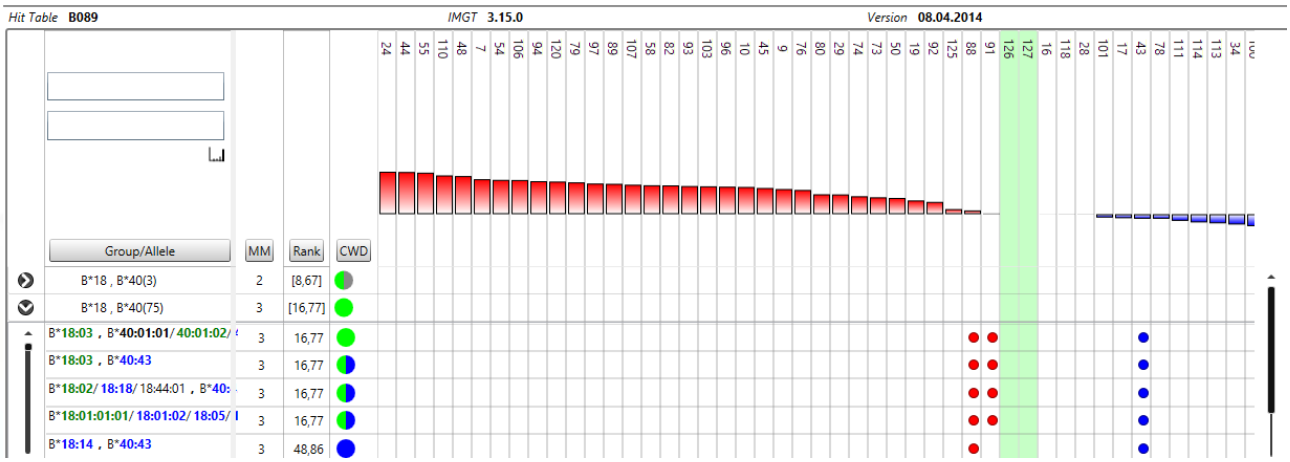
The probe intensities are arranged according to the difference from the cut-off, the left most probes are the most positive, and the right most probes are the most negative. The probes highlighted in green are the control probes.

Results with zero mismatches and including a combination of two common alleles are highlighted in green. Results with only one mismatch and including a combination of two common alleles are highlighted in red and should be checked.

The number in brackets after the 2 digit result gives the number of possible allele strings included in this line. Clicking the expand button in the first column of the grid will expand the 2 digit group and show all the alleles in that group. Moving your mouse over the allele names will display the alleles in a tooltip.



If an allele group contains mismatches these are highlighted in the grid as false positive (red dot) or false negative (blue dot).



The **MM** column indicates the number of mismatches.

The **Rank** column indicates the distance of the mismatched probe from the cut-off. Lower numbers indicate mismatches with weak probes. In the 2 digit grouped row, this value is the best value of the group.

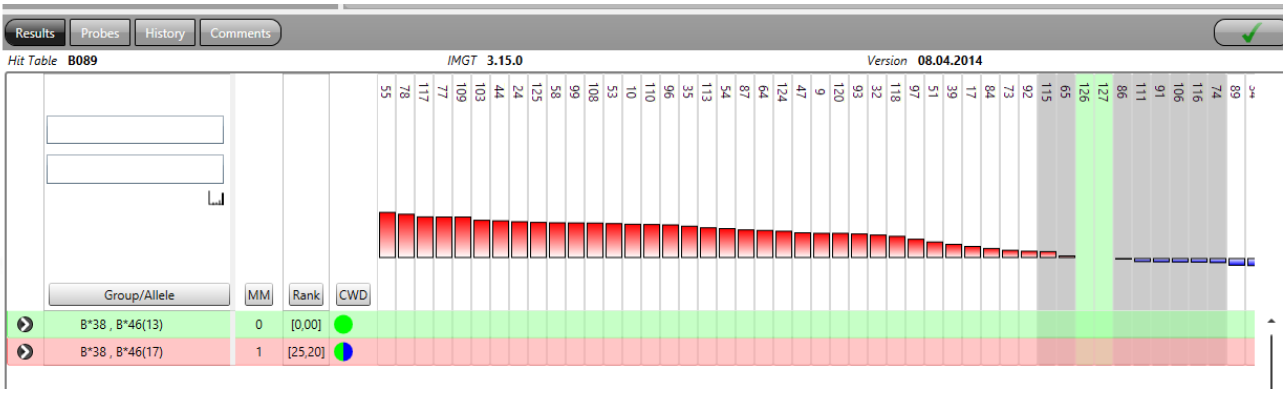
The **CWD** column indicates the number of common haplotypes (with reference to the CWD2.0.0 catalogue) in the potential result. A green dot indicates a result with 2 common (C) alleles, a blue one with two well documented (WD) alleles, and a grey one with two rare alleles. If the dot is half green and half blue it is one C and one WD allele. In the 2 digit grouped row, this value is the best value in the group.

Clicking on the button on top of each column will sort the results according to the respective parameter (Group/Allele, MM, Rank or CWD). Clicking a second time will invert the sorting. The size of the results table can be changed by pressing the CTRL key and turning the mouse wheel at the same time. If probes have been ignored by the software, these are shown in grey on the grid.

14.6 Result assignment

HISTO MATCH will interpret the results, using the values obtained for each probe from the image, and match these to the patterns defined by the hit table. If the software does not find a matching result with two common alleles, it will exclude the probe closest to its cut-off value, and reinterpret. This process will be repeated until a result is found or until the maximum number of probes to be ignored is reached (10 probes by default). This result will be displayed with the ignored probes highlighted in grey in the middle of the table. The software is looking for a common result and this depends on the allele filter that is applied:

4D: Ignore probes until two 4D alleles are found.
C/CWD: Ignore probes until two C alleles are found.
User: Ignore probes until any two of the alleles in the user defined list are found.
All: Ignore probes until two 4D alleles are found.

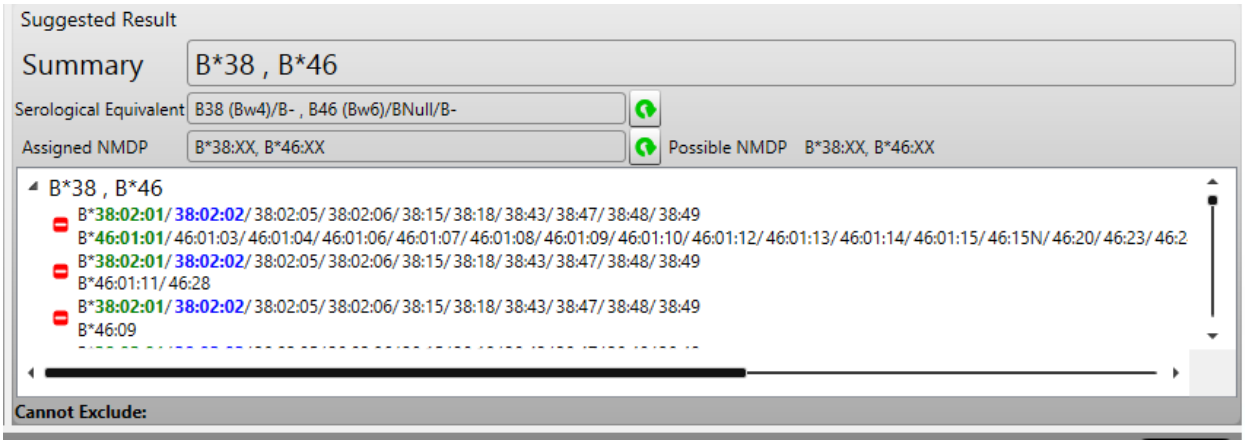


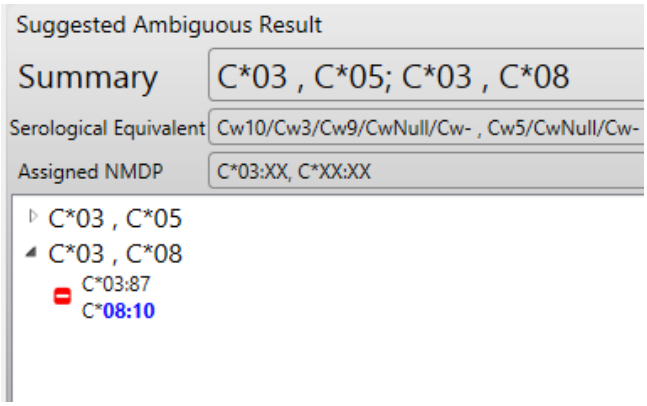
Results with zero mismatches and including a combination of two common alleles are highlighted in green. Results with one mismatch only and containing two common alleles are highlighted in red.

Warning: The results found by the automatic interpretation are suggestions to aid the person who has to make the HLA typing. The automatic interpretation must always be reviewed and checked for plausibility by experienced personnel before giving a clinical result.

14.6.1 Suggested Results

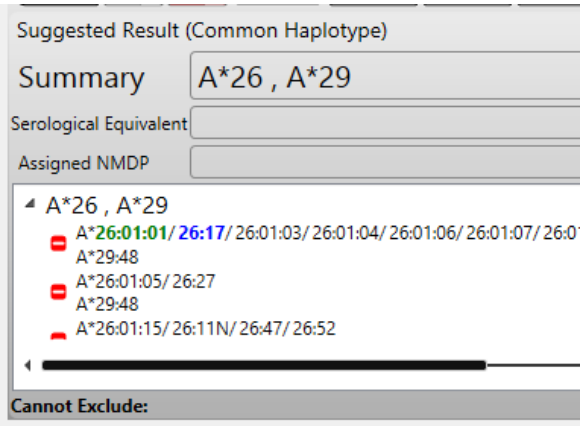
All 0 MM results are automatically added to the **Suggested Result** box. The results are displayed as 2 digit groups with the alleles grouped below them.



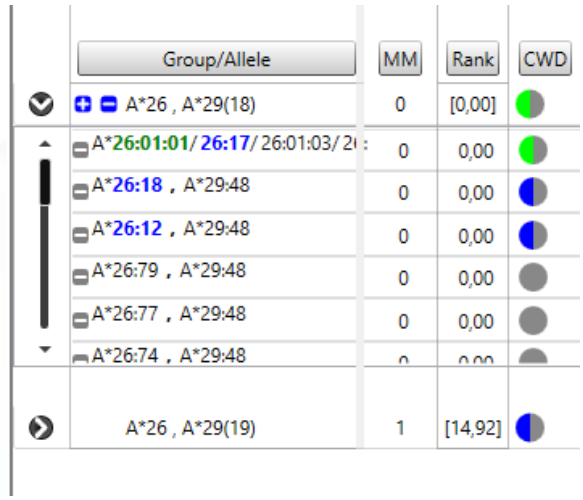


Two digit ambiguous groups will be displayed with more than one group; the title of the control will reflect this ambiguity.

You can remove individual results by clicking the '-' button in either the suggested results box or the main results view.



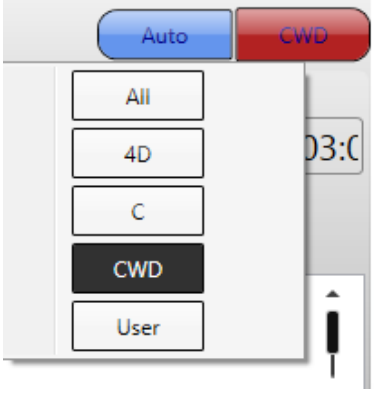
If the result contains only 1 CWD allele, this will be displayed as **Common Haplotype** above the suggested result, or if it contains no CWD allele, it will be displayed as **Suggested Rare Result**.



Results in the main result view, can be added or removed from the suggested results box, by using the '+' and '-' buttons. The blue buttons can also be used at group level to add or remove the entire group. But only fully matched results can be used.

14.6.2 Common allele filters

In the suggested results field you can choose between the display of all results or the display of only common alleles:



The common allele filters can be chosen by a mouse click on the red button and then selecting one of the options in the displayed window. The button will then show the selected filter.

All: results as described in 14.6.1

4D: A list of common alleles based on the population data on www.allelefrequencies.net . Alleles will be included in this list if they have a frequency ≥ 0,5 % in any population with a sample size ≥ 1000. Alleles on this list will generally be typed unambiguously on the 4 digit

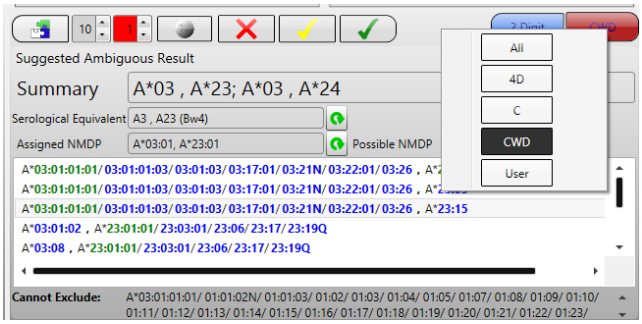
level using this filter with the HISTO SPOT 4D kits. This filter will be removed when all the the HISTO SPOT kits will resolve the C alleles.

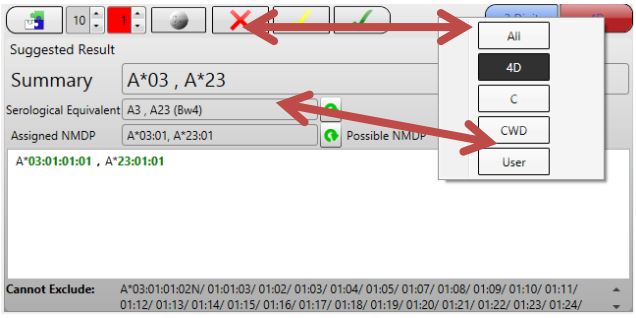
C: This list contains all common alleles of the CWD2.0.0 catalogue (Mack S.J. et al., Common and well-documented HLA alleles: 2012 update to the CWD catalogue, Tissue Antigens 81/4**,** 183-257 (2013)).

CWD: This list contains all alleles of the CWD2.0.0 catalogue.

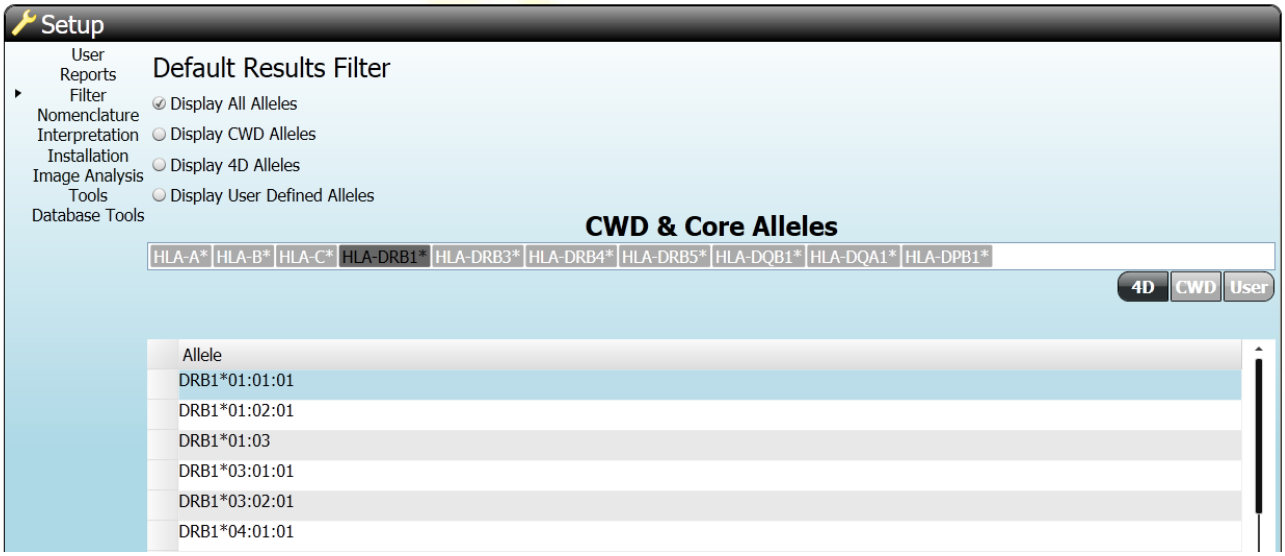
User: A user defined list of common alleles.

Using the filters will change the results as follows: In the results field only combinations of two common alleles are shown as a high resolution result. Below this field there is a list of rare alleles that cannot be excluded. After pressing the resfresh button the assigned NMDP code and the serological equivalent refer to the common alleles only.

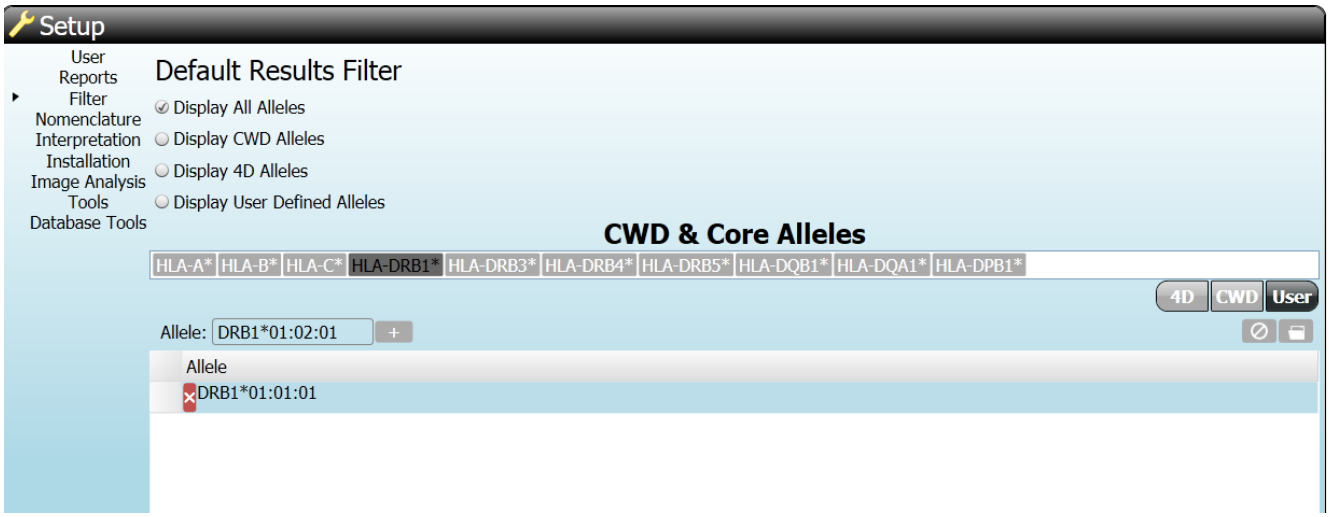




You can choose the default settings for the filters used in the interpretation under **Setup** and **Filter**. In the same screen the common allele lists can be reviewed and the user list can be edited.

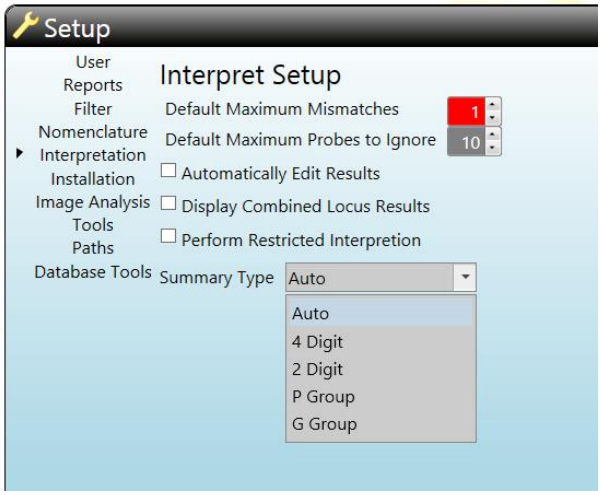


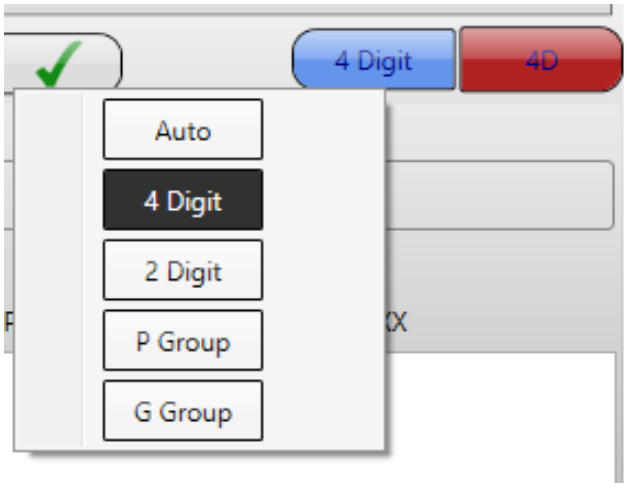
Alleles can be added and deleted from the user defined list manually using the **Allele** field and the **Add** and **Delete** botton. Alternatively, a complete list can be loaded from a text file with the button. You can also copy alleles from either the CWD or 4D and past them into the user list using the standard windows control keys: ctrl+a = select all, ctrl+c = copy, ctrl+v = paste.



14.6.3 Display options for the summary field

There are different options for the display of the results in the summary field. The default settings can be selected under **Setup** and **Interpretation**. They can also be selected for each individual test in the interpretation screen by a mouse click on the blue button.





Auto: The display is adjusted automatically to the chosen allele filter or **All** option.

4 Digit: The summary shows the allelic result depending on the chosen allele filter. When the **All** option is selected the 4D filter is applied automatically.

2 Digit: The summary displays the allele group result on 2 digit / 1 field level independent of the chosen allele filter.

P Group: The summary displays the P groups as defined in the WMDA file on the http:\\hla.alleles.org/wmda website.

G Group: The summary displays the G groups as defined on the http:\\hla.alleles.org/wmda website.

The P/G Group options will choose a group for each allele in the results (without duplicates). If there is no P/G Group (i.e. there is only a single allele in the official group) then the allele is reported.

14.6.4 NMDP codes

The possible NMDP code is assigned on the basis of all possible allele combinations if **All** is selected for the results display. If the common allele filter is switched on the assigned NMDP code is calculated based on the common alleles only. After returning to the **All** view this can be undone by pressing the refreshing button .

You can see which alleles are encoded in a NMDP code by moving the mouse over the result field: NMDP codes are regularly updated. The latest files are available at http://bioinformatics.nmdp.org/HLA/Allele_Codes/Allele_Codes.aspx. It is also possible to subscribe on a mailing list to get the updates automatically. The file "numer.v3.txt" has to be copied somewhere on the PC and can be imported under **Setup** and **Paths**.

14.6.5 Serological equivalents

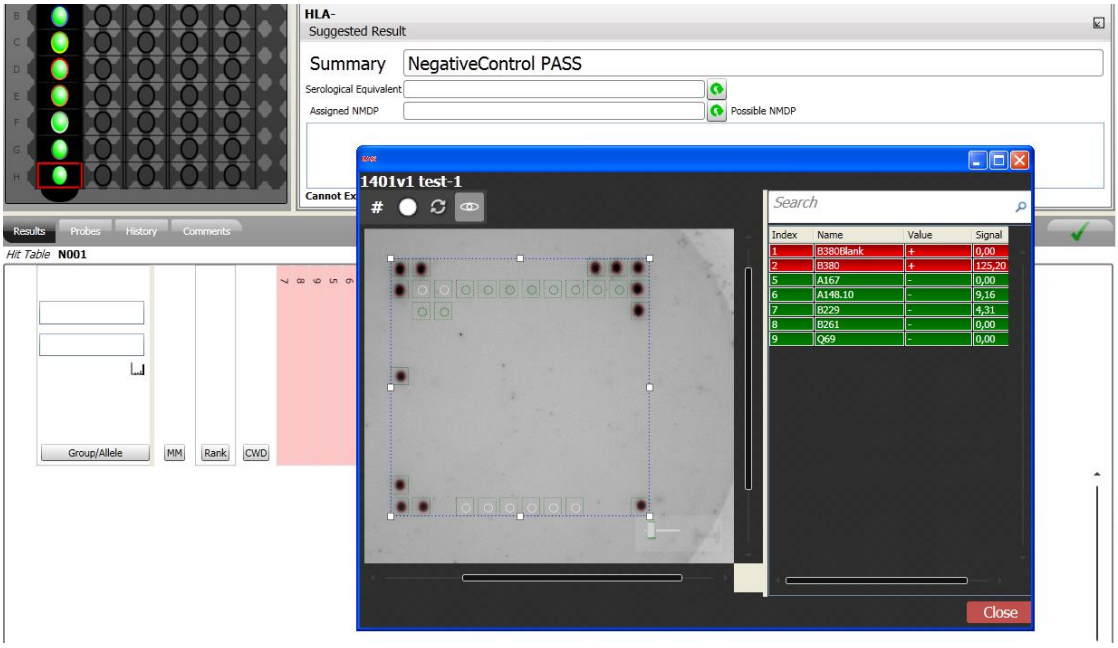
Serological equivalents are given on the basis of all possible alleles if **All** is selected for the results display. If an allele filter is used, the serologic equivalent relates to the possible common alleles only. After returning to the **All** view this can be undone by pressing the refreshing button .

14.6.6 Results Display for DPB1

Two digit (one field) ambiguities are not displayed as yellow dots for the DPB1 locus, because due to the naming of the DPB1 alleles (most of the 2 digit "allele groups" do only contain one or two alleles) the concept does not make sense. All results with 2 common alleles are, therefore, displayed as green dots.

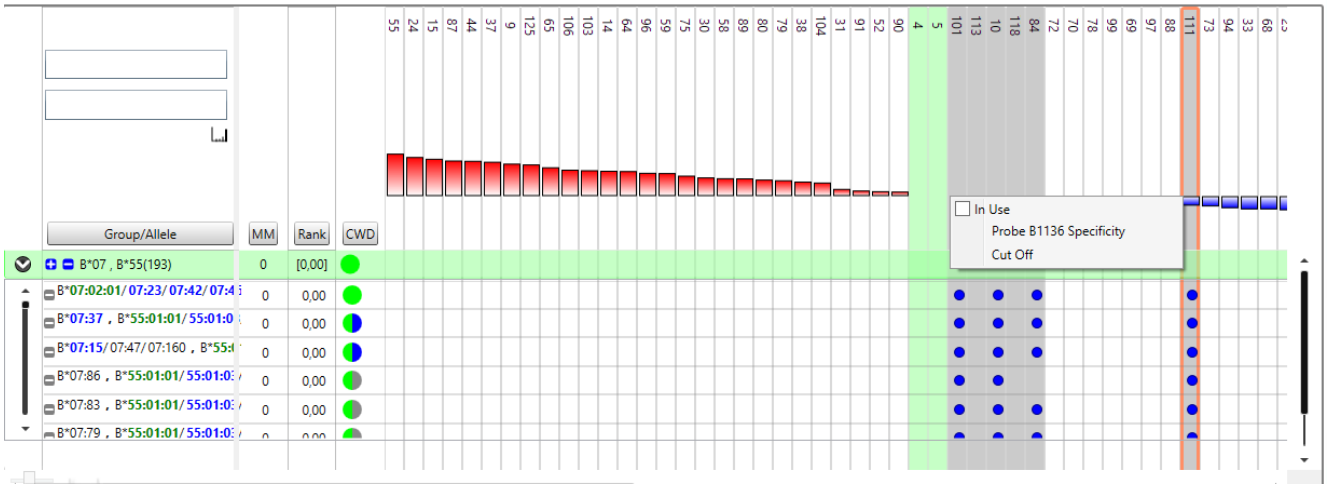
14.6.7 Negative Control

A negative control is currently included in the HISTO SPOT® On-Call Typingkit (REF 726070). It contains positive control probes for HLA-A (exon 2 and 3), HLA-B (exon 2 and 3) and one probe that is positive for the exon 2 of HLA-DRB1 and HLA-DQB1. The negative control fails when the intensity of the positive control spots is higher than 1.5 x the background.



14.7 Manually ignoring probes

You can manually ignore a probe by clicking the probe bar with the right mouse button and changing the status of the “in use” setting with a left mouse click. Manually ignored probes are highlighted in grey and are marked by a red frame.



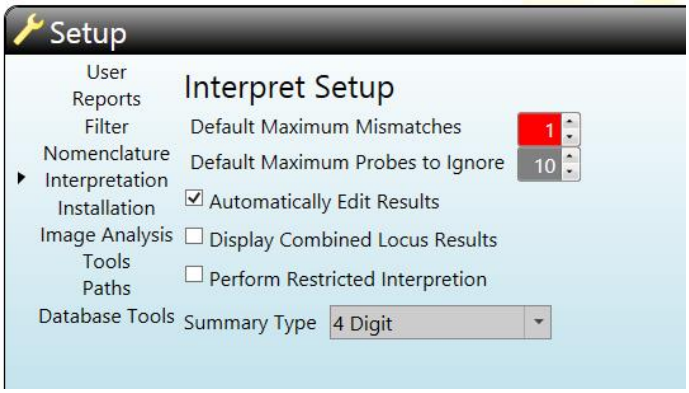
The following are the effect of the values of the check box:

Clear:	In Use	The probe will be excluded from the analysis.
Checked:	In Use	The probe will be included in the analysis.
Greyed:	In Use	The probe will be included or excluded automatically by the software.

The status of a probe can also be changed by clicking the left mouse button while holding the CTRL key. This presents a fast option to ignore several probes in a test. Reinterpret the results to view the changes.

14.8 Auto Edit Function

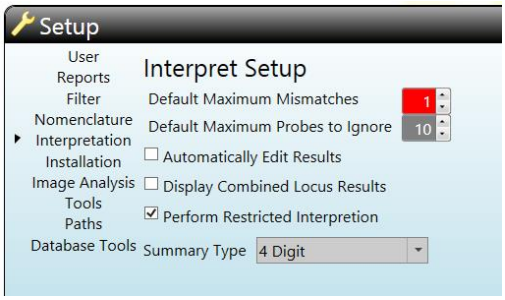
The function to automatically edit results can be switched on or off under **Setup** and **Interpretation**:



If it is switched on, probes that are not matching the reaction pattern of the result that is finally found (2 CWD) are automatically set to “inactive”. As a result, probes that were automatically ignored during the initial interpretation, but are matching the reaction pattern of the result that is finally assigned, are switched on again and used for the interpretation. This reduces ambiguities that are due to the lower resolution caused by ignoring probes that are reacting correctly. Probes set “inactive” by the function “Automatically Edit Results” are marked by a red frame in the histogram, analogous to the display of probes manually set “inactive”. In the history those probes are recorded with the user ”Auto Edit”.

14.9 Perform restricted interpretation

This function makes the interpretation much faster by ignoring combinations of two rare alleles. The restricted interpretation is inactivated by default and can be activated under **Setup** and **Interpretation**:



During the full interpretation all the reaction patterns in the hit table are combined with each other to calculate all possible combined reaction patterns. This is a huge amount of data (around 1.5 million patterns for the B kit).

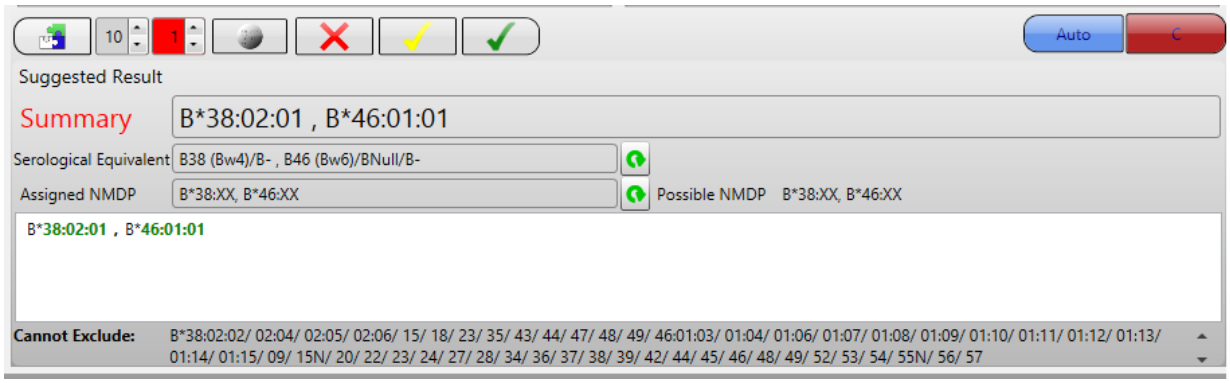
Since combinations of two rare alleles will never really occur (likelihood less than 1 in a million) the interpretation can be restricted to pattern combinations that include at least one common allele. This will reduce the time for interpretation of a result for the B locus from 20-30 sec to 2-3 sec and will use less memory.

The consequence for the result will be:

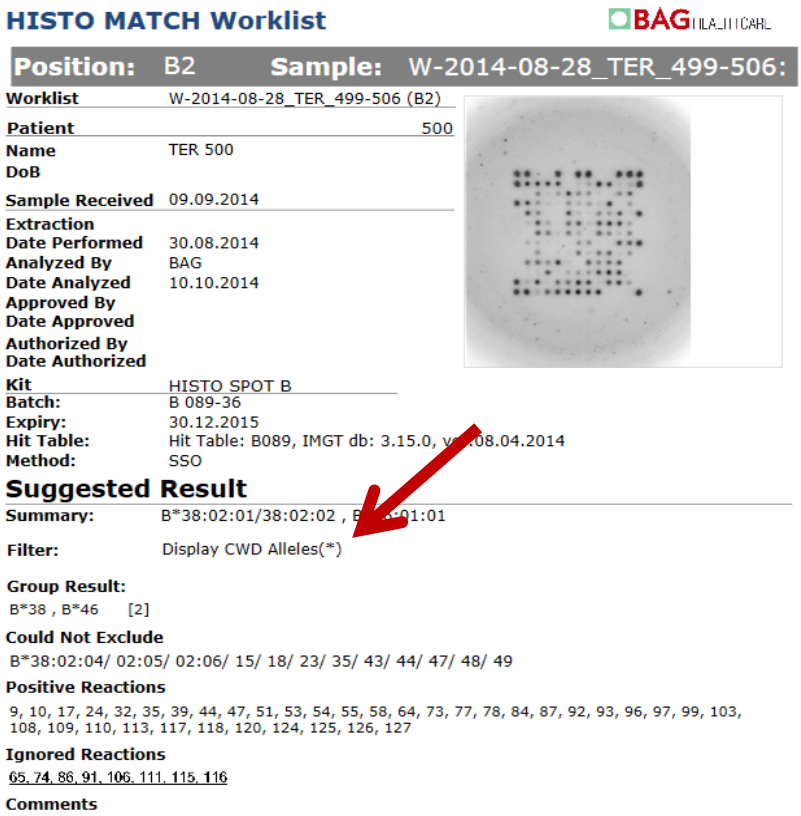
a) no match is found for a combination of two rare alleles

b) rare alleles that are only possible in combination with another rare allele will not be listed in the section **Cannot exclude.**

If a restricted interpretation is done the summary header will be displayed in red:



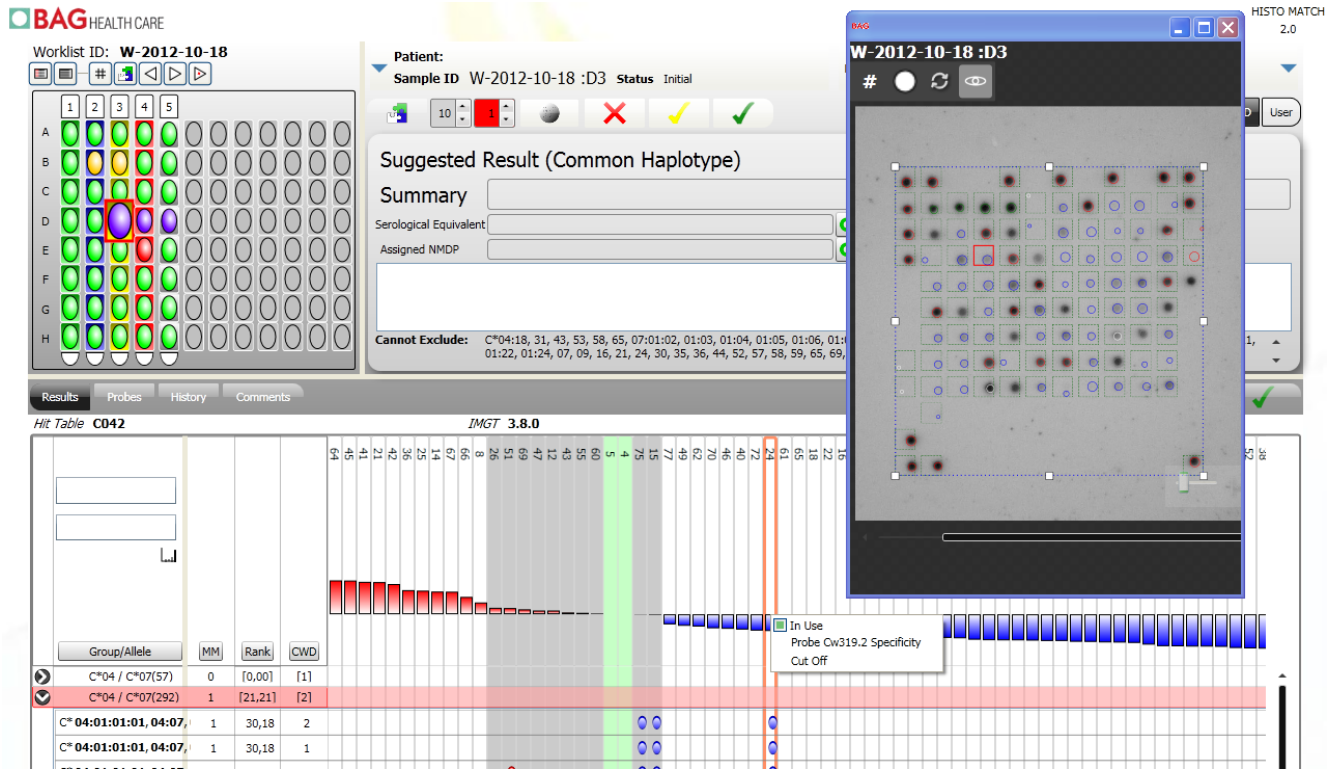
In the typing report there will be "*" suffix for the selected filter:



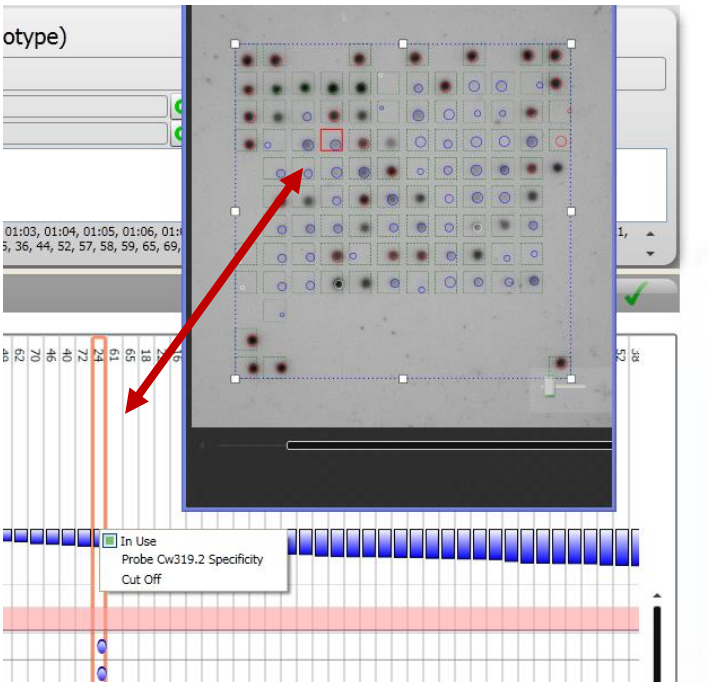
It is possible to perform a full interpretation (when restricted interpretation is activated) from the interpretation screen by pressing the **Interpret** button while holding the CTRL key.

14.10 Interactivity between results view and assay image

Opening the array view enables the user to see the image of the processed test and the status of the single probes.



The highlighted probe in the results table (orange square) is also highlighted in the image view and the other way round.



The colour of the circles indicates the status of the probe:

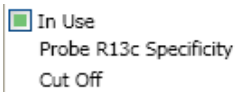
Green: control probe
Blue: negative probe
Red: positive probe
Black: ignored probe
White: inactive probe (not functional)

Moving to the next test in the results view also switches the image. Therefore, it may be useful to leave the window open throughout the interpretation.

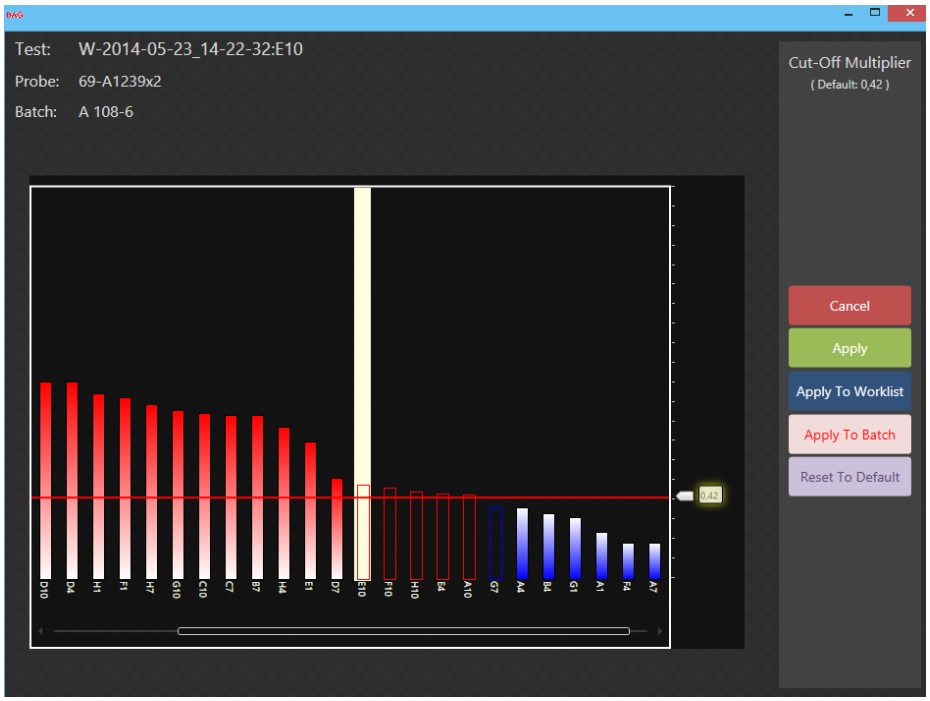
The size of the results table and the size of the array picture can be changed by pressing the CTRL key and turning the mouse wheel at the same time.

14.11 View probe reactivity and change cut off

The reactivity of a probe in relation to the cut off can be displayed for all the tests of a specific worklist. To open the cut off window, click the probe bar with the right mouse button and click on "Cut Off"



The tests of the worklist are sorted according to the intensity of the probe. The red horizontal line indicates the cut off. The active test (opened for interpretation) is highlighted in white. In tests with empty bars the probe has been ignored automatically or manually. This is a helpful tool to evaluate the quality of a probe in general and to decide if a probe should be ignored or not.

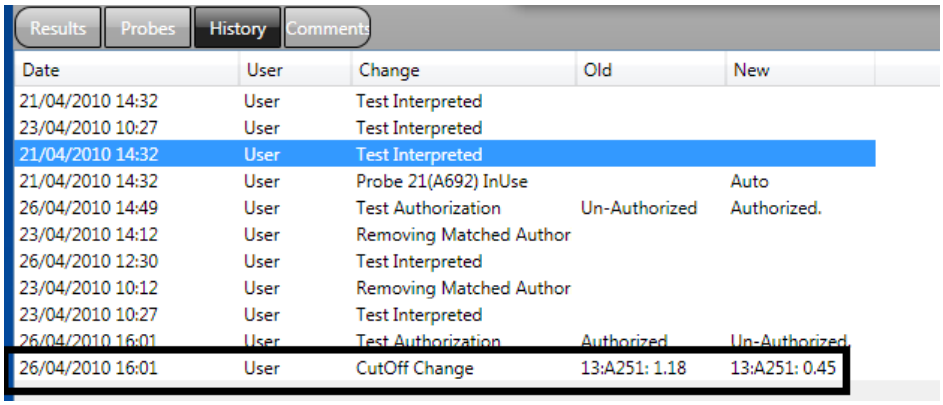


The user can also make changes to the cut off for each probe in this window, and optionally assign the new cut off to the probe in the current test, in every test on the worklist, or use the new cut off for all future use of the probe for this batch. Drag the slider on the right side to change the cut off.

The following options are available:

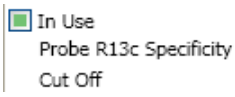
Cancel: Cancel all cut-off changes from this screen.
Apply: Apply cut-off changes to this test.
Apply to Worklist: Apply this change to all tests using this batch in the worklist.
Apply To Batch: Make all future tests using this batch use the new cut-off. Cut off changes for the whole batch can only be made by the supervisor and require a comment.
Reset To Default: Reset the cut off to the manufacturer supplied value.

Any changes to the cut off value are tracked in the history.

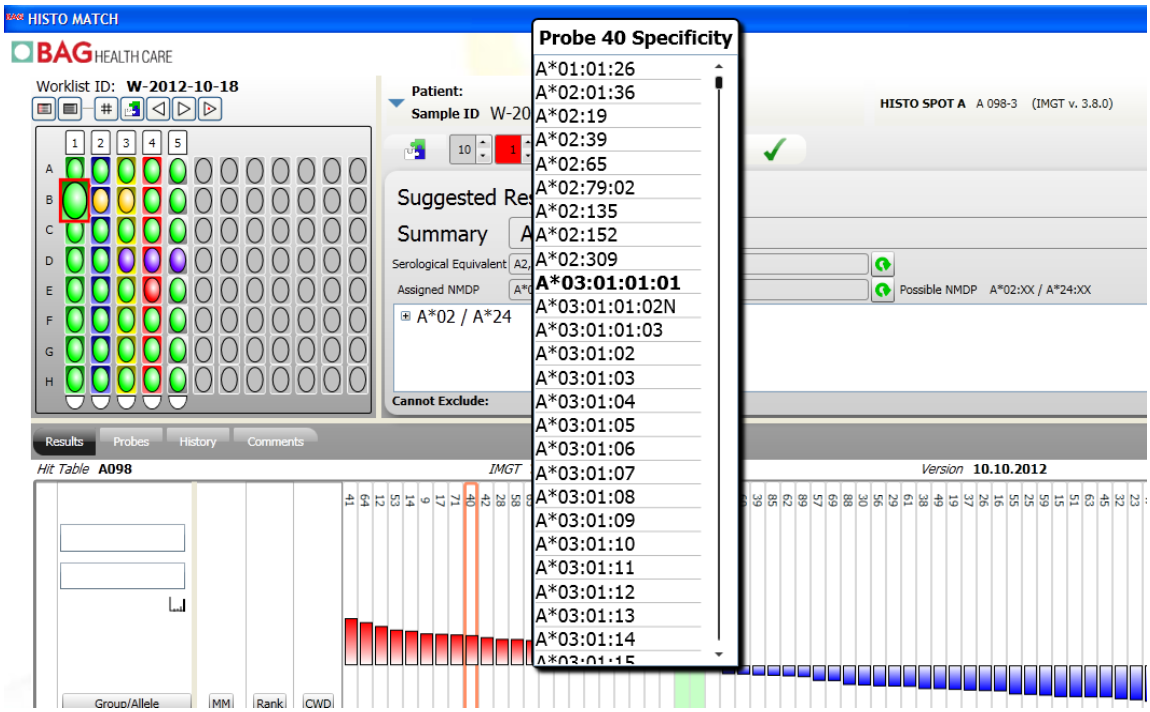


14.12 Show probe specificity

To show the specificity of a probe go to the probe bar in the interpretation screen and click the right mouse button. Choose probe specificity

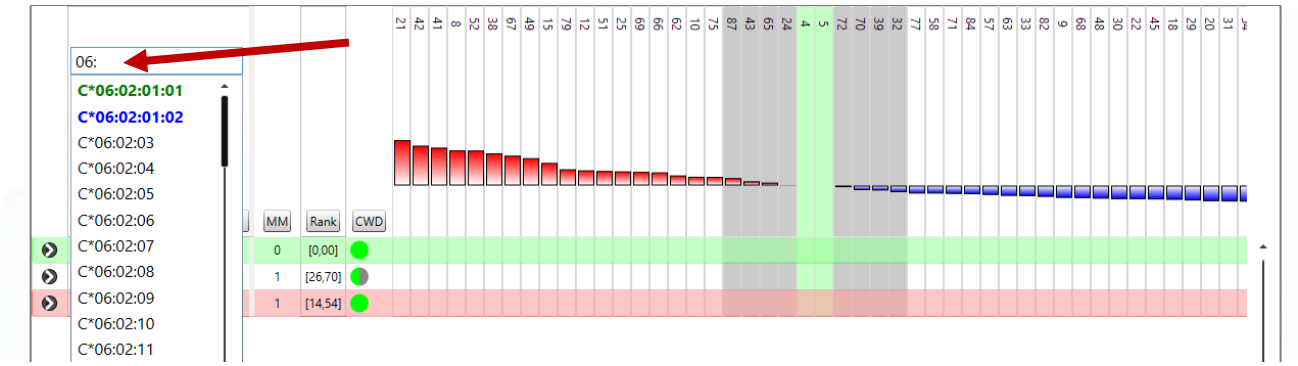


A window with the list of the alleles that are reacting with the probe will open.

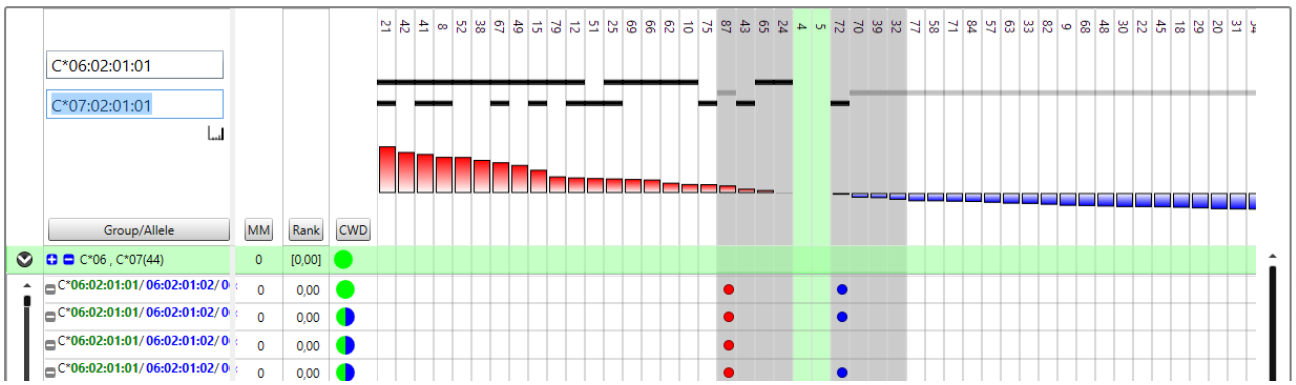


14.13 Allele Pattern Display

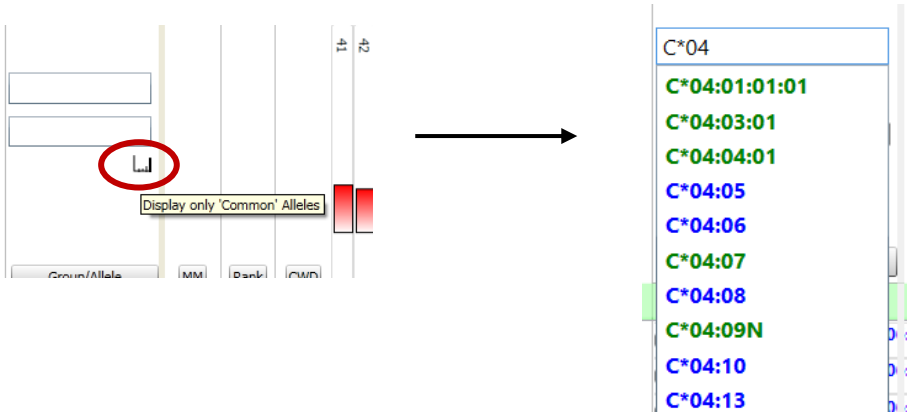
During interpretation it may be helpful to view the reaction pattern of certain alleles or allele combinations. Start typing part of the allele you would like to see in the empty allele field. You can then choose one from the list or type it completely.



Select the allele combination for which you want to see the reaction pattern. Positive probes are marked with a black bar for the respective allele, questionable probes remain grey. Negative probes have a grey bar and are not assigned to an allele.



Clicking on the histogram symbol below the allele fields reduces the displayed list to the CWD alleles.



14.14 Nomenclature display

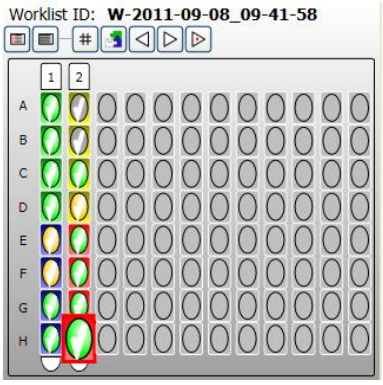
HISTO MATCH can use either to force the IMGTv3 nomenclature or use the source IMGT version for display. The results are displayed in the same way in both, the suggested result view or the main result list. The display can be changed in the **Setup** screen by choosing **Nomenclature**.

14.15 Approving and authorizing results

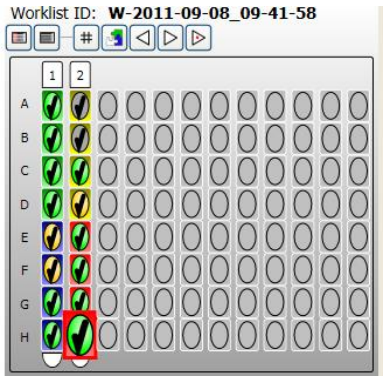
The software supports a two stage authorization process. When a result has been analyzed it can first be approved by a user in the user role (usually a technician) by pressing the approval button . Approved test will be checked by a white check mark. Approval of tests is not mandatory, e.g. they also can be authorized directly.

Afterwards, it can be authorized by a user in the supervisor role, by pressing the authorize button . The test will be authorized, and the next test will be selected. Authorized tests will be flagged with a black check mark on the plate and list view. Clicking the authorize button again will un-authorize the test. Authorized results are fixed and cannot be changed unless they are un-authorized again by a user with the supervisor role.

Approved worklist:

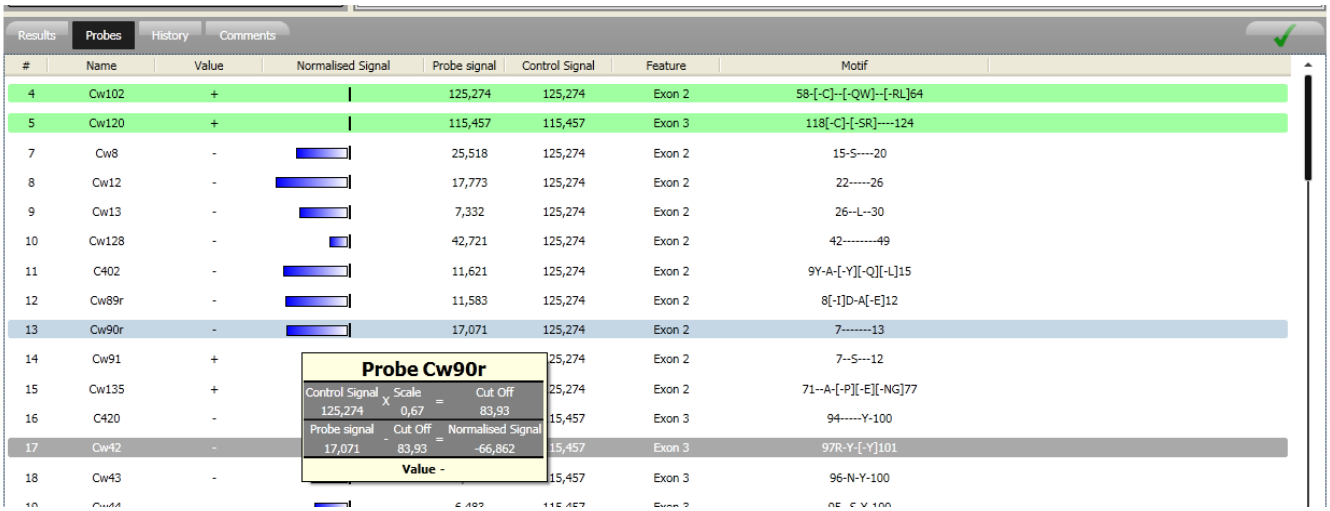


Authorized worklist:



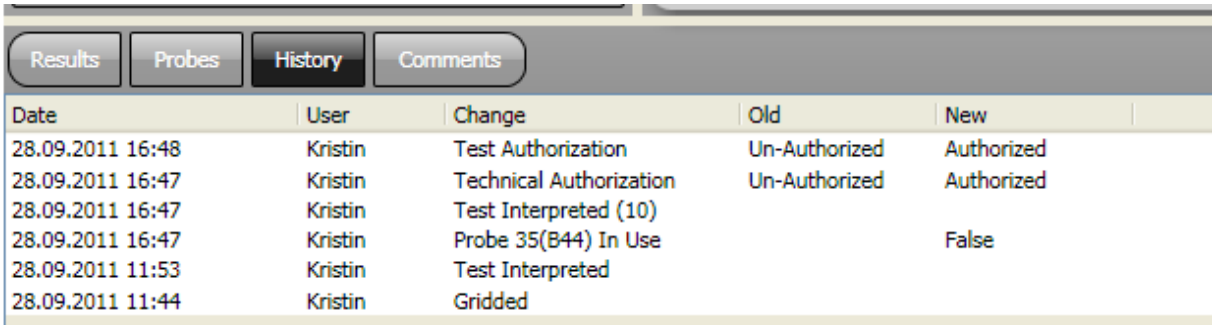
The status of the authorization is indicated in the worklist screen (see 11.3.1 Worklist status).

14.16 Probes view



Clicking the **Probes** button will display the probe view table. This contains intensity information for the probe, the control used and cut off information. Moving the mouse over the signal graph will display the calculation used to calculate the probe value. The last two rows give the exon where the probe is located and the probe binding site.

14.17 History view

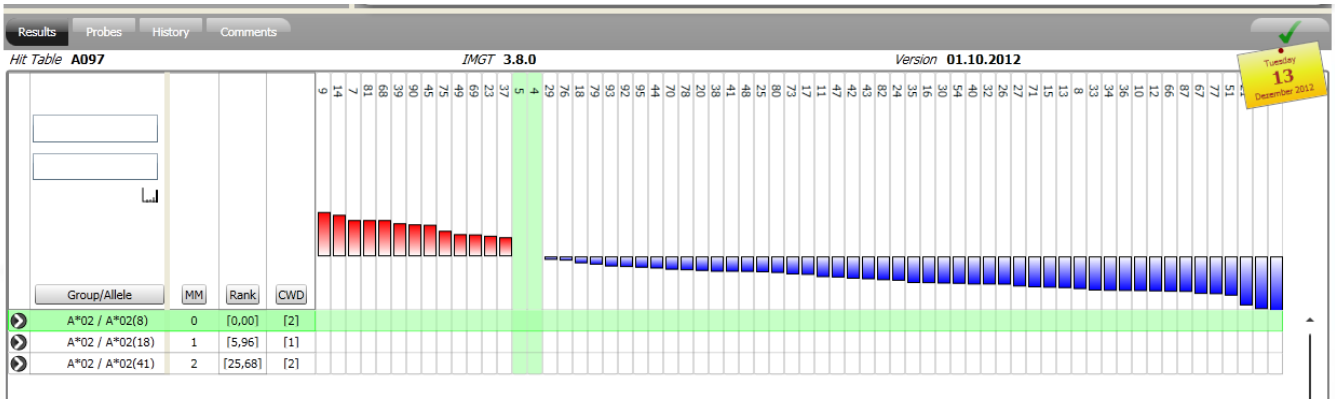


This view displays all changes that the user has made to the test, including any grid changes.

14.18 Result comments

Use this view to add comments about the result. Use the **Add** button to add a comment.

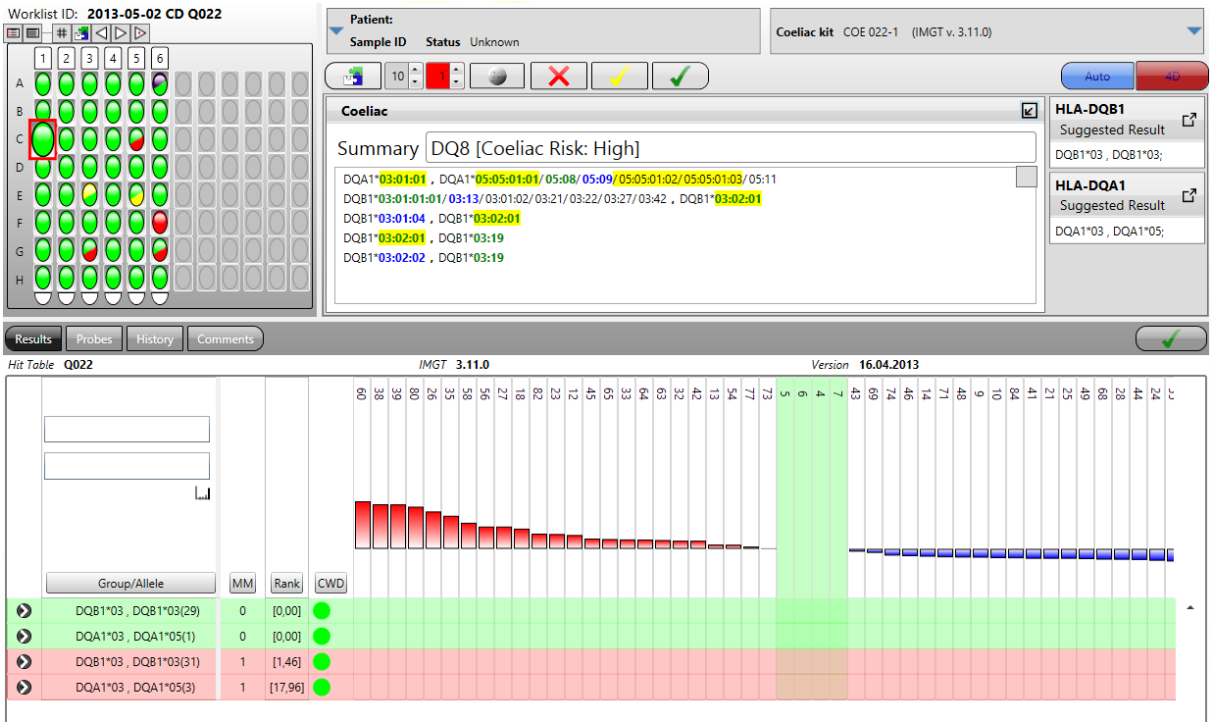
If the “sticky” button is checked, a tag with the date will appear to mark that a comment has been added. This will also be visible in the results screen.



14.19 Interpretation for the HISTO SPOT® Coeliac Disease and DQB1 4D / DQA1 Kit

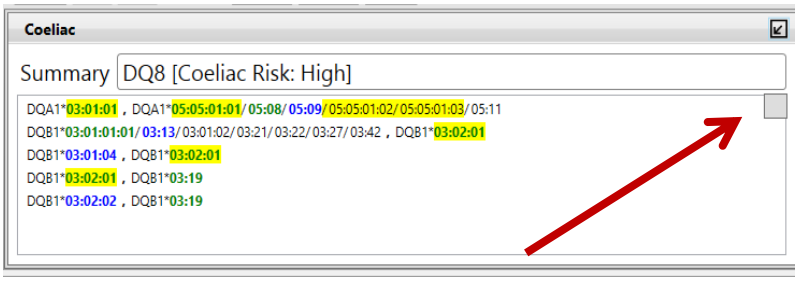
14.19.1 Coeliac disease view

The kit for typing coeliac disease associated alleles combines a DQB1 and DQA1 test in one well. Therefore, the results display looks a bit different from the one for single locus kits. Furthermore the screen displays the results in the context of coeliac disease. The default display for the coeliac disease kit is the following:

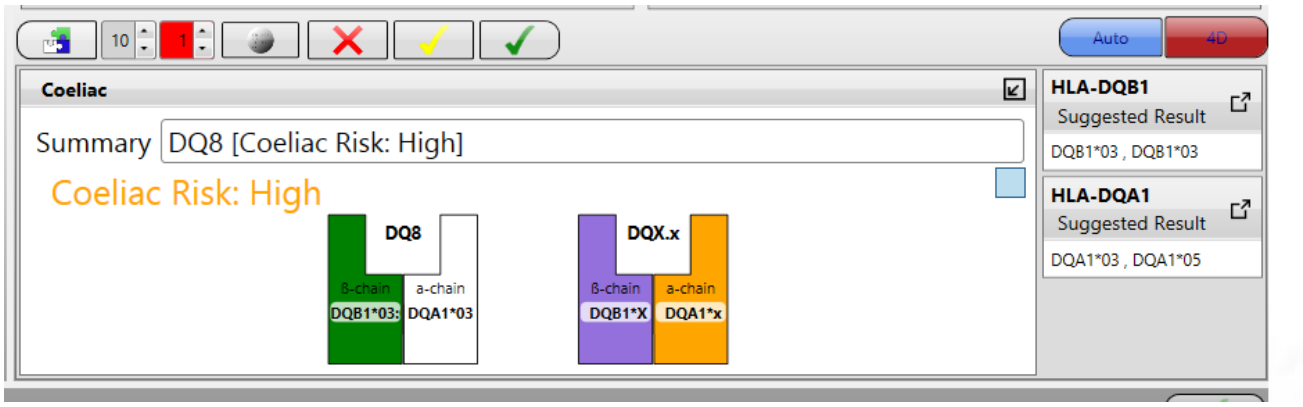


All the probes for DQA1 and DQB1 are displayed and possible allele combinations for both loci are included in the results histogram in the lower half of the screen. The dots are divided if the status for the DQA1 and the DQB1 test are different.

All allele strings that are fitting to the reaction pattern without mismatches and do contain at least one common allele (4D filter), are transferred to the results field. Coeliac disease associated alleles are highlighted in yellow. The summary gives the name of the possible coeliac disease associated DQ molecule. On the right side of the results field the low resolution result for DQA1 and DQB1 is displayed. The common allele filters have no influence on this results display.



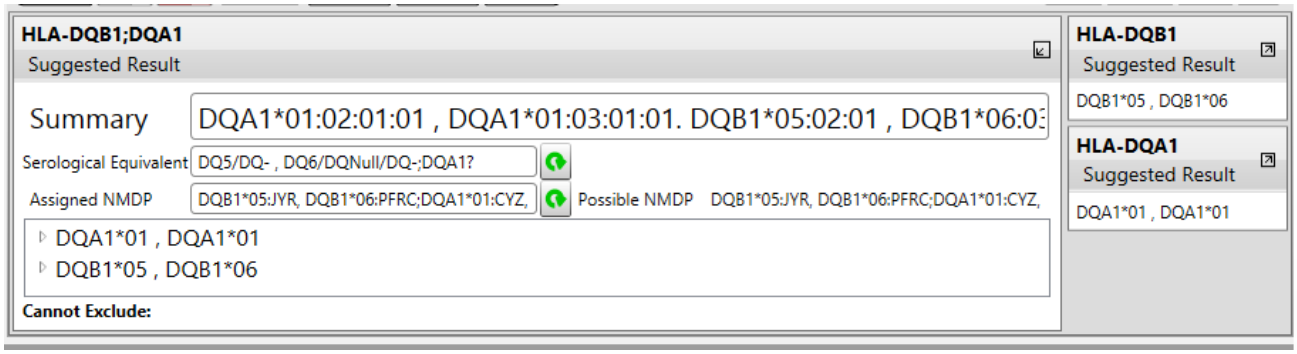
Pressing the button in the upper right corner of the results field changes to the haplotype view and the risk assignment for coeliac disease (based on Megiorni and Pizzuti, Journal of Biomedical Science 2012, 19:88).



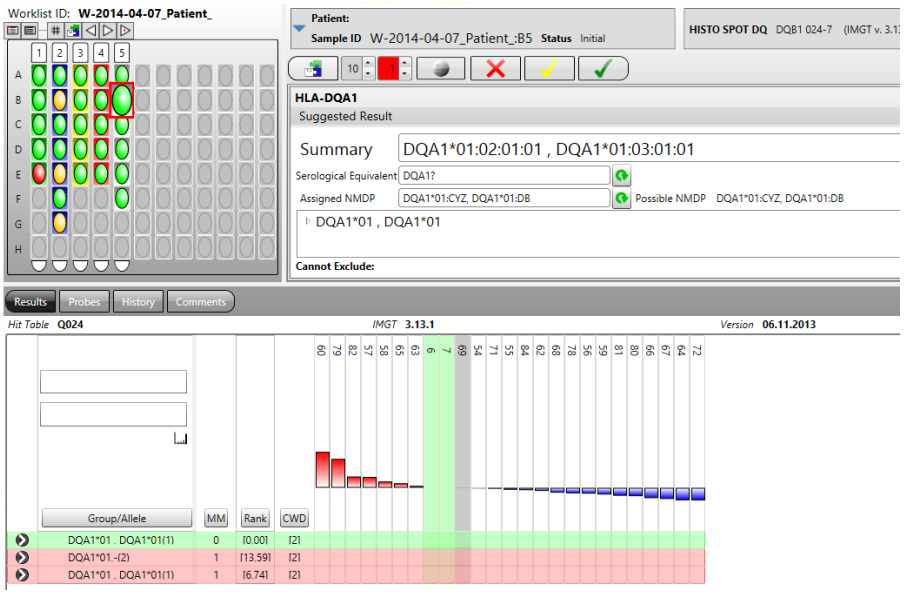
This view shows a diagram with the possible DQ molecules and the associated risk for coeliac disease. The screen is changed to the usual DQA1 and DQB1 interpretation screen by clicking on the arrows in the upper right corner of the results windows as described in the next chapter(,).

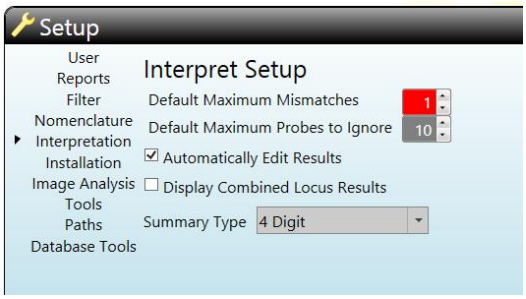
14.19.2 DQB1 / DQA1 interpretation

The default screen when using a HISTO SPOT® DQB1 4D / DQA1 kit looks like this:



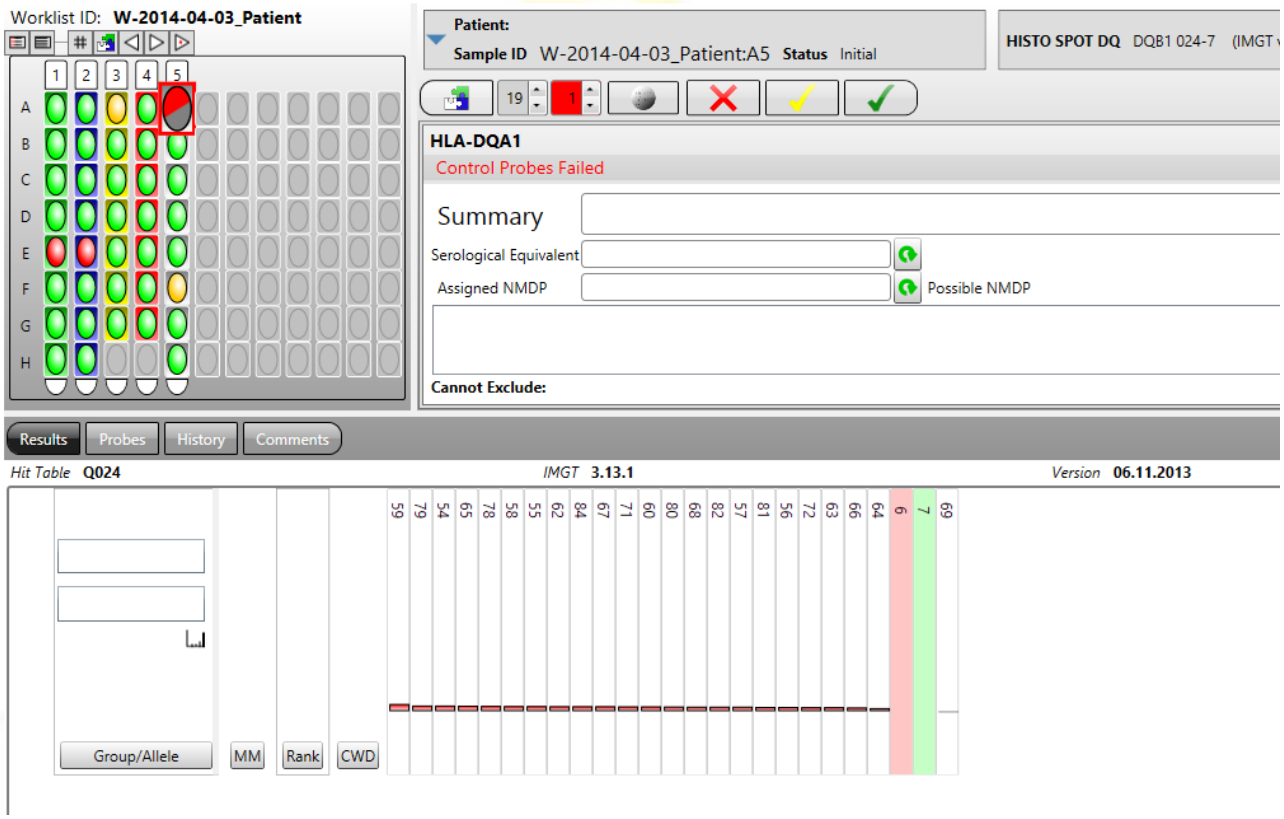
Both loci can be interpreted together or each of them separately. If one of the loci is selected the probes in the results histogram are filtered as well, i.e. only DQA1 or DQB1 specific probes are displayed:





It is possible to inactivate the combined display under **Setup** and **Interpretation** by unchecking the "Display Combined Locus Results" field.

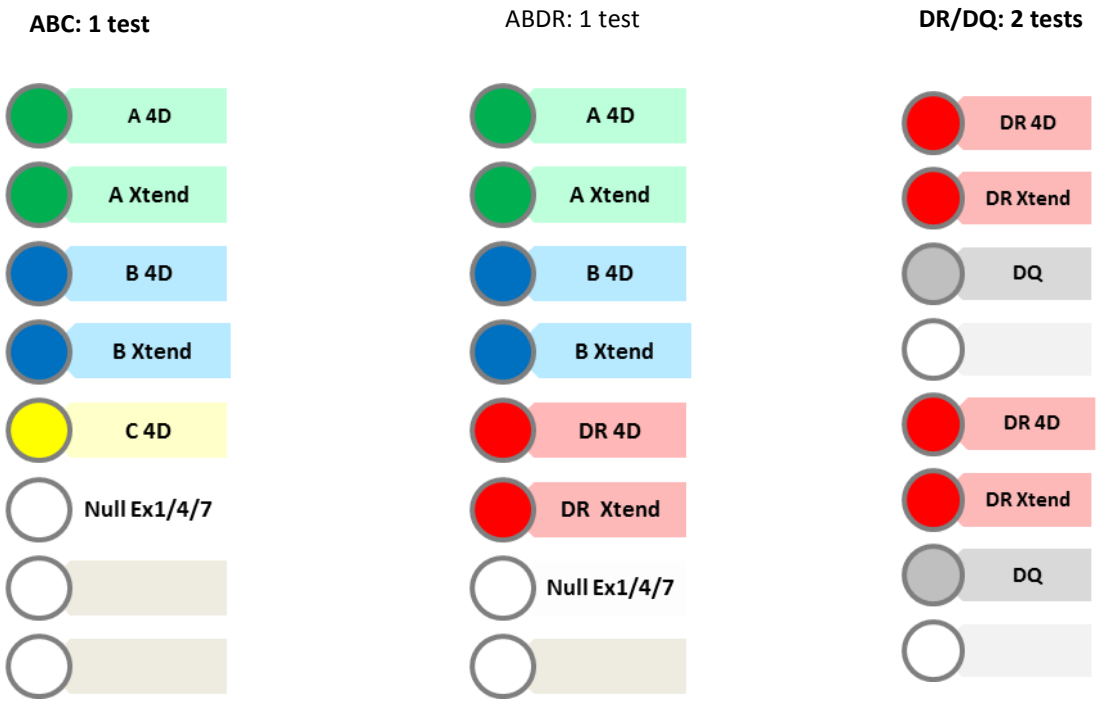
If the control probes for one of the loci failed the test will be marked in grey/red. The other test can still be interpreted.



The two loci will be reported separately in the typing reports and in the different export formats.

14.20 Interpretation of the HISTO SPOT® CWD high res and Xtend kits

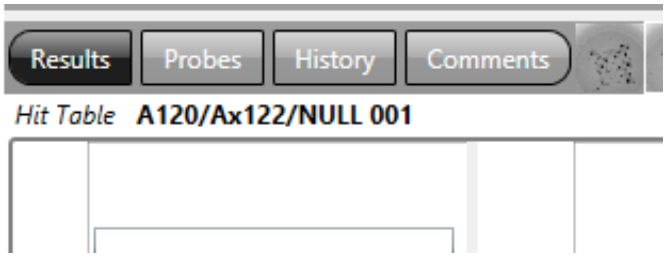
The HISTO SPOT® CWD high res kits are designed to type several loci in one combined strip on a higher level of resolution. To achieve this more than one test well is used to type some of the HLA loci. The kit design is illustrated in the picture below. Please do also refer to the IFU for the HISTO SPOT® kits for more information.



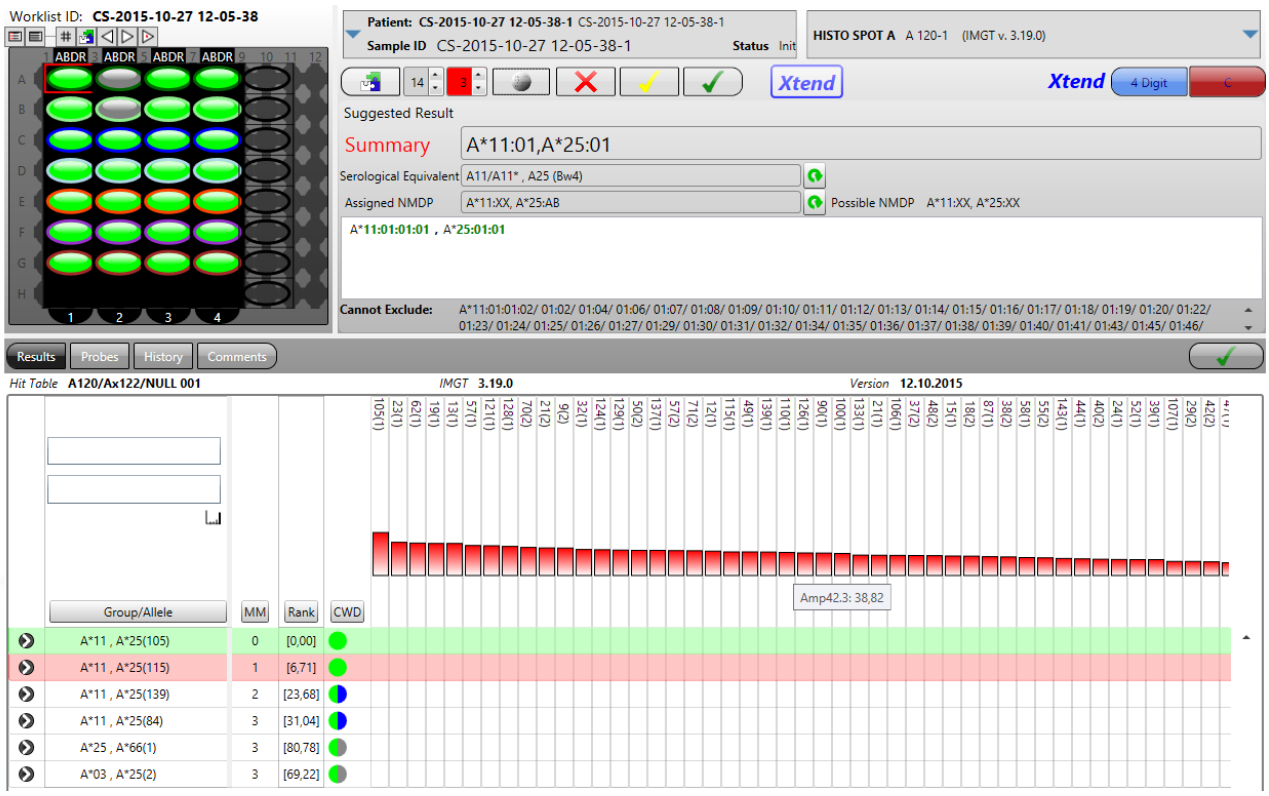
HISTO MATCH uses the probes in both wells for the interpretation of the A, the B and the DRB1 locus. The well for the Null alleles contains probes for common HLA class I alleles. They are included in the interpretation of the locus, too.

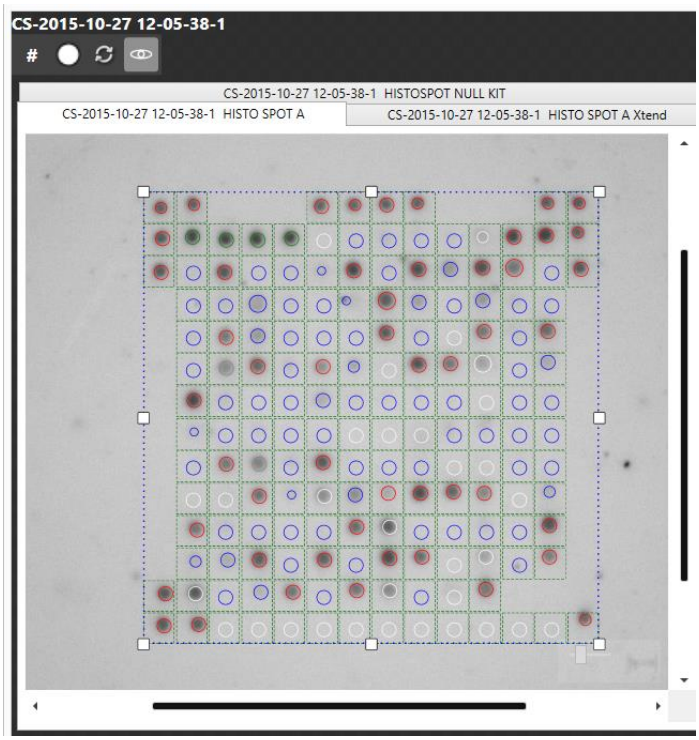
The Xtend kits contain single wells that can be combined with regular 4D kits as described in chapter 11.9 Create tests and worklists with Xtend and Null kits. The interpretation is done in the same way as for the pre-combined CWD high res combistrips.

The summarized results can be viewed and edited by selecting the first well / 4D well of a test. The blue lettering ***Xtend*** indicates that it is a high res test with more than one well. The hit tables used for the interpretation are indicated at the top of the interpretation histogram and all probes are combined here.



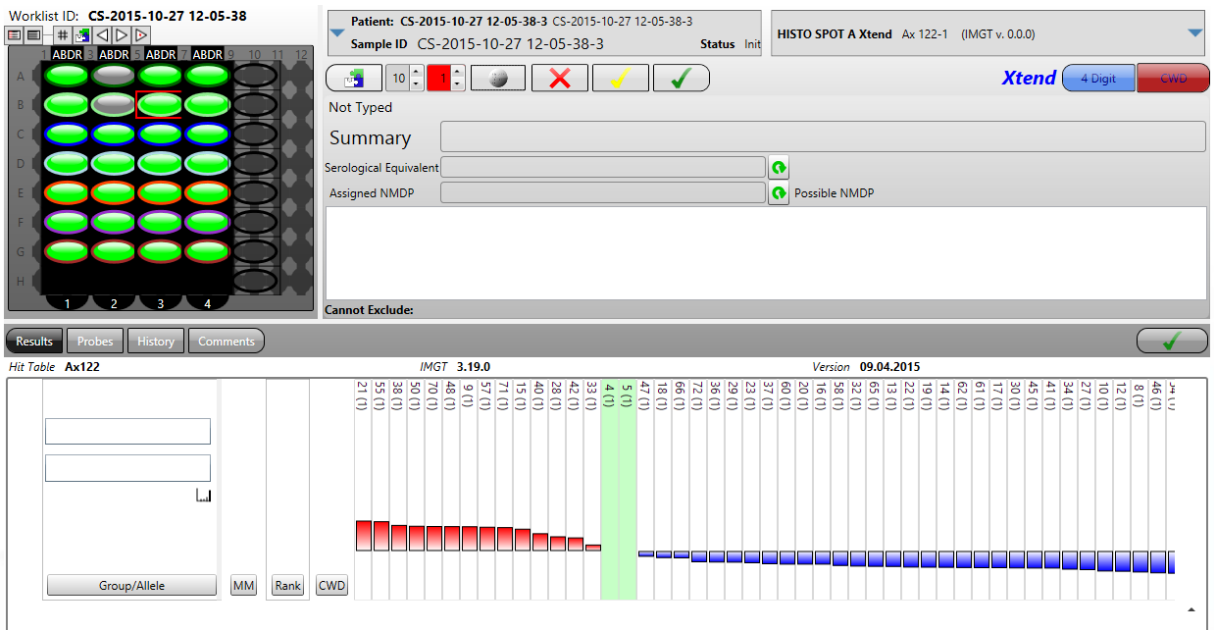
All interpretation functions available for the other HISTO SPOT® kits, described in the previous chapters, apply for the interpretation of the CWD high res kits and the Xtend kits, too. The number in brackets behind the probe number indicates in which well the probe is located.



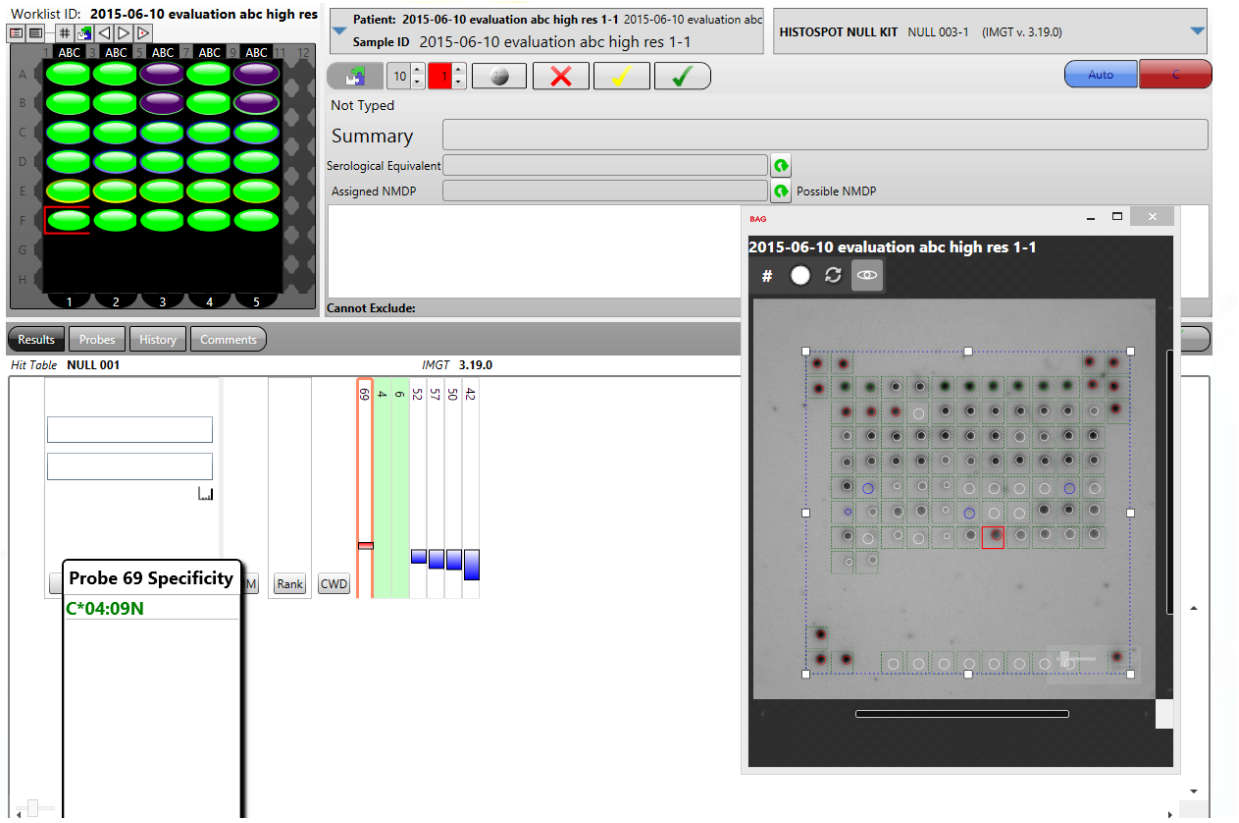


All images of the combined tests are accessible from the 4D well. You can switch between them by clicking on the headers. If a probe is selected in the histogram the correct image is shown automatically.

When you switch to the Xtend or Null allele wells there is no results summary and only the probes contained in the selected well are shown. It does not make sense to interpret the Xtend wells separately.



In the Null allele well you can check the image and have a look at the specificity of the probes:

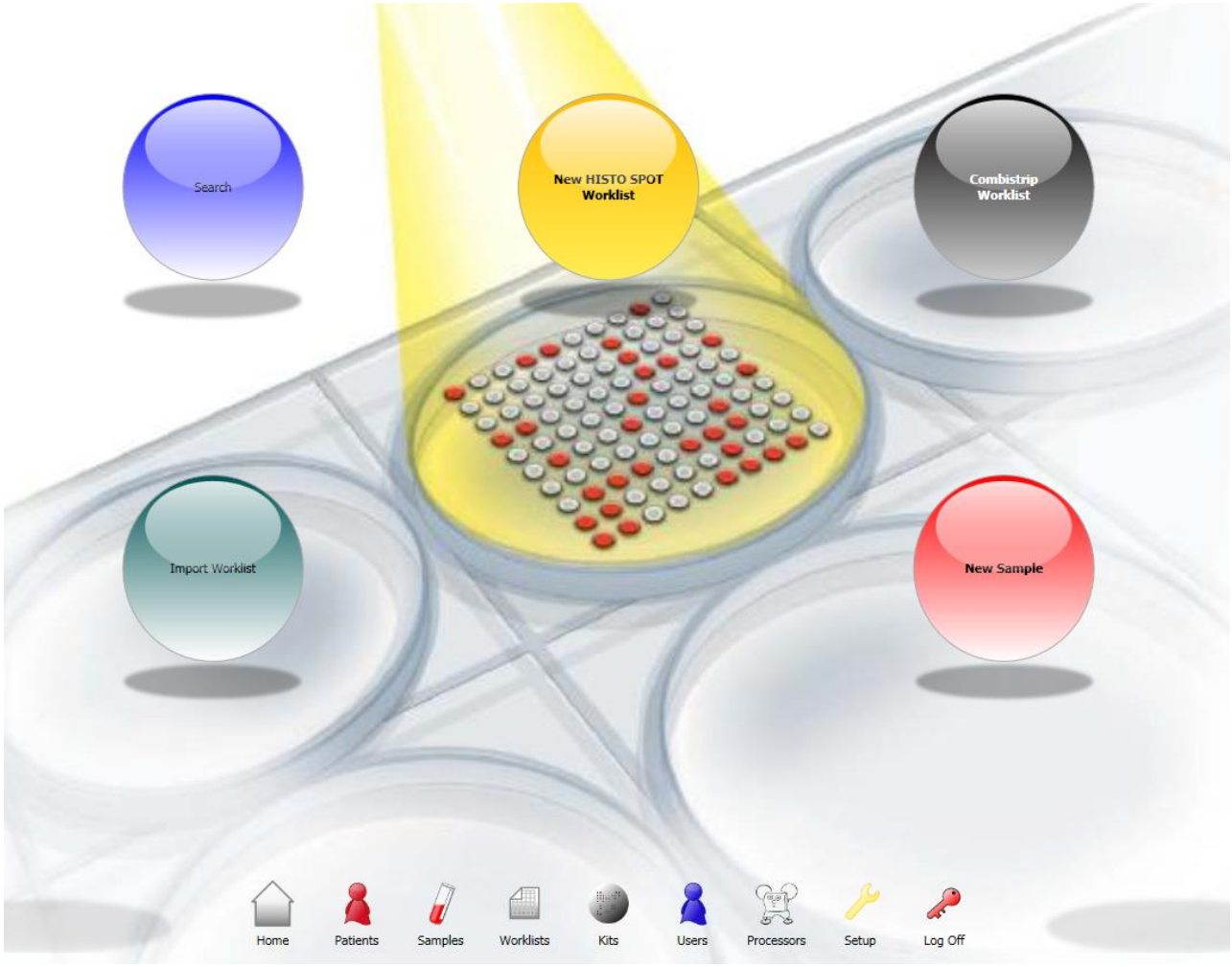


15 INTERPRETATION OF HISTO TYPE SSP TESTS

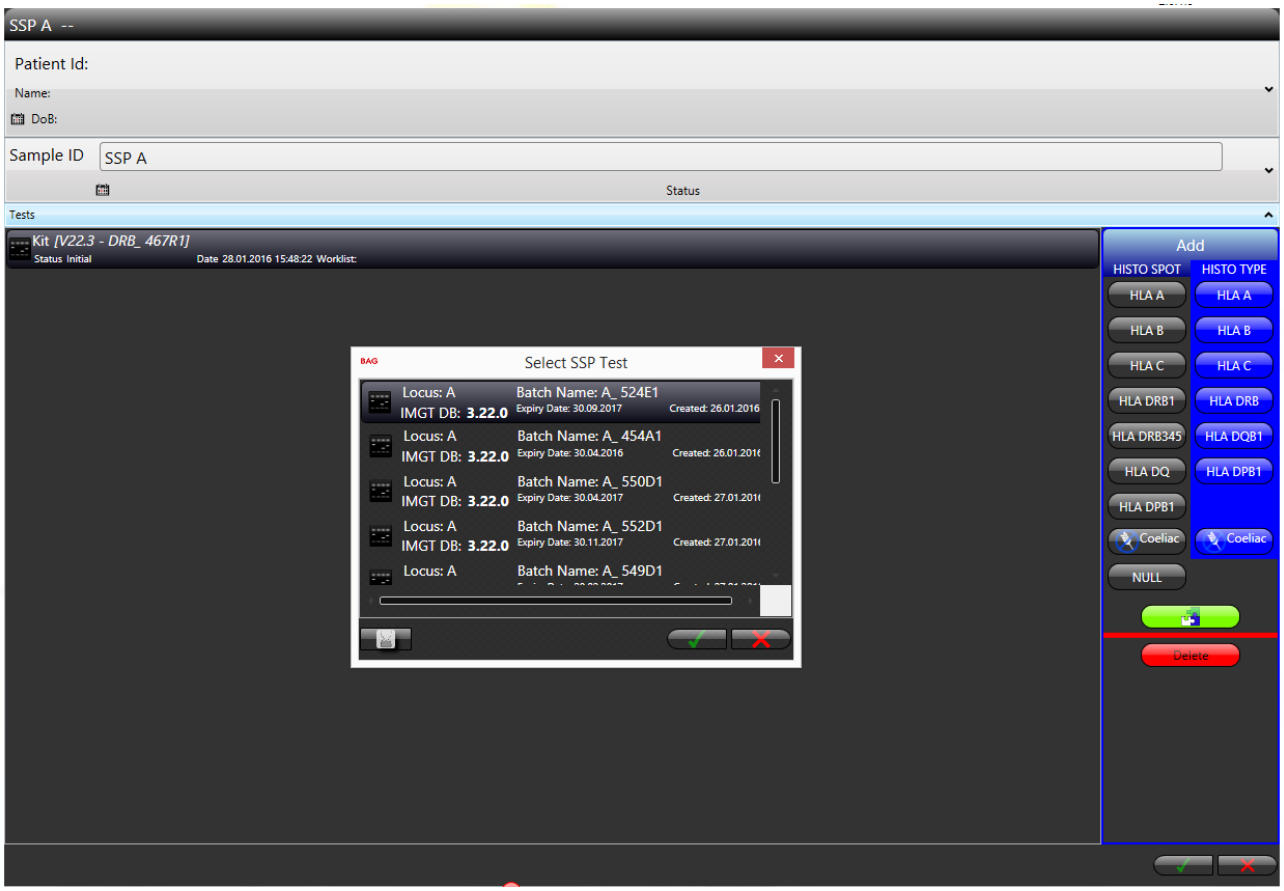
15.1 Import a typing kit

Typing kit files for HISTO TYPE SSP are imported into HISTO MATCH in same way as HISTO SPOT SSO kits: see 6.4 Import kits. It may take a few seconds until the kit files are shown in the import window.

15.2 Define patient, sample and test



In the home screen select **New Sample**. A sample screen open where sample information and SSP tests can be added. Alternatively, define or select a sample that may or may not belong to a patient from the patient or sample management screen (see 9 Patient Management and 10 Sample Management). Then add a new HISTO TYPE SSP test. A window with the available kits for the selected locus opens.

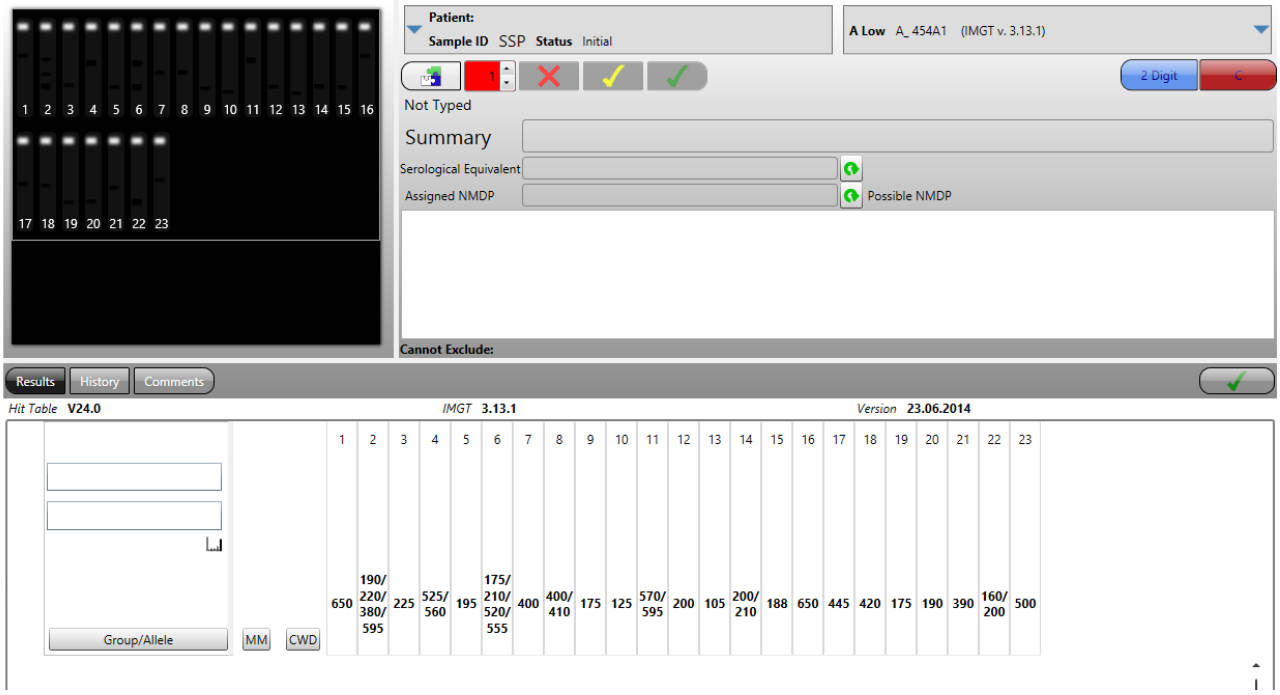


Select the batch you are using and press the **Save** button . The test appears in the list of tests for the sample. By pressing the button expired batches can be hidden or shown if there are too many batches. To enter results for a test you can open the interpretation screen by either double-clicking on the test or by pressing the green **Interpret** button . The interpretation screen shows a virtual gel where the positive reactions can be entered.

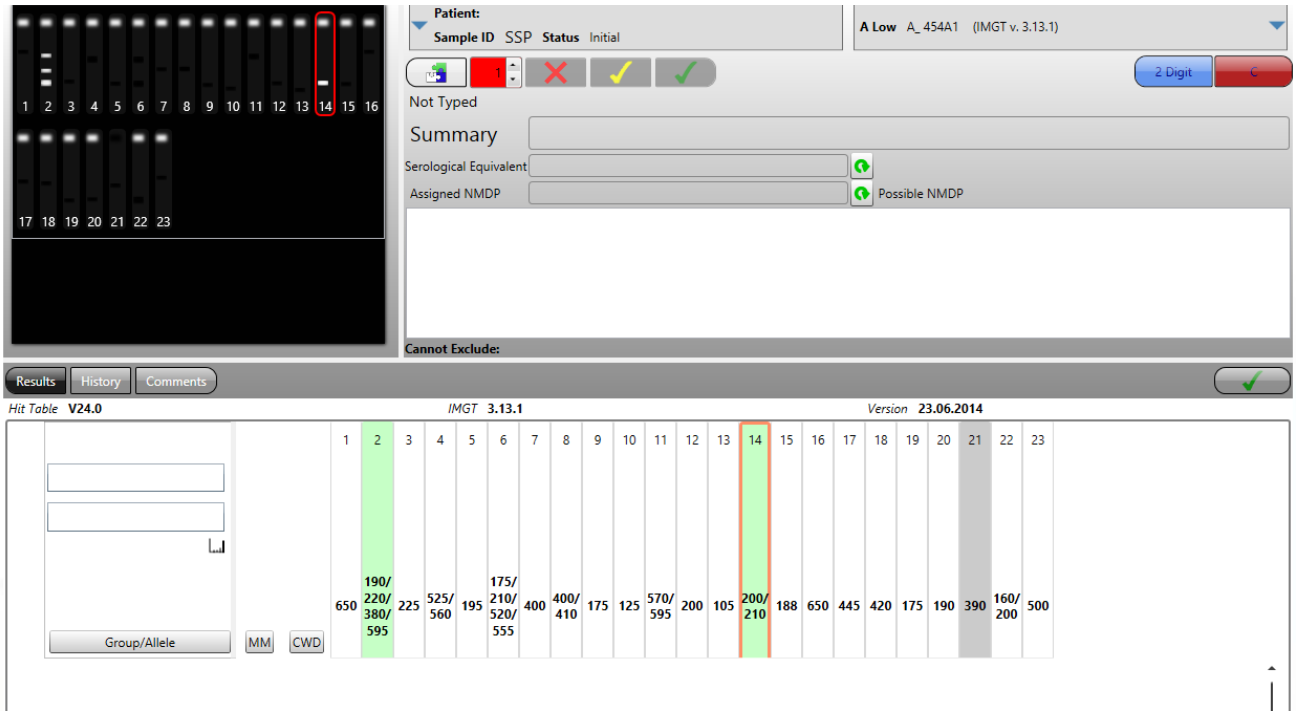
You can also delete tests by pressing the red **Delete** button.

15.3 Interpreting HISTO TYPE SSP tests

The positive reactions can be entered into the virtual gel in the interpretation screen:

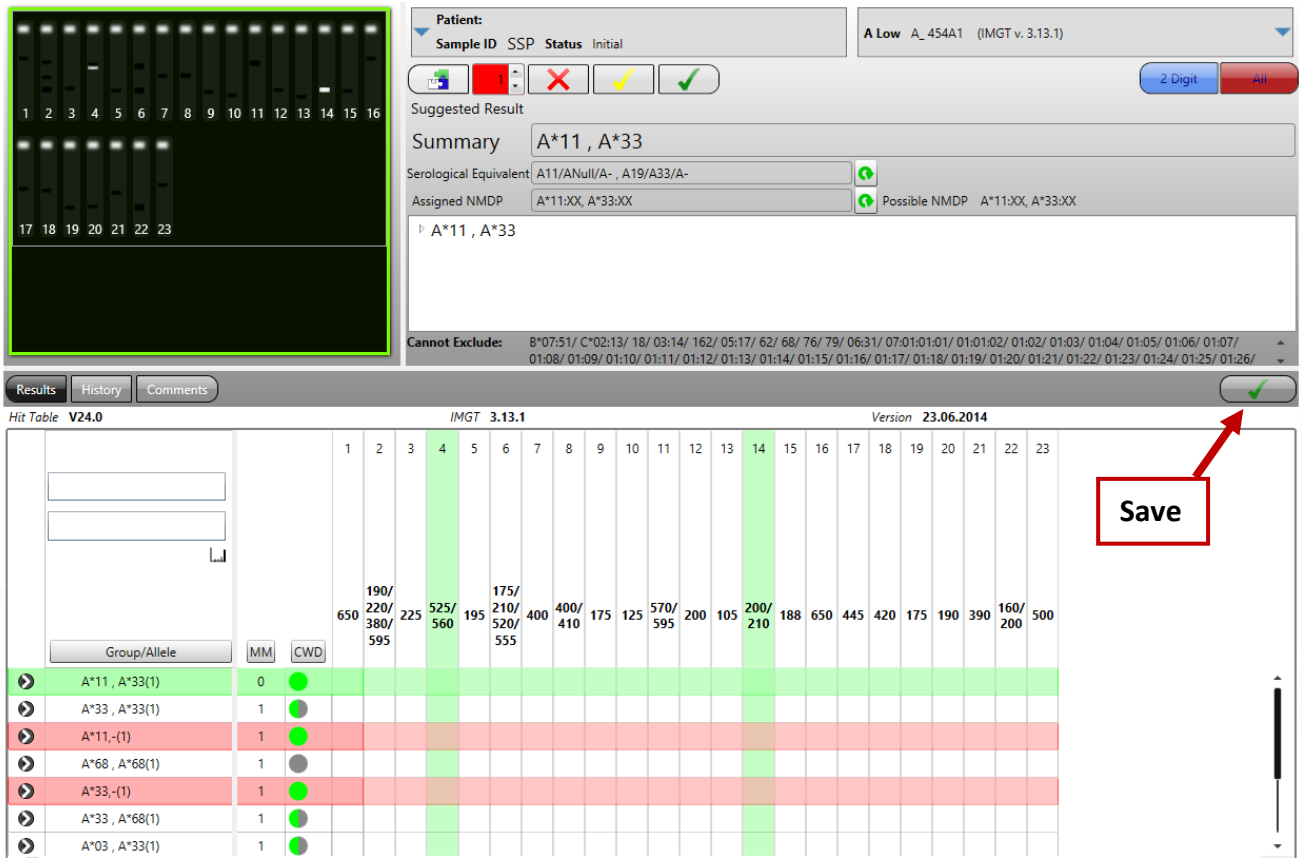


Enter positive reactions by clicking on the black “empty” band in the gel or double clicking on the lane. You can remove them by clicking again. Positive reactions will be highlighted in green in the interpretation diagram below the gel. You can also enter positive reactions by clicking on the mix in the diagram. An amplification failure can be indicated by clicking on the control band of the mix and will be displayed in grey in the diagram. Inactivated mixes will be disregarded in the interpretation.



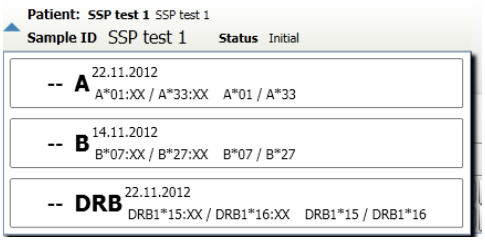
Press the **Interpret** button and the software will analyse the result. Results with zero mismatches and 2 common alleles are highlighted in green in the interpretation diagram and shown in the **Suggested Results** window. Results with only one mismatch and 2 common alleles are highlighted in red. The coloured frame around the gel picture indicates the quality of the result:

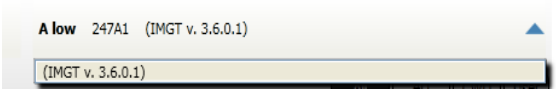
Green: unambiguous common type (depends on the selected filter, C alleles when "All" is selected)
Yellow: ambiguous result
Purple: rare haplotype or two rare alleles (depends on the selected filter, no C alleles when "All" is selected)
Red: no result

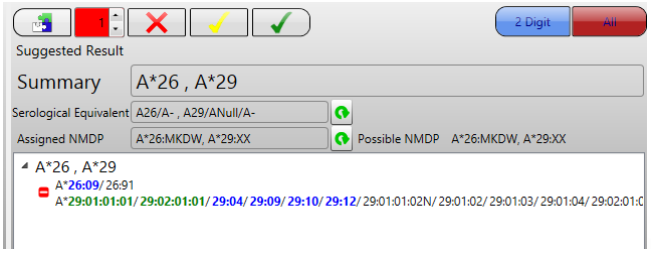


Save results and close the screen by pressing the **Save** button.

15.4 Test information







Patient and sample information for the currently selected test. Clicking on the expander on the left side shows all typing results of this sample.

Kit and batch information for the currently selected test. Different hit tables can be selected -if available- by clicking on the expander .

The suggested/authorized results for the test. This display groups the results by 2 digit group, the expanded allele name can be displayed by expanding the group.

Once expanded, the alleles can be seen. Common (C) alleles are displayed in green, well documented (WD) alleles in blue.

The " " button will remove this result from the suggested result.

Alternatively, filtered alleles are shown here (see 14.6.2 Common allele filters).

15.5 Interpret controls

Interpret: Performs interpretation of the current results.

Max. Number of mismatches shown: Results will be shown with the maximum number of mismatches indicated here.

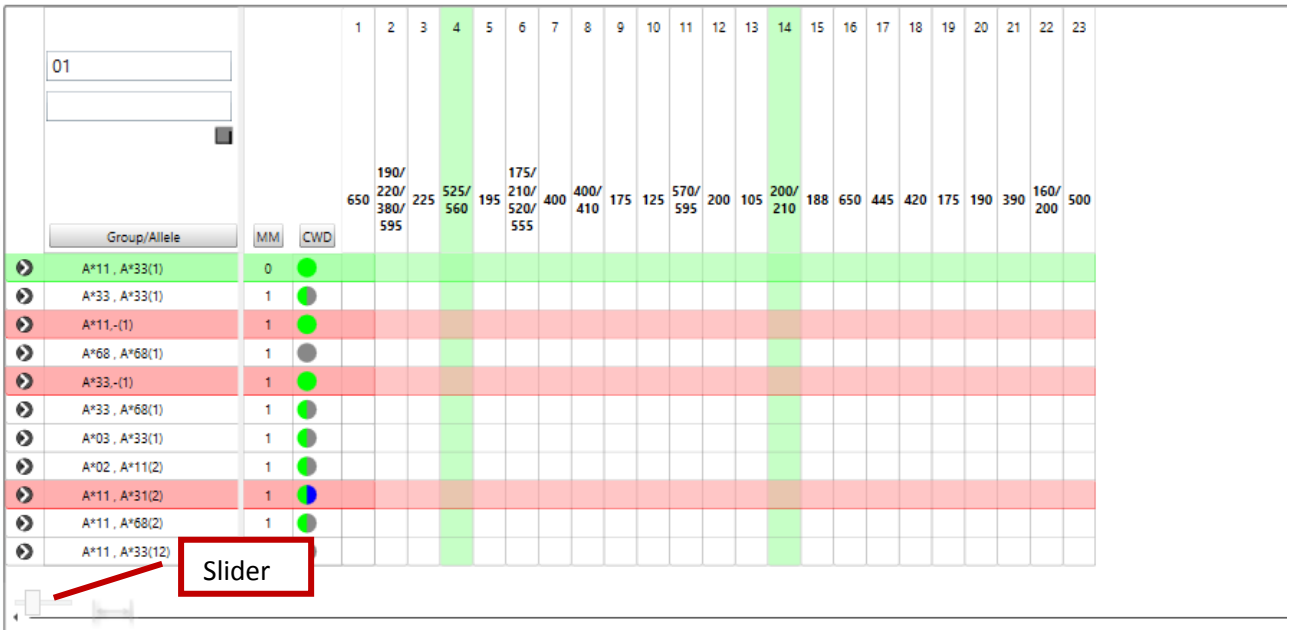
Delete: Deletes the results for the selected test.

Approve: Technical approval by a user.

Authorize: Authorizes/Un-Authorizes the current result. (Supervisor)

15.6 Results view

This view shows the results of the interpretation. The default view shows the possible 2 digit results, along with number of mismatches (MM) required to get the result and the frequency of the alleles found (CWD column). Green indicates a C allele, blue a WD allele and grey a rare allele.

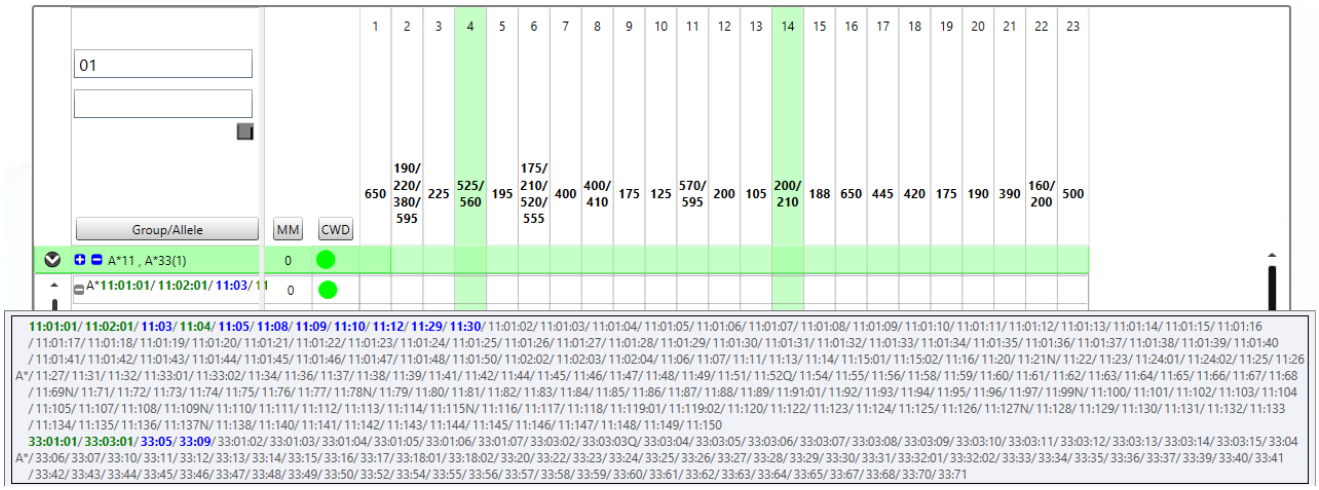


The primer mixes are shown together with the sizes of the positive bands. Positive primer mixes are highlighted in green. Results with zero mismatches and including a combination of two common alleles are highlighted in green (depending on the filter). Results with only one mismatch and including a combination of two common alleles are highlighted in red.

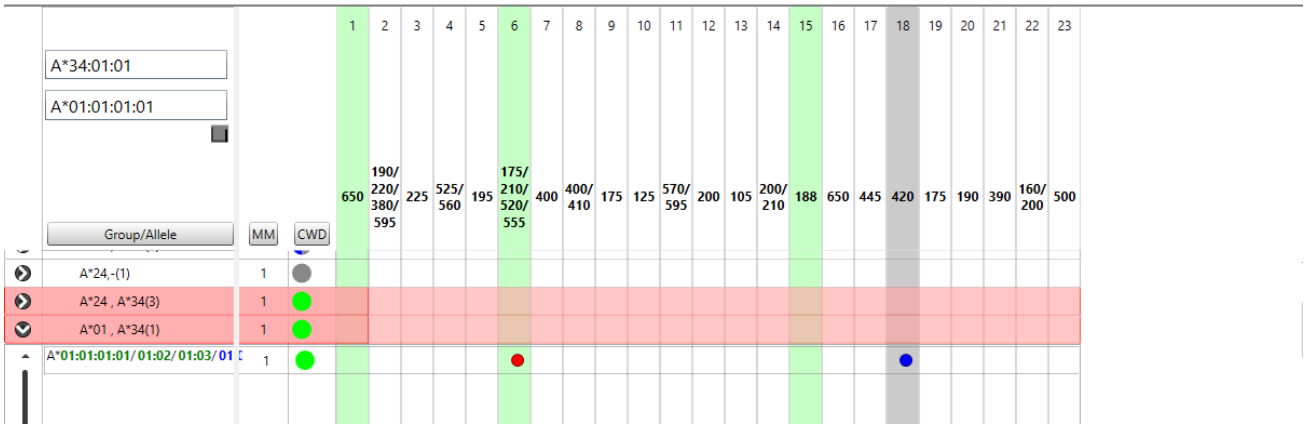
The size of the table can be adjusted using the slider in the bottom left corner or by holding the CRTL key and turning the mouse wheel at the same time.

The number in brackets after the 2 digit result gives the number of possible allele strings included in this line.

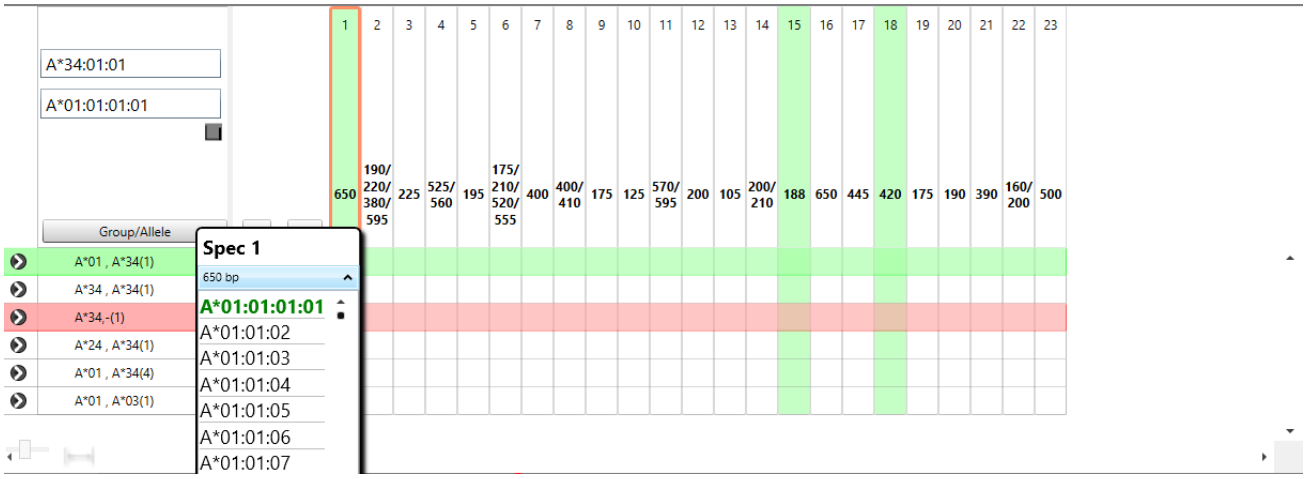
Clicking the expand button in the first column of the grid will expand the 2 digit group and show all the alleles in that group. Moving your mouse over the allele names will display the alleles in a tooltip.



If an allele group contains mismatches these are highlighted in the grid as false positive (red)/false negatives (blue).

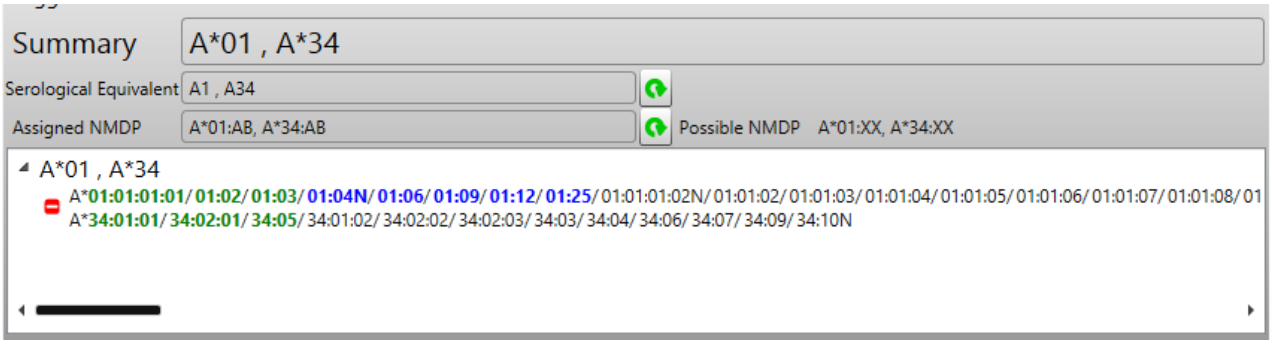


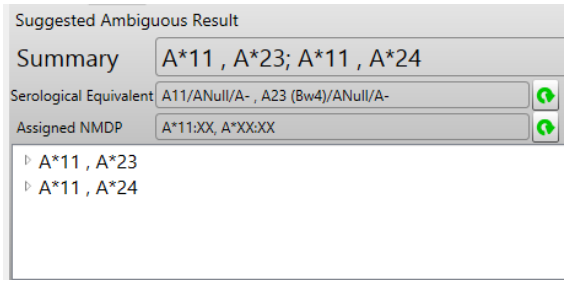
The specificity of a primer mix can be shown by a right mouse click on the respective column:



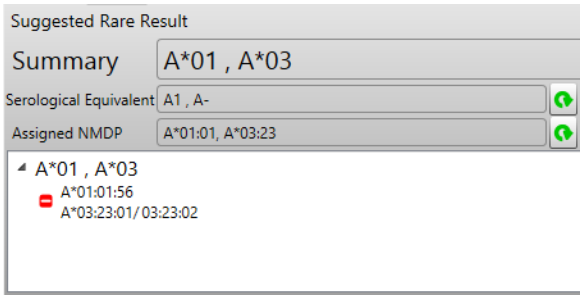
15.7 Suggested Results

All zero MM results are automatically added to the **Suggested Result** box. The results are displayed as 2 digit groups with the alleles grouped below them.

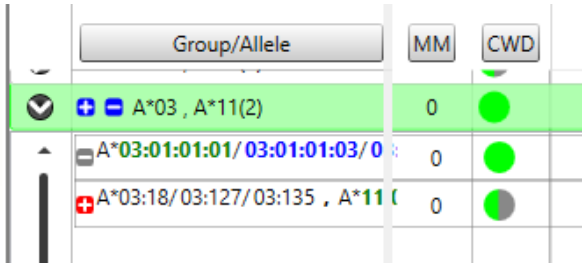




Two digit ambiguous groups will be displayed with more than one group; the title of the control will reflect this ambiguity. You can remove individual results by clicking the '-' button in either the suggested results box or the main results view.



If the result contains only 1 common allele, this will be displayed as **Common Haplotype** above the suggested result, or if it contains 0, it will be displayed as **Suggested Rare Result**.



Results in the main result view, can be added or removed from the suggested results box, by using the + and − buttons. The blue buttons can also be used at group level to add or remove the entire group. But only fully matched results can be used.

15.8 Common allele filters, NMDP Codes and serological equivalents

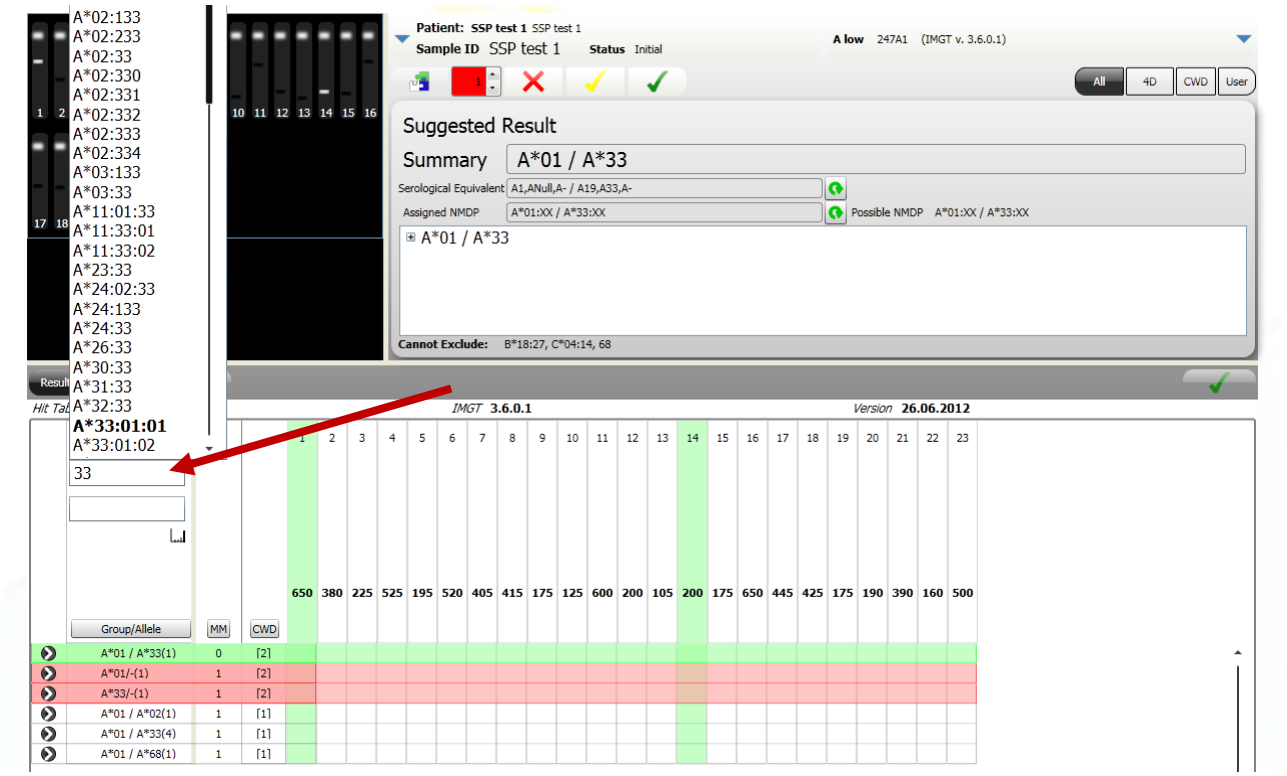
Common allele filters, NMDP codes and serological equivalents are applied in the same way as for SSO results (see 14.6.2 Common allele filters , 14.6.4 NMDP codes and 14.6.5 Serological equivalents).

15.9 Display options for the summary field

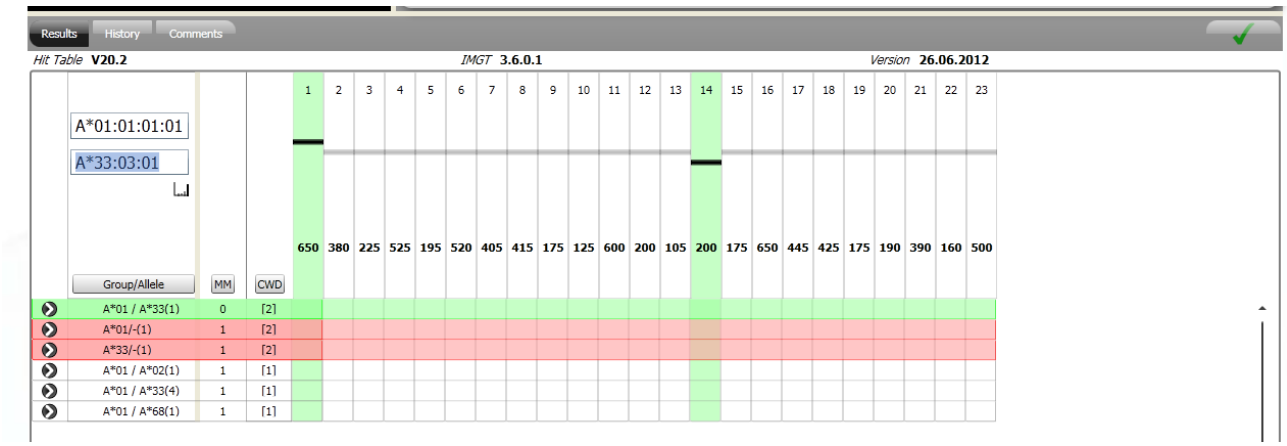
The display options for the summary field are the same as for SSO results (see 14.6.3 Display options for the summary field).

15.10 Allele pattern display

During interpretation it may be helpful to view the reaction pattern of certain alleles or allele combinations. Start typing part of the allele you would like to see in the empty allele field. You can then choose one from the list or type it completely.



Select the allele combination for which you want to see the reaction pattern. Positive mixes are marked with a black bar for the respective allele; questionable reactions remain grey. Negative mixes have a grey bar and are not assigned to an allele.



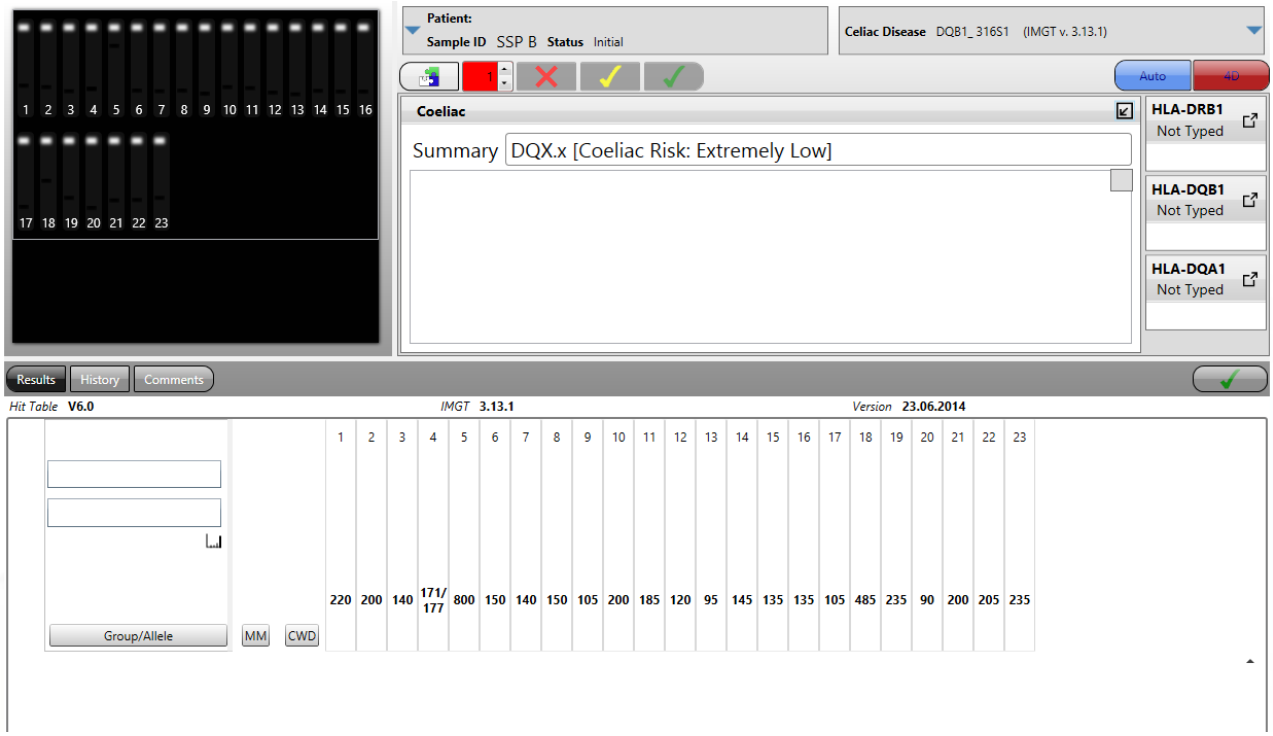
15.11 History and Comments

The test history and comments are applied in the same way as for SSO results (see 14.17 History view and 14.18 Result comments).

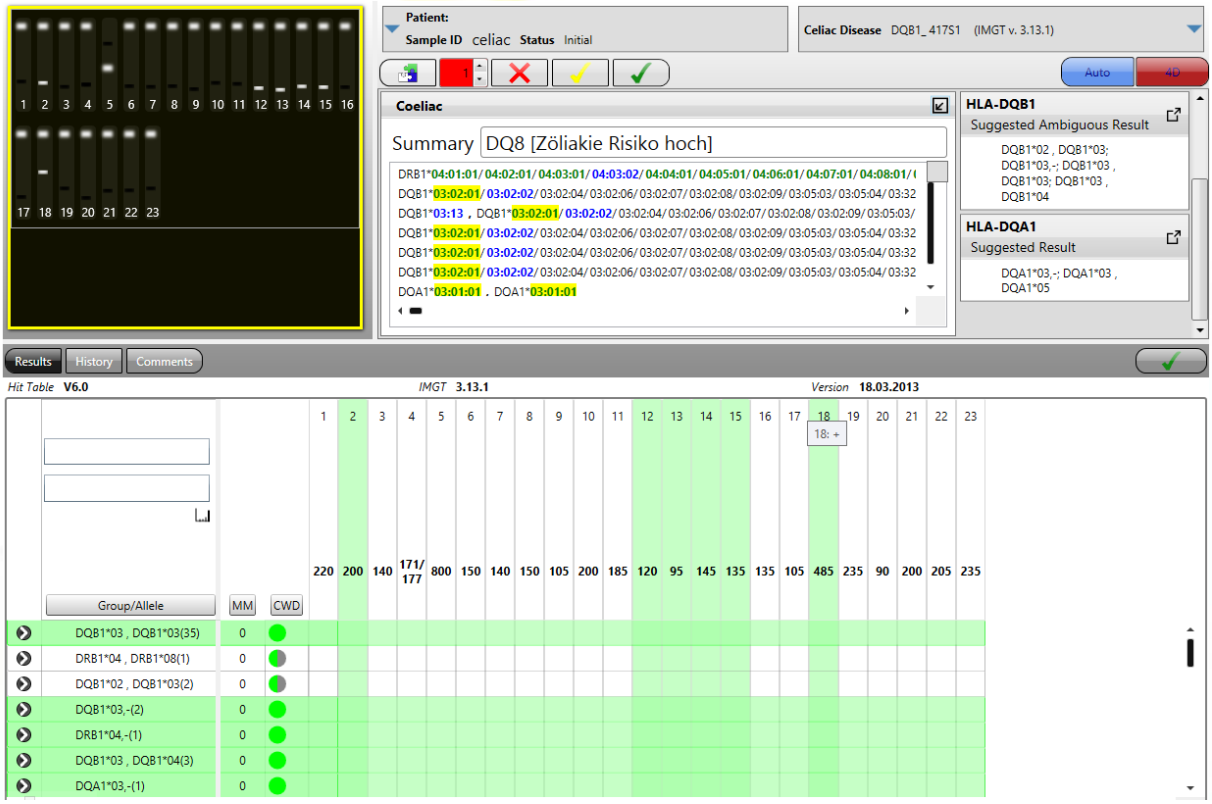
15.12 Interpretation for the HISTO TYPE Celiac Disease Kit

15.12.1 Coeliac disease view

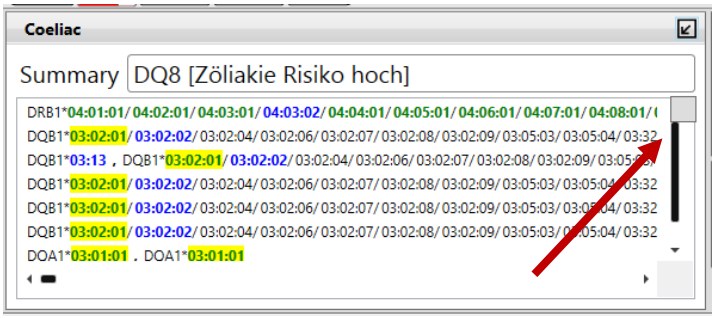
The HISTO TYPE SSP kit for typing coeliac disease associated alleles combines a DQB1, DQA1 and DRB1 test. Therefore, the results display looks a bit different from the one for single locus kits. Furthermore the screen displays the results in the context of coeliac disease. The default display for the coeliac disease kit is the following:



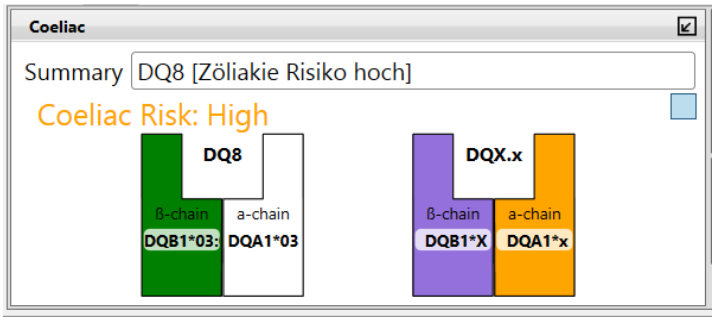
After entering the positive reactions and interpreting the results are displayed and the Coeliac Disease risk is given in the summary field. The loci can be interpreted separately by expanding the results fields on the right side.



All the mixes for DRB1, DQB1 and DQA1 are displayed and possible allele combinations for both loci are included in the results histogram in the lower half of the screen. All allele strings that are fitting to the reaction pattern without mismatches and do contain at least one common allele (C allele), are transferred to the results fields. Clicking on the arrows in the upper right corner of the results field opens a more detailed view of the respective results. Opening the **Coeliac** results field shows the following window:



Coeliac disease associated alleles are highlighted in yellow. The summary gives the name of the possible coeliac disease associated HLA molecule. Pressing the button in the upper right corner of the results field changes to the haplotype view.

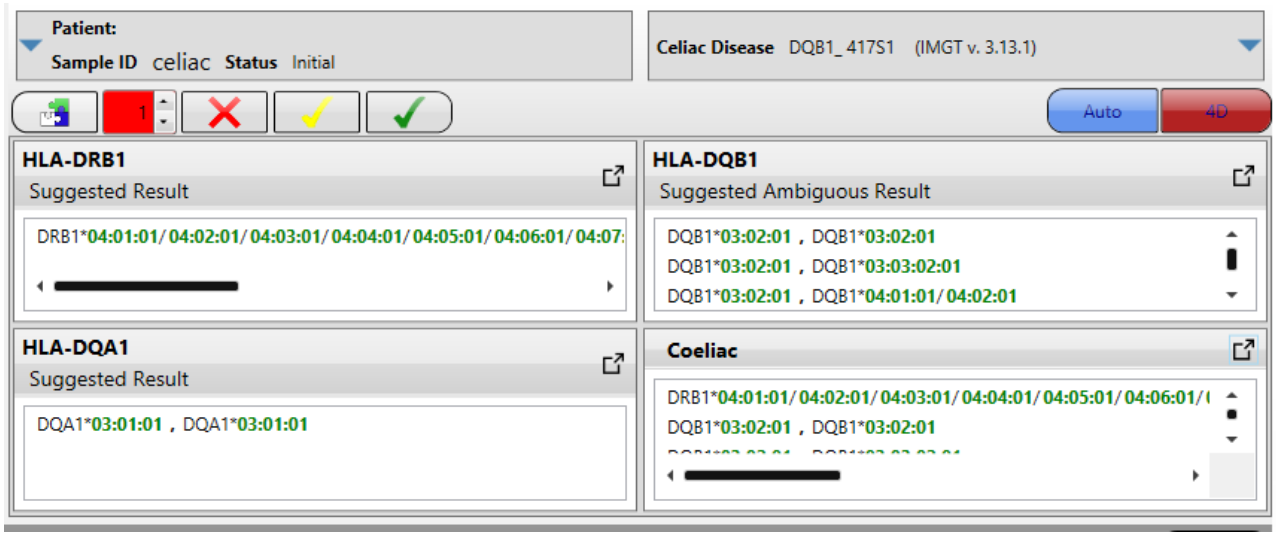


This view shows a diagram with the possible DQ molecules and the associated risk for coeliac disease.

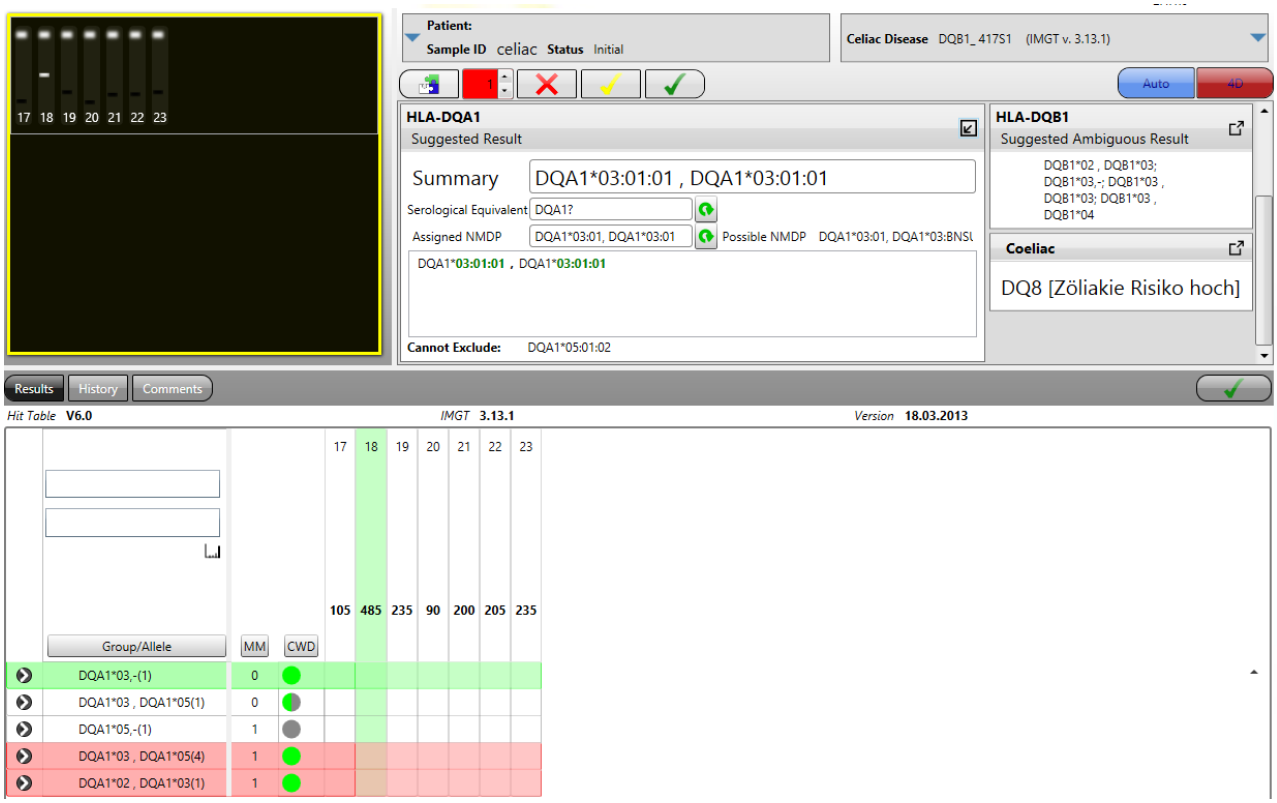
The risk assignment for coeliac disease is based on Megiorni and Pizzuti, Journal of Biomedical Science 2012, 19:88.

15.12.2 DRB1 / DQB1 / DQA1 view

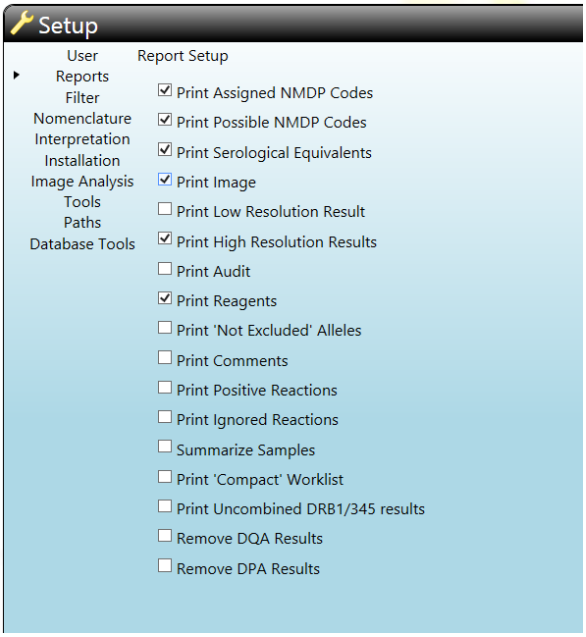
The detailed results view for the single loci can be opened and closed clicking on the arrows in the upper right corner of the results windows (,). All interpretation options and the options to use common allele filters are available as described in chapters 15.3 – 15.10.



All three loci can be interpreted together or each of them separately. If one of the loci is selected the mixes in the results histogram are filtered as well, i.e. only DRB1, DQA1 or DQB1 specific mixes are displayed:



16 TYPING REPORTS



Another worklist status than initial will produce a typing report. The typing report produced depends upon the report type selected in the Setup Options.

If “Summarize Samples” or “Print ‘Compact’ Worklist” is checked a standardized short report is produced for the worklist, sample or patient selected (see below). Changing the other options will have no effects on the summarized reports.

If “Print Uncombined DRB1 / 345 results” is checked the results for these loci are reported separately.

DQA or DPA results may be removed from the reports if they are not required.

16.1 Compact report

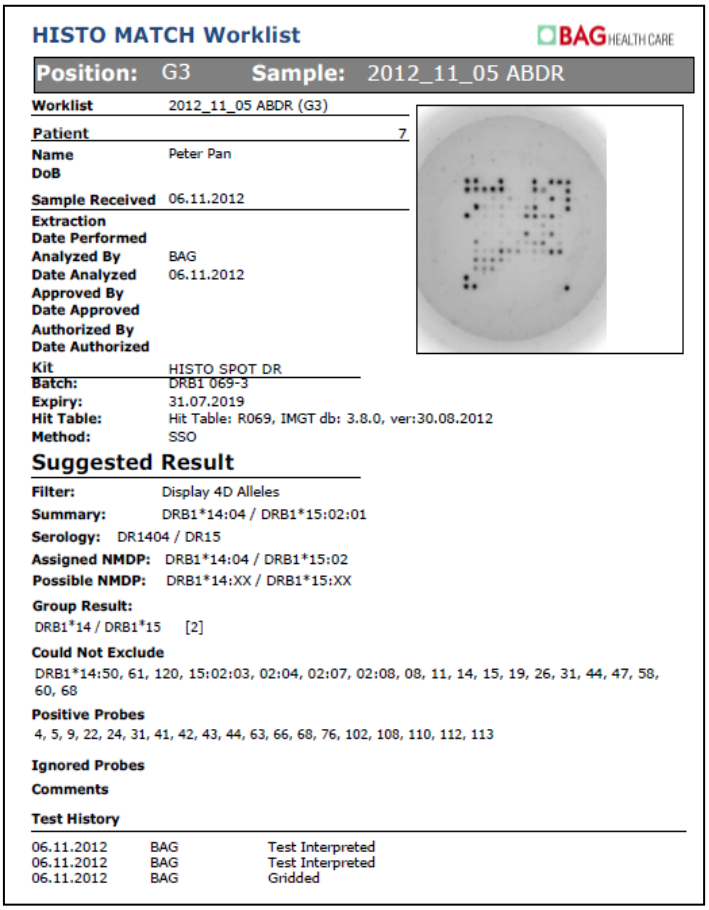
This report shows each test on a single line, each line contains: Position, ID, 2 digit result or common alleles (with allele filter), NMDP code, kit batch, IMGT version, date. This report will produce 3 pages for a worklist of 96 tests. This report will be produced if “Print ‘Compact’ Worklist” is chosen in the report setup.

Worklist: 2012_11_05 ABDR

Date: 06.11.2012

Well	Sample ID	Result	NMDP	Batch	AlleleDB	Date
A1	1	A*02 / A*02	A*02:XX / A*02:XX	A 097-1	3.8.0	13.11.2012
B1	2	A*32 / A*68	A*32:01 / A*68:02	A 097-1	3.8.0	13.11.2012
C1	3	A*03 / A*68	A*03:01 / A*68:02	A 097-1	3.8.0	13.11.2012
D1	4	A*30 / A*30	A*30:02 / A*30:02	A 097-1	3.8.0	13.11.2012
E1	5	A*02 / A*30	A*02:XH / A*30:BD	A 097-1	3.8.0	13.11.2012
F1	6	A*34 / A*34	A*34:01 / A*34:01	A 097-1	3.8.0	13.11.2012
G1	7	A*02 / A*30	A*02:11 / A*30:02	A 097-1	3.8.0	13.11.2012
H1	8	A*02 / A*02		A 097-1	3.8.0	13.11.2012
A2	1	B*15 / B*35	B*15:01 / B*35:01	B 076-1	3.8.0	13.11.2012
B2	2	B*58 / B*58	B*58:01 / B*58:02	B 076-1	3.8.0	13.11.2012
C2	3	B*07 / B*55	B*07:05 / B*55:02	B 076-1	3.8.0	13.11.2012
D2	4	B*47 / B*47		B 076-1	3.8.0	13.11.2012
E2	5	B*15 / B*57	B*15:XX / B*57:XX	B 076-1	3.8.0	13.11.2012
F2	6	B*15 / B*57	B*15:02 / B*57:01	B 076-1	3.8.0	13.11.2012
G2	7	B*15 / B*40	B*15:10 / B*40:02	B 076-1	3.8.0	13.11.2012
H2	8	B*35 / B*44	B*35:03 / B*44:02	B 076-1	3.8.0	13.11.2012
A3	1	DRB1*01:01:01 / DRB1*01:01:01	DRB1*01:01 / DRB1*01:01	DRB1 069-3	3.8.0	13.11.2012
B3	2	DRB1*04:05:01 / DRB1*15:03:01:01	DRB1*04:05 / DRB1*15:03	DRB1 069-3	3.8.0	13.11.2012
C3	3	DRB1*09:01:02 / DRB1*13:03:01	DRB1*09:01 / DRB1*13:03	DRB1 069-3	3.8.0	13.11.2012
D3	4	DRB1*11:02:01 / DRB1*11:03 DRB1*11:03 / DRB1*11:03	DRB1*11:BC / DRB1*11:03	DRB1 069-3	3.8.0	13.11.2012
E3	5	DRB1*04:07:01 / DRB1*08:06	DRB1*04:07 / DRB1*08:06	DRB1 069-3	3.8.0	13.11.2012
F3	6	DRB1*01:01:01 / DRB1*08:01:01	DRB1*01:01 / DRB1*08:01	DRB1 069-3	3.8.0	13.11.2012
G3	7	DRB1*14:04 / DRB1*15:02:01	DRB1*14:04 / DRB1*15:02	DRB1 069-3	3.8.0	13.11.2012
H3	8	DRB1*04:07:01 / DRB1*13:01:01	DRB1*04:07 / DRB1*13:01	DRB1 069-3	3.8.0	13.11.2012

16.2 Worklist report



HISTO MATCH Worklist

BAG HEALTH CARE

Position: G3 **Sample:** 2012_11_05 ABDR

Worklist 2012_11_05 ABDR (G3)

Patient 7

Name Peter Pan
DoB

Sample Received 06.11.2012

Extraction
Date Performed
Analyzed By BAG
Date Analyzed 06.11.2012
Approved By
Date Approved
Authorized By
Date Authorized

Kit HISTO SPOT DR
Batch: DRB1 069-3
Expiry: 31.07.2019
Hit Table: Hit Table: R069, IMGT db: 3.8.0, ver:30.08.2012
Method: SSO

Suggested Result

Filter: Display 4D Alleles
Summary: DRB1*14:04 / DRB1*15:02:01
Serology: DR1404 / DR15
Assigned NMDP: DRB1*14:04 / DRB1*15:02
Possible NMDP: DRB1*14:XX / DRB1*15:XX

Group Result:
DRB1*14 / DRB1*15 [2]

Could Not Exclude
DRB1*14:50, 61, 120, 15:02:03, 02:04, 02:07, 02:08, 08, 11, 14, 15, 19, 26, 31, 44, 47, 58, 60, 68

Positive Probes
4, 5, 9, 22, 24, 31, 41, 42, 43, 44, 63, 66, 68, 76, 102, 108, 110, 112, 113

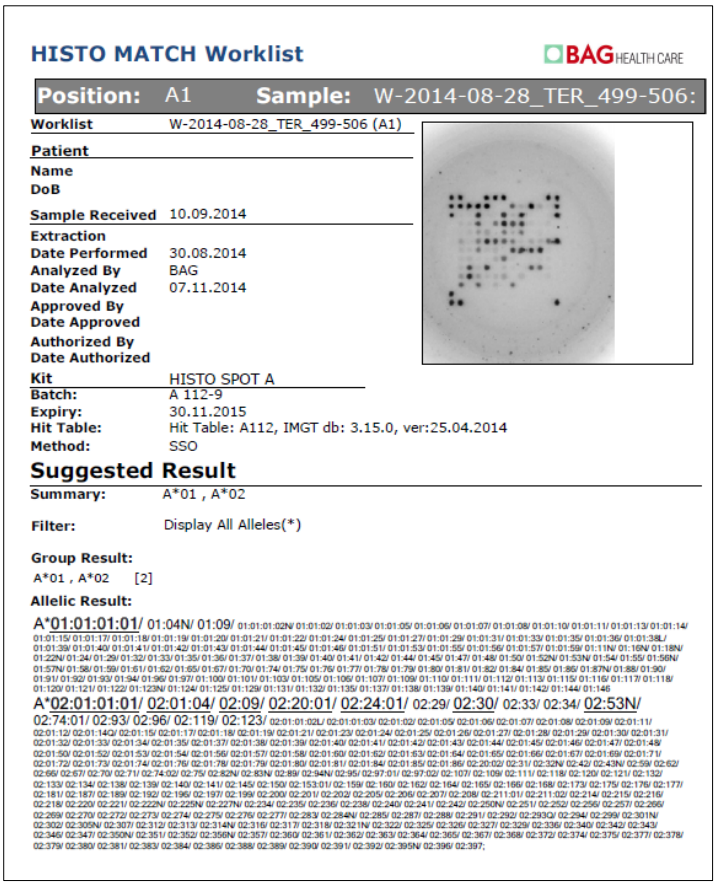
Ignored Probes

Comments

Test History

06.11.2012	BAG	Test Interpreted
06.11.2012	BAG	Test Interpreted
06.11.2012	BAG	Gridded

This report type will produce a front page for the worklist containing the details of the run and reagents used, and then a single page for each test. The information displayed here can be selected in the report setup. The results display in the summary depends on the display options chosen in the interpretation screen or in setup (allele filter and summary options).



HISTO MATCH Worklist

BAG HEALTH CARE

Position: A1 **Sample:** W-2014-08-28_TER_499-506:

Worklist W-2014-08-28_TER_499-506 (A1)

Patient
Name
DoB

Sample Received 10.09.2014

Extraction
Date Performed 30.08.2014
Analyzed By BAG
Date Analyzed 07.11.2014
Approved By
Date Approved
Authorized By
Date Authorized

Kit HISTO SPOT A
Batch: A 112-9
Expiry: 30.11.2015
Hit Table: Hit Table: A112, IMGT db: 3.15.0, ver:25.04.2014
Method: SSO

Suggested Result

Summary: A*01 , A*02

Filter: Display All Alleles(*)

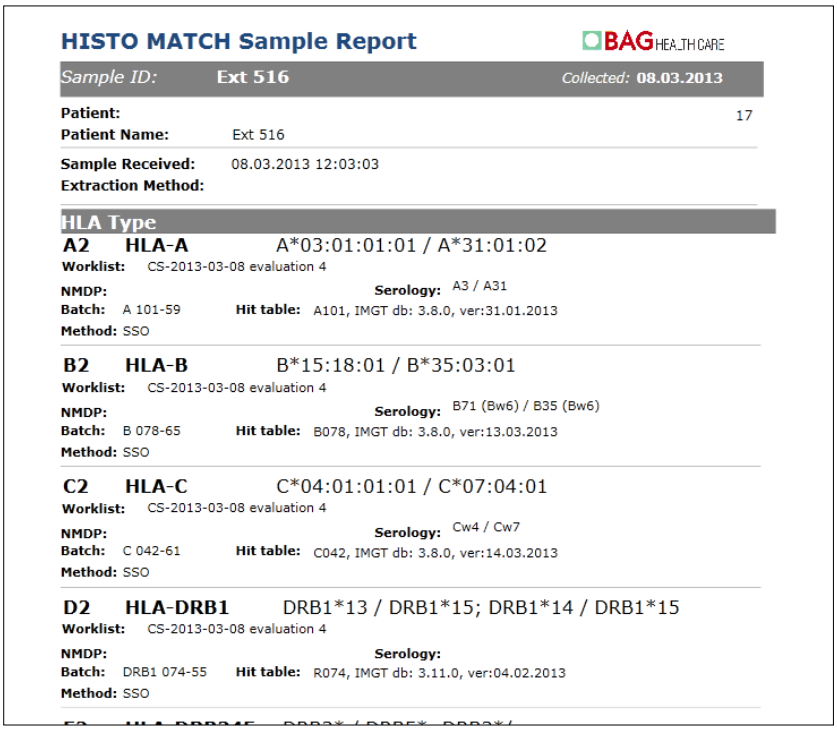
Group Result:
A*01 , A*02 [2]

Allelic Result:

A*01:01:01:01/ 01:04N/ 01:09/ 01:01:01:02N/ 01:01:02/ 01:01:03/ 01:01:05/ 01:01:06/ 01:01:07/ 01:01:08/ 01:01:10/ 01:01:11/ 01:01:13/ 01:01:14/ 01:01:15/ 01:01:17/ 01:01:18/ 01:01:19/ 01:01:20/ 01:01:21/ 01:01:22/ 01:01:24/ 01:01:25/ 01:01:27/ 01:01:29/ 01:01:31/ 01:01:33/ 01:01:35/ 01:01:36/ 01:01:38L/ 01:01:39/ 01:01:40/ 01:01:41/ 01:01:42/ 01:01:43/ 01:01:44/ 01:01:45/ 01:01:46/ 01:01:51/ 01:01:53/ 01:01:55/ 01:01:56/ 01:01:57/ 01:01:59/ 01:11N/ 01:16N/ 01:18N/ 01:22N/ 01:24/ 01:29/ 01:32/ 01:33/ 01:35/ 01:36/ 01:37/ 01:38/ 01:39/ 01:40/ 01:41/ 01:42/ 01:44/ 01:45/ 01:47/ 01:48/ 01:50/ 01:52N/ 01:53N/ 01:54/ 01:55/ 01:56N/ 01:57N/ 01:58/ 01:59/ 01:61/ 01:62/ 01:65/ 01:67/ 01:70/ 01:74/ 01:75/ 01:76/ 01:77/ 01:78/ 01:79/ 01:80/ 01:81/ 01:82/ 01:84/ 01:85/ 01:86/ 01:87N/ 01:88/ 01:90/ 01:91/ 01:92/ 01:93/ 01:94/ 01:96/ 01:97/ 01:100/ 01:101/ 01:103/ 01:105/ 01:106/ 01:107/ 01:109/ 01:110/ 01:111/ 01:112/ 01:113/ 01:115/ 01:116/ 01:117/ 01:118/ 01:120/ 01:121/ 01:122/ 01:123N/ 01:124/ 01:125/ 01:129/ 01:131/ 01:132/ 01:135/ 01:137/ 01:138/ 01:139/ 01:140/ 01:141/ 01:142/ 01:144/ 01:146

A*02:01:01:01/ 02:01:04/ 02:09/ 02:20:01/ 02:24:01/ 02:29/ 02:30/ 02:33/ 02:34/ 02:53N/ 02:74:01/ 02:93/ 02:96/ 02:119/ 02:123/ 02:01:01:02L/ 02:01:01:03/ 02:01:02/ 02:01:05/ 02:01:06/ 02:01:07/ 02:01:08/ 02:01:09/ 02:01:11/ 02:01:12/ 02:01:14Q/ 02:01:15/ 02:01:17/ 02:01:18/ 02:01:19/ 02:01:21/ 02:01:23/ 02:01:24/ 02:01:25/ 02:01:26/ 02:01:27/ 02:01:28/ 02:01:29/ 02:01:30/ 02:01:31/ 02:01:32/ 02:01:33/ 02:01:34/ 02:01:35/ 02:01:37/ 02:01:38/ 02:01:39/ 02:01:40/ 02:01:41/ 02:01:42/ 02:01:43/ 02:01:44/ 02:01:45/ 02:01:46/ 02:01:47/ 02:01:48/ 02:01:50/ 02:01:52/ 02:01:53/ 02:01:54/ 02:01:56/ 02:01:57/ 02:01:58/ 02:01:60/ 02:01:62/ 02:01:63/ 02:01:64/ 02:01:65/ 02:01:66/ 02:01:67/ 02:01:69/ 02:01:71/ 02:01:72/ 02:01:73/ 02:01:74/ 02:01:76/ 02:01:78/ 02:01:79/ 02:01:80/ 02:01:81/ 02:01:84/ 02:01:85/ 02:01:86/ 02:20:02/ 02:31/ 02:32N/ 02:42/ 02:43N/ 02:59/ 02:62/ 02:66/ 02:67/ 02:70/ 02:71/ 02:74:02/ 02:75/ 02:82N/ 02:83N/ 02:89/ 02:94N/ 02:95/ 02:97:01/ 02:97:02/ 02:107/ 02:109/ 02:111/ 02:118/ 02:120/ 02:121/ 02:132/ 02:133/ 02:134/ 02:138/ 02:139/ 02:140/ 02:141/ 02:145/ 02:150/ 02:153:01/ 02:159/ 02:160/ 02:162/ 02:164/ 02:165/ 02:166/ 02:168/ 02:173/ 02:175/ 02:176/ 02:177/ 02:181/ 02:187/ 02:189/ 02:192/ 02:196/ 02:197/ 02:199/ 02:200/ 02:201/ 02:202/ 02:205/ 02:206/ 02:207/ 02:208/ 02:211:01/ 02:211:02/ 02:214/ 02:215/ 02:216/ 02:218/ 02:220/ 02:221/ 02:222N/ 02:225N/ 02:227N/ 02:234/ 02:235/ 02:236/ 02:238/ 02:240/ 02:241/ 02:242/ 02:250N/ 02:251/ 02:252/ 02:256/ 02:257/ 02:266/ 02:269/ 02:270/ 02:272/ 02:273/ 02:274/ 02:275/ 02:276/ 02:277/ 02:283/ 02:284N/ 02:285/ 02:287/ 02:288/ 02:291/ 02:292/ 02:293Q/ 02:294/ 02:299/ 02:301N/ 02:302/ 02:309N/ 02:307/ 02:312/ 02:313/ 02:314N/ 02:316/ 02:317/ 02:318/ 02:321N/ 02:322/ 02:325/ 02:326/ 02:327/ 02:329/ 02:336/ 02:340/ 02:342/ 02:343/ 02:346/ 02:347/ 02:350N/ 02:351/ 02:352/ 02:356N/ 02:357/ 02:360/ 02:361/ 02:362/ 02:363/ 02:364/ 02:365/ 02:367/ 02:368/ 02:372/ 02:374/ 02:375/ 02:377/ 02:378/ 02:379/ 02:380/ 02:381/ 02:383/ 02:384/ 02:386/ 02:388/ 02:389/ 02:390/ 02:391/ 02:392/ 02:395N/ 02:396/ 02:397;

If “Print High Resolution Results” is selected, all possible allele strings are printed. This can be several pages per sample. C alleles have the biggest size and are underlined, WD alleles have a middle size and rare alleles are printed in the smallest size.



HISTO MATCH Sample Report BAG HEALTH CARE

Sample ID: **Ext 516** *Collected:* **08.03.2013**

Patient: 17
Patient Name: Ext 516

Sample Received: 08.03.2013 12:03:03
Extraction Method:

HLA Type

A2 HLA-A A*03:01:01:01 / A*31:01:02
Worklist: CS-2013-03-08 evaluation 4
NMDP: **Serology:** A3 / A31
Batch: A 101-59 **Hit table:** A101, IMGT db: 3.8.0, ver:31.01.2013
Method: SSO

B2 HLA-B B*15:18:01 / B*35:03:01
Worklist: CS-2013-03-08 evaluation 4
NMDP: **Serology:** B71 (Bw6) / B35 (Bw6)
Batch: B 078-65 **Hit table:** B078, IMGT db: 3.8.0, ver:13.03.2013
Method: SSO

C2 HLA-C C*04:01:01:01 / C*07:04:01
Worklist: CS-2013-03-08 evaluation 4
NMDP: **Serology:** Cw4 / Cw7
Batch: C 042-61 **Hit table:** C042, IMGT db: 3.8.0, ver:14.03.2013
Method: SSO

D2 HLA-DRB1 DRB1*13 / DRB1*15; DRB1*14 / DRB1*15
Worklist: CS-2013-03-08 evaluation 4
NMDP: **Serology:**
Batch: DRB1 074-55 **Hit table:** R074, IMGT db: 3.11.0, ver:04.02.2013
Method: SSO

When “Summarize Samples” is selected in the report setup, all results from one sample in this worklist will be combined and a standardized summary report will be generated.

16.3 Patient or sample report

A patient or sample report can be created from the browse patients or browse samples screen:

1. Select a patient / sample from the list.
2. Select the **Report** button .

All available results for the selected patient or sample will be combined in one report. Information displayed can be selected in the report setup.

17 SETUP

Use the **Setup** button on the main menu to access the setup screen. You must choose **Save** to save any changes to the setup. The settings are saved on the user's PC, so will not transfer to another PC if you are on a network.

The following settings are accessible in the setup:

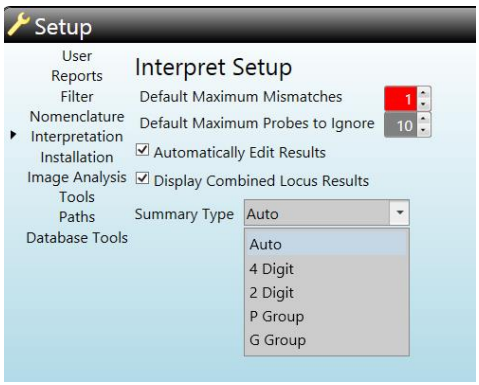
User settings: This contains the option to change the user password (see 6.3 Changing the user password).

Reports: Report options can be chosen (see 16 Typing reports).

Filter: Allele lists for the allele filters can be reviewed and edited (see 14.6.2 Common allele filters).

Nomenclature: Choose between **Auto (**Uses the hit table source version for the display) and **Version 3 (**Force display to IMGT version 3 for all hit tables).

Interpretation: Here the default values for the interpretation can be defined.

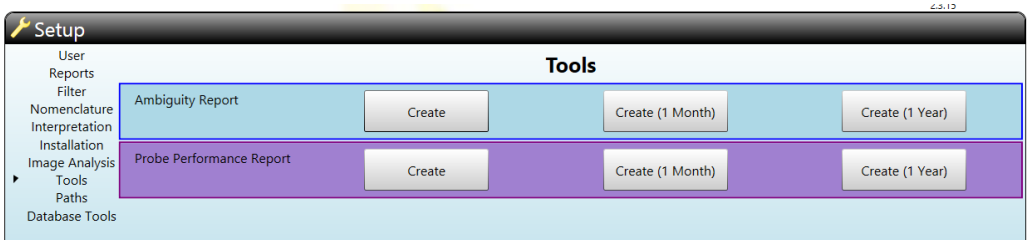


See chapters 14.4 Interpret controls, 14.6.3 Display options for the summary field, 14.8 Auto Edit Function and 14.19 Interpretation for the HISTO SPOT® Coeliac Disease and DQB1 4D / DQA1 Kit for details.

Installation: In this section the Lab Name and the Lab ID can be entered. It is also possible to upload a logo that will appear on the typing reports.

Image Analysis: Switch Auto Rotate Image function on or off.

Tools:



Ambiguity Report: Create a detailed report about your ambiguities (xml file) that can be sent to BAG Health Care to improve the resolution of the kits.

Probe Performance Report: Create a report with automatically and manually ignored probes.

Paths:

Default Import Path: Shows the default path to import data (kits, worklists,...), by clicking on the folder symbol the default path can be changed.

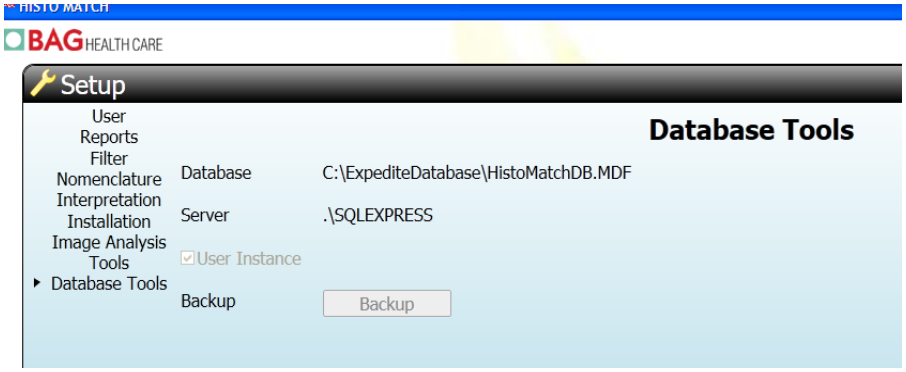
Default Export Path: Shows the default path to export data (worklists, test results, typing reports...), by clicking on the folder symbol the default path can be changed.

NMDP File Date: Gives the date of the NMDP file used. By clicking on the folder symbol the path to import a new NMDP file can be defined.

WMDA Archive File: Shows the default path for the WMDA.zip folder which contains the file for the serological equivalents, P and G groups (available from http://hla.alleles.org/), by clicking on the folder symbol the default path can be changed.

CWD ZIP File: Shows the default path for the zip folder which containing the CWD2.0.0 alleles, by clicking on the folder symbol the default path can be changed.

IMGT Allele File: Shows the default path for the WMDA.zip folder which contains the file with the HLA alleles that is used to create older IMGT databases (available from http://hla.alleles.org/), by clicking on the folder symbol the default path can be changed.

The WMDA.zip folder will be updated with each allele update for the kits and will be available from our customer download server (http://service.bag-healthcare.com).

Database Tools: Information on the location of your current database and backup option (only for server installation):