CellaVision® DM9600

USER'S MANUAL 5.0

CELLAVISION

CellaVision® DM9600 User's Manual

Preface

U.S. patents no. 7450762, 6341180, 6268611, 7327901 and 7034883.

Swedish patent no. 9902863 and 0101319.

German patent no. 602004008471, 60045076, 602008017260, 60231032, 602010005069 and 602009011617.

French patent no. 1646964, 1210634, 2204686, 2383600, 1377865 and 2310892.

U.K. patent no. 1646964, 1210634, 2204686, 1377865, 2383600 and 2310892.

Japanese patent no. 5198476.

Other patents pending.

> **Caution!**
>
> US federal law restricts this device to sale by or on the order of a physician (or properly licensed medical practitioner).

Note:
CellaVision® Image Capture System is not available on all markets.

Note:
The Advanced RBC application is currently undergoing premarket review and not yet cleared by FDA.

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1 Introduction

1.1 About this User's Manual

This User's manual will guide you step-by-step through the activity sequence of normal use of CellaVision® DM9600 (also referred to as the system), aiming for an efficient way to give you good understanding and knowledge of the system and its features. References are made to appendices providing additional information. Some self-explaining dialogs have been left out in the text.

Typographical conventions:

- Names of keys and on-screen objects with which you interact are presented in italics: e.g. click *Print*.

Note:
This User's manual covers all applications (e.g. Peripheral Blood, Body Fluid and Advanced RBC applications) available for the CellaVision® DM9600. The applicability of some sections in this User's manual may therefore depend on the applications installed on the system. Contact your local distributor for more information.

1.1.1 Warnings and Precautions

Study the meaning of symbols and safety alerts carefully and always use the system in the safest possible manner. Read all instructions carefully before starting to use the system. Using it without being suitably qualified, or in a manner not specified in this User's manual, may damage or deteriorate the system, cause misleading results or even lead to injury.

Warning alerts appear in this manual as follows:

Alert	Explanation
Warning!	May cause injury.
Caution!	May cause damage to the system.
Important!	May cause misleading results.

Place the system on a steady table. There shall be at least 20 cm clearance around the system for ventilation purposes. Do not place it where it is exposed to bumps or vibrations, excessive temperature variations or direct sunlight. The

system must be connected to grounded electrical sockets only. Authorized personnel should do the initial installation and reinstallation after moving the system. Do not install or run any software not supplied with the system. To maintain electromagnetic compatibility, use only original components. Spillage of fluid on the surfaces of the system may cause malfunctions or deterioration. Wipe off spilled fluids immediately with a soft tissue.

Warning!

The system should be serviced by authorized personnel only.

Warning!

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The following symbols are found on the system:

Symbol	Explanation
	Documentation needs to be consulted.
IVD	In vitro diagnostic medical device.
	Temperature limitation.
	This symbol is only valid in the European Community and indicates separate disposal of waste of electrical and electronic equipment.
	Standby (Supply).
SN	Serial number.
REF	Catalogue number.
	Manufacturer.
	Consult instructions for use.
CE	The CE-mark shows that the device conforms to the essential requirements of the European directive: 98/79/EC IVD Directive.

1.2 Intended Use of CellaVision® DM9600

DM9600 is an automated cell-locating device.

1.5.2. Mėginiai - Kraujo tepinėliai

DM9600 automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

DM9600 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

1.2.1 Peripheral Blood Application

The peripheral blood application (PB) is intended for differential count of white blood cells, characterization of red blood cell morphology and platelet estimation. The system automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

1.2.2 Body Fluid Application

DM9600 is an automated system intended for in-vitro diagnostic use.

The body fluid application is intended for differential count of white blood cells. The system automatically locates and presents images of cells on cytocentrifuged body fluid preparations. The operator identifies and verifies the suggested classification of each cell according to type.

DM9600 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

1.3 General Description of CellaVision® DM9600

CellaVision® DM9600 consists of an optic unit consisting of a microscope and camera (referred to as a slide scanning unit) and a computer system containing the acquisition and classification software CellaVision® DM software. It is important that slide preparation is performed according to standardized methods (see Appendix - G *Slide Preparation Guidelines*).

General Functionality of the System:

- Receives order information from and sends results to the LIS;
- Scans a user-defined area on a slide;
- Locates and presents images of every located cell or object found on the smear;
- Stores images and results in a database;
- Presents an overview image of a user-defined area on a slide.

1.3.1 Peripheral Blood Application

The Peripheral Blood application is included in the CellaVision® DM software.

General Functionality

- Presents an image on a screen of every located cell or object;
- Organizes and suggests cell classification (preclassification) for white blood cells;
- Makes it possible to identify, confirm or modify (reclassification) the suggested classification of white blood cells;
- Presents and suggests morphological characteristics (precharacterization) in an overview image of red blood cells;
- Makes it possible to confirm or modify the precharacterization of red blood cell morphology;
- Presents an overview image and facilitates platelet estimation.

1.5.4. 1.1. Leukocitų diferencijavimas: įranga diferencijuoja leukocitus ir kt. branduolėtas ląsteles į ne mažiau kaip 12 kategorijų, įskaitant šias: blastai, promielocitai, mielocitai, metamielocitai, lazdeliniai neutrofilai, segmentuoti neutrofilai, eozinofilai, bazofilai, limfocitai, reakciniai limfocitai, plazminės ląstelės, monocitai; yra galimybė įvesti ne mažiau kaip 12 vartotojo pasirinktų leukocitų morfologijos kategorijų.

WBC Preclassification

The system preclassifies the following WBC classes: *Band neutrophils, Segmented neutrophils, Eosinophils, Basophils, Lymphocytes, Monocytes, Promyelocytes, Myelocytes, Metamyelocytes, Blast cells, Lymphocytes variant forms* and *Plasma cells*.

The system preclassifies the following non-WBCs: *Erythroblasts (NRBC), Giant thrombocytes, Thrombocyte aggregations, Smudge cells* and *Artefacts*. Non-WBCs are reported as number of cells or objects /100 WBCs.

Unidentified is a class for cells and objects which the system has preclassified with a low confidence level.

WBC Reclassification for Peripheral Blood

Besides the cell classes mentioned above, the operator can reclassify cells into the following classes: *Immature eosinophils, Immature basophils, Promonocytes, Prolymphocytes, Large granular lymphocytes, Hairy cells, Sézary cells, Other, Megakaryocytes, Not classed* and 15 user defined cell classes.

1.5.4. 2. Yra galimybė įvesti papildomas vartotojo pasirinktas ląstelių/radinių klasifikavimo kategorijas.

Other should be used for cells which the operator identifies as a WBC, but of a type other than those listed. WBCs put here will be included in the differential count.

Not classed should be used for cells and objects which the operator cannot identify and wants to exclude from the differential count.

RBC Precharacterization

1.5.4. 1.2. Eritrocitų vertinimas: įranga turi diferencijuoti eritrocitus į ne mažiau kaip 17 kategorijų

The system precharacterizes the following RBC morphology characteristics in an overview image: *Polychromatic cells, Hypochromatic cells, Anisocytosis, Microcytes, Macrocytes and Poikilocytosis.*

RBC characterization

The operator can characterize to *Target cells, Schistocytes, Helmet cells, Sickle cells, Spherocytes, Elliptocytes, Ovalocytes, Tear drop cells, Stomatocytes, Acanthocytes, Echinocytes, Howell-Jolly bodies, Pappenheimer bodies, Basophilic stippling, Parasites* and 10 user defined characteristics.

1.5.4. 2. Yra galimybė įvesti papildomas vartotojo pasirinktas ląstelių/radinių klasifikavimo kategorijas.

Platelet Estimation

The operator counts or estimates platelets in an overview image.

Sample Preparation

To perform a peripheral blood differential count a thin blood film is wedged on a glass slide (a blood smear) from a peripheral blood sample and stained with Romanowsky stain (see Appendix - G *Slide Preparation Guidelines*) for recommended staining recipes).

1.3.2 Advanced RBC Application

1.5.4. 1.2. Eritrocitų vertinimas: įranga diferencijuoja eritrocitus į ne mažiau kaip 17 kategorijų, įskaitant šias: anizocitozė, makrocitai, ovalūs makrocitai, mikrocitai, hipochromija, akantocitai, echinocitai, dakriocitai, eliptocitai, pjautuvo formos eritrocitai, sferocitai, šistocitai, stomatocitai, taikinio formos eritrocitai, polichromatofilija, bazofilinis taškuotumas, Howell-Jolly kūnai; yra galimybė įvesti ne mažiau kaip 10 vartotojo pasirinktų eritrocitų morfologijos kategorijų.

The Advanced RBC application is an optional application which replaces the standard RBC functionality.

General Functionality

- Presents and suggests morphological characteristics (precharacterization) in an overview image of red blood cells on a screen;
- Makes it possible to confirm or modify the precharacterization of the red blood cell morphology;
- Organizes, presents and suggests a morphology for every individual red blood cell image on a screen;
- Makes it possible to confirm or modify the suggested classification of the red blood cells.

Precharacterization for Advanced RBC

The system precharacterizes the following RBC morphology characteristics in an overview and individual cells image: *Polychromatic cells, Hypochromatic cells, Anisocytosis, Microcytes, Macrocytes, Poikilocytosis, Target cells, Schistocytes, Helmet cells, Sickle cells, Spherocytes, Elliptocytes, Ovalocytes, Tear drop cells, Stomatocytes, Acanthocytes, Echinocytes, Howell-Jolly bodies, Pappenheimer bodies, Basophilic stippling* and *Parasites*.

Characterization for Advanced RBC

Besides the RBC morphology characteristics mentioned above, the operator can characterize into 10 user defined characteristics.

1.3.3 Body Fluid Application

The Body Fluid application is an optional application.

General Functionality

- Presents an image on a screen of every located cell or object;
- Organizes and suggests cell classification (preclassification) for the located nucleated cells;
- Makes it possible to identify, confirm or modify (reclassification) the suggested classification of the located cells;
- Presents an overview image.

Preclassification for Body Fluid

The system preclassifies the following WBC classes: *Neutrophils, Eosinophils, Lymphocytes, Macrophages (including Monocytes)* and *Other*. Cells preclassified as *Basophils, Lymphoma cells, Atypical lymphocytes, Blasts* and *Tumor cells* are automatically forwarded to the cell class *Other.*

Unidentified is a class for cells and objects which the system has preclassified with a low confidence level.

The system preclassifies the following non-WBCs: *Smudge cells* and *Artefacts*. Non-WBCs are reported as number of cells or objects /100 WBCs.

WBC Reclassification for Body Fluid

Besides the cell classes mentioned above, the operator can reclassify cells into the following cell classes: *Not classed* and 15 user defined cell classes.

Not classed should be used for cells and objects which the operator cannot identify and wants to exclude from the differential count.

Sample Preparation

Body fluid samples are prepared by using a cytocentrifuge and a staining unit. The sample is centrifuged onto a glass slide and stained with Romanovsky stain (see Appendix - G *Slide Preparation Guidelines*).

1.4 Components and Mechanical Operation

1.4.1 Major Parts of the System

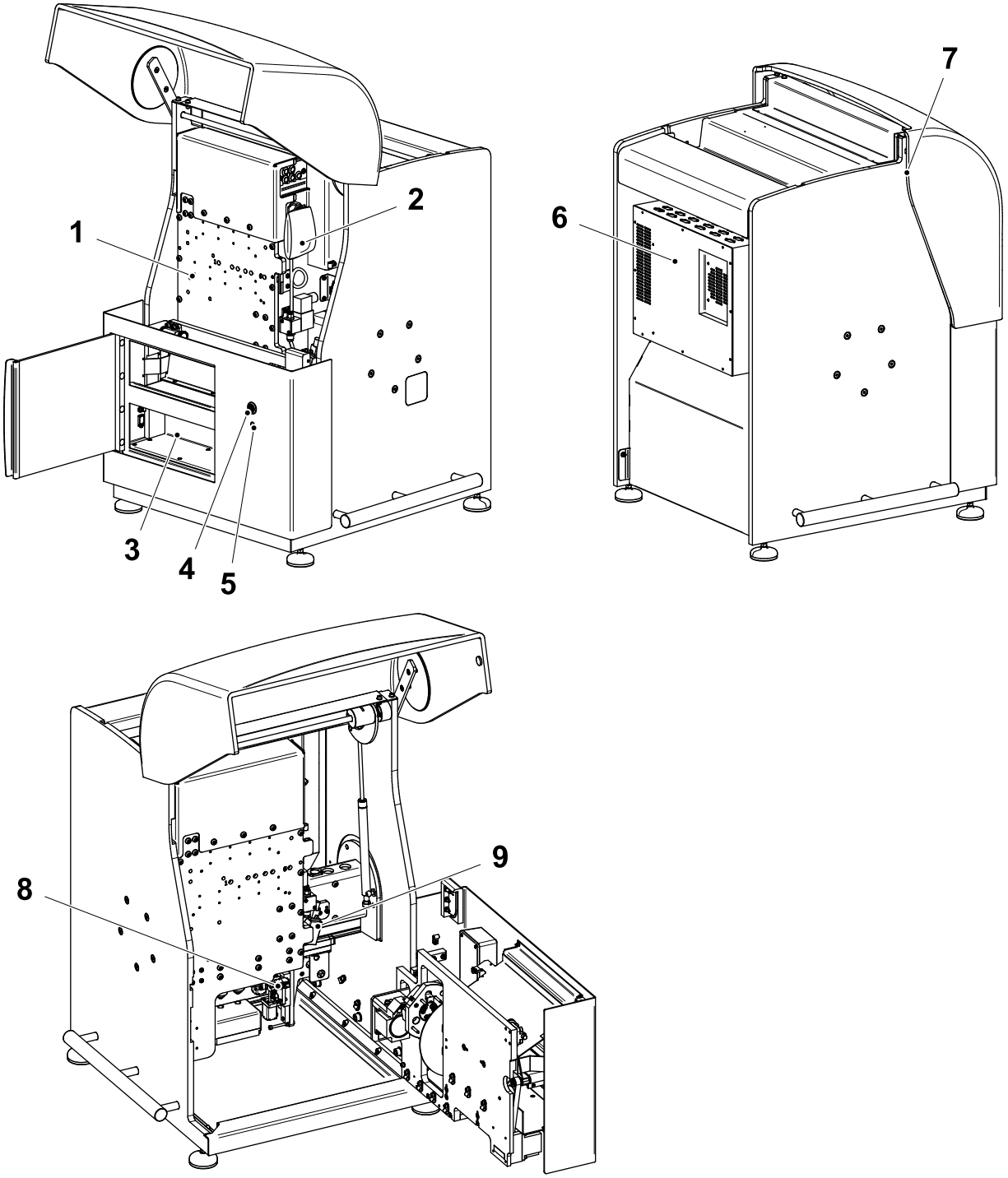
The system comprises the following major units:

- System computer
- Slide scanning unit (SSU)
  - Motorized microscope
  - Digital color camera
  - Immersion oil unit
  - Robot gripper unit
  - Barcode reader
  - Magazine feeder unit
  - Control unit
  - Casing

System Computer

A PC system running Microsoft® Windows® and CellaVision® DM software.

Slide Scanning Unit:



1. Motorized microscope
2. Digital color camera (inside)
3. Magazine feeder unit
4. Power switch
5. Status LED
6. Control unit
7. Casing
8. Robot gripper unit
9. Barcode reader

> **Warning!**
>
> Never tamper with sensors or other safety devices. These make sure that the system can operate without any risk of personal injury.

Motorized Microscope

1.5.3. 1. Tiesinės šviesos mikroskopas su LED apšvietimo sistema.

The motorized microscope is an upright light microscope with a LED illumination system. It has one 10x objective and one 100x objective and intermediate optics switching between 1.0x and 0.5x magnification which combined yields images with 5x, 10x, 50x, or 100x magnification.

1.5.3. 2. vaizdų didinimo nustatymai: 5, 10, 50 ir 100 kartų.

Digital Color Camera

1.5.3. 2. Aukštos kokybės progresinio nuskaitymo CCD spalvotas fotoaparatas, didele sparta pateikiantis geriausios kokybės atvaizdą

The camera is a high-quality progressive-scan CCD color camera, for maximum image quality and high speed image acquisition.

Immersion Oil Unit

The unit automatically applies drops of immersion oil to a slide. An optical drop counter controls the procedure.

Robot Gripper Unit

The robot gripper unit enables fully automated focusing and XY-positioning of the slide during process. It transports the slide from the magazine and back again after the slide has been processed.

Barcode Reader

The barcode reader scans the barcode of both the slide and the magazine. For maximum safety, the barcode of the slide is scanned before processing. See Appendix - A *System Specification*.

Magazine Feeder Unit

The unit feeds magazines, one by one, from the infeed conveyor to gripper unit and from the gripper unit to the outfeed shelf. It is equipped with a sensor that alerts the user if the outfeed shelf is full.

Control Unit

The control unit controls motors, sensors, oil applying and illumination. It functions as a slave computer to the system computer via an unshared Ethernet connection.

Casing

The casing comprises a metal cabinet and the main hood.

1.5 References to Scientific Literature

- F. Glassy, Eric (1998)

  Color Atlas of Hematology, An Illustrated Field Guide Based on Proficiency Testing, College of American Pathologists Hematology and Clinical Microscopy Resource Committee

  Northfield, Illinois, USA, College of American Pathologists

- Lewis SM, Bain BJ, Bates I (2001)

  Dacie and Lewis, Practical Hematology, Ninth Edition

  London, Harcourt Publishers Limited

2 Operating Procedures

2.1 Starting the System

The system computer is configured with a Windows policy restricting access to the operating system for the normal user. When starting the system computer the user will automatically be logged onto Windows and then the software logon window will be displayed.

Start the system as follows:

1. Switch on the slide scanning unit.
2. Switch on the system computer.
3. Wait until the status lamp on the slide scanning unit is flashing or continuously lit (see picture in 1.4.1 *Major Parts of the System*).
4. In the *Log On* dialog, type username, password and select the desired database. The following icons indicate available database types:


Processing database


Export database


Scan database

5. Click *OK*.

2.2 System Control View

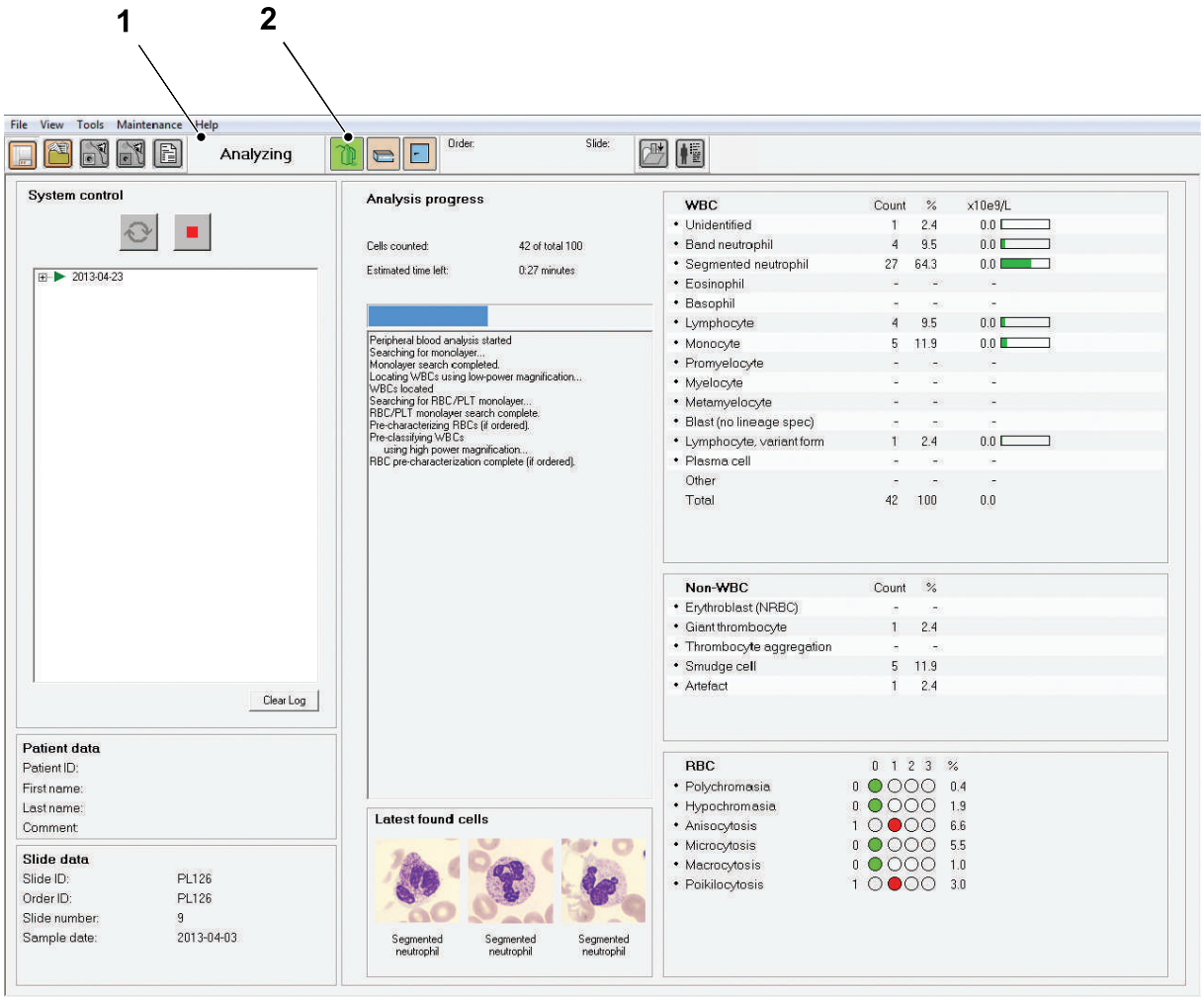
The *System Control View* shows the ongoing slide processing, gives an overview of the preclassification and presents a log of processed slide holders. The layout of the *System Control View* depends on the type of application.


Click *System Control View* in the toolbar.

Information in Toolbar

System indicators show oil level, hood position etc. For a description of these indicators, see Appendix - C *Buttons and Indicators*.

System status is shown as a text: *Idle, Analyzing, Stopped, Paused* or *Error*.



1. System status
2. System indicators

2.3 Slides and Magazines

2.3.1 Barcodes

> **Important!**
>
> Only slides labeled with barcodes can be processed. Use only barcode formats appropriate for the system (see Appendix - A *System Specification*).

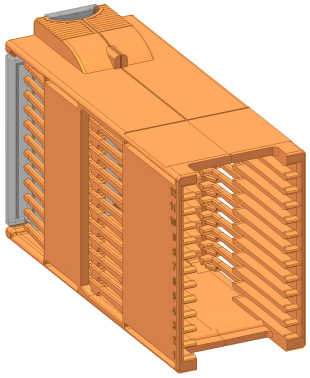
Magazine ID

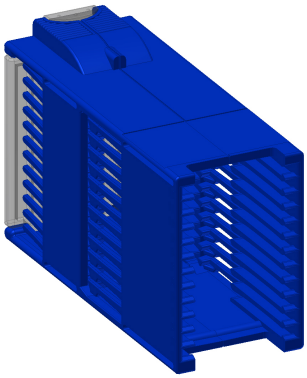
The barcode on the magazine is the magazine ID. When the system has no LIS connection, the magazine ID determines the analysis type.

- Orange magazines with barcodes consisting of prefix ‘PB’ followed by at least three digits - a peripheral blood analysis will be performed.
- Blue magazines with barcodes consisting of the prefix ‘BFS’ followed by at least three digits - a body fluid analysis will be performed.

Note:
A LIS order will override the magazine barcode in determining analysis type.

Note:
The magazines are supplied with barcode labels. If you replace the barcode label, the new barcode must not contain the '/' character.





Order/Slide ID

The Order/Slide ID is the barcode printed on the slide's label.

Note:
The Order/Slide ID may be up to 24 characters (ASCII) including spaces. No leading spaces are allowed. The Order/Slide ID may not begin with ‘PB’ or ‘BFS’.

When processing a slide the system searches for order data in the following order:

1. In the database, unsigned orders with the same Order/Slide ID.
2. In the database, pending orders.
3. From the LIS.
4. Default values defined in the *Analysis* tab in *Settings*.

2.4 Loading Slides into a Magazine

> **Caution!**
>
> Use only clipped/round/beveled corner slides. Failing to do so may cause jams and excessive wear on magazines and the system.

> **Caution!**
>
> If you want to process an already processed slide, carefully wipe the oil off and make sure the barcode is clean and undamaged.

Load the slide into the magazine with the barcode upwards and towards the open end. 12 slides can be loaded into a magazine. The slide positions in the magazine are numbered 1-12 from the bottom up. Make sure that slides are fully inserted in the magazine before using the magazine.

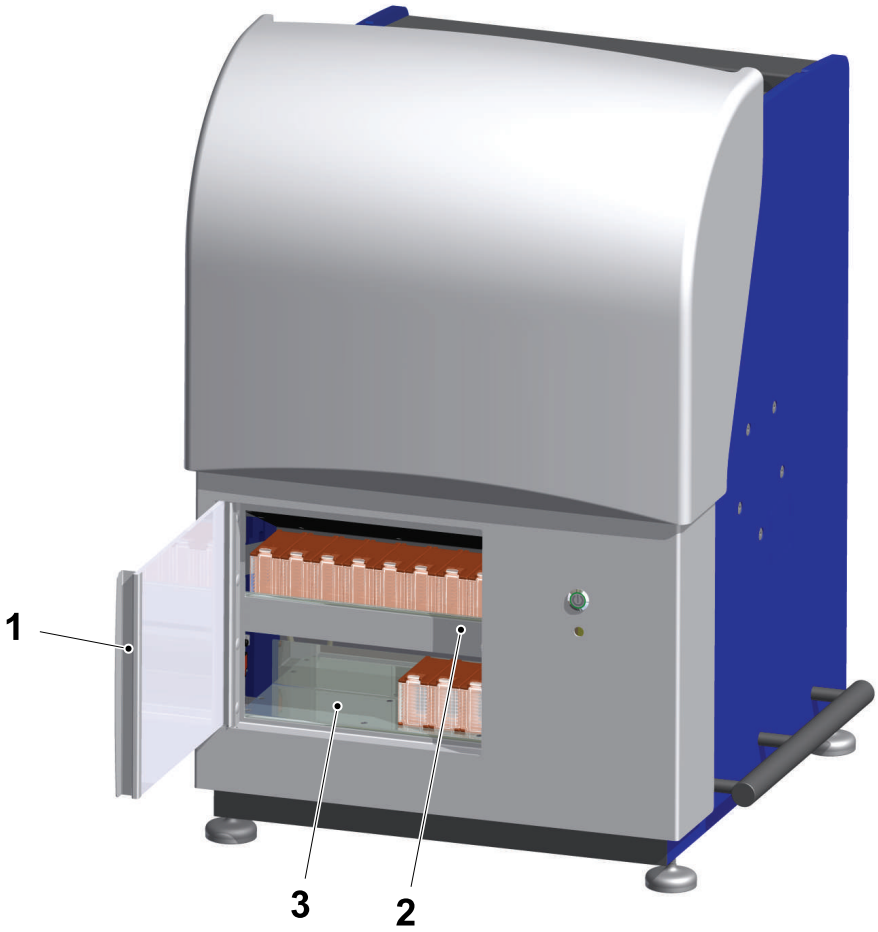
Note:
The same magazine can be used up to 100 times. When this limit is reached a warning is shown.

2.5 Processing Slides

2.5.1 Adding Magazine

1. Open the input hatch.
2. Put the magazines on the infeed conveyer.

   The magazines must have the barcode facing upwards and the open end of the magazine facing inwards.



1. Input hatch
2. Infeed conveyer
3. Outfeed shelf

When all slides in a magazine have been processed, the magazine is automatically ejected into the outfeed shelf.

2.5.2 Starting the Slide Processing

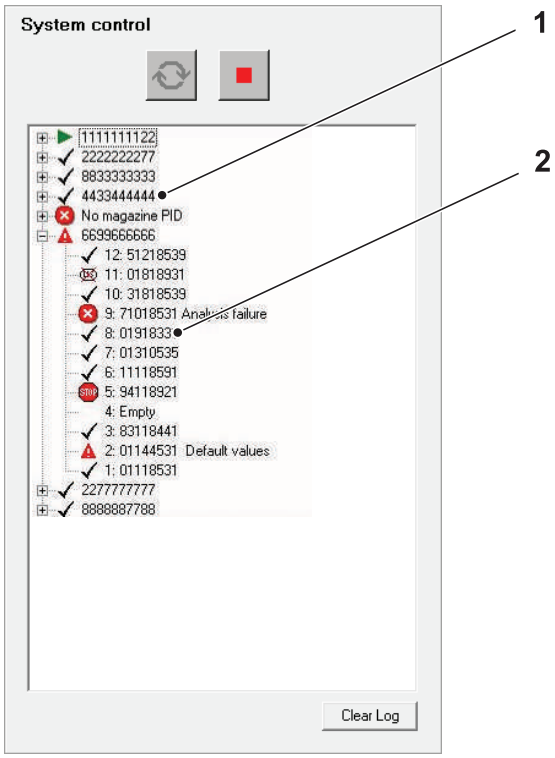
The processing starts automatically when a magazine is inserted into the system. You have to manually start the processing if the system has been stopped, restarted or if an error has occurred.


Start button


Autostart - Replaces the Start button.


Stop button

The tree in the *System Control* panel displays a status log of processed magazines and slides.



1. Magazine
2. Slide

To empty the log from all information, click *Clear Log*.

2.5.3 Magazine Status

The following information is available for each magazine:

Magazine status	Magazine ID (barcode)
⚠	PB2345678912

Magazine Status:

	Analyzing	
	Finished	All the slides in the magazine have been processed with no warnings or errors.
	Warning	A slide with status Warning, Stopped, Failed or Canceled exists in the magazine.
	Failed	The magazine has no magazine ID.

2.5.4 Slide Status

The following information is available for each slide:

Slide status	Slide position	Order/Slide ID (barcode)	Error/warning text
	7	2345678912	Default values

Slide Status:

	Processing	
	OK	The slide has been processed with no warning or error.
	Warning	The slide has been processed with a warning. Results exist.
	Stopped	Slide processing stopped by user. No results exist.
	Error	All ordered analyses failed. No results exist.
	Canceled	The slide was canceled in the LIS. The slide has not been processed.
Empty	Empty	The slide position in the magazine was empty.

Slide Information Dialog

Double-click on a slide to open the Slide Information dialog. Additional information on the processed slide, e.g. the cause of an error, is displayed here.

2.6 Ejecting Magazine

The magazine currently being processed can be ejected.

1. Click *Stop*.
2. Select *Eject* in *Tools* menu.

3. The magazine is ejected into the outfeed shelf.

2.7 Shutting Down the System

Shut down the system as follows:

1. Eject and remove the magazine from the system.
2. Select *Exit* in the *File* menu.
3. Switch off the system computer.
4. Switch off the slide scanning unit.

3 Quality Control

3.1 Cell Location Performance

The Cell Location Test is used to verify the slide preparation process and the system hardware. The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by running the Cell Location Test.

Note:
Running the test once or twice a day is a recommended interval at the high-load laboratory.

3.1.1 Cell Location for Peripheral Blood

The test establishes how many percent of the nucleated cells (i.e., WBC and NRBC) that are found on a slide.

The *Cell Location* tool can be accessed in the *Tools* menu.

Slide Requirements

Use a freshly stained blood sample with a WBC count in the normal WBC range. To reduce processing time, a WBC count above $7x10^9$/l is recommended. If the system cannot locate at least 100 nucleated cells, the result will be discarded.

The percentage of non-nucleated cells (i.e., all other objects that are not identified as being a WBC or an NRBC, e.g. smudge cells) must not exceed 30% of the total number of objects.

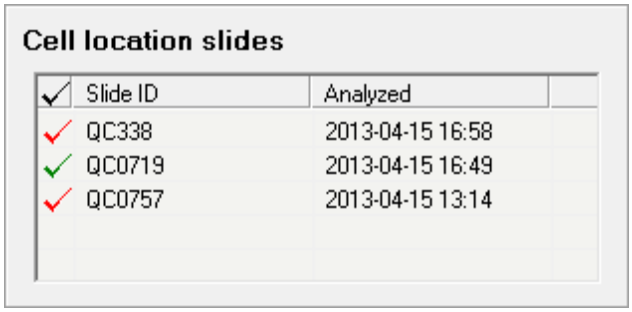
The slides must have a barcode label, starting with the text "QC". All slides with this kind of label are automatically treated as cell location test slides. When the slide has been processed it will only be available in the *Cell Location* tool. Pre-printed QC labels are available from your local dealer.

Running a Cell Location Test

1. Select a slide that meets the requirements and put a QC label on it.
2. Put the slide in a magazine, place it in the system and process the slide.
3. Go to the *Cell Location* tool when the slide has finished.

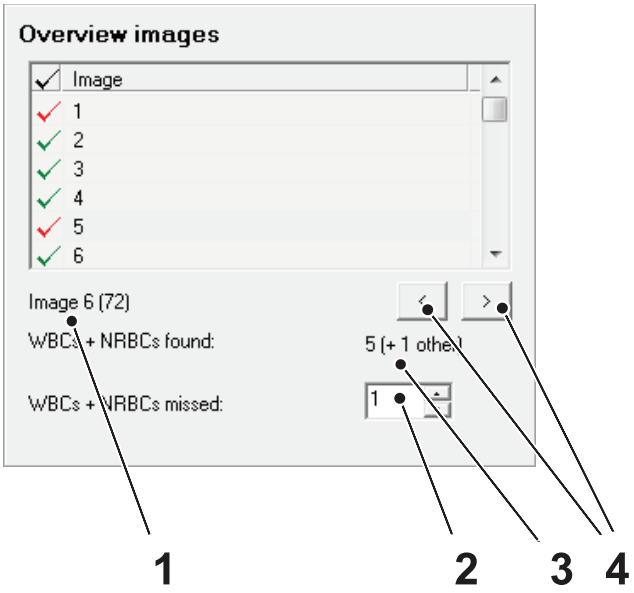
Examining a Cell Location Slide

1. Select the slide in question from the list of cell location slides.
2. Go through all the images belonging to the slide and examine them for missed nucleated cells. Enter the number of missed cells, if any, in the input field for each image. See the following section “Overview Images” for more information.



Slide status	✓
Empty	Slide has no result (not all images have been examined).
✓	Slide has a result and no missed nucleated cells (all images have been examined).
✓	Slide has a result but contains missed nucleated cells (all images have been examined).
⊗	Slide error, probably due to a failure in slide processing (e.g., not enough nucleated cells were found).

Overview Images:

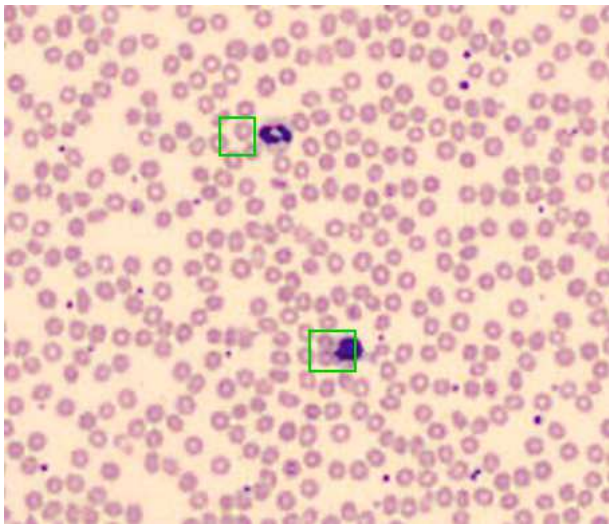


1. Looking at image X of a total of Y images.
2. Number of missed nucleated cells in the image shown (number entered by the user).
3. Number of nucleated cells in the image shown.
4. Step one image back or forth.

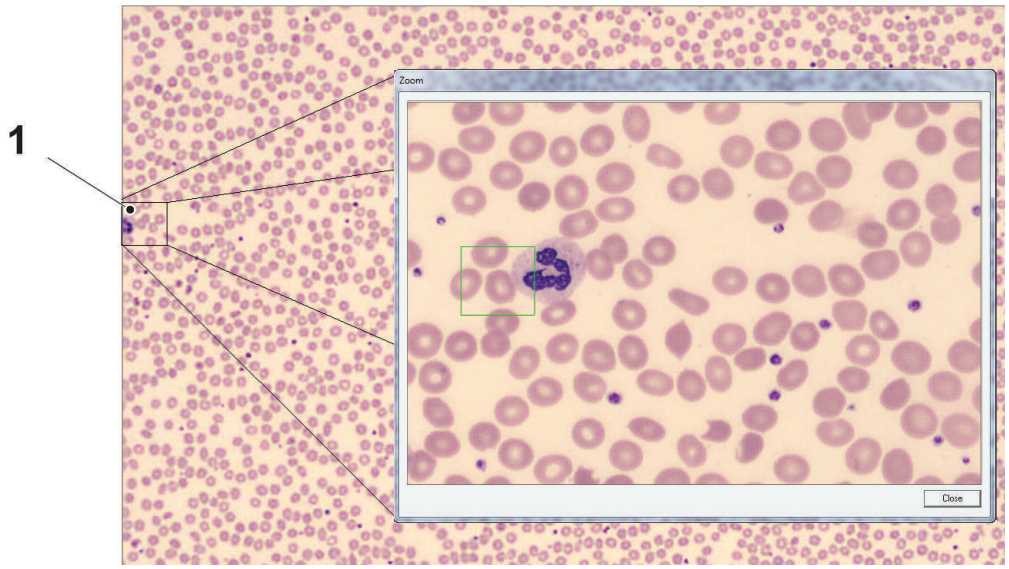
Image status	✓
Empty	Image has not been viewed.
✓	Image has been viewed and has no missed nucleated cells.
✓	Image has been viewed but contains missed nucleated cells.

Green boxes mark cells pre-classified as nucleated cells and blue boxes mark other found objects pre-classified as not nucleated cells (e.g. artefacts). Double-click in the overview image to magnify the area of interest.

Black boxes mark the number of cells that were located but not needed for the test, indicating that the system has located enough cells for the test and is coming to an end.



The object has been located by the system if there is a box associated with it. The boxes are not always centered on the cells and can be completely separated from the cells. As long as there is a box associated with a cell this indicates that the system has found the cell.

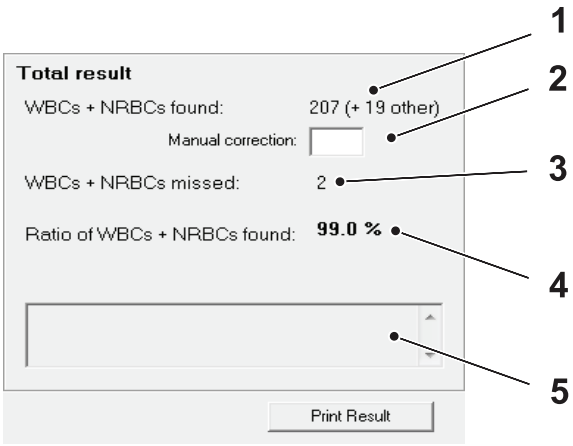


1. Cell at the edge of the image

If a cell is at the edge of the image the cell box can sometimes be 'outside' the image. To confirm that the cell has been located, double click on the cell to view the magnified image and confirm that the cell has a box associated with it.

Note:
On screen, cell images are not always presented in the same order as the system is working. Cells marked with black boxes may occur in the middle of the test, not only towards the end.

The Result



1. Total number of nucleated cells and non-nucleated cells found in all the images.
2. Manual correction of nucleated cells found.
3. Total number of nucleated cells missed in all the images.
4. Percentage of how many nucleated cells were found compared to the actual number of nucleated cells on the images.
5. Messages about faulty slide analysis etc.

When a slide has been examined the result is automatically calculated. The percentage indicates how many nucleated cells the system has found, including the manually added number of missed cells. Check that it is within acceptable limits.

The result should be compared to the laboratory's own established limits. Performance characteristics when using standardized staining and smear preparation procedures are presented in Appendix - A *System Specification*.

It is possible to adjust the total number of found nucleated cells, if it is determined that some found cells are neither WBC nor NRBC. For instance, if the system identifies 187 nucleated cells but the user thinks 3 of them do not fall under this category, the user can enter 184 in the *Manual correction* field and this number will be used in the calculation.

If any of the requirements regarding the number of nucleated cells or non-nucleated cells are not fulfilled, an error message will be shown in the *Total result* panel.

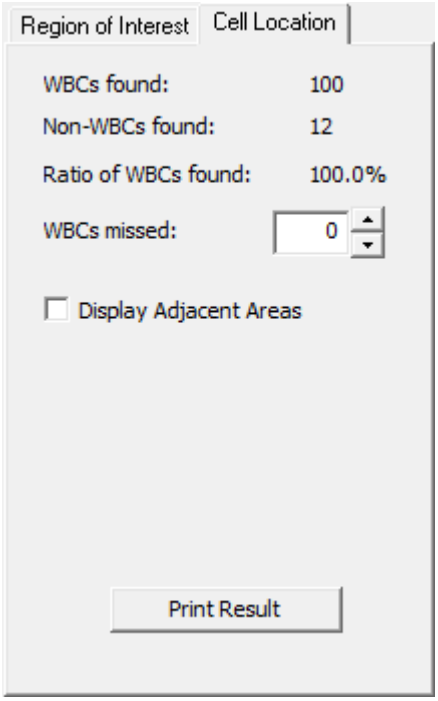
The cell location results can be printed by clicking the *Print Result* button.

Deletion of Cell Location Tests

Images and results from a Cell Location Test older than five days are automatically deleted at program startup/logon.

3.1.2 Cell location for Body Fluids

The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by examining the Cell Location Test. It is also recommended to run cell location test for each new body fluid specimen analyzed in the laboratory. For the definition of body fluid specimens see CLSI H56-A Body Fluid Analysis for Cellular Composition; Approved Guideline. Running the test once or twice a day is a recommended interval at the high-load laboratory. The test establishes how many percent of the nucleated cells that are found on a slide.



The Cell Location tool may be accessed by clicking on the *Cell Location* tab in the body fluid *Overview* view. Cell location information is available for all BF slides.

Slide Requirements

Use a freshly stained body fluid sample with a total number of nucleated cells less than 12 000.

Running a Cell Location Test

Select a slide that meets the requirements and process it like a regular BF slide.

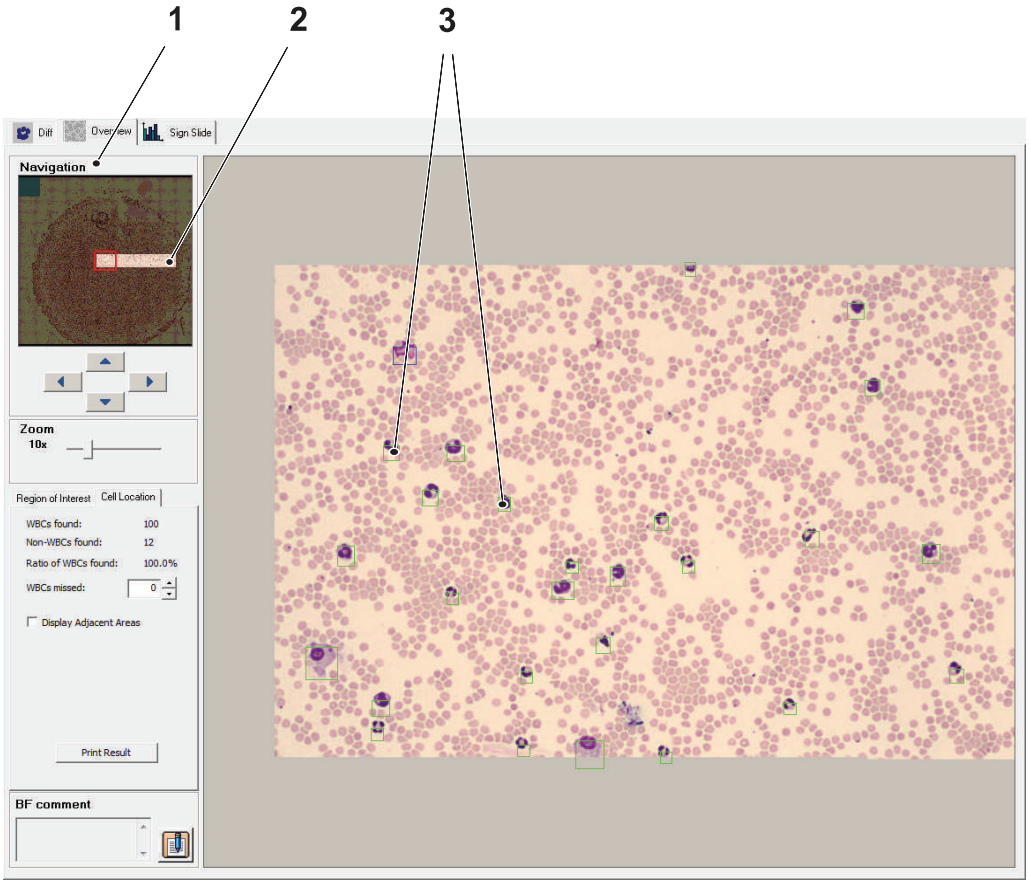
It is recommended that you order 10x+50x overview images for cell location slides.

Note:
QC labels are not required for running a cell location test on body fluid slides.

Examining a Cell Location Slide

1. Open the slide in question from the *Database view*.
2. Select the *Overview* tab and then select the *Cell Location* tab in that view.
3. Navigate through the entire analysis area and look for missed nucleated cells. Enter the number of missed cells, if any, in the input field. See the following section for more information.

Overview:



1. Mini Map
2. Analysis area
3. Located cells

The analysis area used for collecting cells is represented by the bright part of the mini map.

Navigate through the analysis area and check if it contains any missed nucleated cells. Green boxes mark cells pre-classified as nucleated cells and blue boxes mark other found objects pre-classified as not nucleated cells (e.g. artefacts).

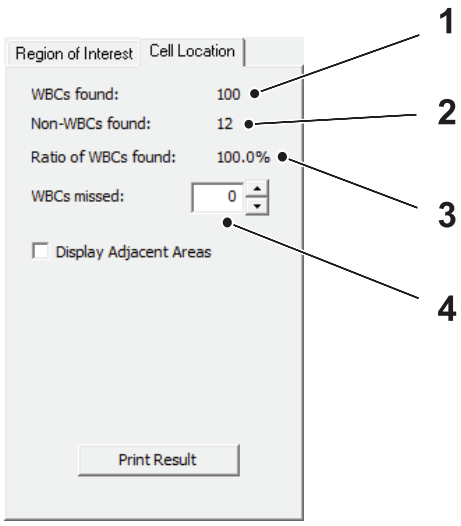
Black boxes mark the cells that were located but not needed for the test, indicating that the system has located enough cells for the test and is coming to an end.

The object has been located by the system if there is a box associated with it. The boxes are not always centered on the cells and can be completely separated from the cells. As long as there is a box associated with a cell this indicates that the system has found the cell.

Note:
On screen, cell images are not always presented in the same order as the system is working. Cells marked with black boxes may occur in the middle of the test, not only towards the end.

Note:
The last collected cell will be marked with both a black and a green or blue box.

The Result



1. Number of nucleated cells found in the sample.
2. Number of non-WBCs found in the sample.
3. Cell location percentage.
4. Number of missed nucleated cells in the analysis area.

The result is automatically calculated. The percentage indicates how many nucleated cells the system found including the manually added number of missed cells. Check that the result is within acceptable limits.

The result should be compared to the laboratory's own established limits. Performance characteristics when using standardized staining and smear preparation procedures are presented in Appendix - A *System Specification*.

The cell location results can be printed by clicking the *Print Result* button.

3.2 Self Tests

The system performs self-tests during startup of the software, and at certain points during the operation of the system. When the software starts, the system is checked before the operator can start analyses. During this phase, both the hardware and the software components are tested for anomalies, as well as various requirements for the operation of the system. If the LIS communication is enabled, the program will also check the connection to the LIS.

After each slide the system has processed, it checks the positioning of the motors. While the program is running, the database size is compared intermittently to the rules set for archiving or automatic deletion of old entries, thus ensuring that the database is kept at a reasonable and maintainable size.

The communication with, and response of the hardware, is tested continuously during the operation of the system, and a message will inform the operator if an error occurs during slide processing or other operations on the system.

4 Verifying Processed Slides

4.1 Peripheral Blood

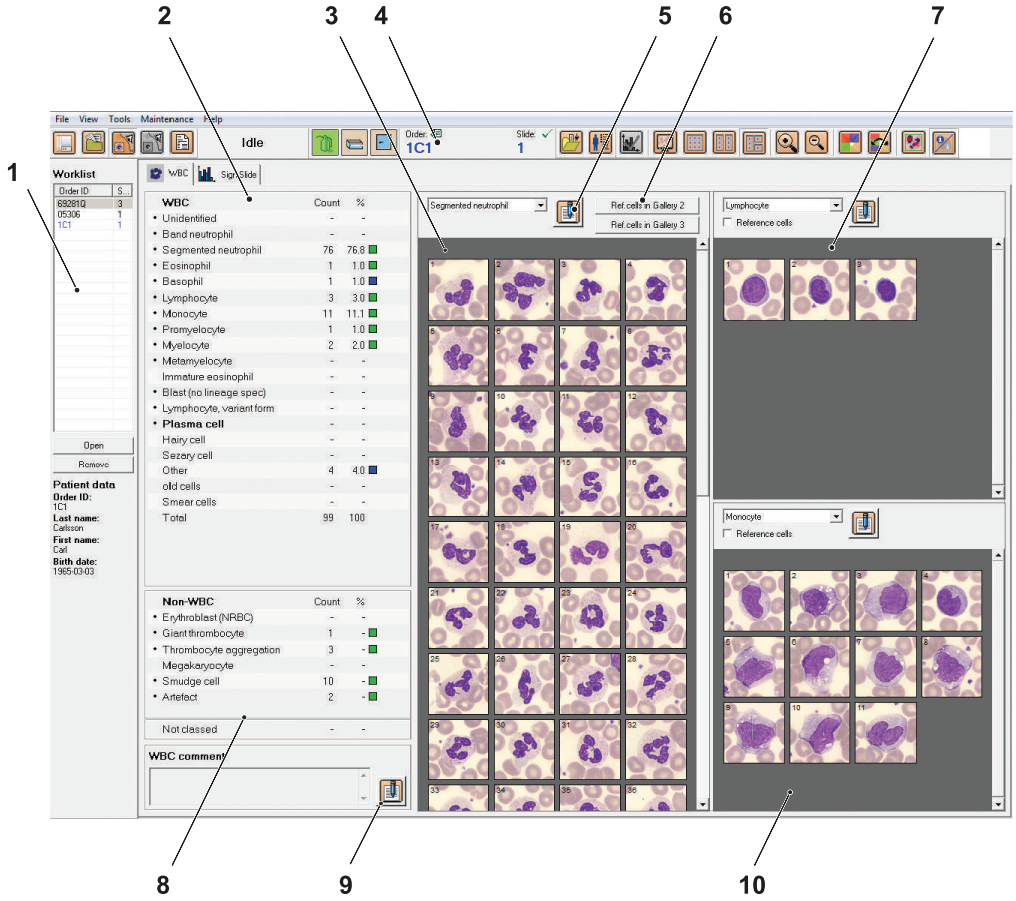
Opening an unsigned slide leads directly to the *Verification View*, where various tabs can be selected in order to review WBC, RBC and PLT and to sign the slide. To open a slide, see 6.1.3 *Opening an Order/Slide*.

 Click *Verification View* in the toolbar.

Note:
With DMConfiguration tool it is possible to add user defined WBC cell classes and RBC morphologies. To do this, contact your service personnel.

4.1.1 White Blood Cell Classification

You can view all WBCs identified by the system. You may also reclassify WBCs and add comments.



1. Worklist
2. WBC panel
3. Main gallery
4. Opened order/slide
5. Add cell class comment
6. Shortcuts to reference cells
7. 2nd gallery
8. Non-WBCs panel
9. Add WBC comment
10. 3rd gallery

All cell classes handled by the system are displayed in the figure on the following page. WBCs and non-WBCs automatically preclassified by the system are marked with a small dot or an arrow.

In settings, see 9.4 *Adjusting PB Reclassification Settings*, you may choose to auto-forward preclassified WBCs to another cell class as follows:

Band neutrophil to *Segmented neutrophil*

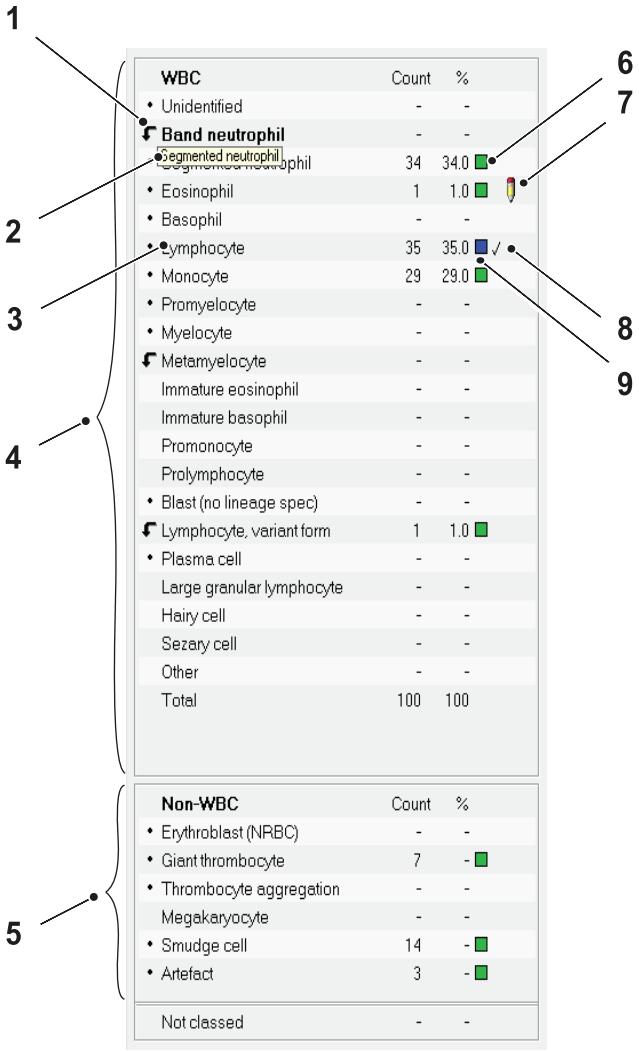
Metamyelocyte to *Segmented neutrophil*

Lymphocyte, variant form to *Lymphocyte*

Plasma cell to *Lymphocyte*

Blast cell, Metamyelocyte, Myelocyte and *Promyelocyte* to *Other.*

An arrow indicates that preclassified WBCs are auto-forwarded to another cell class. Place the cursor over the arrow to see the destination cell class.



1. Auto-forwarded cell class
2. Destination cell class
3. Preclassified by the system
4. WBC panel
5. Non-WBC panel
6. Green - Contains no reclassified cells or objects.
7. Pen icon - Indicates Cell class comments.
8. Tick mark - All images have been viewed
9. Blue - Contains at least one reclassified cell or object.

Customizing Views

Galleries:

WBCs are presented, by class, in galleries. The main gallery is always shown together with up to two additional galleries. Click *WBC Galleries* to change the number of galleries.

WBC Galleries

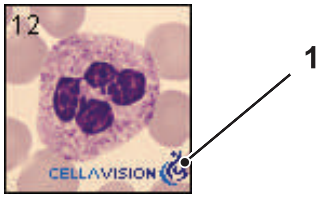
Left- and right-clicking in the WBC and Non-WBCs panels also changes cell class in the main and the 2nd gallery, respectively. You can also select cell class in the drop-down list.

The system keeps track of all WBCs viewed by the operator. A tick mark appears when all WBCs of a cell class have been displayed. It is not possible to sign the slide unless all cell classes have been viewed.

Reference Cells:

A library of reference cells for different cell classes is provided with the system. These cells are marked with a CellaVision® logo. The main gallery always displays WBCs from the slide, while the other show reference cells when checkbox *Reference cells* is activated. The main gallery has shortcuts to display reference cells in the other galleries. Click *Ref.cells in Gallery 2* and the 2nd gallery will display reference cells of the cell class selected in the main gallery.

Reference cells for body fluids are not provided with the system.



1. Indicates reference cell provided with the system

You may expand this library by saving WBCs from processed slides as custom reference cells.

1. Right-click on the WBC.

2. Select *Save as custom ref. cell* in the menu.

3. Restart the software.

The WBC will be displayed at the top of the 2nd or 3rd galleries, followed by the reference cells provided with the system. If you want to organize your custom reference cells, see 9.10 *Adjusting PB Reference Cells Settings* or 9.11 *Adjusting BF Reference Cells Settings*.

Cell Class Comments:

Click *Comment* in the galleries to add a cell class comment. A pen icon will appear to the right in the *WBC* and *Non-WBC*s panels. Click this icon to view, edit or add more comments (see 4.1.5 *Comments*).

WBC Full Screen View:

Click *WBC Full Screen View* to display all WBCs sorted by class.

WBC Full Screen View

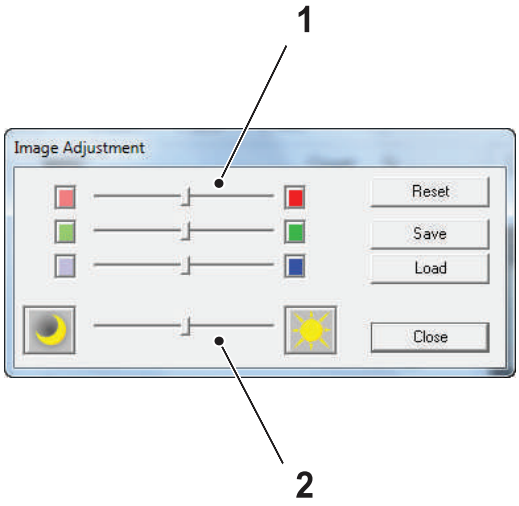
Note:

Cell classes that have been fully displayed in WBC Full Screen View will also be tick marked.

Adjusting Image Color and Brightness:

Click *Color/Brightness* to display the *Image adjustment* dialog.

Color/Brightness



1. Color sliders
2. Brightness

Color sliders: Changes the color composition of the image.

Brightness: Adjusts the brightness of the image.

Reset: Restores original settings.

Save: Stores individual settings.

Load: Gets individual settings.

Individual settings can also be switched using *Toggle Color/Brightness*.

Toggle Color/Brightness

Adjusting Magnification:

Click *Zoom In* or *Zoom Out* to change the magnification in all galleries and in the *WBC Full Screen View*.

 Zoom In

 Zoom Out

You may also double-click on a WBC to enlarge it, and use the scroll wheel to zoom in/out.

Reclassifying White Blood Cells

Reclassify WBCs by dragging and dropping them from one gallery to another:

1. Place cursor over the cell image.
2. Click and hold down left mouse button.
3. Move cursor to the destination gallery then release button.

You may also drag and drop cells to the WBC and Non-WBCs panels. Press *Ctrl* or *Shift* to select multiple cells.

Reclassified cells always appear at the top of the gallery.

A cell class containing at least one reclassified cell is marked blue in the WBC and Non-WBCs panels. If a cell is reclassified to its own cell class, it is considered reclassified and moved to the top of the gallery.

Note:
You can never reclassify WBCs on a signed slide.

Cell Marker

When the Cell Marker function is turned on, a green square marking the cell the system has identified, appears in every cell image. The *Cell Marker* is used to split cells and identify duplicate cells.

 Cell Marker

Splitting cells:

Occasionally the system fails to separate WBCs that are close to each other, and more than one cell in an image will be outlined by the cell marker (green square). These cells should be split so that each can be identified by the operator. With the cursor over the image, use the right-click menu and select *Split cells*. A dialog appears explaining the procedure. The appearance of the green square is not changed for split cells. Instead a copy of the same image is created, and a red cross will mark the cell which is to be identified.

Cells created by splitting can always be removed, using the right-click menu.

Identify duplicate cells:

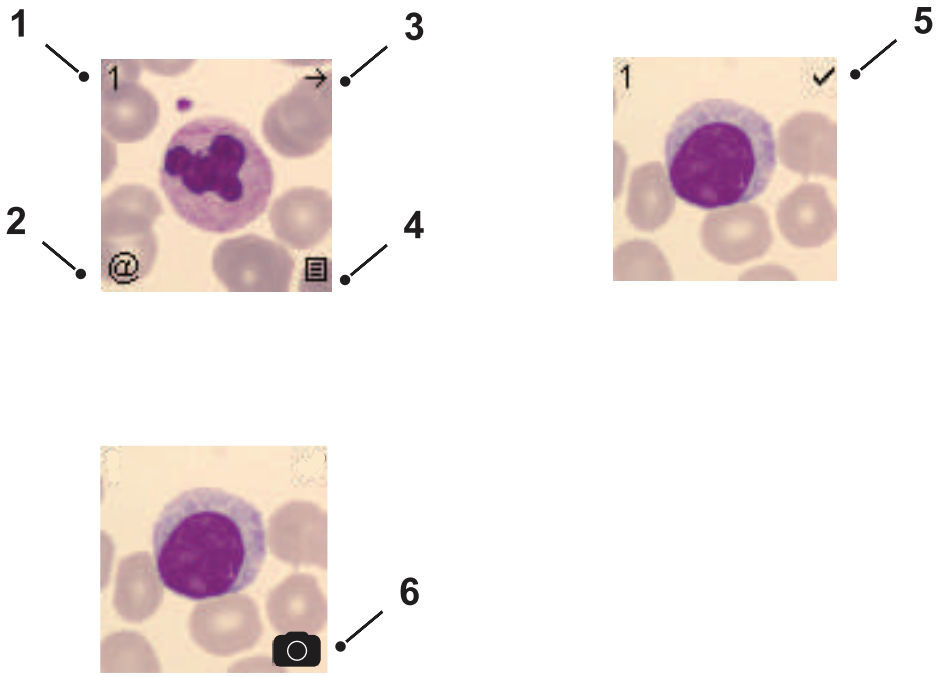
If the green square outlines only part of a cell, the system has only used this part for cell identification. There is a risk that the system has identified the other part of the cell as a completely different cell, thus the same cell can be counted more than once.

To make sure duplicate cells are not included in the differential count it is recommended to screen all cell images for duplicate cells when a green square only covers part of a cell. A duplicate cell should be removed from the differential.

See 11 *Troubleshooting* for more information.

WBC Attributes

Each cell is associated with attributes.



1. Indicates the order in the class
2. Cell is selected for e-mail.
3. Cell has been forwarded from another cell class
4. Cell comments exist
5. Reclassified cell
6. The image has been manually captured on a CellaVision® Image Capture System

WBC attributes are shown by default. Click *WBC Attributes* to show/hide them.

Note:
It is not possible to hide the CellaVision® Image Capture System symbol.

 WBC Attributes

Right-click Menu:

Right-click on a cell to set/view attributes. A menu appears, allowing the following options:

1. *View DM's 1st, 2nd and 3rd suggestions of classification*.
2. *Reclassify cell*.
3. *Add/view cell comments* (see 4.1.5 *Comments*).
4. *Split cell* or *remove split cell*.

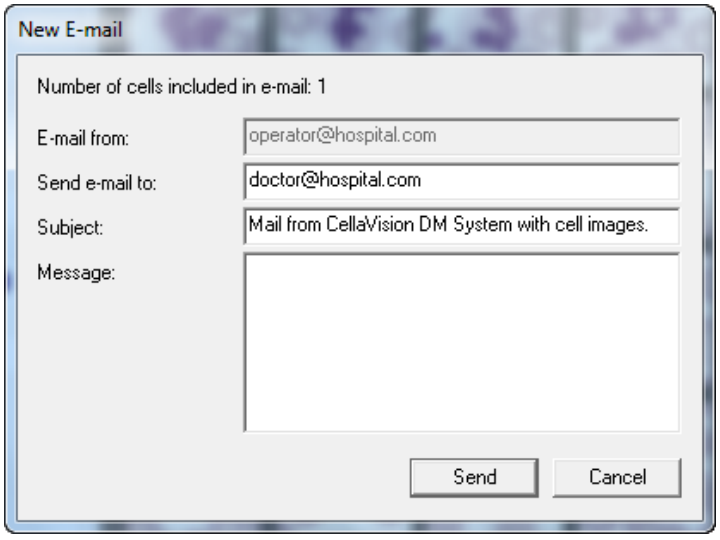
5. *Select cell for e-mail*.
6. *Save cell as custom reference cell*.
7. *Save images to disk*.

Note:
All alternatives are not available for images captured on a CellaVision® Image Capture System.

E-mail

You may send cell images by e-mail.

1. Select *select for e-mail*, using the right-click menu.
2. Select *Tools/Send E-mail* and the *New E-mail* dialog appears.



For default values, see *E-mail* tab in *Settings*.

3. If desired, change receiver address.
4. If desired, add *Subject* and *Message*.
5. Click *Send*.

Note:
You may only send cells from one slide in each e-mail.

Note:
No patient data is sent in the e-mail.

Copying Images to Disk

You may copy selected images to disk.

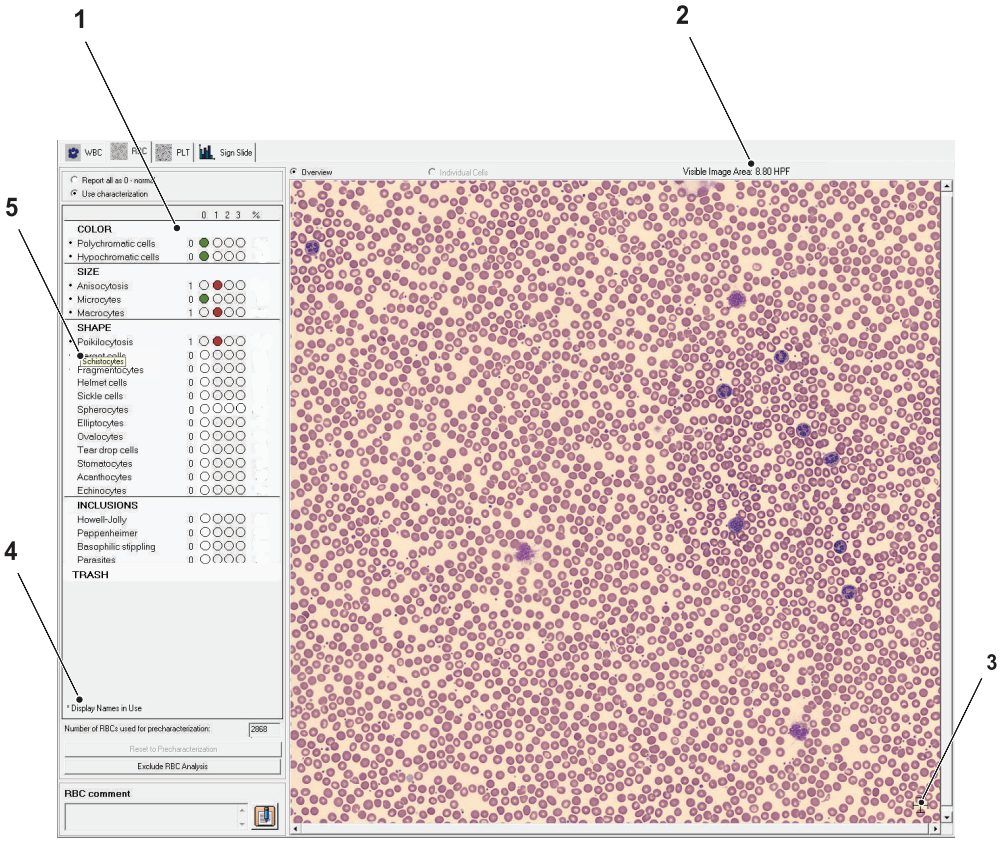
1. Select cells for copying.
2. In the right-click menu select *Copy images to disk…* and the *Copy images to disk* dialog appears.
3. Specify the destination path where you want the images to be saved, use the browse button to navigate to a suitable folder.
4. Click *OK*.

Note:
The directory you specify in the destination path must exist.

4.1.2 Red Blood Cell Characterization

The RBC overview image corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22 mm ocular).

See 9.5 *Adjusting RBC Precharacterization Settings*.



1. RBC panel
2. Visible Image Area
3. Ruler
4. Display Names in Use
5. Original name

RBC Panel:

The RBC panel is used for characterization of the RBC morphology. All morphologies handled by the system are listed. Morphologies precharacterized by the system are marked with a small dot.

The columns labeled 0 to 3 grade the morphology characteristics.

Normal	Green dot in column 0 indicates a normal level.
Slight	Red dot in column 1 indicates that the morphology is present at a low level.
Moderate	Red dots in column 1-2 indicate that the morphology is present at a moderate level.
Marked	Red dots in column 1-3 indicate that the morphology is present at a high level.

The rightmost column shows the percentage of RBCs in the overview image with the characteristic in question. If the precharacterization is overridden by manual characterization, the percentage is shown dimmed.

Note:
You can never recharacterize RBCs on a signed slide.

Note:
The RBC precharacterization is not available for images captured on a CellaVision® Image Capture System .

Visible Image Area:

The visible image area is shown in numbers of estimated microscopic high power fields (HPF). If you zoom in/out and then open another slide, the magnification of the red blood cell overview image will be the same as the previous.

Ruler:

In the bottom right-hand corner of the RBC image there is a cross-shaped ruler that represents 14 µm across. As the image magnification is increased, numbers will appear at the ends of the ruler to indicate the scale in micrometers. The ruler can be moved around the RBC image by moving the mouse pointer (in either zoom mode or scroll mode) over the ruler, depressing the left mouse button and then by dragging it to its desired placement. The ruler shape can be toggled between the default cross shape and a line shape by double-clicking on it.

Display Names in Use:

With DMConfiguration tool it is possible to edit the names of the RBC morphologies. To do this, contact your service personnel.

Move the mouse pointer over the morphology in the RBC panel to show the original name.

Customizing the Red Blood Cell Overview Image

Change the magnification of the image by using these buttons:

 Zoom In

 Zoom Out

 Entire RBC Image - Shows the entire RBC image.

Navigate the image by switching between different control modes. The mouse pointer changes accordingly.

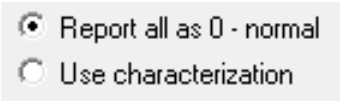
  Zoom Mode - Hold left mouse button down and zoom in/out by moving the mouse pointer up/down.

  Scroll Mode - Hold left mouse button down and pan in any direction using the mouse.

You may also double-click in the RBC image to enlarge a limited area, and use the scroll wheel to zoom in/out.

Characterizing Red Blood Cell Morphology

There are two ways to report the RBC result:



1. Report all as normal
    a. Select radio button *Report all as 0 - Normal*.
2. Use characterization
    a. Select radio button *Use characterization*.
    b. If you disagree with a precharacterization, click the dot that corresponds to your opinion.

Click *Reset to Precharacterization* to restore the precharacterization result done by the system. All manual characterization will be lost.

If you want to remove a specific type of morphology from the report, deselect the dot by clicking on it.

Excluding the Red Blood Cell Analysis

Click *Exclude RBC Analysis* to exclude the RBC analysis results from the slide.

4.1.3 Advanced Red Blood Cell Characterization

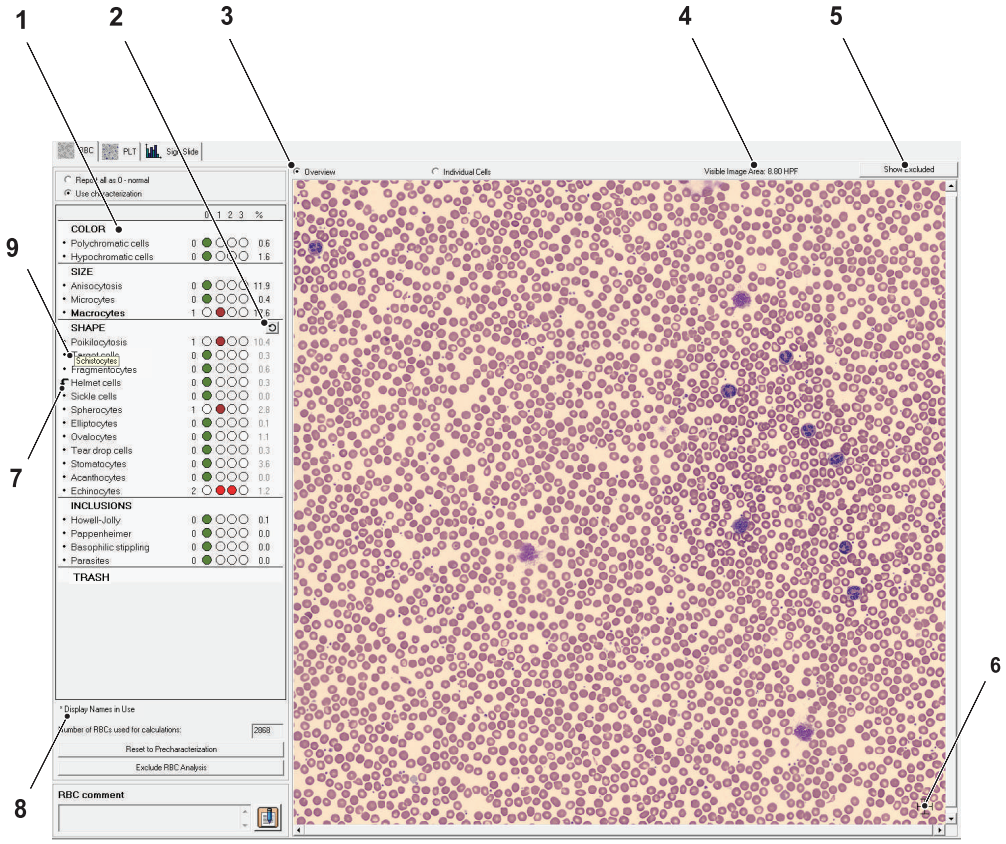
The Advanced RBC precharacterization is only available for images captured on a system with the Advanced RBC application activated.

Overview

Click *Overview* to view the RBC overview image.

The RBC overview image corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22 mm ocular).

See 9.6 *Adjusting Advanced RBC Settings*.



1. RBC panel
2. Automatic grading
3. Overview
4. Visible Image Area
5. Show excluded
6. Ruler
7. Auto-forwarded morphology
8. Display Names in Use
9. Original name

RBC Panel:

The RBC panel is used for characterization of the RBC morphology. All precharacterized morphologies handled by the system are listed.

The columns labeled 0 to 3 grade the morphology characteristics.

Normal	Green dot in column 0 indicates a normal level.
Slight	Red dot in column 1 indicates that the morphology is present at a low level.
Moderate	Red dots in column 1-2 indicate that the morphology is present at a moderate level.
Marked	Red dots in column 1-3 indicate that the morphology is present at a high level.

The rightmost column shows the percentage of RBCs in the overview image with the characteristic in question. If the automatic grading is overridden by manual grading, the percentage is shown dimmed and the dot is shown in a lighter color. Click  if you wish to go back to use automatic grading.

RBCs automatically precharacterized by the system are marked with a small dot or an arrow.

Click on a morphology to highlight these cells. The same cells will still be highlighted if you switch to view cells in the Individual cells view.

Note:
You can never recharacterize RBCs on a signed slide.

Note:
The RBC precharacterization is not available for images captured on a CellaVision® Image Capture System  .

Visible Image Area:

The visible image area is shown in numbers of estimated microscopic high power fields (HPF). If you zoom in/out and then open another slide, the magnification of the red blood cell overview image will be the same as for the previous slide.

Show Excluded Objects:

Click *Show Excluded* to highlight objects that are not included in the analysis.

Ruler:

In the bottom right-hand corner of the RBC image there is a cross-shaped ruler that represents 14 µm across. As the image magnification is increased, numbers will appear at the ends of the ruler to indicate the scale in micrometers. The ruler can be moved around the RBC image by moving the mouse pointer (in either zoom mode or scroll mode) over the ruler, depressing the left mouse button and then by dragging it to its desired placement. The ruler shape can be toggled between the default cross shape and a line shape by double-clicking on it.

Auto-forwarded Morphology:

In settings, see 9.4 *Adjusting PB Reclassification Settings*, you may choose to auto-forward precharacterized RBCs to another morphology as follows:

Helmet cells to *Schistocytes*

Ovalocytes to *Elliptocytes*

An arrow indicates that precharacterized RBCs are auto-forwarded to another morphology. Place the cursor over the arrow to see the destination morphology.

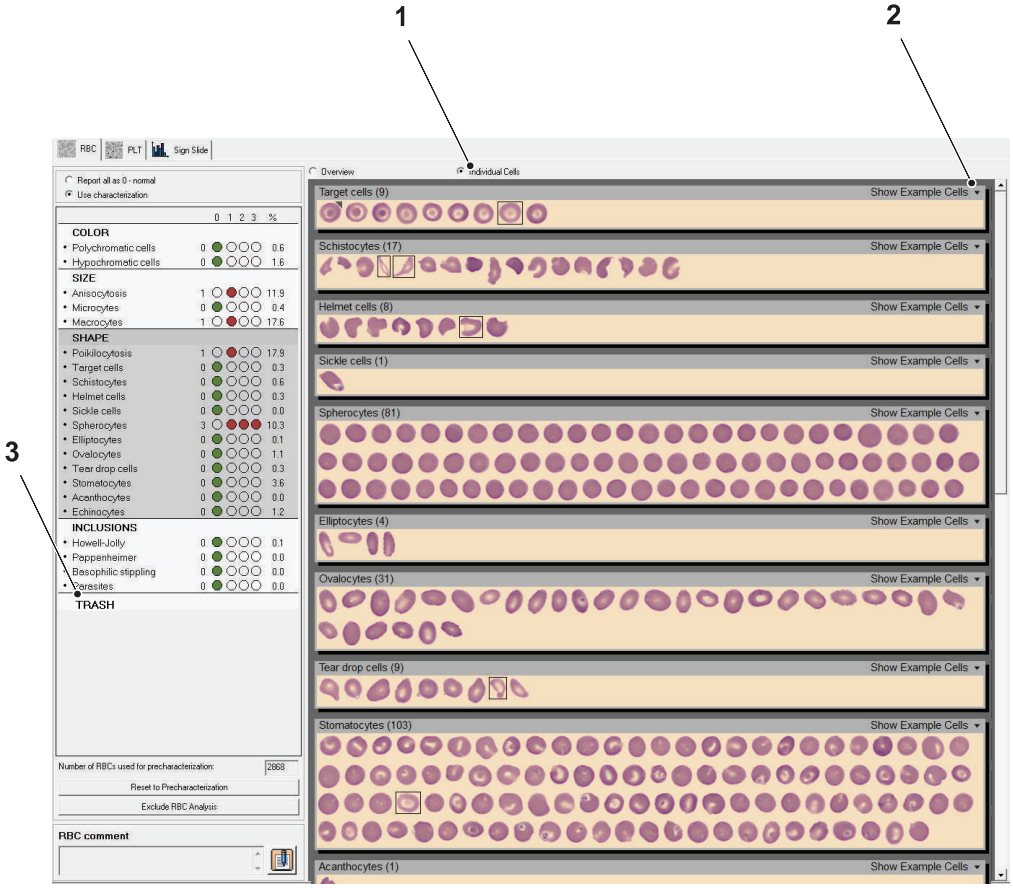
Display Names in Use:

With DMConfiguration tool it is possible to edit the names of the RBC morphologies. To do this, contact your service personnel.

Move the mouse pointer over the morphology in the RBC panel to show the original name.

View Individual Cells

Click *Individual Cells* to view the classified cells individually.



1. Individual Cells
2. Show Example Cells
3. Trash

Click on one of the headers in the list to the left to view the cells within that group.

Click on one of the morphologies under another header in the list to the left to view two morphologies at the same time. A black box appears around those cells. The same cells will still be highlighted if you switch to view the cells in the Overview image.

Double-click on a cell image to view an enlarged image, including the surrounding parts of the image. Use the scroll wheel to zoom in/out.

Reclassify Red Blood Cells:

Reclassify RBCs by dragging and dropping them from one morphology to another:

1. Place the cursor over the cell image.
2. Click and hold down the left mouse button.
3. Move the cursor to the destination gallery then release the button.

You may also drag and drop cells to the RBCs panels or use the right-click menu.

Press *Ctrl* or *Shift* to select multiple cells.

Reclassified cells will appear at the top of the gallery and be marked with a small triangle in the right top corner. Click on the reclassified cell to view the preclassification.

Note:
If a morphology has been manually graded it is not possible to reclassify cells within that specific group.

Trash:

Drag and drop objects to *Trash* to exclude them from the analysis.

Example Cells:

Right-click on a cell to *Save as custom example cell*.

Click on the small arrow next to *Show Example Cells* and choose a morphology in the drop-down list to view the example cells.

Right-click on a saved custom example cell to *Remove from example cells*.

Customizing the Red Blood Cell Overview Image

Change the magnification of the image by using these buttons:


Zoom In


Zoom Out


Entire RBC Image - Shows the entire RBC image.

Navigate the image by switching between different control modes. The mouse pointer changes accordingly.



Zoom Mode - Hold left mouse button down and zoom in/out by moving the mouse pointer up/down.

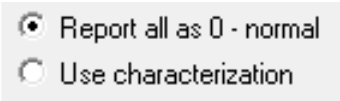


Scroll Mode - Hold left mouse button down and pan in any direction using the mouse.

You may also double-click in the RBC image to enlarge a limited area, and use the scroll wheel to zoom in/out.

Characterizing Red Blood Cell Morphology

There are two ways to report the RBC result:



1. Report all as normal
    a. Select radio button *Report all as 0 - Normal*.
2. Use characterization
    a. Select radio button *Use characterization*.
    b. If you disagree with a precharacterization, recharacterize the red blood cell morphology.

Click *Reset to Pre-characterization* to restore the precharacterization result done by the system. All manual characterization and classification will be lost.

If you want to remove a specific type of morphology from the report, deselect the dot by clicking on it.

Excluding the Red Blood Cell Analysis

Click *Exclude RBC Analysis* to exclude the RBC analysis results from the slide.

4.1.4 Estimating Platelets

The complete PLT overview image (same image as for RBC) corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22mm ocular). The overview image is divided into 4, 9 or 16 sub-images (grid squares) as defined by the grid size. The grid size options are 2x2, 3x3 and 4x4. The 4x4 grid size gives the largest magnification of the image. There are as many entry fields as there are grid squares.

By clicking *Help Lines* in the toolbar, a grid of lines is drawn over the image to facilitate the counting of PLTs.

Note:
Help Lines are disabled for images captured on a CellaVision® Image Capture System.

There are two ways, or modes to perform the PLT estimation. This is determined in PLT settings (see 9.7 *Adjusting PLT Settings*).

1. Counting PLTs in the overview image

2. Estimating the PLT concentration level

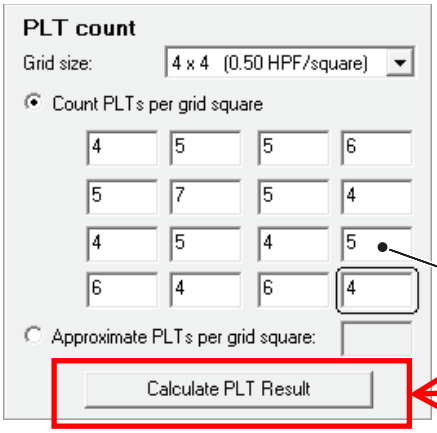
When a slide is opened for the first time, the slide gets mode according to the settings and the mode can then not be changed for that order. The system ensures that all slides in a multi-slide order have the same mode.

Note:
It is not possible to use the mode "Counting PLTs in the overview image" for images captured on a CellaVision® Image Capture System.

Counting Platelets in the Overview Image

PLT Count:

The estimation of the PLT concentration is based on the number of PLTs, which must be counted manually. You can choose to count the number of PLTs in each grid square or to specify an approximate number of PLTs per grid square.



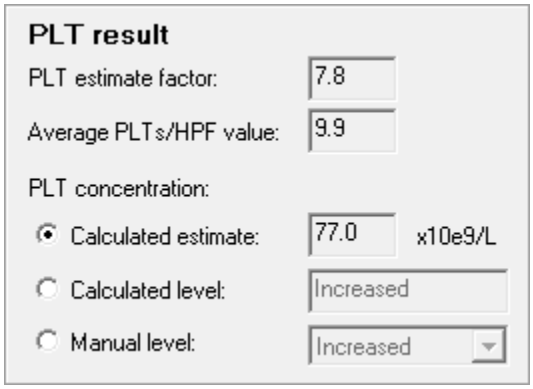
1. Entry field

1. Counting PLTs per grid square
    a. Select the *Count PLTs per grid square* radio button.
    b. Select the entry fields one by one, count the PLTs in the image window and type the number in the entry field. You can use *Tab* and *Shift+Tab* to move between entry fields.
2. Specifying an approximate PLT count per grid square
    a. Select the *Approximate PLTs per grid square* radio button.
    b. Use the entry fields to view different grid squares.
    c. Estimate the average PLT count per grid square and type this value in the field.

Note:
It is not possible to count PLTs per grid square or to specify an approximate PLT count per grid square for images captured on a CellaVision® Image Capture System.

PLT Result:

1. Click *Calculate PLT Result* in the *PLT Count panel*.



2. If you wish to report the PLT results calculated from the number of PLTs per HPF, you have two choices:
   - Select *Calculated estimate* to report a concentration. The estimate is calculated as [Average PLTs/HPF value] x [PLT estimate factor].
   - Select *Calculated level* to report one of four levels: *Significantly decreased, Decreased, Normal* or *Increased*.
3. If you wish to override the calculated PLT results, select *Manual level* and choose one of the four levels.

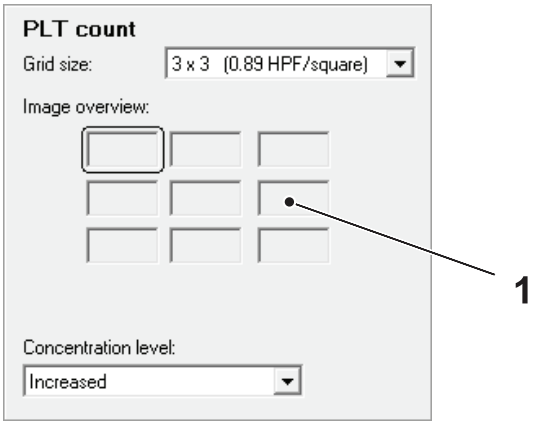
> **Important!**
>
> You have to determine your own PLT estimate factor and enter it in the PLT settings. By default, it is set to "0".

Note:
In the calculations, several decimals are used. The presented results are truncated to 1 decimal.

Note:
It is not possible to calculate a PLT result for images captured on a CellaVision® Image Capture System.

Estimating the Platelet Concentration Level

The PLT concentration level can be estimated by setting it to four levels: *Significantly decreased, Decreased, Normal* or *Increased* directly from viewing the image.

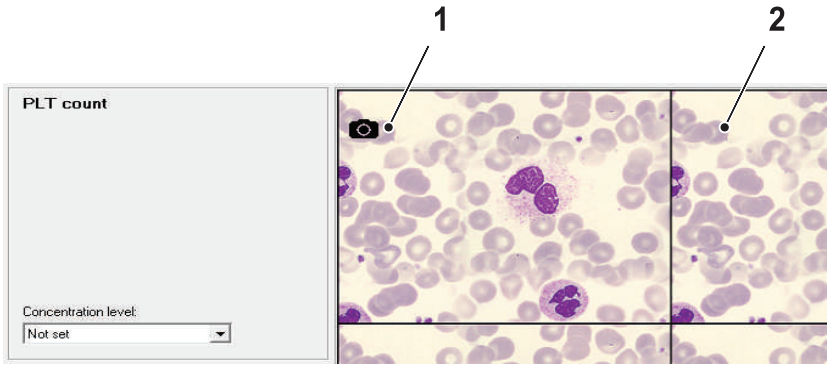


1. Entry field

1. Use the entry fields to view all parts of the overview image.
2. Select *Concentration level*.

Images captured on a CellaVision® Image Capture System:

The PLT concentration level can be estimated by setting it to four levels: *Significantly decreased, Decreased, Normal,* or *Increased* directly from viewing the image.



1. The image has been manually captured on a CellaVision® Image Capture System
2. Square

Select *Concentration level*.

> **Important!**
>
> The area covered by each square may vary between different CellaVision® Image Capture Systems.

Excluding the Platelet Analysis

Click *Exclude PLT Analysis* to exclude PLT analysis results from the slide.

4.1.5 Comments

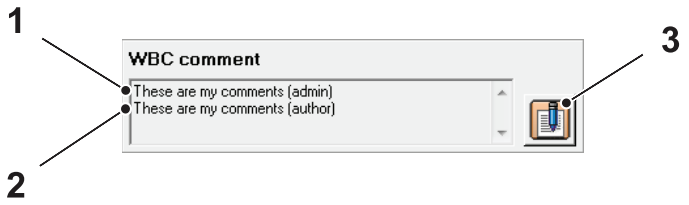
For each slide, you can add comments to the WBC, RBC and PLT results. For WBC analyses, you can also add comments to cell classes and individual cells.

WBC, RBC and PLT comments are added in *Verification View* in each tab respectively. Cell class and cell comments are added in the *WBC tab* in *Verification View.*

Note:
All comments, except comments on individual cells, are printed in the report.

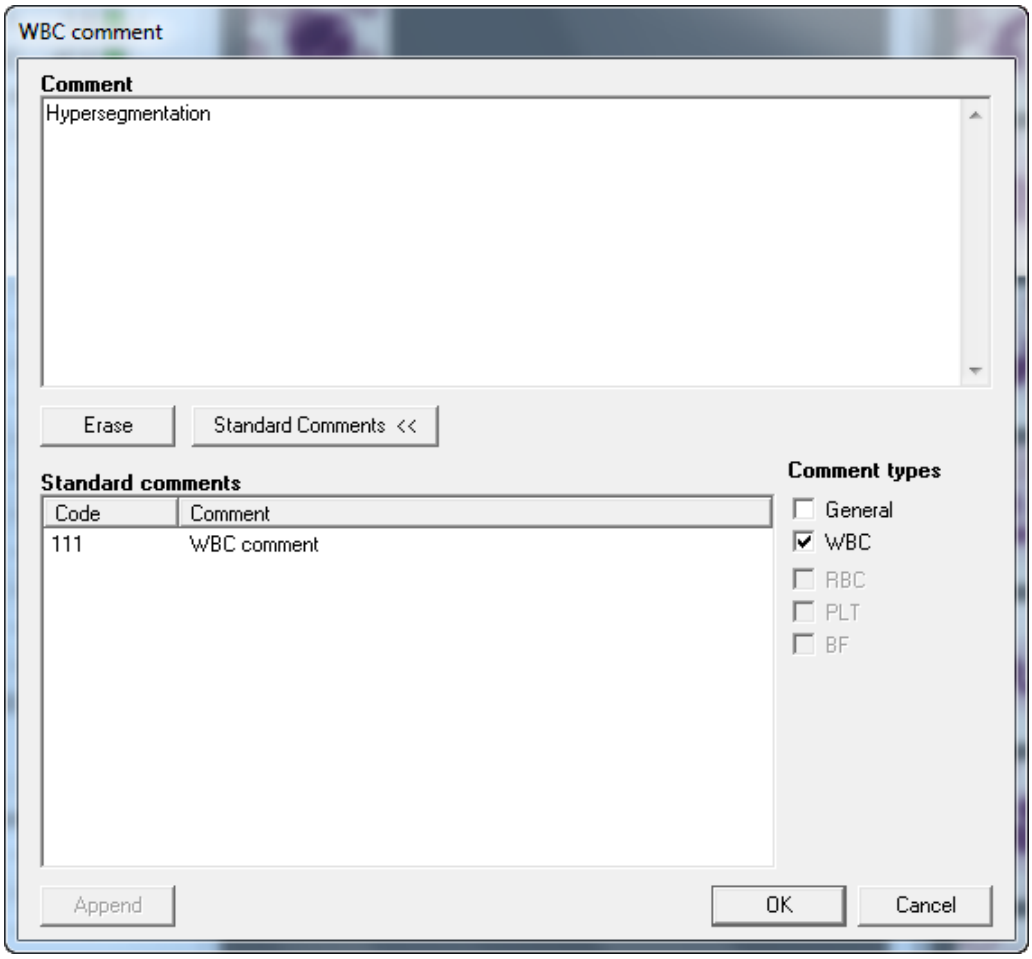
Adding Comments

The system records the author of each comment, except for comments to cell classes and individual cells. If another operator logs in, each comment is tagged with the name of the operator who wrote it. An operator can view all comments but can only edit his/her own.



1. Comment added by operator "admin".
2. Comment added by operator "author".
3. Comments.

Click *Comments* to add comments to WBC, RBC and PLT.



You may write/edit comments in the *Comment* box. Click *Standard Comments* to show/hide standard comments. Double-click on a standard comment to add it to the *Comment* box. You may also select a standard comment and click *Append*.

You may activate the Comment types you want to display. Standard comments of type WBC, RBC or PLT will only be available in the respective tab. Standard comments can be added and edited in *Settings,* see 9.9 *Adjusting Standard Comments Settings*.

To clear comments, click *Erase*.

4.1.6 Order Data

To edit order data, click *Order Data* in the toolbar.

A dialog is shown containing information about the open order.

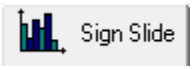
The *Order Data* dialog can also be accessed by right-clicking on an order in the database view.

The Order ID can only be edited if it starts with 'ER' or ‘ERR’.

If barcode labels can't be generated (printer is broken, out of printer ribbon, or out of labels) pre-printed labels with the prefix 'ER' (available through your local dealer) can be used.

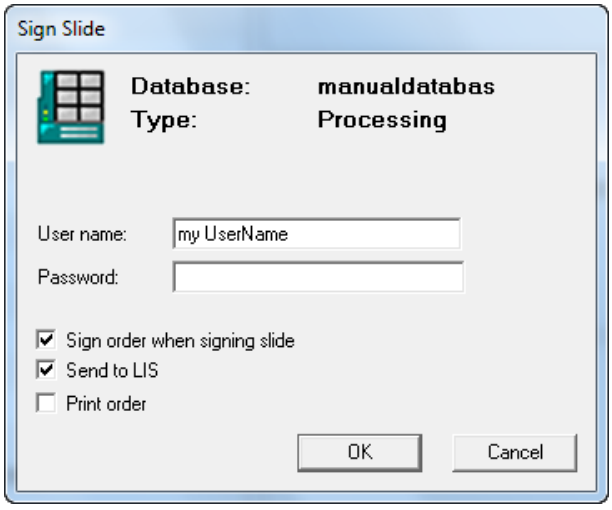
4.1.7 Signing a Slide

A summary of the WBC, RBC and PLT analyses is presented in the *Sign Slide* tab.



The signing procedure is as follows:

1. Click *Sign*. The *Sign Slide* dialog appears.



2. Enter *User name* and *Password*.
3. Activate/deactivate the automatic options *Sign order when signing slide*, *Send to LIS* and *Print order*.
4. Click *OK*.

Note:
If the slide is part of a multi-slide order, all slides in the order must be signed before the operator is given the option to sign the order.

Note:
Slide data cannot be changed after signing. Comments may still be added.

If all ordered analyses have been viewed when the *Sign Slide* tab is selected, the *Sign Slide* dialog will automatically appear. Default values for the *Sign Slide* dialog are set in *Settings* under *Report/Sign*. The option to send results to the LIS is activated in *Analysis* in *settings*.

When the last slide is signed in a multi slide order, the operator has the option to sign the order.

White Blood Cells, Red Blood Cells and Platelets

Before signing a slide, all ordered analyses must have been viewed by the operator. The following conditions must be fulfilled:

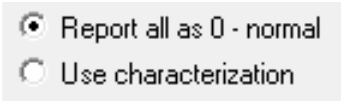
WBC:

- All cell classes must have been viewed, i.e. there should be tick marks after each cell class.
- No WBCs remain in *Unidentified*.

RBC:

An RBC characterization must be reported or excluded from the analysis:

- Report a characterization, by selecting one of the following options:



or:

- Click *Exclude RBC Analysis*.

PLT:

A PLT concentration must be reported or excluded from the analysis:

- Report a PLT concentration as described in 4.1.4 *Estimating Platelets*.

or:

- Click *Exclude PLT Analysis*.

4.2 Body Fluids

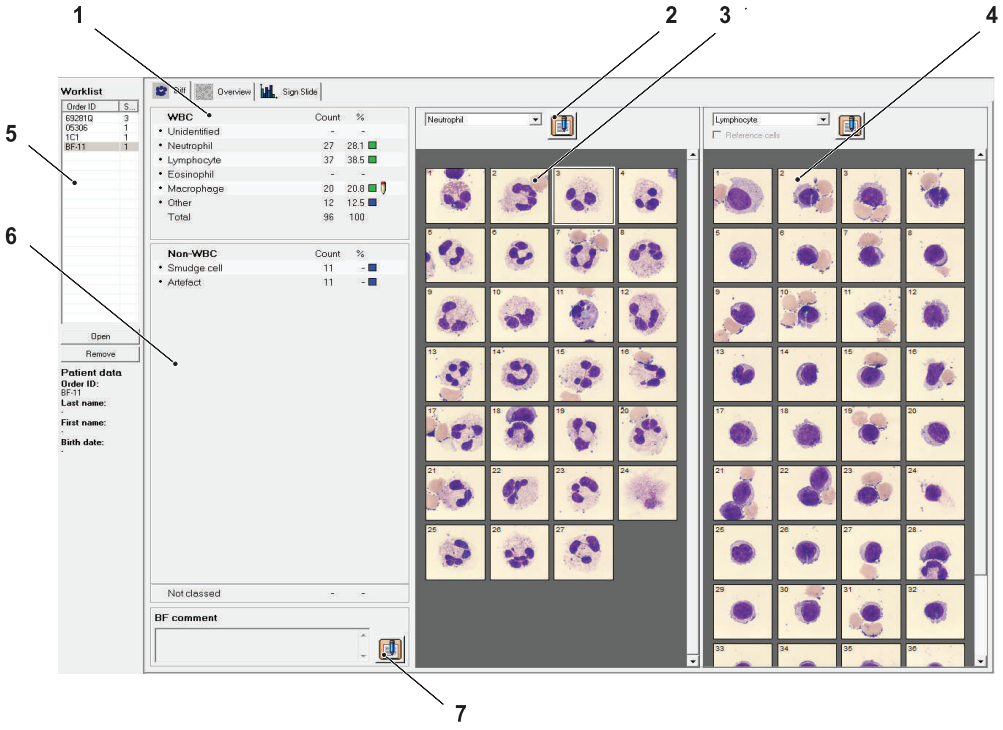
Opening an unsigned slide leads directly to the Verification View, where the tabs for *Overview*, *WBC* and *Sign Slide* are shown. To open a slide, see 6.1.3 *Opening an Order/Slide*.

Click *Verification View* in the toolbar.

Note:
With DMConfiguration tool it is possible to add user defined WBC cell classes, add user defined Non-WBC classes and to change the cell class name Macrophage to Macrophage/Monocyte. To do this contact your service personnel.

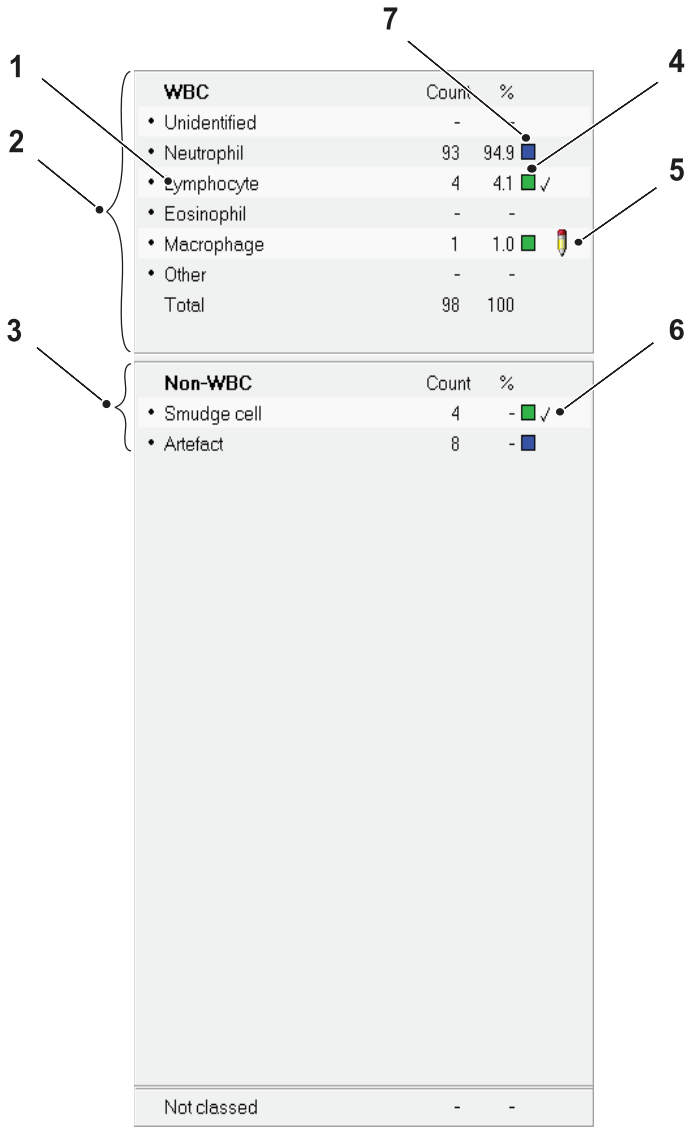
4.2.1 Body Fluids Differential

You can view and reclassify all cells identified by the system.



1. WBC panel
2. Add cell class comment
3. Main gallery
4. 2nd gallery
5. Worklist
6. Non-WBCs panel
7. Add BF comment

All cell classes handled by the system are displayed in the figure below. WBCs and non-WBCs automatically preclassified by the system are marked with a small dot.



1. Preclassified by the system
2. WBC panel
3. Non-WBC panel
4. Green - Contains no reclassified cells or objects
5. Pen icon - Indicates Cell class comments
6. Tick mark - All images have been viewed
7. Blue - Contains at least one reclassified cell or object

Customizing Views

To Customize views, see *Customizing Views* under 4.1.1 *White Blood Cell Classification*.

Reclassifying Cells

To reclassify cells, see *Reclassifying White Blood Cells* under 4.1.1 *White Blood Cell Classification*.

E-mail

To email cell images, see *E-mail* under 4.1.1 *White Blood Cell Classification*.

Copying Images to Disk

To copy cell images, see 6.1.8 *Copying Images to Disk*.

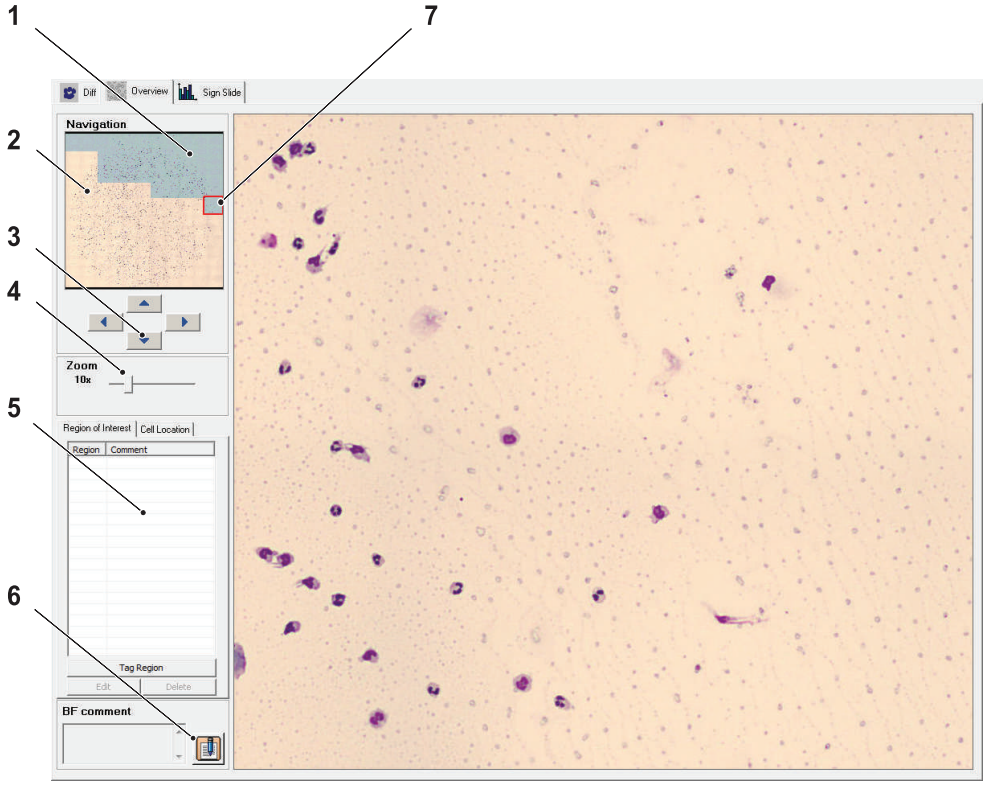
4.2.2 Body Fluids Overview Image

The body fluid overview image displays the entire sample area.

See 9.15 *Adjusting BF Analysis Area* for more information.

The overview image can be used to find cells of interest and for getting an overall impression of the sample. The overview image can either have one 10x zoom level or both 10x and 50x zoom levels. Using both zoom levels will increase the processing time.

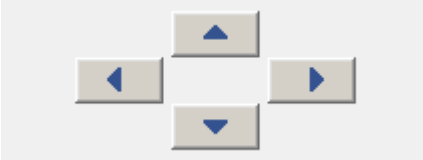
See 9.3 *Adjusting Analysis Settings* for more information.



1. Trace
2. Mini map
3. Navigation buttons
4. Zoom panel
5. Region of interest panel
6. Add slide comment
7. Current position

Navigating in the Overview Image

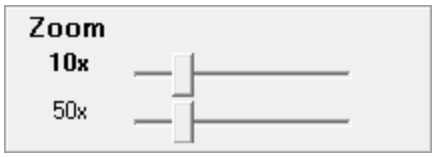
Navigate in the overview image by using the keyboard arrow buttons or the navigation buttons.



The image shown in the right part of the screen is an enlargement of the area inside the red rectangle shown in the *Mini map*. Click on the *Mini map* to enlarge another part of the sample. A blue trace in the *Mini map* indicates which parts of the overview image that have been viewed by the operator

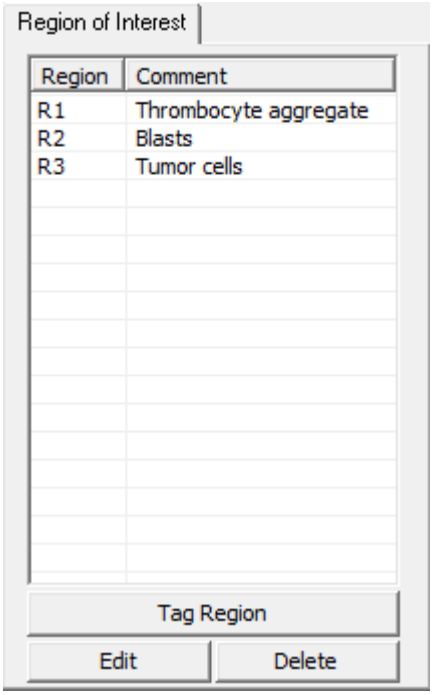
Hold left mouse button down and scroll in any direction using the mouse.

Switch between the two zoom levels by right-clicking in the overview image. Adjust the zoom level by dragging the sliders in the *Zoom* panel.

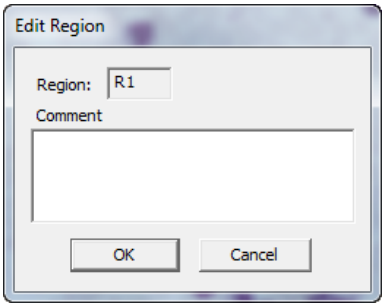


Tagging Regions of Interest

The image shown in the right part of the screen can be saved as a region of interest for later reference.



1. To save the current image, click *Tag region.*
2. Add a comment as an identifier for the region of interest and click *OK.*



Copying Regions of Interest to Disk

You can copy an individual region of interest image to disk.

1. Select a region of interest.
2. On the right-click menu select *Copy image to disk…* and the *Copy the image to disk* dialog appears.
3. Specify the destination path where you want the image to be saved, use the browse button to navigate to a suitable folder.
4. Click *OK*.

Note:
The directory you specify in the destination path must exist.

4.2.3 Comments

Comments can be added to the Overview, the differential result, each cell class and all individual cells.

Note:
All comments, except comments on individual cells, are printed in the report.

Adding Comments

To add a comment, click *Comment*. For more details, see 7.2.5 *Adding Comments*.

 Comments

4.2.4 Order Data

To view or edit the order data, see 4.1.6 *Order Data*.

4.2.5 Signing a Slide

The Body Fluid differential is presented in the *Sign slide* tab. To sign a slide, see 4.1.7 *Signing a Slide*.

5 Reporting Results

For detailed information on settings, see 9.8 *Adjusting Report/Sign Settings*.

Click *Report View* in the toolbar.

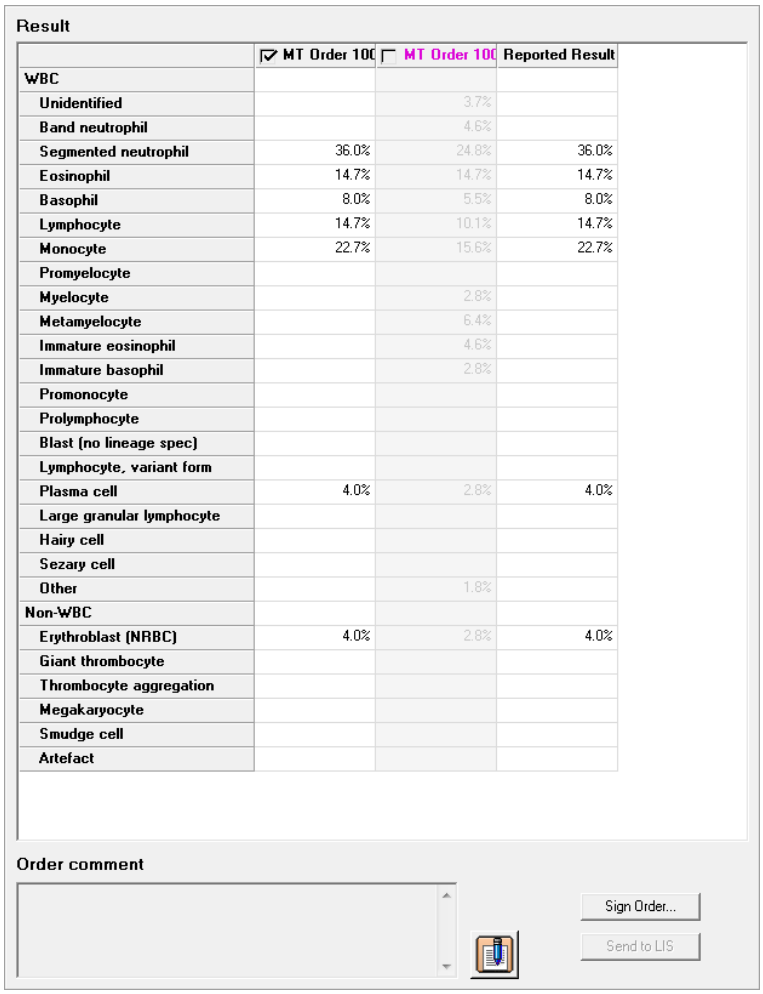
Compare slide results and exclude slides from the reported result in the Report View. You can also:

- Sign or cancel an order
- Send order data to the LIS
- Write a general comment on the order
- Preview the report by clicking on the Report Preview tab.

5.1 Merging Slides

Compile analysis results for the whole order based on one or several slides in the *Slide Merge* tab. You can also view all comments associated with an order.

Result Panel



Here you see the results of each slide in the order. In the *Reported Result* column you see the summarized results. An unsigned slide has a Slide ID written together with slide number in cerise color.

Including and Excluding Slides in/from the Reported Result

Signed slides are automatically included in the reported result. To include or exclude a slide, activate/deactivate the checkbox next to the Slide ID.

When excluding slides, a dialog is shown where you may write a comment explaining the exclusion.

Note:
Only signed slides can be included.

Note:
Do not merge slides if one or more slides have a "confirm cell counter result" flag. If you do, the calculated result in the reported result column will be displayed incorrectly.

Changing the Reported Result

It is possible to change the RBC results and the PLT concentration for the order, if reported as a level. Changeable results are written in bold text.

1. Click on the result to change.
2. Change the value in the dialog.
3. Click *OK*.

Note:
If you include or exclude a slide, all manually changed values will be replaced by new, automatically calculated values.

Comment Panel

View all comments associated with the order in the *Comment* panel. All comments will be included in the report. Note that only the beginning of the comment is shown. To view the whole comment, click on it.

It is not possible to edit comments in this panel.


Comment

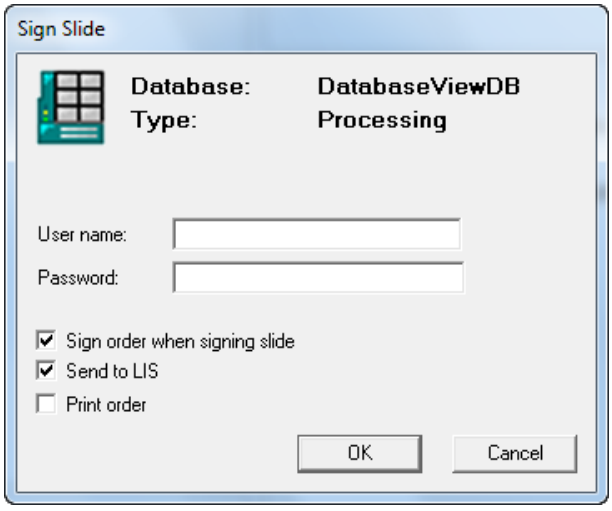
	MT Order 100 (1)	MT Order 100 (2)
Exclusion comment		
WBC comment		
WBC cell class comments		
Unidentified		
Band neutrophil		
Segmented neutrophil		
Eosinophil		
Basophil		
Lymphocyte		
Monocyte		
Promyelocyte		
Myelocyte		
Metamyelocyte		
Immature eosinophil		
Immature basophil		
Promonocyte		
Prolymphocyte		
Blast (no lineage spec)		
Lymphocyte, variant form		
Plasma cell	Comment to this cellclass	
Large granular lymphocyte		
Hairy cell		
Sezary cell		
Other		
Non-WBC cell class comments		
Erythroblast (NRBC)		
Giant thrombocyte		
Thrombocyte aggregation		
Megakaryocyte		
Smudge cell		
Artefact		

5.2 Report Preview

Click on the tab *Report Preview* to preview the report. The report's format is template based and can be selected in Settings. See 9.8 *Adjusting Report/Sign Settings* for more details.

5.3 Signing an Order (result)

1. Click *Sign Order*.



2. If not prefilled, type *User name* and *Password*.
3. Select whether the order should be sent to the LIS and/or printed.
4. Click *OK*.

5.4 Sending an Order to the LIS

If the LIS is activated in the *Analysis* tab in *Settings*, it is possible to send signed order results to the LIS.

1. Open a signed order.
2. Select the *Slide Merge* tab in the *Report* View.
3. Click *Send to LIS*.

5.5 Canceling an Order

Sign the order with no included slides to cancel it.

1. Open the order in the *Database* View.
2. Select the *Slide Merge* tab in the *Report* View.
3. Make sure no slides are included.
4. Click *Sign Order*. The *Sign Order* dialog appears.
5. Sign the order as described in 5.3 *Signing an Order (result)*.

Note:
When the order is sent to the LIS the order will be reported as canceled.

6 Database

Click *Database View* in the toolbar.

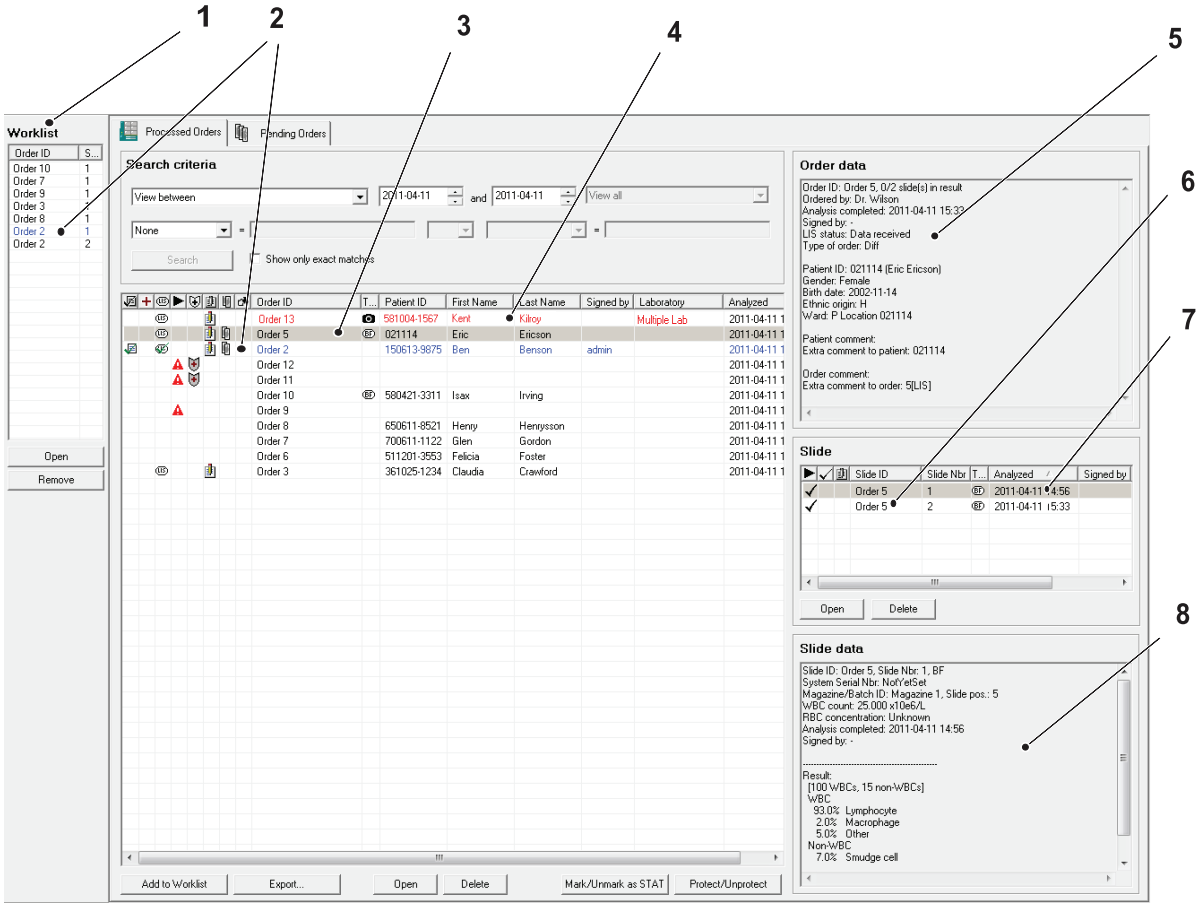
Processed and pending orders are stored in the database. Switch between the two using the tabs *Processed Orders* and *Pending Orders*.

6.1 Processed Orders

You can search for and open processed orders and slides stored in the system. Orders are displayed according to the *Search Criteria*. For more information on Search Criteria, see 6.1.5 *Searching for an Order/Slide*.

In the *Processed Orders* tab and *Worklist* the text colors indicate:

- Blue: opened order and slide.
- Red: order is locked by another user.
- Highlighted in blue or grey: selected order or slide.

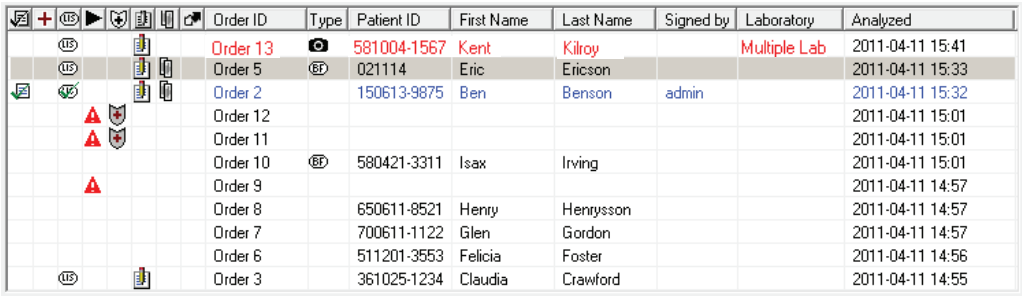


1. Worklist
2. Opened order and slide (written in blue text)
3. Selected order (marked blue or grey)
4. Orders locked by another user (written in red text)
5. Data for selected order
6. Slides in selected order
7. Selected order (marked blue or grey)
8. Data for selected slide

An order/slide opened by another operator is written in red text. In the *Order data* and *Slide data* panels, *Locked by* indicates who has opened the order/slide (the person logged on to Windows) and on which computer.

6.1.1 Order List

The *Order List* displays an overview of the orders. Click on the column headers to sort the list. The date in column "Analyzed" corresponds to the processing date for the last slide in an order.



Order ID	Type	Patient ID	First Name	Last Name	Signed by	Laboratory	Analyzed
Order 13		581004-1567	Kent	Kilroy		Multiple Lab	2011-04-11 15:41
Order 5	BF	021114	Eric	Ericson			2011-04-11 15:33
Order 2		150613-9875	Ben	Benson	admin		2011-04-11 15:32
Order 12							2011-04-11 15:01
Order 11							2011-04-11 15:01
Order 10	BF	580421-3311	Isax	Irving			2011-04-11 15:01
Order 9							2011-04-11 14:57
Order 8		650611-8521	Henry	Henrysson			2011-04-11 14:57
Order 7		700611-1122	Glen	Gordon			2011-04-11 14:57
Order 6		511201-3553	Felicia	Foster			2011-04-11 14:56
Order 3		361025-1234	Claudia	Crawford			2011-04-11 14:55

Order status

Empty field	No slide is signed.
✓	At least one slide is signed.
	Order is signed.
	Order is canceled.

STAT mark +

1.5.4. 4. Skubaus tyrimo funkcija.

Empty field	Not a STAT order.
+	Order is marked as a STAT order.

LIS status

Empty field	No data sent or received.
	Data received.
	Waiting to send result.
	Result is sent.

	Result send failure.
	Result is successfully sent.

Process status	
Empty field	All slides in the order have process status OK.
	Slide with process error in the order.
	Stopped slide in the order.
	Slide with process status in the order.

Archive status	
Empty field	Order is unprotected.
	Order is protected. Order and slides in this order cannot be deleted or archived.
	Order is archived.
	All images except *Region of interest* images have been deleted (only applicable for scan databases).

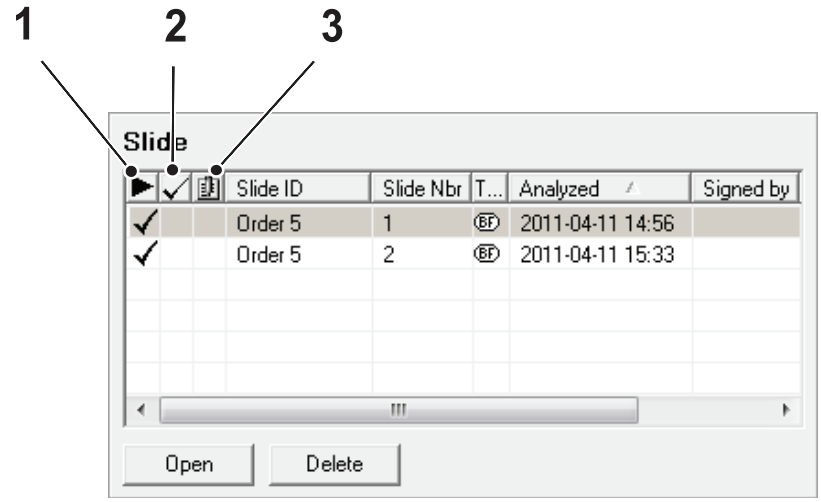
Comments	
Empty field	No comments.
	Comments exist.

Multi-slide status	
Empty field	One slide in order.
	More than one slide in order.
C	The order contains a cell counter confirmed result.

Transfer Tool status	
Empty field	Not marked for Transfer Tool.
	Marked for Transfer Tool.
Order type	
Empty field	Peripheral blood order.
	CellaVision® Image Capture System order.
	Body fluid order.

6.1.2 Slide List

Comments, slide- and processing status are indicated in the slide list.



1. Processing status
2. Comments
3. Slide status

Process status ▶

✓	Slide processing OK.
STOP	Slide processing stopped. No result exists.
⚠	The required numbers of WBCs were not found, one of the ordered analyses failed, or the order was not found in the LIS, slide processed with default values.
✖	Processing error. No result exists.

Slide status ✓

Empty field	Not signed.
✓	Signed.

Comments

Empty field	No comments.
	Comments exist.

6.1.3 Opening an Order/Slide

Opening an order automatically opens a slide belonging to it. In the same manner, opening a slide automatically opens the order it belongs to. The currently opened order and slide are always shown in the toolbar.

1. Order status
2. Slide status

Double-click on an order in the *Order list*, and the first slide of that order opens. You can also click *Open* in the *Order panel*. In the *Slide list* you can open specific slides in the same way.

You may close the order and slide using the *Close Order/Slide* button in the toolbar:

 Close Order and Slide

6.1.4 Protecting an Order

You may protect orders to prevent slides from being deleted or archived.

1. Select the order/orders.
2. Click *Protect/Unprotect*, or right-click and select *Protect/Unprotect* from the menu.

To select multiple orders:

- Select an order, then hold down *Ctrl* and select each additional order by clicking on it.
- Mark a sequence of orders by clicking on the start order, then hold down *Shift* before selecting the last order of the sequence.

6.1.5 Searching for an Order/Slide

You select the orders to be displayed using the *Search criteria*. Here, you may specify date intervals for desired orders. Use *View latest* as a shortcut for orders less than one week old. You may also add search strings for patient data, order data and comments. If the database contains a slide which is captured on a CellaVision® Image Capture System and you choose *View CellaVision® Image Capture System* you can also specify a laboratory in the drop-down list to the right.

6.1.6 Deleting an Order/Slide

A selected order/slide can be deleted by pressing *Delete*. Select multiple orders/slides using *Ctrl* or *Shift*. When all slides in an order have been deleted, the order is automatically deleted.

Note:
Only Administrators can delete signed orders. Deleting an order deletes all slides in the order, signed or not.

6.1.7 Exporting Orders

From the *Database View,* you may export signed orders from the current database to another one. Before you begin to export create an Export database.

To create an Export database go to the *Tools* menu, select *Settings* and then the *Database* tab. For more information, see 9.1.1 *Creating a New Database*.

Exporting to an Export database

1. Select one or several orders.
2. Click *Export.*
3. Select an *Export database* from the list.
4. Check *Delete orders after export*. If not, the order will remain in the database you exported from.
5. Click *Export*.

Restrictions

- Only signed orders can be exported.
- Orders imported to an Export database will always have a "protected" flag preventing them from being autodeleted (if autodelete is enabled).
- Orders residing in a Scan database cannot be exported.

6.1.8 Copying Images to Disk

You can copy all images from selected orders to disk.

1. Click on *Database View*.
2. Select one or several orders.
3. Right-click and select *Copy images to disk*.
4. In the Copy images to disk dialog, specify the *destination path* where you want to save the images, use the browse button to navigate to a suitable folder.
5. Per default, *WBC images* and *Overview images* are checked. Uncheck according to preferences.
6. Click *OK*.

Note:
The specified directory in the destination path must exist.

6.1.9 Printing Orders

Print order data and data for all slides belonging to it by selecting the order or slide of choice in the *Database View* and then *Print* in the *File* menu.

Note:
Order results exist only if the order contains at least one signed slide.

6.1.10 The Worklist

The Worklist contains shortcuts to slides facilitating an automatic workflow (see Appendix - D *Recommended Workflow*). The Worklist is active in the *Database View* and the *Verification View* to simplify opening of new slides.

Open slides by double-clicking or click *Open*. Remove slides by clicking *Remove*. Signed and closed slides are automatically removed.

Note:
Show or hide the Worklist by pressing CTRL + W on the keyboard.

Adding Slides to the Worklist

Slides can be added to the worklist manually or automatically.

A) Manually

1. Select one or more orders.
2. Click *Add to worklist*. All slides belonging to the order(s) are added.

B) Automatically

1. Slides are added when the system finishes processing them. This option is set in *Analysis* in *Settings*.
2. When you open an order, all slides belonging to it are added.

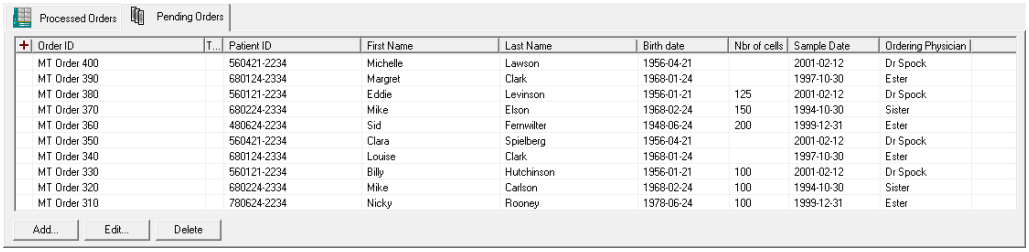
Note:
The Worklist is emptied when the program is closed.

Note:
Body fluid slides are not automatically added to the Worklist.

6.2 Pending Orders

The tab *Pending Orders* contains a list of all pending orders. A pending order is an order that has been manually added to the database, but not yet processed. This is useful when you do not have a connection to the LIS.

When an order has been processed it will be removed from the *Pending Orders* list and added to the *Processed Orders* list.



STAT mark	+
Empty field	Not a STAT order.
+	Order is marked as a STAT order.
Order type	
Empty field	Peripheral blood order.
BF	Body fluid order.

Click *Add* to add a new pending order.

Double-click on a pending order, or click *Edit*, to *view/edit* the Order Data.

Note:
The Order/Slide ID and Patient ID may be up to 24 characters (ASCII) including spaces. No leading spaces are allowed. The Order/Slide ID may not begin with 'PB' or 'BFS'.

6.3 Archiving Data

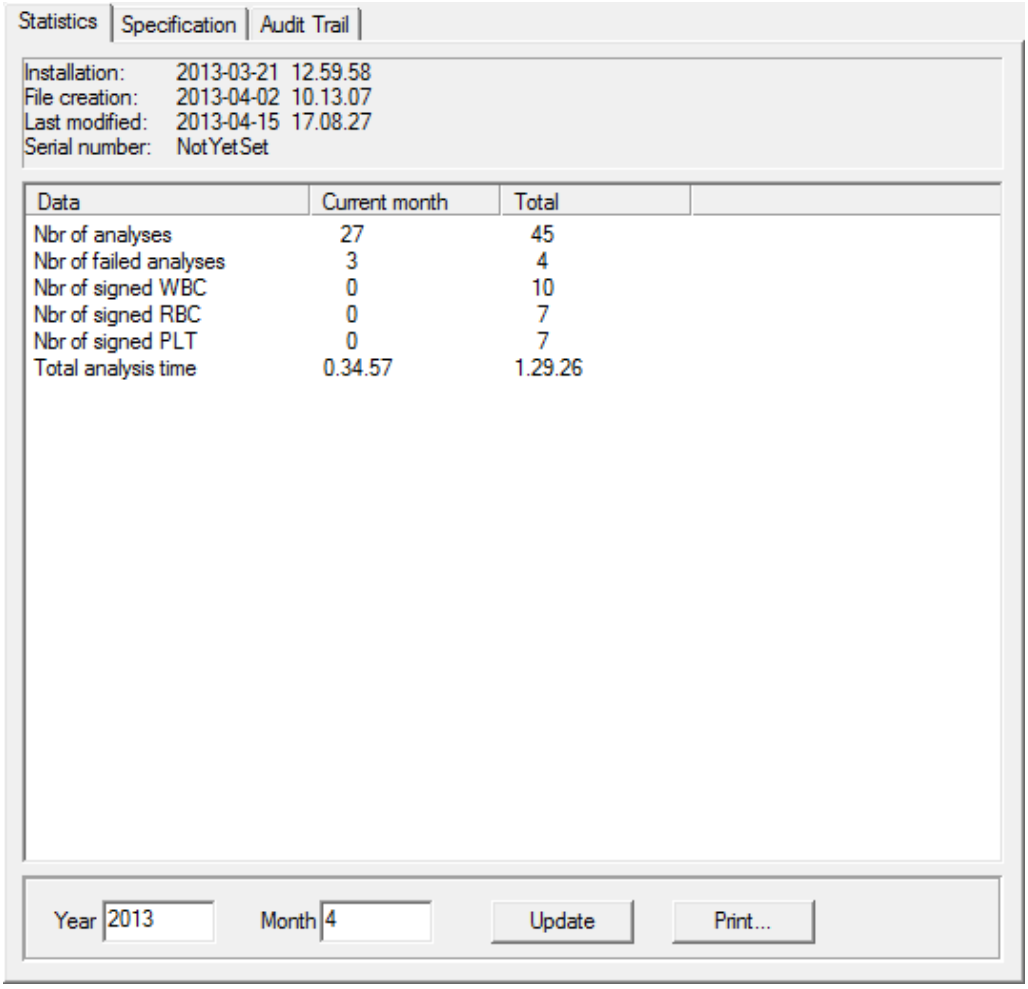
Before archiving data, make sure valid archiving settings have been specified. Refer to 9.13 *Adjusting Archiving/Autodelete Settings* for details.

Select *Tools* and *Archive*. The *Archiving Guide* will appear, explaining the procedure on how to archive data.

6.4 Usage Log

The system continuously saves data of processed slides and stores it in a *Usage Log*. To view the log select *Tools* and *View Log*.

6.4.1 Statistics



The *Statistics* page contains dates and times of program installation and creation and modification of the Usage log. It also displays the number of successfully processed and failed slides, the number of signed analyses and the total processing time.

6.4.2 Specification

The *Specification* page is only accessible to Administrators. It contains a list of dates and times for events that have occurred in the system, e.g. start and completion of slide processing and hardware malfunctions.

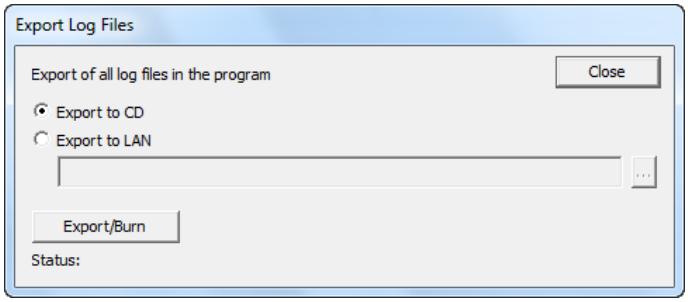
6.4.3 Audit Trail

The *Audit Trail* page is only accessible to Administrators. It contains a list of dates and times for which users that have logged on to the system or deleted a slide.

6.5 Export Log Files

It is possible to export all logging information from the system. If a system error occurs, the information is needed for troubleshooting. Select *Tools/ Export Log Files*. The log files can be burnt directly to a CD, or exported to the LAN (and then, for instance, attached to an e-mail). The Export log files dialog is only accessible to Administrators.

Note:
The system must be idle during export. Otherwise, the export will not be complete.



6.6 Backup and Recovery of the Database

It is important to backup the database often. If a hard disk crash occurs, the whole database will be lost. It will only be possible to recover the data up to the time when the last backup was made. For more information, see CellaVision® IT Configuration Guidelines or contact your distributors.

7 Digital Slides

> **Important!**
>
> The digitalized image generated provides a general overview of the prepared sample within the intended use of the applications. All other use is for research use only and not for use in diagnostic procedures.

7.1 Scanning a Slide

Make sure that a Scan Database is available on your system. To create a Scan Database, see 9.1.1 *Creating a New Database*.

Log on to a Scan Database, see 2.1 *Starting the System*.

To customize your system, such as scan area and magnification, see 9 *Customizing the System*.

7.1.1 Slide Requirements

Requirements for the slides used when scanning:

- Glass
- Size in mm: 75.0-76.0 x 25.0-26.0 x 0.9-1.2*
- Ground edges
- Clipped or round corners
- Barcode labeled
- Frosted end

*ISO 8037/1-1986 and JIS R 3703:1998

Coverslipped slides are supported as long as the total thickness of the slide is within the requirements. When using cover slips, make sure the scanning area is within the cover slip area.

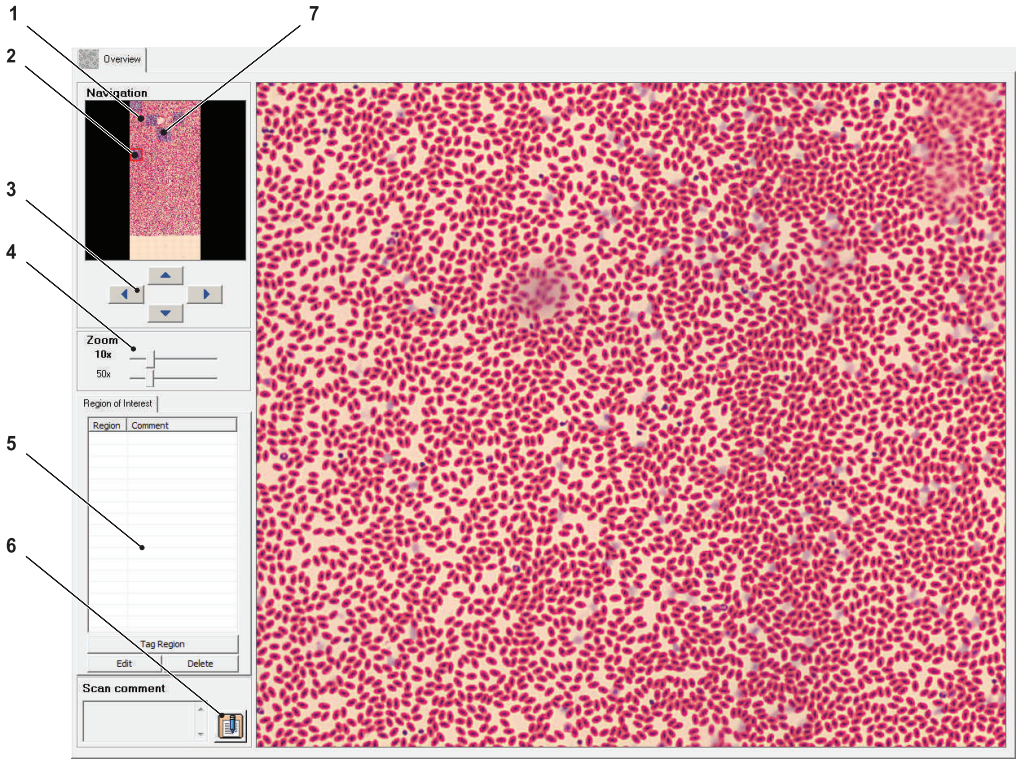
Any type of CellaVision® magazines can be used for a scan analysis.

7.2 Scan Overview Image

Opening a scanned slide leads directly to the *Scan Verification View*. To open a slide, see 6.1.3 *Opening an Order/Slide*.

7.2.1 Overview

The *Mini Map* shown in the *Overview* displays the entire sample area. To enlarge a specific area of the sample, click in the *Mini Map*. The magnified area will be displayed in the large image on the screen. On the *Mini Map*, a red rectangle marks the area requested for enlargement. A blue trace marks an already viewed area.

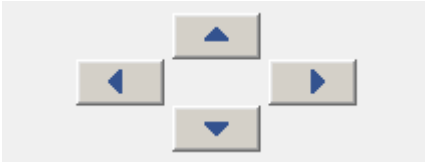


1. Mini Map
2. Current position
3. Navigation buttons
4. Zoom panel
5. Region of interest panel
6. Add scan comment
7. Trace

The enlarged area can either have a 10x zoom or a combined 10x and 50x zoom. Using both zoom levels will increase the processing time.

7.2.2 Navigating

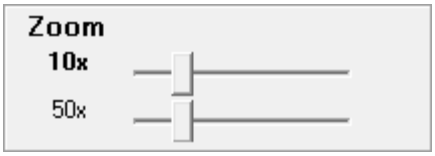
Move efficiently in the *Mini Map* by using the keyboard arrows or the *Navigation Buttons*.



The image shown in the right part of the screen is an enlargement of the area inside the red rectangle shown in the *Mini map*. Click on the *Mini map* to enlarge another part of the sample. A blue trace in the *Mini map* indicates which parts of the overview image that have been viewed by the operator.

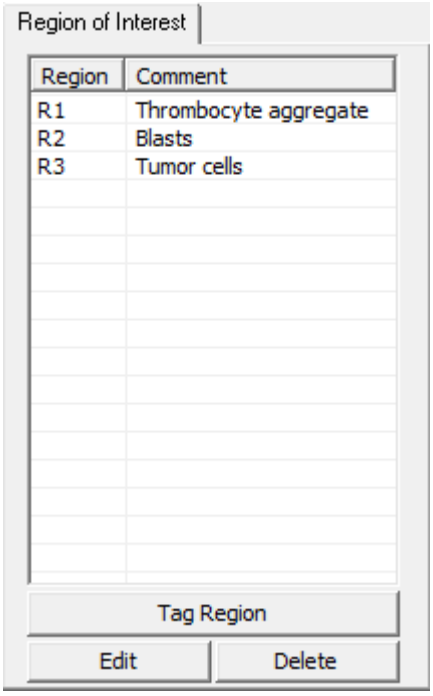
Hold left mouse button down and scroll in any direction using the mouse.

Switch between 10x and 50x zoom levels by right-clicking in the enlarged image. Adjust the zoom level by dragging the sliders in the *Zoom* panel.

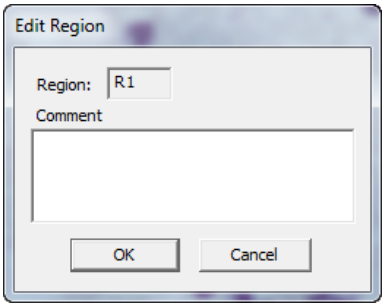


7.2.3 Tagging Regions of Interest

To save an enlarged area as a region of interest for later reference, click *Tag region*.



Identify your region of interest by adding a comment.



7.2.4 Copying Regions of Interest to Disk

You can copy a region of interest to disk.

1. Select a tagged region of interest in the list.
2. Right-click and select *Copy the image to disk*....
3. Specify the destination path where you want the image to be saved.

4. Click *OK*.

7.2.5 Adding Comments

To add a comment to the Overview, click *Scan comment*.

Scan comment

7.2.6 Order Data

To view information about the order, e.g. scanned area and comments, click *Order Data* in the toolbar. The *Order Data* dialog can also be accessed by right-clicking on an order in the database view.

To view/edit order data, click *Order Data* in the toolbar.

7.3 Database View

To view processed and pending orders, click *Database View.*

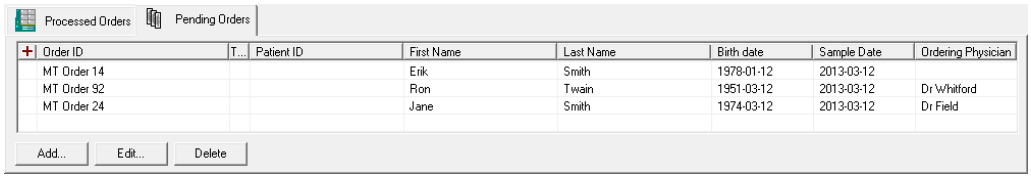
Database View

7.3.1 Processed Orders

Scanned slides are automatically signed. For more details about Processed orders, see 6.1 *Processed Orders*.

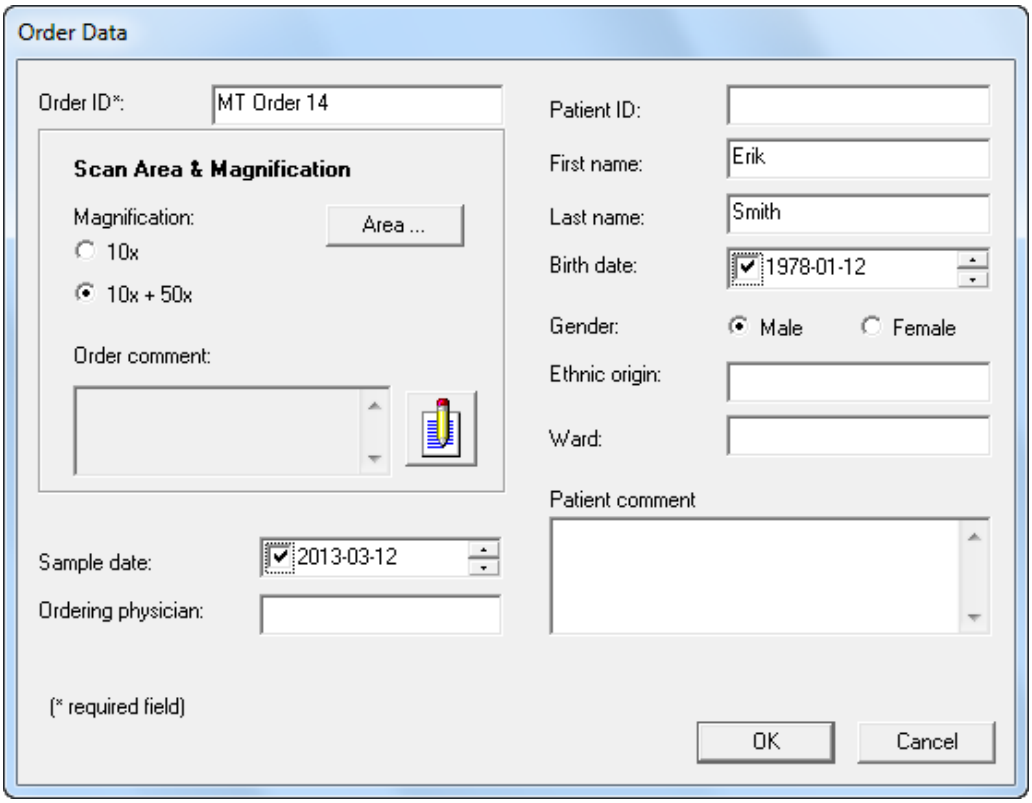
7.3.2 Pending Orders

A pending order has manually been added to the database and has not yet been processed. Pending Orders are useful when defining scan area for individual slides.

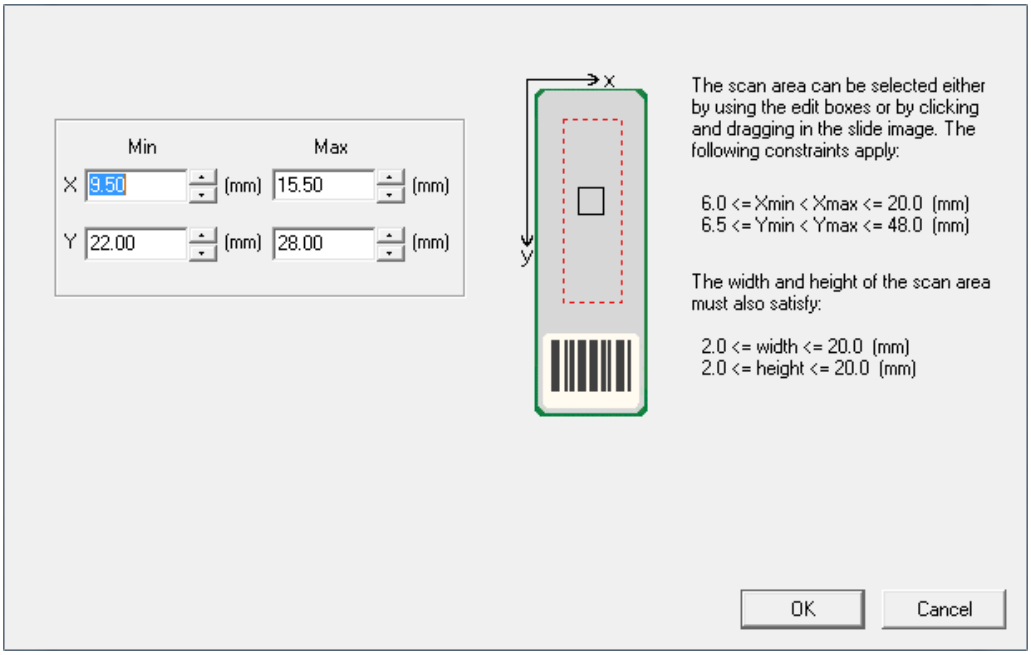


To add an order, click *Add*.

To view or edit order data, double-click on an order or click *Edit*.



To define scan area for the slide, click *Area*. Define the area that you want to scan on this particular slide. If no scan area is defined, the default scan area setting will be used.



7.4 Customizing the System

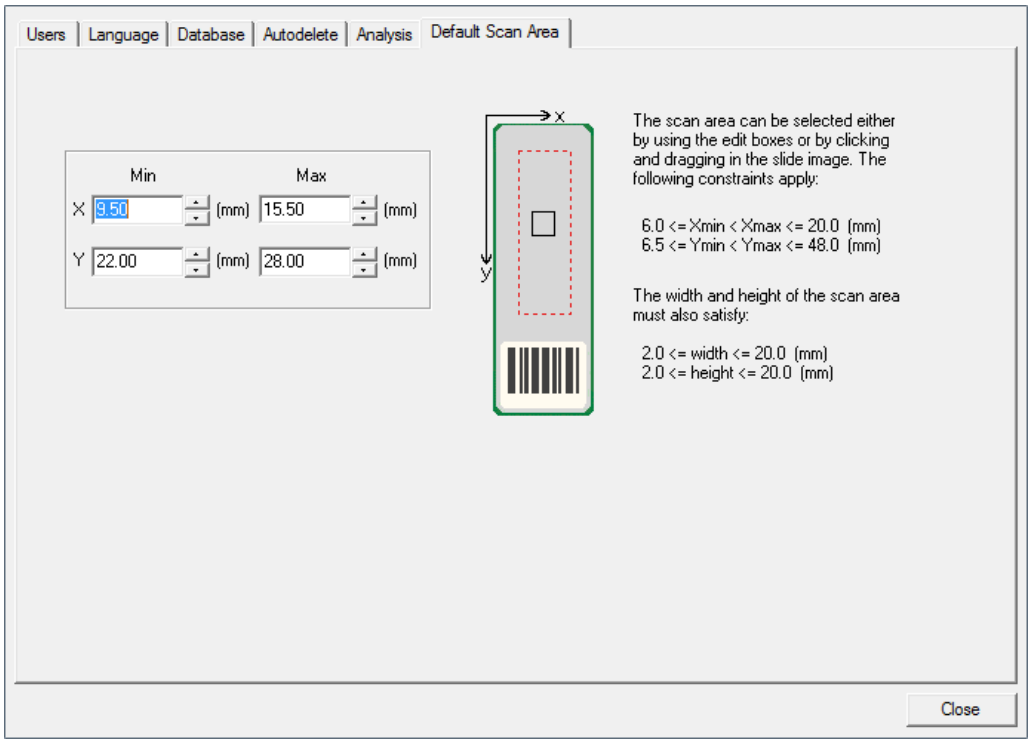
To customize the system, go to the *Tools* menu and select *Settings*.

7.4.1 Adjusting Database, Users and Language

To adjust the settings for database, users and language, see 9.1 *Adjusting Database Settings*, 9.2 *Adjusting Users Settings* and 9.14 *Adjusting Language Settings*.

7.4.2 Adjusting Default Scan Area

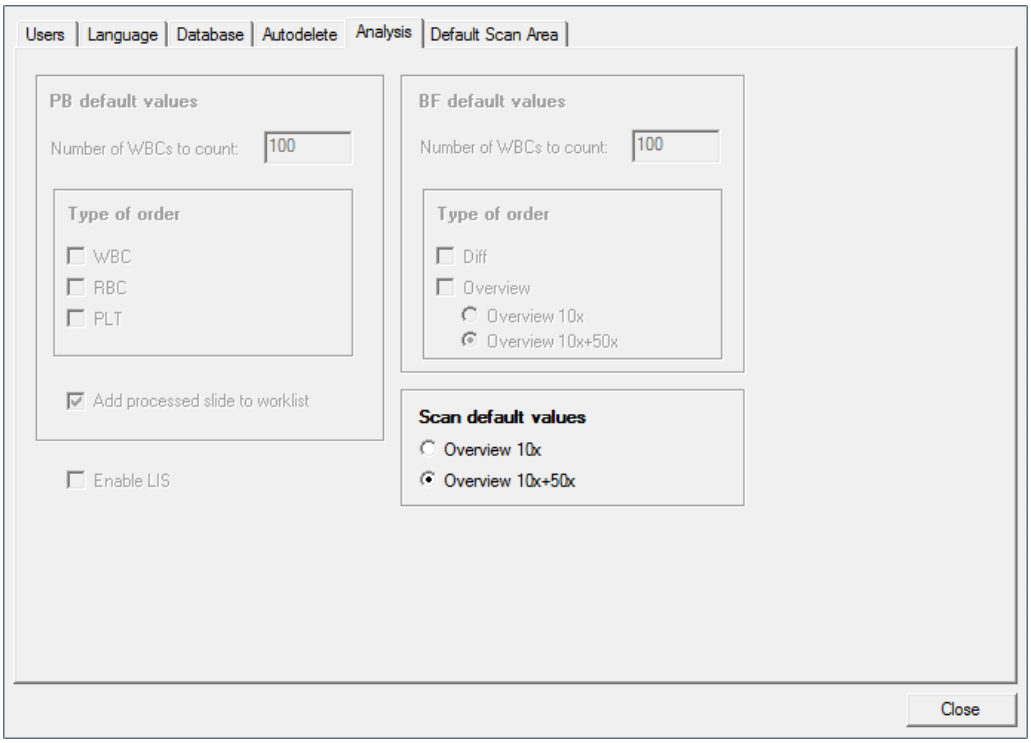
To adjust the default scan area, go to *Tools/Settings/Default Scan Area*.



To adjust the scan area settings for individual slides, click *Database View* and select *Pending Orders*. See 7.3.2 *Pending Orders*.

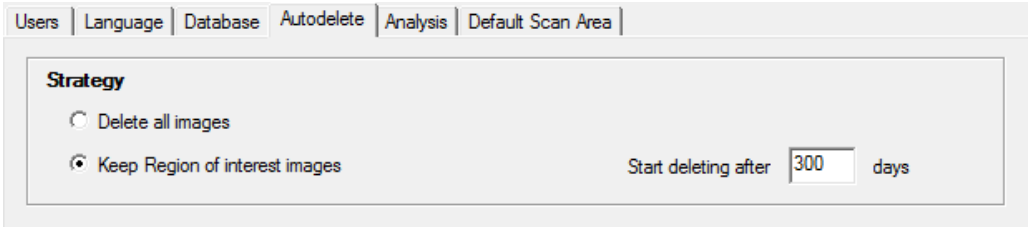
7.4.3 Adjusting Analysis

To adjust the default analysis settings, 10x or 10x and 50x magnification, go to *Tools/Settings/Analysis*.



To adjust the analysis settings for individual slides, click *Database View* and choose *Pending Orders*. See 7.3.2 *Pending Orders*.

7.4.4 Adjusting Autodelete



It is not possible to archive the orders. All orders will be autodeleted after a specified number of days.

Autodelete Strategy

The autodelete strategy depends on your throughput and the need for saving images for future use. The autodelete settings are database specific, enabling each database to have its own autodelete strategy.

Delete all images:

All orders and images are permanently deleted when the time has expired.

Keep Region of interest images:

The orders are not deleted, but all images except the *Region of interest* and *Mini map* images are deleted when the time has expired.

8 System Information

In the toolbar, click *Help* and then *System Information* for information about your system.

The information presented depends on your system and installed software. Some of the following information is present in the *System Information* dialog:

- Serial number of your system.
- The type of Artificial Neural Network (ANN) used.
- The computer name.
- The computer's IP address.
- Free disk space.
- Free physical and virtual memory.
- Total physical and virtual memory.
- Licensed software.
- License expiry date.

9 Customizing the System

Settings are stored in either the system or the database.

A setting that is stored in the system applies to that system only. Other systems connected to the same database as the system may have other values of the setting.

The following settings are stored in the system:

- Email settings
- Language
- Body fluid analysis area

A setting that is stored in the database applies to all systems connected to the same database. If you change the setting, it will be changed for all systems connected to the database.

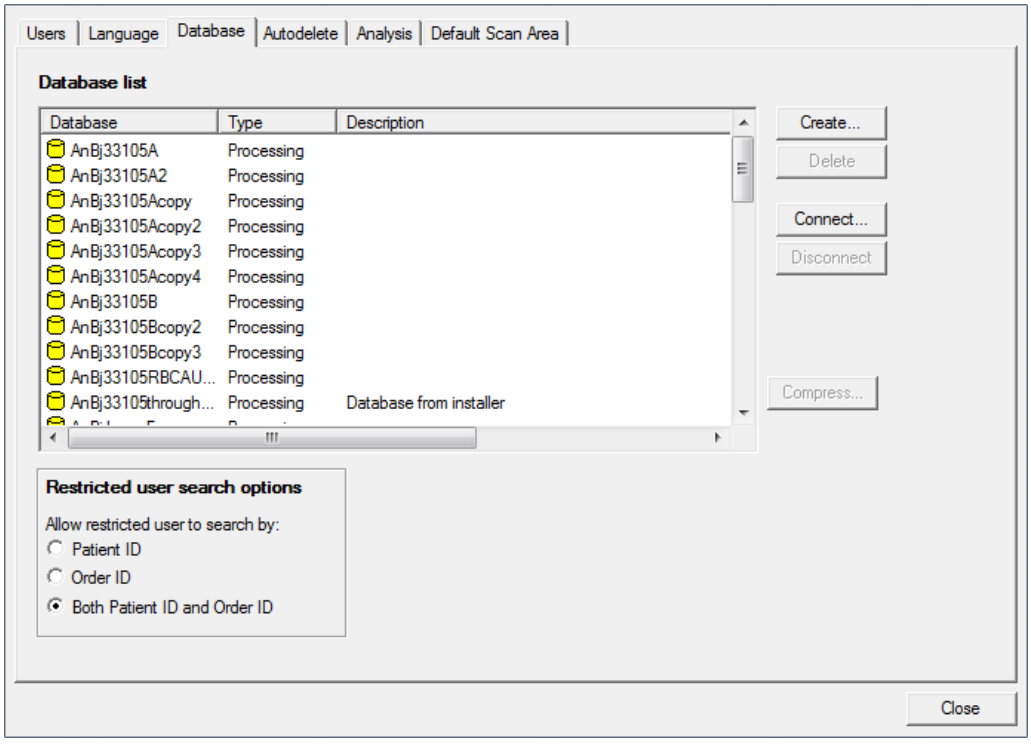
The following settings are stored in the database:

- Restricted user search options
- User settings
- Analysis default values
- Enable LIS
- Add processed slide to worklist
- WBC reclassification settings
- RBC settings
- PLT settings
- Active report template
- Report template contents
- Default settings for sign dialogs
- Standard comments
- Custom reference cells
- Autodelete/Archiving settings

Go to the *Tools* menu, and select *Settings* and then select the appropriate tab to customize the system. Different users are allowed to edit different settings (see Appendix - E *User Authorization Levels*).

9.1 Adjusting Database Settings

Here you create new databases and new database connections. In the *Log On* dialog you select which database to use. It is also possible to compress an existing local database.



Local database

Remote database

9.1.1 Creating a New Database

1. Click *Create*. A dialog appears, where you may enter *Database name*, *Description*, *Home directory* and *Database size*.
2. Select one of the following types of database:
   - Processing database, a database for processing slides.
   - Export database, a database that is used when you want to export orders from another database. This type cannot be used for processing slides.
   - Scan database, a database for scanned slides.
3. Click *Create*. A new folder with the chosen Database name will be created in the specified *Home directory*.

Creating a database requires sufficient free disk space. A processing database requires 20 GB, a scan database requires 20 GB and an export database requires 1 GB.

Note:
Having many databases affects system performance negatively.

Note:
A database can be created only on your local computer.

9.1.2 Deleting a Database

1. Select the database in the list.
2. Click *Delete*.

9.1.3 Creating a New Database Connection

1. Click *Connect*. A dialog appears where you may enter Database name, Description and Remote computer.
2. Click *OK*. A new connection will be shown in the list.

Note:
On the remote computer, select Help/System Information to find out the name of the computer.

9.1.4 Deleting a Database Connection

1. Select the connection in the list.
2. Click *Disconnect*.

9.1.5 Compressing a Database

A compressed database will occupy less space on the hard disk. The performance might also be improved.

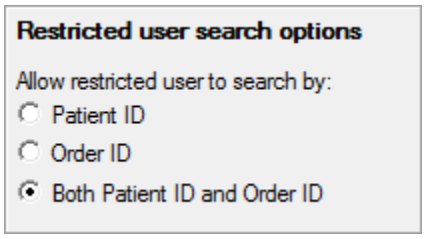
1. Select the database in the list.
2. Click *Compress*. A dialog appears.
3. Click *Compress database*.
4. Click *Close*.

Note:
It can take a long time to compress a database. If the database is >10 GB in size it can take some hours. The process requires free disk space twice the size of the database to be compressed.

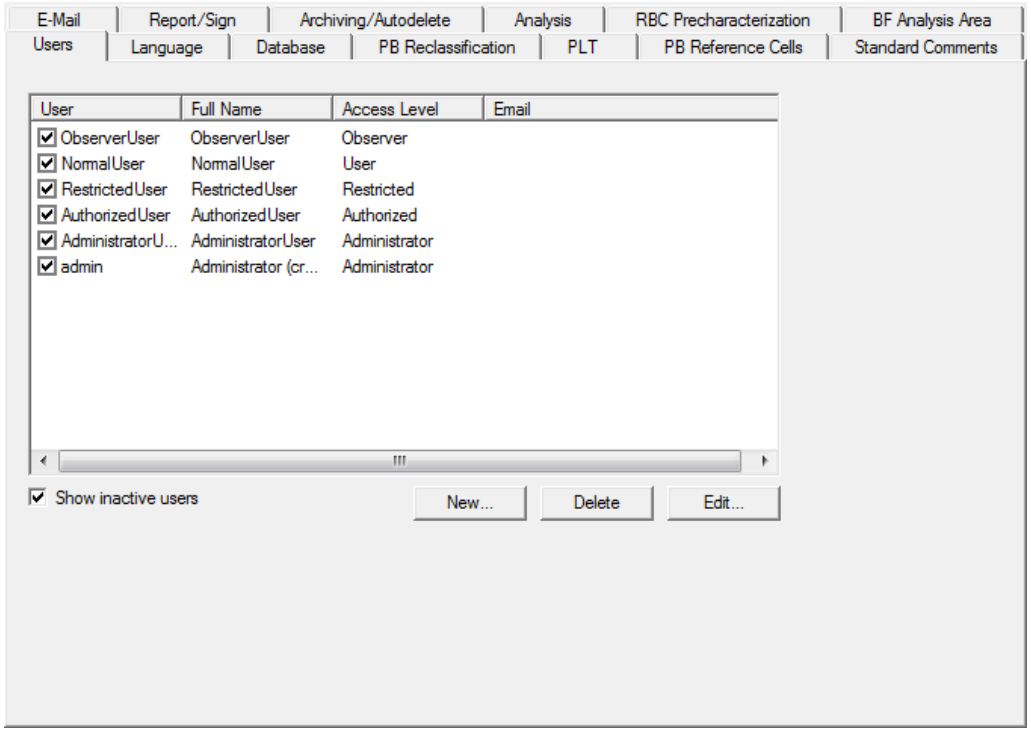
Note:
During compression, no client may be connected to the database! This means that you cannot compress the database you are currently logged on to.

9.1.6 Setting User Restrictions

Here you set the available database search criteria for the Restricted user. Select the desired *Restricted user search options*.



9.2 Adjusting Users Settings



Show inactive users: Activate this checkbox if inactive users shall be shown in the list.

New: Add a new user (see dialog below).

Edit: Edit user information (see dialog below).

Delete: Delete selected users.

There are six levels of user authorization:

Observer: Only allowed to view images and results.

User: Can reclassify and recharacterize WBC, RBC and PLT, but not sign slides.

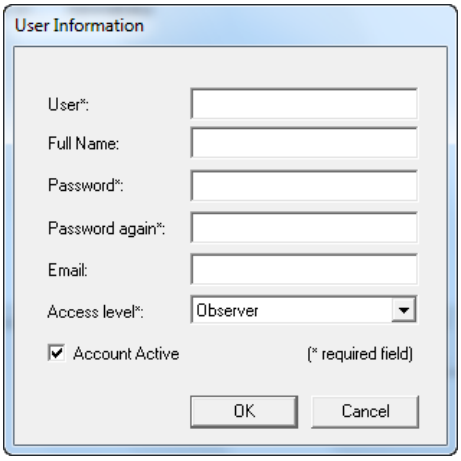
Authorized: Same as User, but can sign slides and orders.

Restricted: Same as Authorized, but with restricted database access.

Administrator: Full access to the system.

Service: Same as Administrator but with no access to patient data or rights to add/delete/edit users.

The authorization level determines the different functions and features the operator can access (see Appendix - E *User Authorization Levels*).



User: User name. When you create a new user the user name must be unique. The valid characters are A-Z, a-z and 0-9. Passwords and usernames may start either with letters or numbers. The following words are reserved: USER, SYSTEM, SELECT, TABLE, UPDATE, CREATE, GET, IF, IS, GRANT, IN, LOCAL, OF, ON, OR, OUT, SET, TO, SYSADM, SYS.

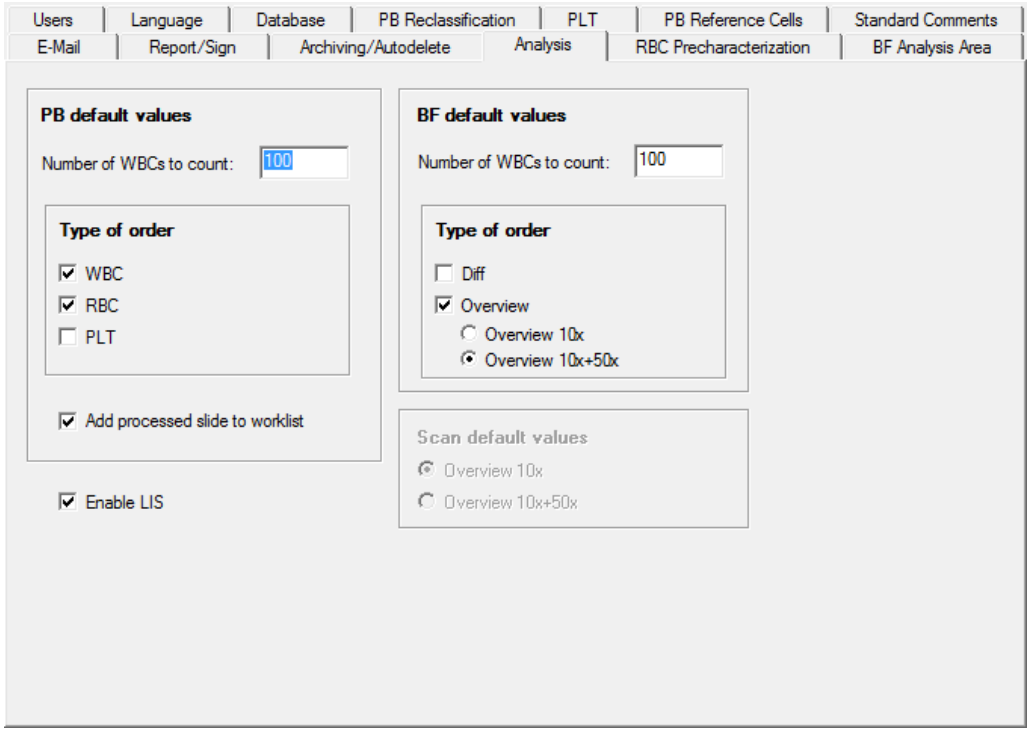
Full Name: Full name of the operator.

E-mail: The operator's e-mail address.

Access Level: Level of user authorization.

Account Active: The account is active if the checkbox is checked.

9.3 Adjusting Analysis Settings



Default Values

These values are used if the order to analyze is not found in the database or in the LIS. Type of order is the analysis to perform.

Enable LIS

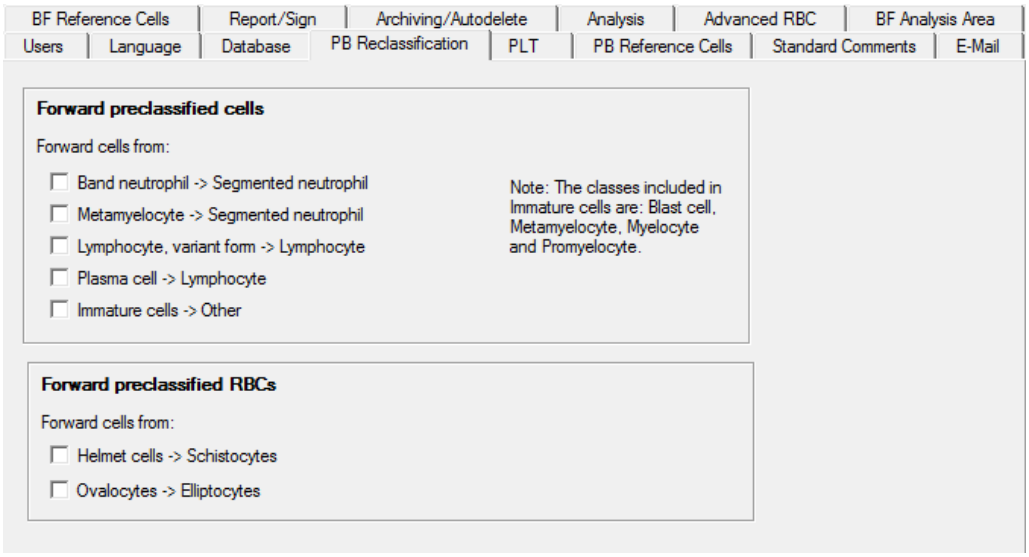
Activate this checkbox and restart the program if the LIS will be used.

Add Processed Slide to Worklist

If this checkbox is activated, processed slides will automatically be added to the Worklist.

Note:
BF slides are not automatically added to the worklist.

9.4 Adjusting PB Reclassification Settings



Forward Preclassified WBCs

Select your forwarding criteria using the checkboxes.

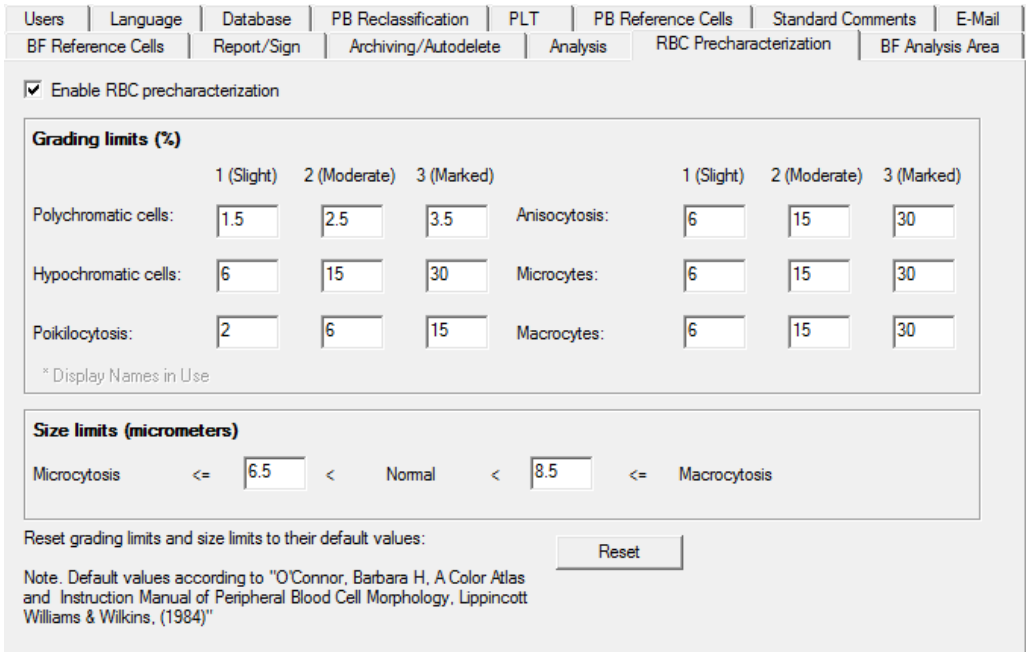
Forward Preclassified RBCs

Select your forwarding criteria using the checkboxes.

Note:
The Forward preclassified RBCs settings are only available on a system running the Advanced RBC application.

9.5 Adjusting RBC Precharacterization Settings

Here you adjust the percentage limits for the different levels of the morphology characteristics. It is also possible to disable the RBC precharacterization.



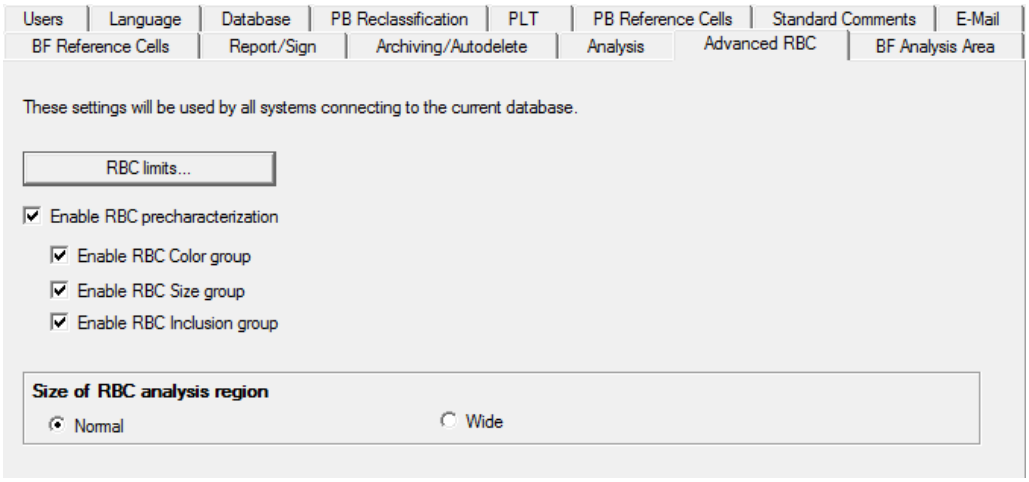
Enable RBC precharacterization: Deactivate this checkbox if RBC precharacterization shall not be performed. Manual RBC characterization will still be possible.

Grading limits: Set limits for RBC precharacterization in percent. Poikilocytosis is a general term used to describe the presence of abnormally shaped red blood cells. Anisocytosis denotes variation in size among red blood cells. The default values are set according to O'Connor, Barbara H, A Color Atlas and Instruction Manual of Peripheral Blood Cell Morphology, Lippincott Williams & Wilkins, (1984).

Size limits: Set size limits for RBC precharacterization of Anisocytosis.

Reset: Resets all grading limits and size limits to their default values.

9.6 Adjusting Advanced RBC Settings



RBC limits: Click to open a pop-up window to set the limits for the different levels of the morphology characteristics.

Enable RBC precharacterization: Deactivate this checkbox if RBC precharacterization shall not be performed. Manual RBC characterization will still be possible.

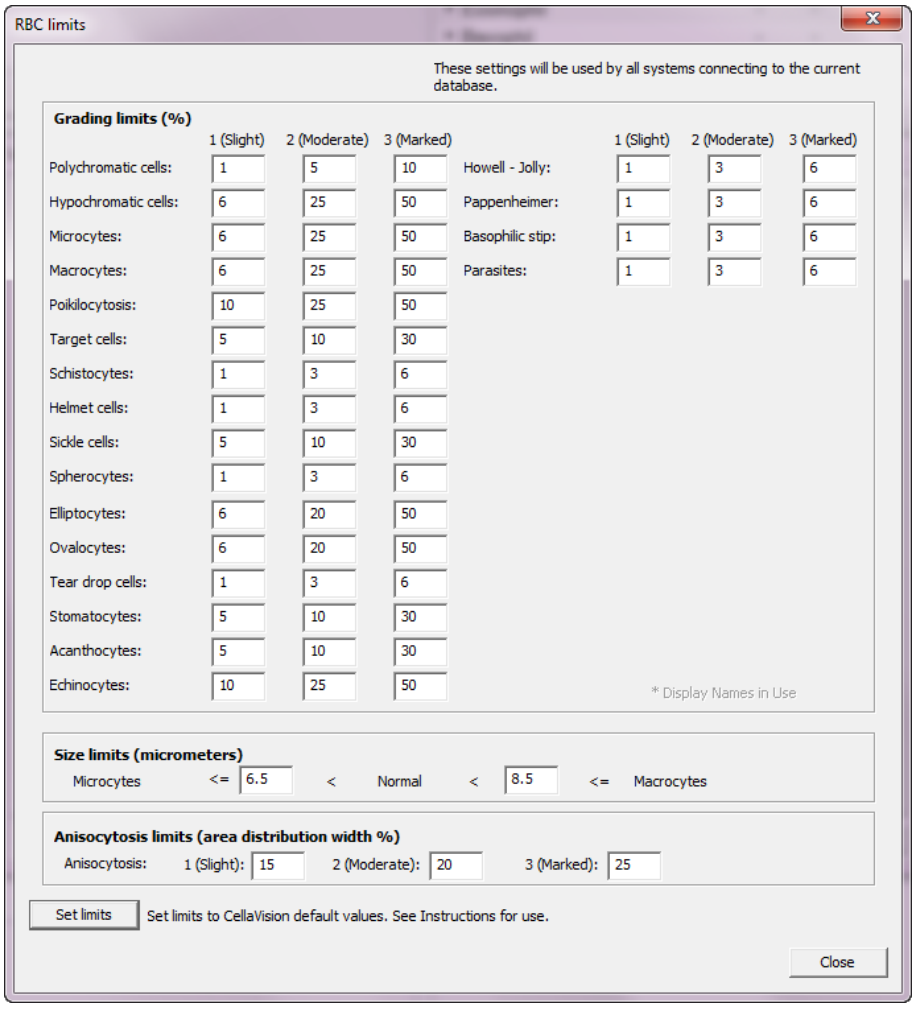
Enable RBC Color group: Deactivate this checkbox to disable this specific morphology group.

Enable RBC Size group: Deactivate this checkbox to disable this specific morphology group.

Enable RBC Inclusion group: Deactivate this checkbox to disable this specific morphology group.

Size of RBC Analysis Region: Choose between *Normal* and *Wide* size of RBC analysis region. *Normal* is optimized for monitors with aspect ratio 4:3 and *Wide* is optimized for monitors with aspect ratio 16:9.

RBC Limits



Grading limits: Set limits for RBC precharacterization in percent. Poikilocytosis is a general term used to describe the presence of abnormally shaped red blood cells meaning all abnormally shaped red cells as percentage of all red cells in the analysis.

Size limits: Set size limits for Microcytes and Macrocytes in micrometers.

Anisocytosis limits: Set limits for variation in cell area in percent. Anisocytosis denotes variation in size among red blood cells. The red blood cell distribution area width is a measure of the variation of red blood cell area that is reported as part of a standard complete blood count.

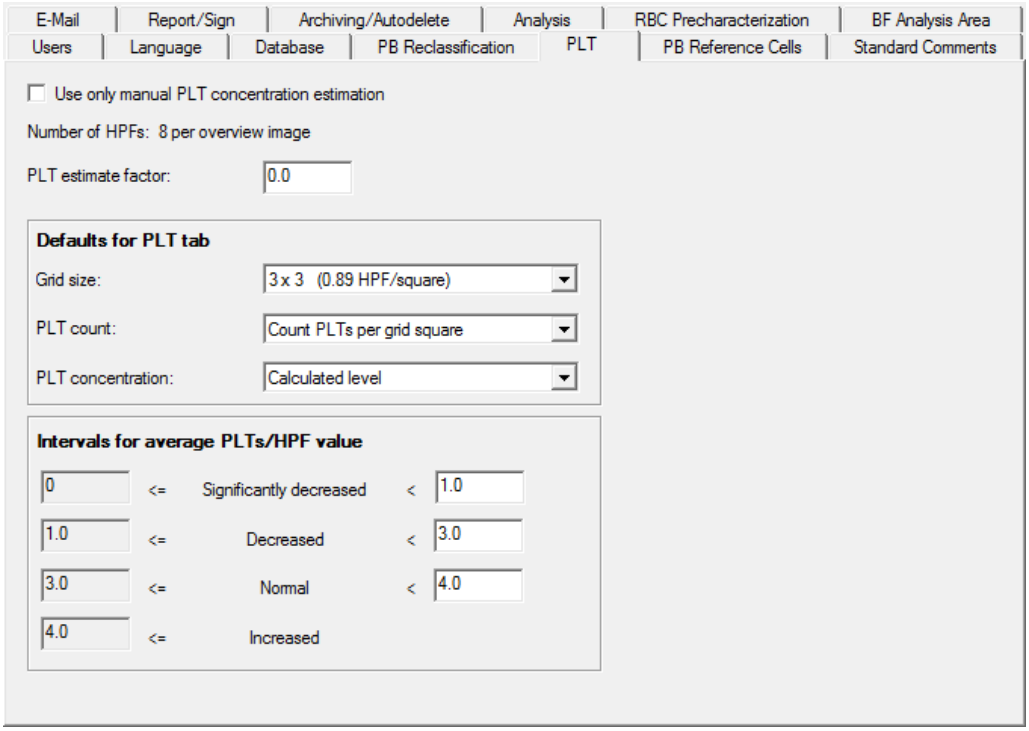
Set limits: Resets all grading limits, size limits and Anisocytosis limits to CellaVision default values. The default values are based on Gene Gulati, Blood Cell Morphology Grading Guide, American Society for Clinical Pathology (2009).

Important!

The RBC limits are not set when installing the Advanced RBC Application. You have to set your own RBC limits or click *Set limits* to use the CellaVision default values.

9.7 Adjusting PLT Settings

In the *PLT* tab you set the *PLT estimate factor* and the limits for the PLT concentration levels. You also set the default settings for the *grid size*, *PLT count* and *PLT concentration result*. It is also possible to enable the option to use manual PLT concentration estimation.



Use only manual PLT concentration estimation: When this checkbox is activated PLT estimation is done by estimating the concentration level to *Significantly decreased, Decreased, Normal* or *Increased*. No values for the PLT count can be entered and no calculation can be performed. This setting takes effect the very first time a slide is opened and can then not be changed for the order.

PLT estimate factor: See Appendix - F *Determining the Platelet Estimate Factor* for how to determine the PLT estimate factor.

Important!

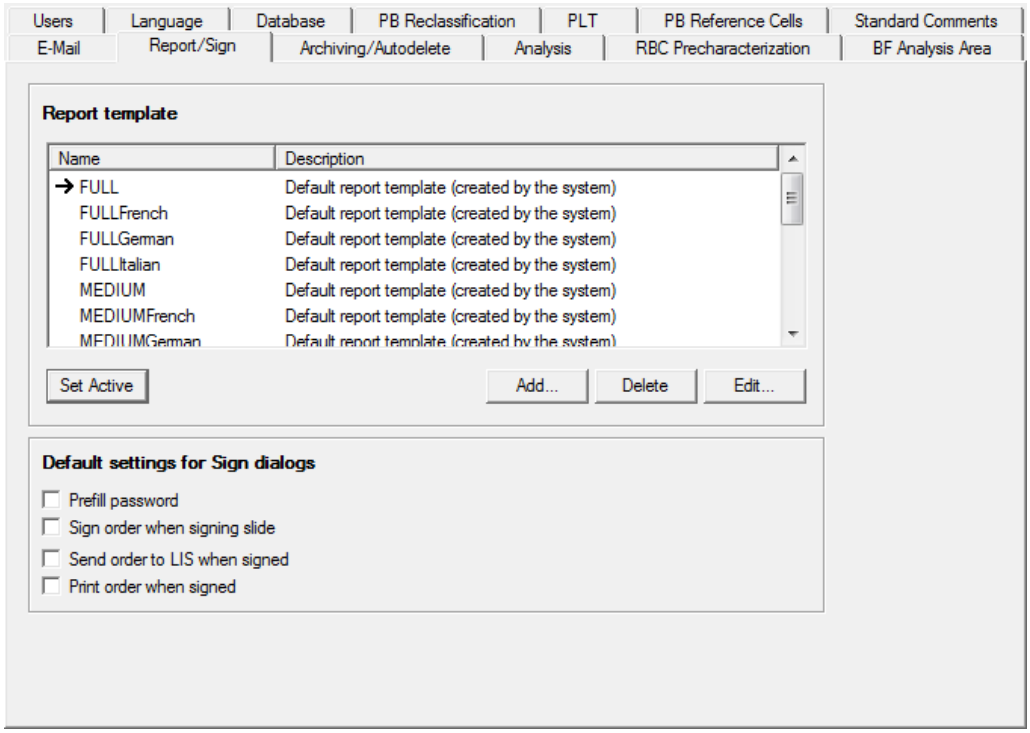
You have to determine your own PLT estimate factor. By default, it is set to "0".

Defaults for PLT tab: Sets the default values for Grid size, PLT count and PLT concentration.

Intervals for average PLTs/HPF value: These intervals are used to calculate the PLT result Calculated level.

9.8 Adjusting Report/Sign Settings

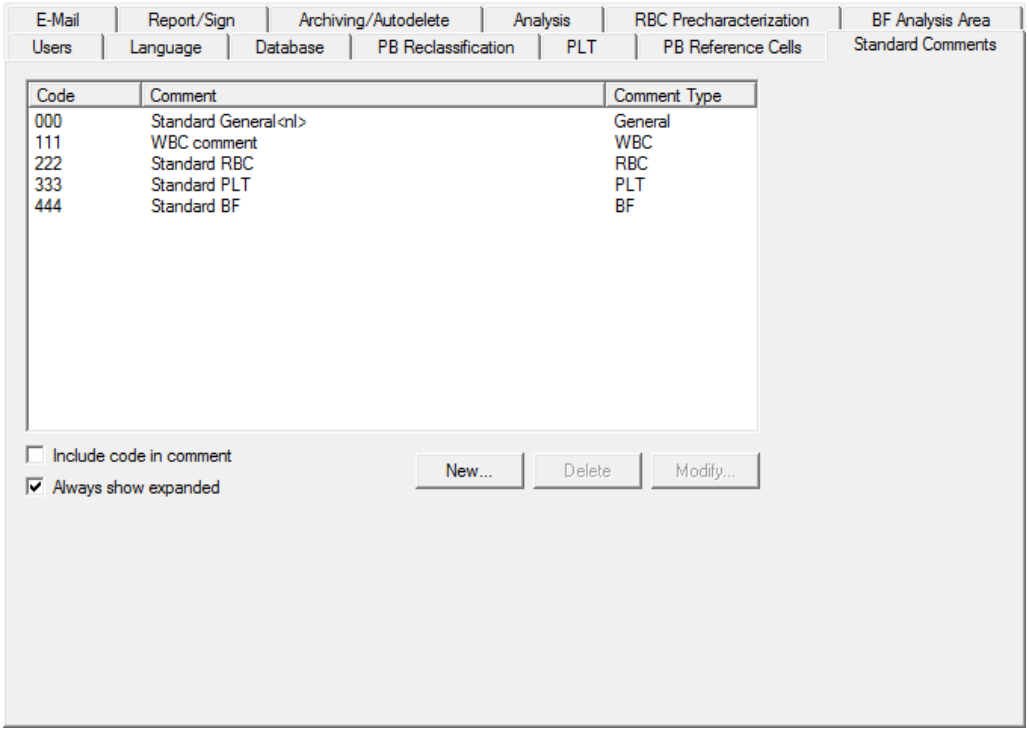
In the *Report/Sign* tab you set the template to use in printed reports and the default settings for the signing dialogs.



Report: All available templates are displayed in the list. The currently used template is indicated with an arrow. To change which template to use, select a template in the list and click *Set Active*.

Default settings for Sign dialogs: Here you set the default values for the *Sign Slide* and *Sign Order* dialogs.

9.9 Adjusting Standard Comments Settings

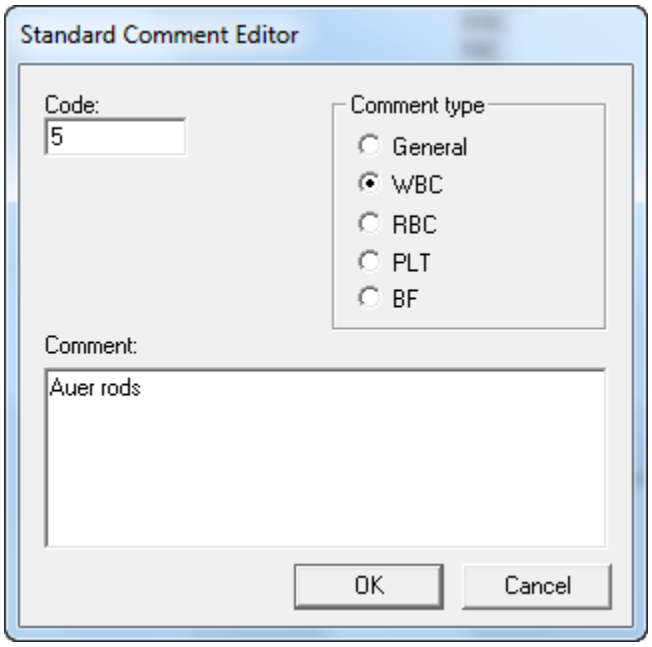


Include code in comment: If activated, the code is written together with the standard comment.

Always show expanded: If activated, the standard comments are visible by default when the comment dialog is opened.

Adding a New Standard Comment

1. Click *New*.
2. The *Standard Comments Editor* appears.



3. *Enter Code, Comment type* and *Comment*. Standard comments of type WBC, RBC, PLT or BF will only be available in the respective tab. General comments are always accessible.
4. Click *OK*.

Deleting a Standard Comment

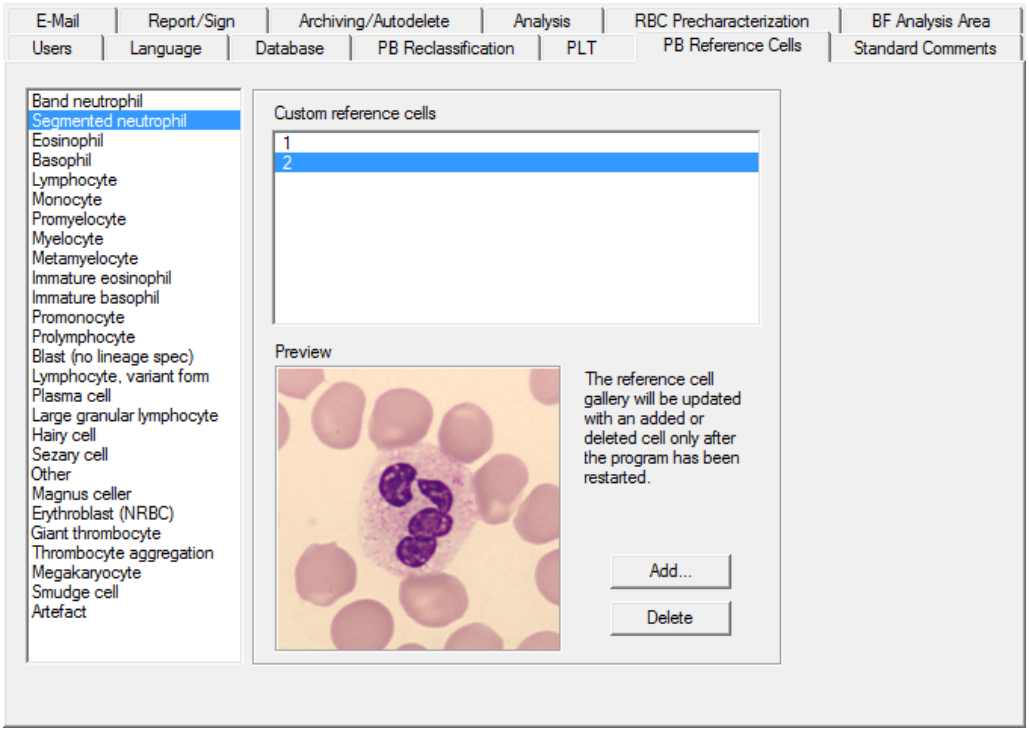
1. Select the standard comment in the list.
2. Click *Delete*.

Modifying a Standard Comment

1. Select the standard comment in the list.
2. Click *Modify* and the *Standard Comments Editor* appears.
3. Edit *Code*, *Comment type* and *Comment*.
4. Click *OK*.

9.10 Adjusting PB Reference Cells Settings

Click on a cell class to see a list of all *Custom reference cells* belonging to it. Click on a specific cell to display it in the *Preview* window.

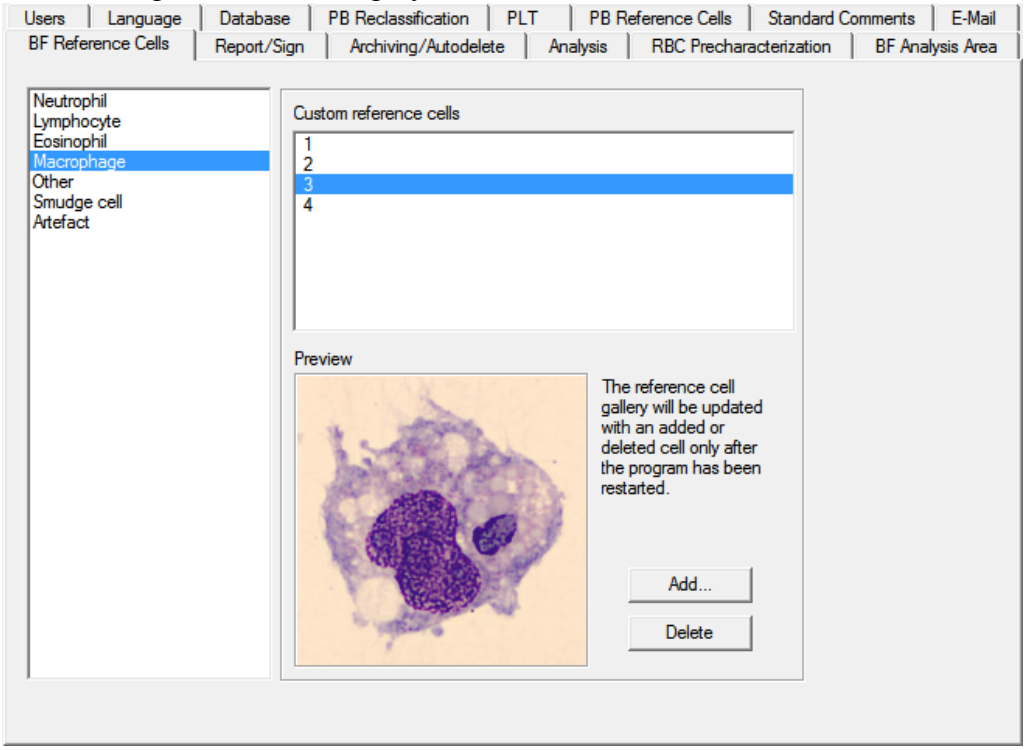


Click *Add* to add custom reference cells from disk. Valid file formats are JPEG (".jpg") and bitmap (".bmp"). All cell images will be stored in the JPEG format. You can also store cells from processed slides (see "Right-click Menu" in *Reclassifying White Blood Cells*) as custom reference cells.

Click *Delete* to remove the selected custom reference cell.

9.11 Adjusting BF Reference Cells Settings

Click on a cell class to see a list of all *Custom reference cells* belonging to it. Click on a specific cell to display it in the *Preview* window.

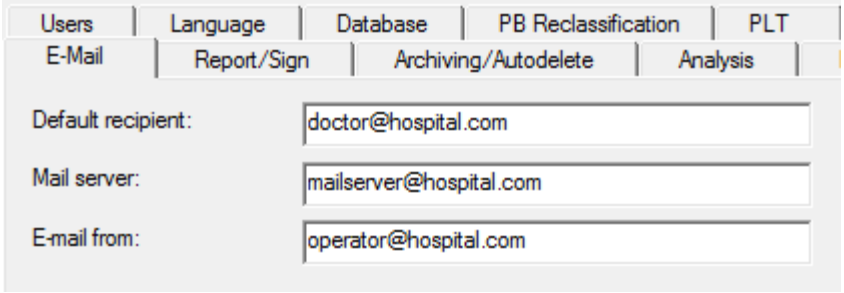


Click *Add* to add custom reference cells from disk. Valid file formats are JPEG (".jpg") and bitmap (".bmp"). All cell images will be stored in the JPEG format. You can also store cells from processed slides (see "Right-click Menu" in *Reclassifying White Blood Cells*) as custom reference cells.

Click *Delete* to remove the selected custom reference cell.

9.12 Adjusting E-mail Settings

Enter *Default recipient* of e-mail, specify *Mail server* and *E-mail from*, i.e. sender of e-mail.



9.13 Adjusting Archiving/Autodelete Settings

For storage safety reasons and limited hard disk capacity, it is recommended that you regularly archive the cell images or delete the orders.

Keep the size of the database below 20 GB for optimal database performance.

Hard disk space requirements, examples:

PB: 100 WBC + RBC + PLT = about 4 MB

PB: 100 WBC + Advanced RBC + PLT = about 5 MB

BF: 100 WBC = about 3 MB

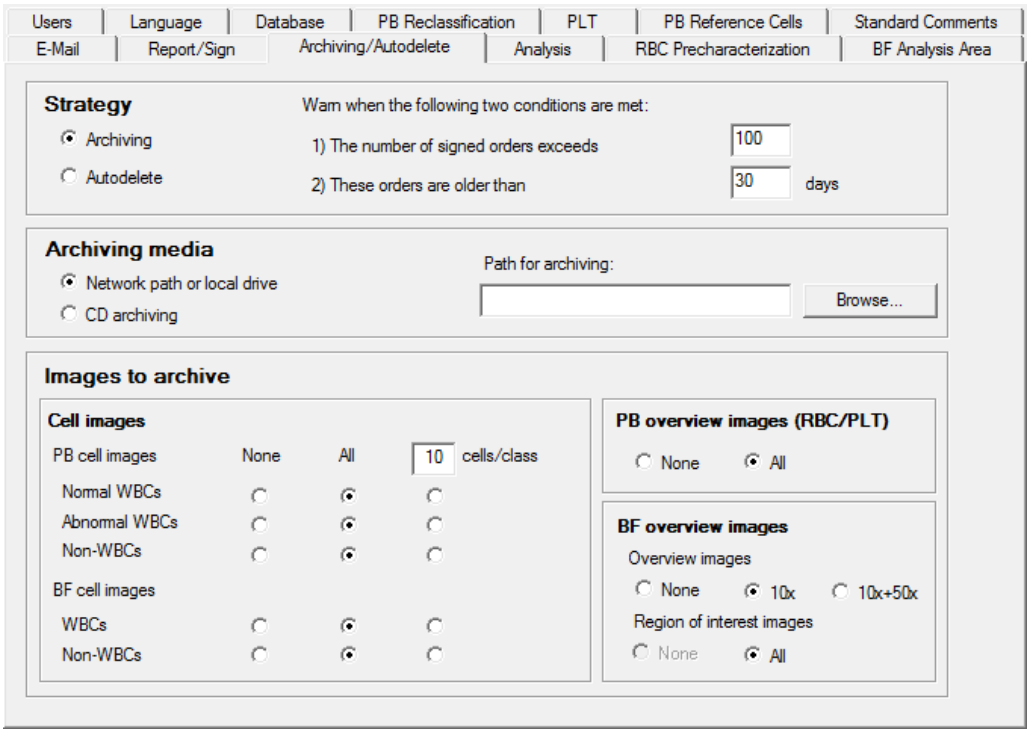
BF: Overview image (6 mm, 10x) = about 15 MB

BF: Overview image (6 mm, 50x) = about 130 MB

> **Caution!**
>
> Increasing the analysis area from 6 mm to 8 mm will require 78% more disk space for the BF overview images.

To view information about a database log on to another database, go to *Tools/Settings/Database*, select the database you need information about, click *Compress* and a pop-up window with information will appear.

Always delete unsigned or failed orders.



Strategy

The archiving/autodelete strategy depends on your daily throughput and the need for saving images for future use. The archiving/autodelete settings are database specific, enabling each database to have its own archiving/autodelete strategy.

Archiving:

Select *Archiving* and specify the two conditions:

- *The number of signed orders exceeds:* Specify the maximum number of signed orders that may be present in the database before images from the signed slides shall be archived.
- *These orders are older than:* Specify the minimum number of days that images from signed slides shall be stored before being archived.

The program prompts the user with a message to archive images when both of the conditions are met.

Only images from signed orders can be archived.

When you archive, the cell images and comments are transferred from the database to a CD or a hard disk.

Always combine archiving with a backup of the database. The database contains the path to the archived images. If a hard disk crash occurs, it will not be possible to restore the archived images, unless a backup exists.

Autodelete:

Select *Autodelete* and specify the two conditions:

- *The number of signed orders exceeds:*Specify the maximum number of signed orders that may be present in the database before signed slides shall be deleted.
- *These orders are older than:* Specify the minimum number of days that signed slides shall be stored before being deleted.

The program prompts the user with a message to delete images when both of the conditions are met.

If you delete an order with archived images, you will not be able to access these images again. The order is needed to access archived images.

Archive Media

Select your archive media.

- CD Archiving
- Network path or local drive

Images to Archive

The images are divided into groups. Use the radio buttons to archive either a certain number of images from each cell class in a group, or all available images, or no images at all from a group.

PB cell images:

Normal cells:

- Segmented neutrophils
- Monocytes
- Basophils
- Eosinophils
- Lymphocytes

Abnormal cells:

- Band neutrophils
- Lymphocytes variant forms
- Prolymphocytes
- Promyelocytes
- Plasma cells
- Large granular lymphocytes
- Myelocytes
- Immature eosinophils
- Hairy cells
- Metamyelocytes
- Immature basophils
- Sézary cells
- Blast cells
- Promonocytes
- User defined WBCs

Non-WBCs:

- Other
- Giant thrombocyte
- Smudge cell
- Not classed
- Thrombocyte aggregation
- Artefacts
- Erythroblast (NRBC)
- Megakaryocyte
- User defined Non-WBCs

1.5.4. 1.3. Įjranga suklasifikuoja trombocitus į ne mažiau kaip 2 kategorijas, įskaitant šias: trombocitų sankaupos, gigantiniai trombocitai.

1.5.4. 2. Yra galimybė įvesti papildomas vartotojo pasirinktas ląstelių/ radinių klasifikavimo

BF cell images:

WBCs:

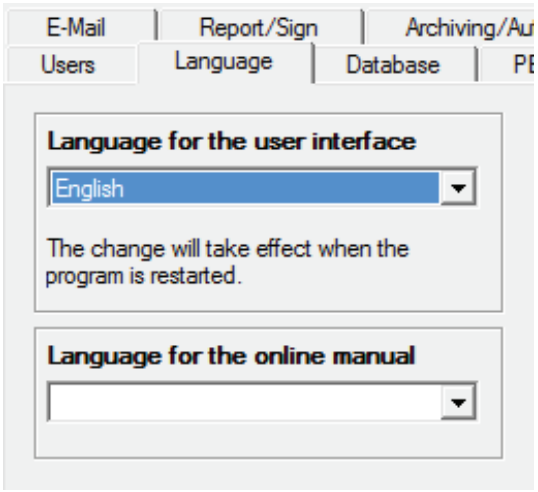
- Neutrophils
- Eosinophils
- Lymphocytes
- Macrophages
- Other
- User defined WBCs

Non-WBCs:

- Smudge cell
- Artefacts
- User defined Non-WBCs

9.14 Adjusting Language Settings

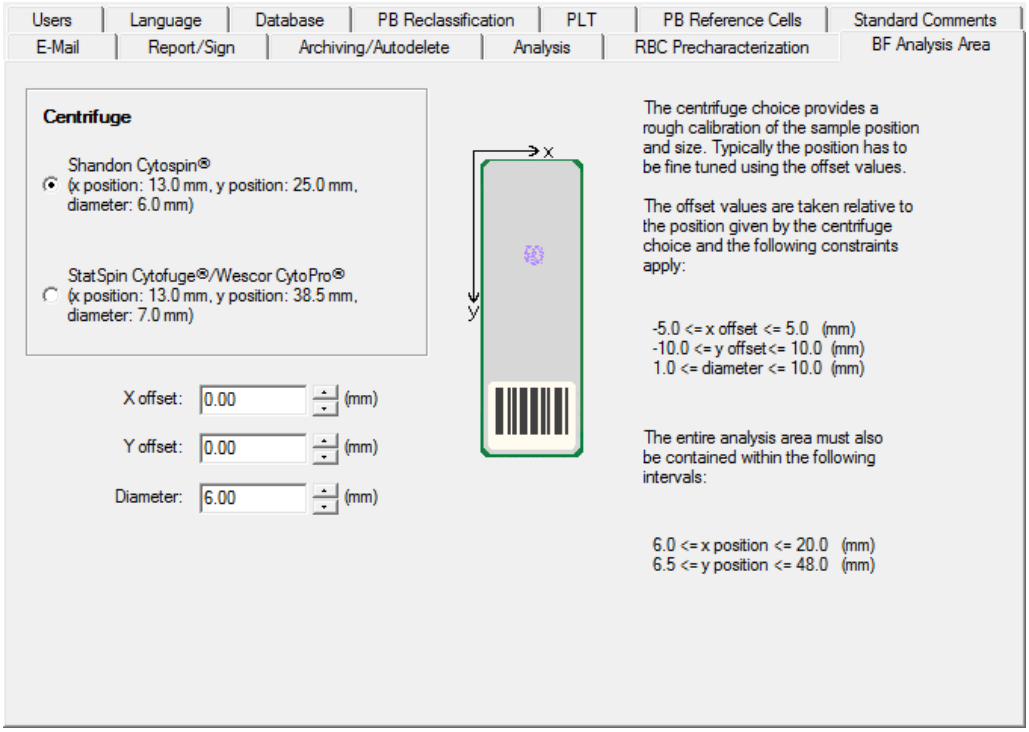
In the *Language* tab you set language for the user interface and the instruction for use.



9.15 Adjusting BF Analysis Area

9.15.1 Centering the Analysis Area

Before using the system for the first time or when necessary, define the sample spot location. This is done in *Tools/Settings/BF Analysis Area*.

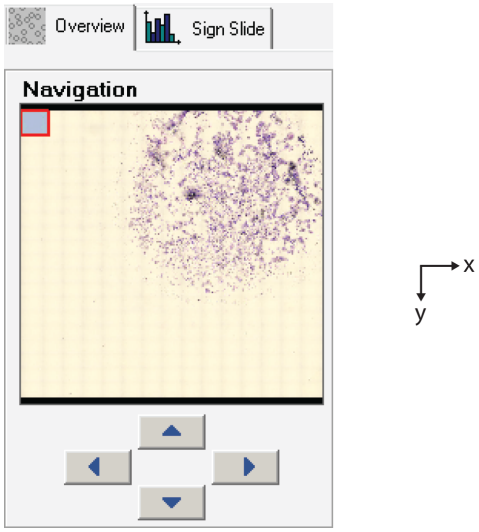


1. Go to *Tools/Settings/BF Analysis Area* and select the desired setting for *Centrifuge*.
2. Process a Body Fluid slide with a representative sample spot location.

3. Go to the *Overview* tab. Use the *Navigation* display to establish whether the analysis area needs to be adjusted.
4. If further adjustments are needed, go to *Tools/Settings/BF Analysis Area* and adjust the *X-offset* and *Y-offset* settings (see example below).
5. Restart the program, delete the order and rerun the slide to verify your new settings.

Note:
It is important to delete the order before the slide is processed again. Otherwise the settings from the previous run will be used, which means that your changes to the analysis area settings will have no effect.

The *Diameter* setting was 8 mm in the following example. In order to center the analysis area on the sample spot, the analysis area needs to be offset by 1.5 mm in the positive x direction and 1.5 mm in the negative y direction.



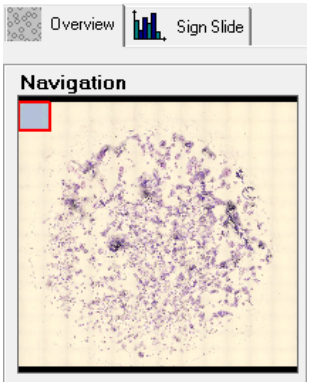
9.15.2 Adjusting the Size of the Analysis Area

> **Caution!**
>
> Increasing the analysis area from 6 mm to 8 mm will require 78% more disk space for the BF overview images.

To adjust the size of the analysis area, do as follows:

1. Go to *Tools/Settings/BF Analysis Area* and select the desired setting for Diameter.
2. Restart the program, delete the order and rerun the slide to verify your new setting.

As a rule of thumb, the analysis area diameter should be 1 mm larger than the sample spot diameter. The slightly larger analysis area diameter will allow for variation in sample spot location between slides. The image below shows an example where the analysis area covers the sample spot well.



Take the last analysis performed and check how well the analysis area covers the sample spot. If the analysis area is too large or too small, go to *Tools/Settings/BF Analysis Area* and adjust the *Diameter* setting.

Note:
Increasing the analysis area will increase the processing time.

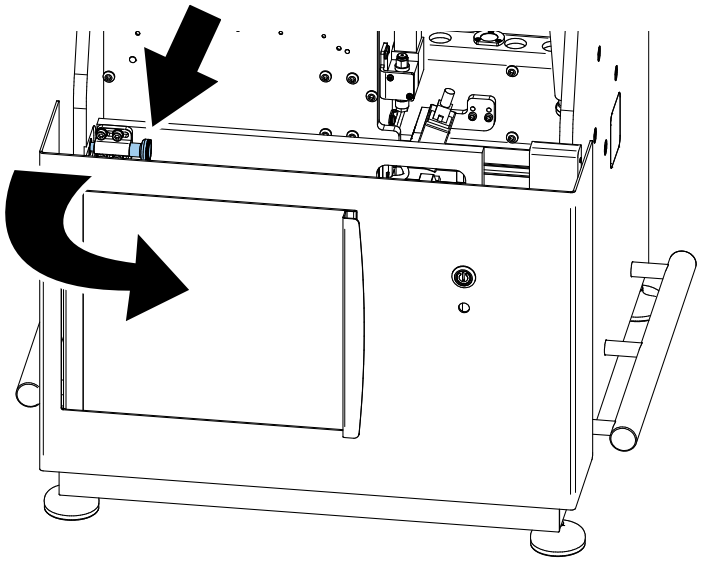
10 Maintenance

> **Caution!**
>
> Be careful not to bend or put excessive force to any part of the system interior.

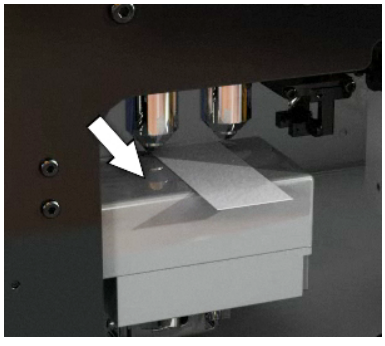
10.1 Weekly Maintenance

10.1.1 Clean Objectives and LED Table

1. Open the hood.
2. Pull out the stop pin and open the magazine feeder.



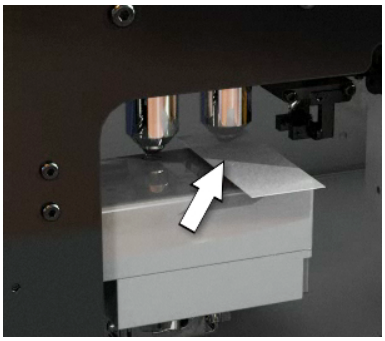
3. Gently wipe the LED table with a lint free soft cloth.



> **Caution!**
>
> Do *not* use any solvents when cleaning the LED table.

4. Use lens paper and gently wipe the lens of each objective. Use a fresh lens paper for each lens.

   When needed, use Isopropylalcohol to clean the objectives.



Important!

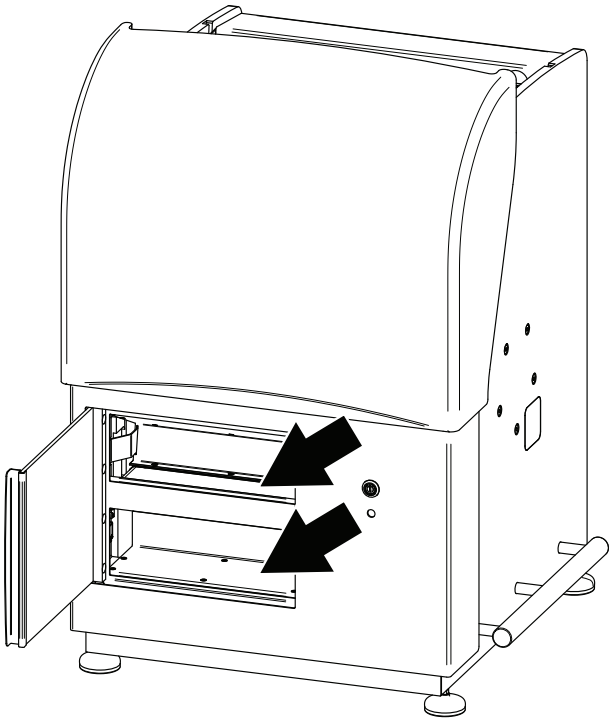
Always use a fresh lens paper for each lens in order not to get oil on the low power (10x) dry objective.

Important!

Cleaning with alcohol increases the risk of air bubbles on the objective, which affects the image quality for the first two slides. To avoid the problem, it is recommended to run two slides after weekly maintenance. Delete these slides immediately to avoid the risk of result mix-ups.

10.1.2 Clean Magazine Feeder

1. Open the input hatch.
2. Wipe the infeed conveyor and the outfeed shelf with a moist cloth.



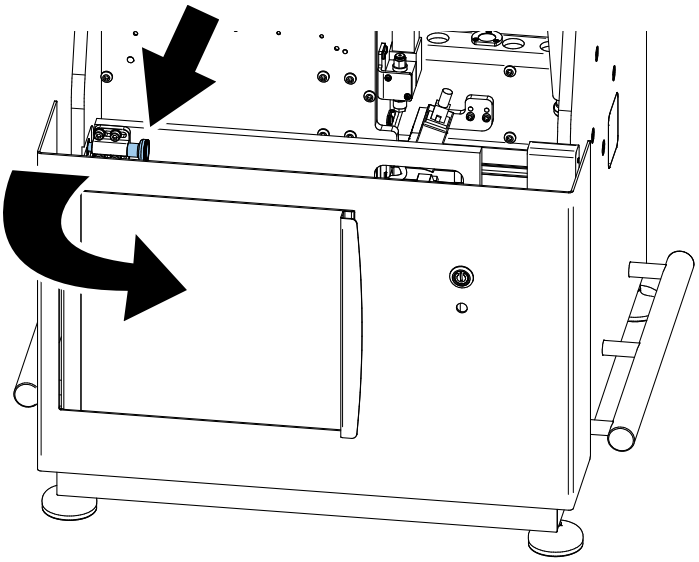
10.1.3 Clean Hood

Wipe the hood with a moist cloth when necessary.

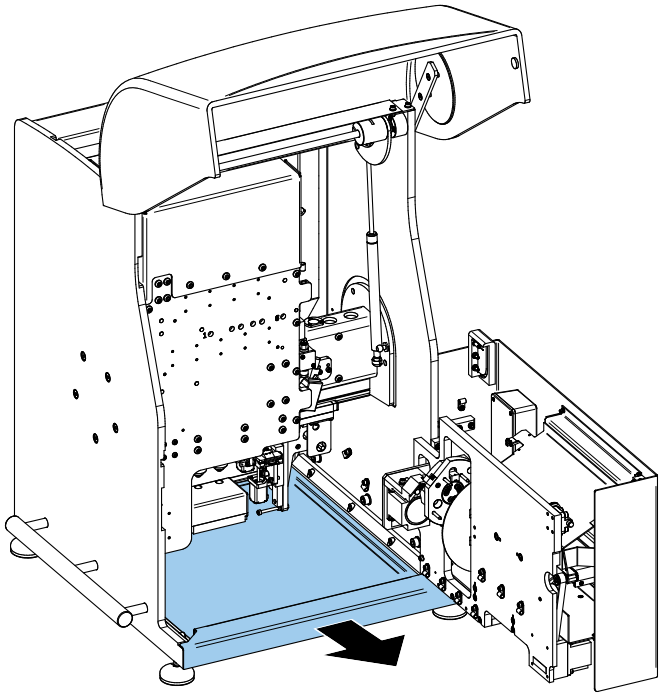
> **Caution!**
>
> Use water only when cleaning the hood.

10.1.4 Clean Bottom Tray

1. Open the hood.
2. Pull out the stop pin and open the magazine feeder.



3. Pull out the bottom tray and wipe clean any immersion oil.



10.1.5 Delete Unsigned Orders

Delete unsigned and failed orders to minimize the size of the database.

10.1.6 Restart System Computer

Restart the system computer at least once a week.

10.2 Preventive Maintenance

No preventive maintenance by the user is necessary. Preventive maintenance is to be performed by CellaVision® authorized personnel.

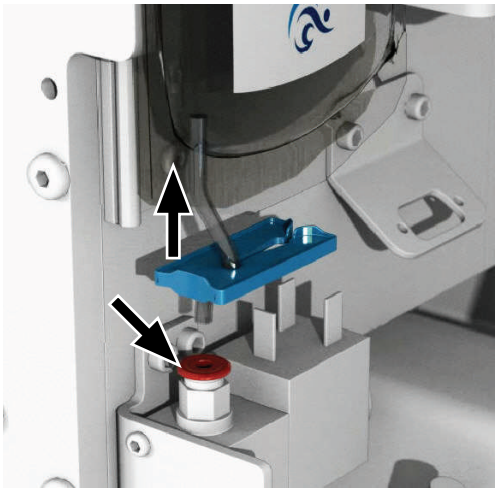
10.3 Remedial Maintenance

10.3.1 Change Immersion Oil Pack

> **Warning!**
>
> The oil may cause sensitization by skin contact. We recommend using gloves.

> **Caution!**
>
> Use only immersion oil recommended by (see Appendix - A *System Specification*).

1. Open the hood.
2. Place clip on hose.
3. Push down on the oil hose connection and pull out the hose.



4. Change the oil pack and connect the hose.
5. Remove the clip from the hose.
6. Go to *Maintenance/Oil*.
7. If the old oil pack ran dry and all hoses are empty, click *Prime Oil*.

8. Click *Reset Oil Drop Counter*.

10.4 Database Performance

To maintain a high database performance, it is very important to control the size of the database. It is also recommended to restart the system computer at least once a week. It is allowed to install an anti virus program, but it is not recommended to scan the database files.

10.4.1 Control Database Size

A large database will have lower performance (access time, database search time etc.) compared to a smaller database. The size of the database can be controlled by two methods:

1. Activate autodelete of orders.
2. Archive images onto CD-R/RW or LAN.

Recommendation:

Keep the maximum size of the database to approximate 20 GB. See 9.13 *Adjusting Archiving/Autodelete Settings* for more information.

Delete all unsigned and failed orders.

Note:
Select Compress Database to view the database size (see 9.1.5 Compressing a Database).

11 Troubleshooting

11.1 Troubleshooting Steps

If a problem occurs, follow these steps:

1. Observe any unusual circumstances surrounding the problem.
2. Note any error messages displayed.
3. See 11.2 *Troubleshooting Chart*.
4. If the problem remains, contact your distributor for assistance.

11.2 Troubleshooting Chart

11.2.1 General Startup Problems

Problem	Cause	Action
Message box: The program has already been started and you cannot start another until the previous one is closed.	Previous program has not closed.	Make sure the program is closed. Wait 10 seconds and try again.
Message box: Could not log on to the system. Make sure you typed your username and password correctly.	Wrong user name and/or password.	Enter correct username and password.
	Caps Lock is activated.	Deactivate Caps Lock.
Message box: Could not log on to the system. Network connection error!	The database server could not be reached.	If the database is stored on the system computer, restart the computer and the program. Otherwise, check the network connection and that the computer that stores the database is turned on.
Message box: Disk space exhausted.	The database is located on the C:\ drive.	Move the database to the E:\ drive.
Logging on to the system takes time.	The database server needs to be restarted.	Restart the system computer, or the computer on which the database resides.
	The database is too large.	Keep the database size at the recommended level (see 10.4 *Database Performance*).
	The database files are fragmented.	Compress the database (see 9.1.5 *Compressing a Database*).

11.2.2 Error Message List

Error Message	Cause	Action
Startup error messages		
The system is not ready	Temporary software error.	Restart the SSU and the system computer.
The configuration of the Control Unit is incorrect	The Control unit has lost its configuration.	Contact your local vendor's technical support.
Communication failure	No connection between the SSU and the system computer.	Check the connection between the SSU and the system computer. Check power connection to the SSU. Restart the system and the program.
The hood or the input hatch was open during startup	The hood or the input hatch was open.	Make sure that the magazine feeder, the hood and the input hatch are closed. Restart the system and the program.
Jam error occurred during initialization	At least the motor specified in the message box reported a positioning failure.	Restart the SSU and the program. If error persists, contact your local vendor's technical support.
Internal error	Temporary software error.	Restart the SSU and the system computer.
Temperature is too high	The air filter is dirty.	Check that the air filter on the back of the SSU is not dirty. Change if needed.
	The fan in the control unit does not function.	The fan has to be exchanged.
File system or registry failure	The File system or registry is corrupt.	Reinstall the program.
A slide was detected in the gripper during startup	A slide is in the gripper.	Move gripper to service position and remove slide (see 11.2.8 *Gripper Service*). Restart the SSU and the program.
Hardware errors during analysis/eject/maintenance		
This operation can not be performed at this time	Communication error between SSU and system computer.	Restart the SSU and the program.
Communication failure	No connection between the SSU and the system computer.	Check the connection between the SSU and the system computer. Check power connection to the SSU. Restart the system and the program.

Error Message	Cause	Action
Temperature is too high	The air filter is dirty.	Check that the air filter on the back of the SSU is not dirty. Change if needed.
	The fan in the control unit does not function.	The fan has to be exchanged.
Oil dispensing failed	The oil bag is empty.	Change oil bag (see 10.3.1 *Change Immersion Oil Pack*).
File system or registry failure	The File system or registry is corrupt.	Reinstall the program.
Internal error	Temporary software error.	Restart the SSU and the system computer.
Magazine eject failure	The magazine is stuck.	Remove the magazine manually. Restart the SSU and the program.
Positioning failure	At least the motor specified in the message box reported a positioning failure.	Move gripper to service position and remove slide (see 11.2.8 *Gripper Service*). Restart the SSU and the program. If error persists, contact your local vendor's technical support.
	The slide is stuck or broken.	Move gripper to service position and remove slide (see 11.2.8 *Gripper Service*). Restart the SSU and the program.
	Magazine is broken, and fragments are blocking the slide.	Remove any magazines and slides. Load the slides to a new magazine. Restart the SSU and the program. If error persists, contact your local vendor's technical support.
	The barcode could not be read after the slide was processed.	Wipe off oil from the barcode label.
Verify that the hood is closed	The hood was open.	Close the hood.
The slide gripper has unexpectedly lost the slide	Gripper has dropped the slide.	Pull out bottom tray and remove slide. Restart the SSU and the program.
The slide could not be returned to the magazine	Magazine is broken, and fragments are blocking the slide.	Move gripper to service position and remove slide (see 11.2.8 *Gripper Service*). Restart the SSU and the program.

Error Message	Cause	Action
Barcode reader failure	The barcode reader cable is disconnected.	Make sure that the barcode reader cable is connected to both the barcode reader and the system computer. Restart the program.
A slide is not fully inserted in the Magazine	Slides not fully inserted.	Eject the magazine and insert the slide fully. Restart the SSU and the program.
Errors during analysis		
No camera found	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
Critical error. No connection with the database	Connection with the database has been lost.	Check network connection. Restart the system computer, or the computer on which the database resides.
Critical internal error during cell collection	Temporary software error.	Restart the SSU and the system computer.
Critical internal error	Temporary software error.	Restart the SSU and the system computer.
Camera initialization error	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
Barcode reader failure	The barcode reader cable is disconnected.	Make sure that the barcode reader cable is connected to both the barcode reader and the CCU. Restart the program.

11.2.3 General Processing Problems

Problem	Cause	Action
WBC images are not centered on the cell, but the cell can still be seen.	System needs calibration or alignment.	Contact your local vendor's technical support.
Slide status:  Incomplete analysis Less than the ordered number of cells are collected.	Too small monolayer found.	Prepare the slides with longer blood films.
	Artefacts (staining precipitates) on the slide.	Make sure that the solutions are changed according to the recommendations in Appendix - G *Slide Preparation Guidelines*.
	Dust on objectives.	Perform weekly maintenance on the current objective (see 10.1.1 *Clean Objectives and LED Table*)

Problem	Cause	Action
Slide status:  Incomplete analysis Could not find RBC monolayer.	Oil on the slide.	Clean the oil off the slide and process it again.
Slide status:  Incomplete analysis No RBC/PLT image is saved.	Excessive amount of small artefacts in the smear.	Make sure that the slides are prepared according to the recommendations in Appendix - G *Slide Preparation Guidelines*.
Slide status:  Analysis failure View the *Slide Information* dialog for more details.	No monolayer found.	Make sure that the slides are prepared according to the recommendations in Appendix - G *Slide Preparation Guidelines*.
	Oil on the slide.	Clean the oil off the slide and process it again.
	Oil or dust on the objective.	Perform weekly maintenance on objectives (see 10.1.1 *Clean Objectives and LED Table*)
Images are not in focus.	Dust on the objective.	Perform weekly maintenance on objectives (see 10.1.1 *Clean Objectives and LED Table*
	Incorrect objective settings.	Contact your local vendor's technical support
Seemingly normal slides get slide status: Empty or no slide PID.	The barcode reader is not connected.	Check the cabling of the barcode reader.
	No barcode found.	Check positioning and size of the barcode (see Appendix - A *System Specification*).
	The barcode could not be read due to bad print quality.	Clean the barcode printer head.
		Replace the printer ribbon on the barcode printer.

Problem	Cause	Action
Database access is slow.	The database server needs to be restarted.	Restart the system computer, or the computer on which the database is stored.
	The database is too large.	Keep the database size at the recommended level (see 10.4 *Database Performance*).
	The database files are fragmented.	Compress the database (see 9.1.5 *Compressing a Database*.
Body fluid sample spot is not centered.	Incorrect configuration of BF analysis area.	Configure the BF analysis area settings (See 9.15 *Adjusting BF Analysis Area*).
	The sample spot location varies too much between samples.	Make sure your sample preparation process produces slides where the sample spot is always in the same location.
The analysis area does not cover the entire body fluid sample spot.	Incorrect configuration of BF analysis area.	Configure the BF analysis area settings (See 9.15 *Adjusting BF Analysis Area*).
Seemingly normal scan slides get slide status: Analysis failure, with the additional information: No image data in scanned area.	Too little specimen on the slides.	Prepare a slide with more specimen.
	Wrong area selected.	Select the correct area and process the slide again.

11.2.4 LIS Errors

Problem	Cause	Action
Slide status:  Default values The slides are analyzed with default values even though LIS is used for order information.	The orders are not in the LIS.	Make sure that orders for the slides that are to be processed are already available in the LIS.
	The connection to the LIS is broken.	Make sure that the cable to the LIS is connected.
LIS status: 	The connection to the LIS has been broken.	Make sure that the cable to the LIS is connected. Results are automatically resent when connection is established.

Problem	Cause	Action
Critical error in the database.	The Order ID contains more than 24 characters.	Do not use an Order ID with more than 24 characters.
Could not find the order in the LIS.	Leading spaces in the Order ID.	Remove leading spaces in the Order ID.
		Also see section 11.2.5 *Cell Location Problems* for LIS errors.

11.2.5 Cell Location Problems

Cell Location Problems Peripheral Blood

Problem	Cause	Action
Too many non-nucleated cells.	Too many smudge cells.	Run another slide with less smudge cells.
		Verify smear preparation process.
	Too many artefacts.	Increase wash step.
		Filter the stain.
		Ensure that the stain has not exceeded the expiration date.
	Cells misclassified as non-nucleated cells.	Run another slide and if the problem remains prepare new staining solutions.
Too few nucleated cells located.	Low WBC count.	Prepare a new slide with a higher WBC count.
	Too short smear.	Prepare longer smears.
	Poor smear quality.	Verify smear preparation procedure.
Nearly all boxes are far from the cells.	Stage or calibration error.	Contact your local vendor's technical support.
Too many missed cells.	Too high WBC count.	Do not process slides with a WBC count that exceeds $100x10^9/l$.
	Poor staining.	Verify staining procedure.
Long processing time.	Low WBC count.	Prepare a new slide with a higher WBC count.
	Poor staining.	Verify staining procedure.
Same cell counted more than once/ duplicate cell images are shown by the system.	Sample contains disintegrated cells or smudge cells and the system identifies different parts of a cell as two or more different cells.	To minimize the amount of disintegrated cells, make sure the blood films are prepared within four hours of blood collection (see Appendix - G *Slide Preparation Guidelines*). To minimize the amount of smudge cells, verify your smear preparation process. To be able to identify and exclude duplicate cells, activate the Cell Marker function during verification (see *Reclassifying White Blood Cells*.
Cells are split into two or more parts.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.

Cell Location Problems Body Fluids

Problem	Cause	Action
Too many non-WBCs.	Too many smudge cells.	Run another slide with less smudge cells.
		Verify sample preparation process.
		Decrease centrifuge speed.
	Too many artefacts.	Increase wash step.
		Filter the stain.
		Ensure that the stain has not exceeded the expiration date.
	Cells misclassified as non-nucleated cells.	Run another slide and if the problem remains prepare new staining solutions.
Too few WBCs located.	Few WBCs in sample.	Use a larger sample volume.
Nearly all boxes are far from the cells.	Stage or calibration error.	Contact your local vendor's technical support.
Too many missed cells.	Too many WBCs in the sample.	Do not process slides where the number of WBCs exceeds the recommended amount.
	Poor staining.	Verify staining procedure.
Same cell counted more than once/ duplicate cell images are shown by the system.	Sample contains disintegrated cells or smudge cells and the system identifies different parts of a cell as two or more different cells.	To minimize the amount of disintegrated cells, make sure the slides are prepared within two hours of collection (see Appendix - G *Slide Preparation Guidelines*). To minimize the amount of smudge cells, verify your smear preparation process. To be able to identify and exclude duplicate cells, activate the Cell Marker function during verification (see *Reclassifying White Blood Cells*.
Cells are split into two or more parts.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.

11.2.6 Barcode Problems

Problem	Cause	Action
The barcode could not be read.	Blurry barcode, caused by immersion oil on the barcode.	Make sure the barcode is resistant to immersion oil.
		Print the barcode as defined in Appendix - A *System Specification*.
	There is no quiet zone.	Make sure there is a quiet zone according to specifications (and that the barcode is not printed too close to a logotype, if applicable).
	Symbology contrast is too low.	Adjust the printer.
		Use slides with a white, smooth, frosted area.
	The barcode is damaged (barcode cells are missing).	Adjust the printer.
		Use slides with a white, smooth, frosted area.
The magazine is not detected by the system when fully inserted.	A tissue has been placed on the bottom tray to absorb immersion oil.	Remove the tissue.

11.2.7 Staining Problems

Problem	Cause	Action
The red cells appear bright red, the white cells will appear indistinct with pale blue rather than purple nuclei, and brilliant red eosinophilic granules will be seen microscopically.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.
	Use of stain, buffer or wash water that is too acidic.	The pH of the buffer may be checked with a pH meter and adjusted.
	The increased acidity is due to exposure of the stain or buffer to acid fumes.	Use a new batch of stain or buffer.
Pale, inadequately-stained red cells, nuclei or eosinophilic granules.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.

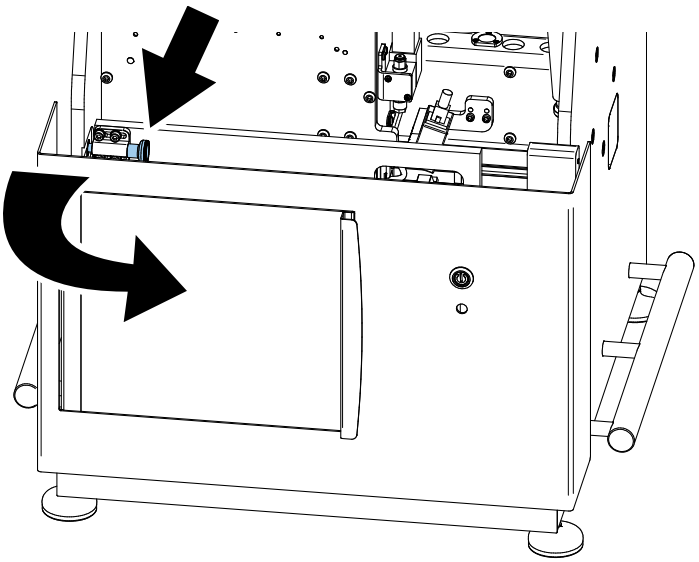
Problem	Cause	Action
The erythrocytes appear blue or green, the nuclear chromatin is deep blue or black and the granules of the neutrophilic granulocytes are deeply overstained and appear large and prominent. The granules of the eosinophils are blue or gray.	Overstaining.	Decrease the fixation time.
		The amount of stain used may be decreased (shorten the staining time) and the amount of buffer increased (increase the stain/ buffer time).
	Inadequate washing.	Increase the wash step.
	Too high an alkalinity of stain or buffer.	The pH of the buffer may be checked with a pH meter and readjusted to a lower pH.
	Thick blood smears.	Prepare a thinner blood smear.
Samples have dark areas of stain or other artefacts.	Drying is occurring during the period of staining.	Ensure the adequate drying of samples previous to staining.
	Unclean slides.	Use clean slides.
	Inadequate washing (not washing enough to remove the metallic scum).	Increase wash step.
	A stain is forming precipitate in the solution.	Filter the stain.
		Ensure that the stain has not exceeded the expiration date.
Same cell counted more than once/ duplicate cell images are shown by the system.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.
Cells are split into two or more parts.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.

11.2.8 Gripper Service

> **Warning!**
>
> A broken slide can cause serious cuts and poses a danger of infection. Always use protective gloves and tweezers when removing glass shards from the system.

11.2.8.1 Move Gripper to Service position

1. Go to *Maintenance/Gripper Service.*
2. Click *OK*.
3. Wait until *The gripper is in service position* dialog appears.
4. Open the hood.
5. Pull out the stop pin and open the magazine feeder.



6. Remove the slide.
7. Close the hood and the magazine feeder.
8. Restart the SSU and the progam.

Appendix - A System Specification

Climate Specification

The CellaVision® DM9600 is designed to be safely operated in the following environment:

Temperature	18 °C to 31 °C (64 °F to 88 °F)
Relative humidity	20% to 80%, non-condensing
Altitude	Up to 2 000 m above sea level
Indoor use only	

Physical Specification

Weight	93 kg, excluding PC and monitor
Width	58 cm (22.8″)
Depth	56 cm (22.8″)
Height	79 cm (31.1″)

Important!

In order to always keep the instrument in compliance with current device registrations, it is a prerequisite to always use original CellaVision® listed spare parts and their specified components. All original CellaVision® listed spare parts are safe to use in accordance with regulatory requirements and approvals. CellaVision® will not be liable under any warranty (whether express or implied, by law or otherwise) regarding an instrument containing components which are not original CellaVision® listed spare parts. CellaVision® will not be liable for any malfunction of an instrument containing components which are not original CellaVision® listed spare parts. CellaVision® will not be liable for any lack of compliance with current device registrations regarding an instrument containing components which are not original CellaVision® listed spare parts.

Electric Specification (monitor not included)

Voltage input	100 to 240 VAC
Voltage frequency	50/60 Hz
Current input, system computer	1.4 to 0.7 A
Current input, slide scanning unit	0.6 to 0.3 A
Total current input for the system	2.0 to 1.0 A
Total power consumption	240 W (754 BTU/h)
Sound level	50 dB(A) (peak)
Pollution degree	2
Installation category	II
Over voltage category	II
Mains supply voltage fluctuation	Not to exceed ±10% of nominal voltage

The system complies with the emission and immunity requirements described in the IEC 61326-2-6: 2005 (EN 61326-2-6:2006).

The system complies with the requirements described in the IEC 61010-2-101:2002 (EN 61010-2-101:2002).

Warning!

Do not use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

Warning!

Connect to ground sockets only.

Warning!

The mains supply cord and plug of the equipment shall comply with any national regulations.

Warning!

External computing devices connected to the communication connector (LAN) of the system have to comply with the standard UL 60950.

Warning!

The mains supply cord shall be used for disconnection from mains supply.

Warning!

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Caution!

The electromagnetic environment should be evaluated prior to operation of the device.

Performance Specification Peripheral blood

1.5.1. Tepinėlių mikroskopijos įrangos našumas - Mikroskopija – ne mažiau kaip 30 tepinėlių per valandą.

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2 %.

Throughput*: Approximately 30 slides/h for complete orders containing RBC, PLT and 100-cell WBC.

Results of short-term imprecision found in a clinical evaluation on 230 patient samples, based on NCCLS standard H-20A:

Cell class	SD (%)	Cell class	SD (%)
Segmented neutrophils	3.8	Basophils	0.7
Band neutrophils	1.6	Lymphocytes	3.4
Eosinophils	1.0	Monocytes	2.0

Limitations: Distinctions between band and segmented neutrophils, metamyelocytes and myelocytes, myelocytes and promyelocytes, lymphocyte and lymphocytes variant forms are subjects to variations among individual operators.

Performance specifications for the Advanced RBC application is included in the application pack.

Performance Specification Body Fluid

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2%.

Throughput*: Approximately 15 slides/h for orders (100 WBCs) containing only 10x overview images (6 mm analysis area). Approximately 3 slides/h for orders (100 WBCs) containing both 10x and 50x overview images (6 mm analysis area).

To evaluate the Accuracy and Short-term imprecision of the Body Fluid application, a comparison study was conducted at two sites with 5 operators. The body fluid application running on the CellaVision® DM1200 was compared with the reference method, the body fluid application run on a CellaVision® DM96. 200-cell differential counts were performed by qualified blood examiners. The study was performed according to *CLSI EP9A-2 Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. The short-term imprecision was calculated as defined in *CLSI H56-A Body Fluid Analysis for Cellular Composition; Approved Guideline*. The results are presented in the tables.

* “Depending on WBC concentration, number of non-WBCs and the quality of the smear.”

Accuracy results for the body fluid application:

Specimen	Cell class	Slope	Intercept (%)	R^2	# of samples
CSF	Neutrophils	1.0005	0. 16	0.9919	62
	Lymphocytes	0.9703	0. 27	0.9897	62
	Eosinophils	0.7573	0. 05	0.7893	62
	Macrophages	0.9944	-0. 44	0.9821	62
	Other cells	0.9843	1.15	0.9435	62
Serous fluid	Neutrophils	0.9967	0. 63	0.9896	151
	Lymphocytes	0.9879	-0. 28	0.9813	151
	Eosinophils	1.1326	-0. 002	0.9763	151
	Macrophages	1.0099	-0. 37	0.9809	151
	Other cells	0.9432	0. 06	0.9261	151
Synovial fluid	Neutrophils	1.0007	0. 15	0.9959	47
	Lymphocytes	0.9891	1.10	0.9786	47
	Eosinophils	0.7701	0.04	0.9262	47
	Macrophages	0.9551	0.06	0.9586	47
	Other cells	0.5027	0.19	0.1735	47

Short-term imprecision results for the body fluid application:

Specimen	Cell class	SD (%)
CSF	Neutrophils	3.1
	Lymphocytes	3.9
	Eosinophils	0.6
	Macrophages	3.0
	Other cells	2.8
Serous fluid	Neutrophils	3.2
	Lymphocytes	6.3
	Eosinophils	0.9
	Macrophages	6.7
	Other cells	1.1
Synovial fluid	Neutrophils	3.3
	Lymphocytes	5.3
	Eosinophils	0.1
	Macrophages	5.6
	Other cells	1.0

A reproducibility study was conducted at three different sites on three different instruments, each site processing the samples in duplicates. The study was performed during 20 days at each site and run by in total 10 operators. The results are an extract from the study and based on preclassification data presented in the next table.

Reproducibility data. CV is only presented for results where the average is higher than 10%:

Sample ID	Specimen	Cell class	Average (%)	S_D (Reproducibility %)	CV (Reproducibility %)
A	CSF	Neutrophils	74.8	1.4	2
		Lymphocytes	3.2	0.6	–
		Eosinophils	0.5	0.7	–
		Macrophages	20.5	1.6	8
		Other cells	0.4	0.3	–
B	Serous fluid	Neutrophils	61.4	1.5	2
		Lymphocytes	16.8	1.2	7
		Eosinophils	4.0	1.0	–
		Macrophages	13.4	1.1	8
		Other cells	1.7	0.5	–

Performance Specification Scan

Throughput data and disk space requirements for the scanned slides:

Analysis area size	Overview images	Processing time	Disk space
5x5 mm	10x	1.5 min	10 MB
5x5 mm	10x+50x	12 min	130 MB
10x10 mm	10x	3 min	45 MB
10x10 mm	10x+50x	45 min	500 MB

The given values are approximate. Processing time and required disk space vary depending on the sample.

Materials Specification

Immersion oil: CellaVision® Immersion Oil Pack. 150 ml oil bag should be sufficient for approximately 3000 analyses.

CellaVision® Slide magazines.

Stain: May Grünwald Giemsa, Wright, or Wright Giemsa.

Slide requirements (mm): glass, 75.0-76.0 x 25.0-26.0 x 0.9-1.2*, ground edges, clipped or round corners.

*ISO 8037/1-1986 and JIS R 3703:1998

Slide descriptions:

Clipped corners

Round corner

Images provided by Erie Scientific (www.eriesci.com)

Caution!

Use only clipped/round corner slides. Failing to do so may cause jams and excessive wear on magazines and the system.

Caution!

Using the magazines more than 100 times may damage the system.

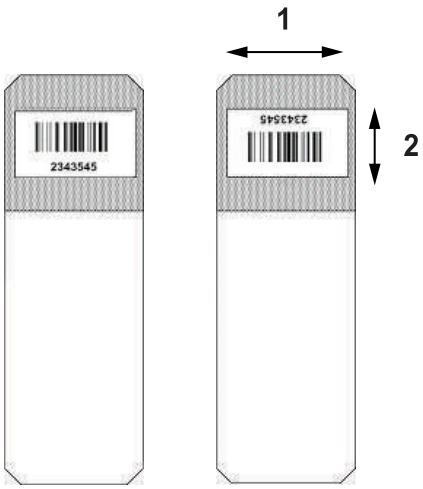
Barcode

The system requires high quality barcode labels on the slides. Maximize the barcode width for best result.

Note:
The magazines are supplied with barcode labels. If you replace the barcode label, the new barcode must not contain the '/' character.

The label should be positioned as shown in the figure below. The edges of the label shall be at least 1 mm from the edges of the slide.

Note:
Avoid oil on the slide label.



1. Barcode length
2. Barcode width

2D Barcode Scanner

The following barcode formats are accepted by the system:

Linear codes			
CODE 39	CODABAR/NW7	Code 128	Interleave 2 of 5
2D-D codes			
DataMatrix	QR		

Requirements

Order/Slide ID:

When using either a DataMatrix or a QR code the only information allowed in the code is a Order/Slide ID (i.e. no other data), which may be up to 24 characters (ASCII) including spaces. No leading spaces are allowed. The Order/Slide ID may not begin with ‘PB’ or ‘BFS’.

Print quality:

The printed barcode shall be resistant to immersion oil and be printed with a high contrast ratio between background and the printed barcode. If the barcode is printed directly onto a slide, it must be printed on a white, smooth, frosted area of the slide.

Barcode size:

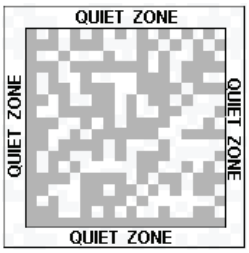
The following barcode resolutions have been verified at.

Supported code resolution	
Code	**Cell size, mil**
QR	13
DataMatrix	9
Code 39	7
Code 128	7
Codabar/NW7	7
Interleave 2 of 5	7

Quiet zone:

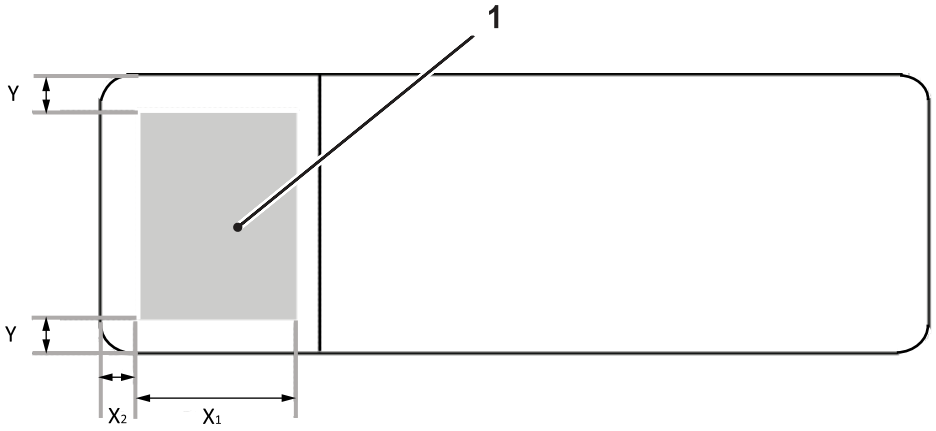
The recommended quiet zone is listed in the table below.

Symbology	**Vertical quiet zone, cells**		**Horizontal quiet zone, cells**	
	Top	Bottom	Top	Bottom
DataMatrix	1	1	1	1
QR	4	4	4	4



Barcode position:

The barcode shall be positioned within the area as illustrated in the figure below.



1. Area where the 2D barcode can be printed

Where

$X_1 < 18$ mm; $X_2 > 6$ mm; $Y > 4$ mm

Firefighting Procedures

Fire and explosion hazard:

Flash point (immersion oil) : >300 ºF / 149 ºC

Upper explosive limit: N/A

Lower explosive limit: N/A

Fire fighting media: Carbon dioxide, foam and dry chemical.

Fire response procedures: Fire fighters must use self-contained breathing apparatus.

Unusual fire and explosion hazards: Containers should be kept cool in the event of fire.

Appendix - B Storage and Handling

Storage

The system shall be stored within the following climate condition:
–10°C to 60°C (14°F to 140°F). The relative humidity should be between 20% and 80% with no condensation allowed at 40 °C (104 °F).

Transporting the System

The system shall be packaged, transported and unpacked by authorized personnel/carrier only. We recommend saving the package for possible future transports.

The system must be acclimatized to operating conditions for 24 hours, see Appendix - A *System Specification* for climate specification, before taken into operation.

Disposal Information

Magazines: As combustible plastics (PC + PBT).

The system: Please contact your distributor.

Appendix - C Buttons and Indicators

If you place the mouse-pointer over the buttons or indicators, you can view tool tips in the Status bar (bottom left-hand corner).

Note:
Before using the shortcuts F6 and F7 an order must be selected.

Buttons

	CellaVision® DM software	
	System Control View	F4
	Database View	F5
	Verification View	F6
	Report View	F7
	Close Order and Slide	
	Order Data	
	Help Lines	Enables help lines for PLT estimate.
	Confirm Cell Counter Results	
	Comments	
	WBC Full Screen View	
	WBC Galleries	
	Zoom Mode	
 	Zoom Out/Zoom In	
	Scroll Mode	
	Color/Brightness	Adjusts image color and brightness.

	Toggle Color/Brightness	Toggles between default color and lights settings and personal settings.
	Cell Marker	Shows/Hides square for cell identification.
	WBC Attributes	Shows/Hides WBC attributes.
	Entire RBC Image	Shows the entire RBC image.
	Start	
	Stop	

Indicators

	Autostart	Automatic start of slide processing.
	Oil Level Indicators	Indicates an empty oil pack.
		Indicates need for changing oil pack.
		Indicates a full oil pack.
	Outfeed Shelf	Indicates room left in the outfeed shelf.
		Indicates a full output drawer.
	Hatch Indicator	Indicates all hatches closed.

Keyboard shortcuts

Ctrl+w	Show/hide Worklist.

Appendix - D Recommended Workflow

Laboratories handle their peripheral blood differential counts in different ways making it hard to suggest one general workflow suitable for all laboratories. See flowcharts of the three workflows below.

Note:
Before using the shortcuts F6 and F7 an order must be selected.

D.1 Recommended Settings

(see 9.8 *Adjusting Report/Sign Settings*)

1. Single slide differentials

   Pre-fill password: Enabled

   Sign order when signing the slide: Enabled

   Send order to LIS when signed: Enabled

   Review the cells in the WBC Galleries.

2. Confirmation of cell counter results - Quickly scanned slides for verification of cell counter results.

   Pre-fill password: Enabled

   Sign order when signing the slide: Enabled

   Send order to LIS when signed: Enabled

   Review the analysis type you want to confirm and then click *Confirm Cell Counter Results*.

    Confirm Cell Counter Results

   When using the *Confirm Cell Counter Result* for any analysis type (WBC, RBC, or PLT) the normal sign slide checks (cells in the Unidentified class, all cells reviewed etc.) are disabled.

   Note:
   When using Confirm Cell Counter Results the results sent to the LIS are: a WBC confirmation flag, a RBC confirmation flag and/or a PLT confirmation flag.

   For a slide it is possible to report the WBC result and a RBC confirmation flag and a PLT result or any other combination.

3. Duplicate slides - An order consists of two slides. Two persons sign one slide each.

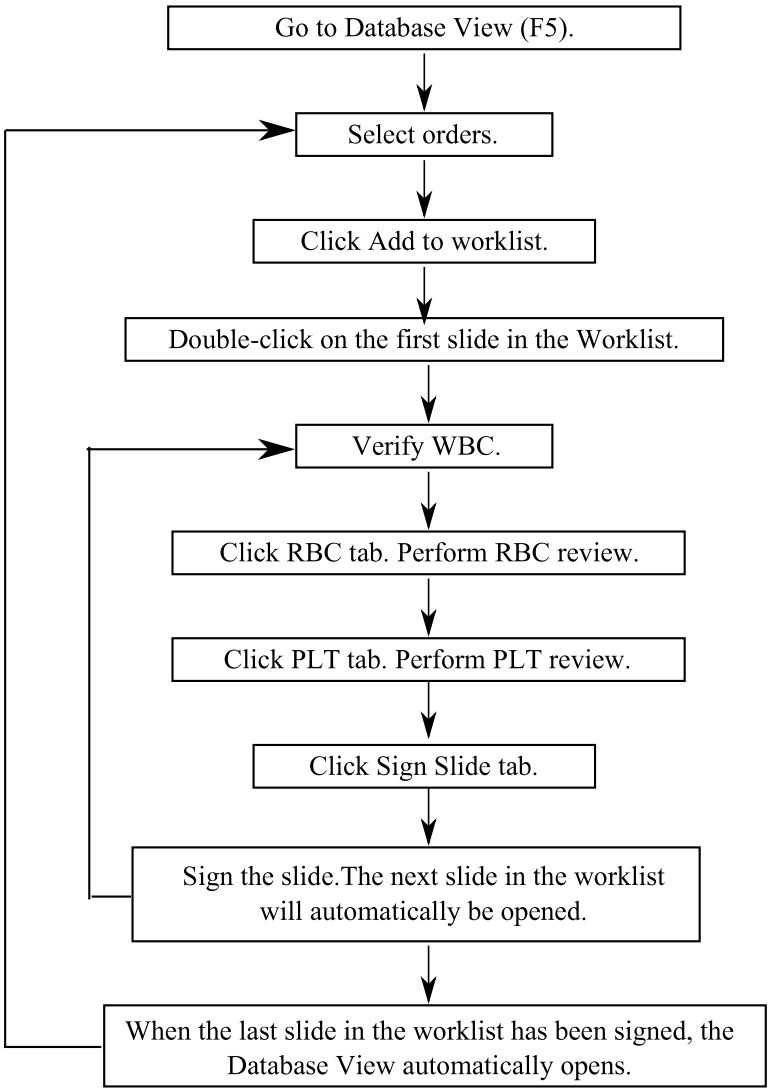
   Pre-fill password: Enabled

   Sign order when signing the slide: Disabled

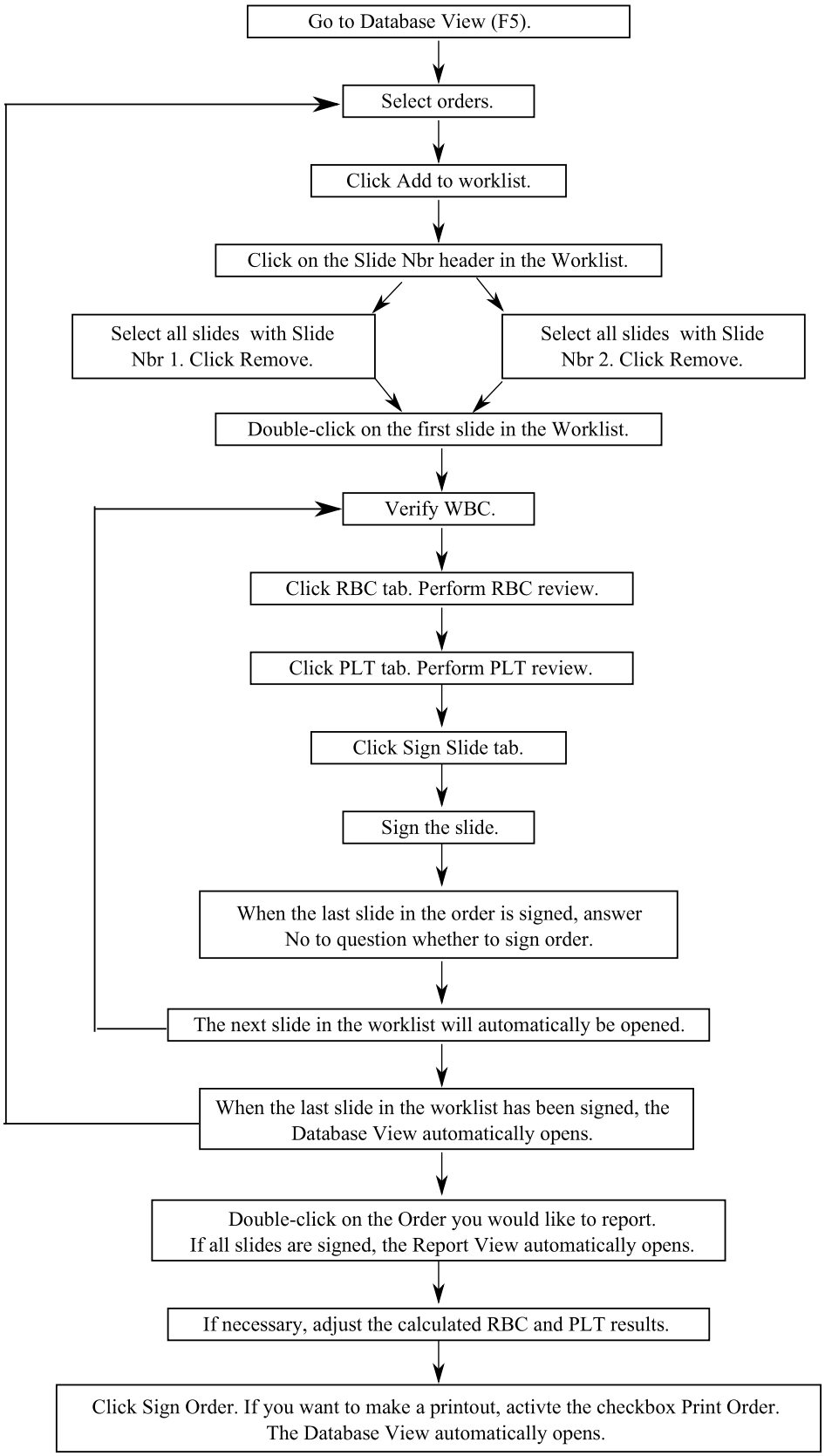
   Send order to LIS when signed: Enabled

   Review the cells in the WBC Galleries.

D.2 Workflow Single Slides / Confirm Cell Counter Results



D.3 Workflow Duplicate Slides



Appendix - E User Authorization Levels

Action/Setting	Observer	User	Restricted	Authorized	Administrator	Service
Start slide processing		X		X	X	X
Search in the database on Order ID and Patient ID	X	X	X	X	X	
Search in the database on other criteria	X	X		X	X	X
Verify and comment WBC, RBC and PLT		X	X	X	X	X
Edit Order data				X	X	
Add/edit pending orders		X	X	X	X	X
Sign slides and reports			X	X	X	X
Send results to the LIS			X	X	X	X
Delete unsigned slides/orders				X	X	X
Delete signed orders					X	X
Archive					X	X
Export orders				X	X	X
Protect order from archiving				X	X	X
Send images with e-mail	X	X	X	X	X	X
Export log files					X	X
Database settings					X	X
Users settings					X	
Analysis settings						
Default values Add processed slide to worklist				X	X	X
Enable LIS					X	X
WBC reclassification settings					X	X
RBC precharacterization settings					X	X
PLT settings						
Use only manual PLT concentration estimation Defaults for PLT		X	X	X	X	X

Action/Setting	Observer	User	Restricted	Authorized	Administrator	Service
PLT estimate factor Intervals for average PLTs/HPF					X	X
Report/Sign settings					X	X
Standard comments settings				X	X	X
Reference cells settings				X	X	X
Cell Location				X	X	X
E-mail settings					X	X
Archiving settings					X	X

Appendix - F Determining the Platelet Estimate Factor

Follow the procedure below to determine the PLT estimate factor.

1. Perform automated PLT counts with a cell counter on 30 consecutive blood samples.
2. Prepare and stain one smear for each sample.
3. Perform PLT analyses on the system. Let the system calculate the average PLTs/HPF values for each sample.
4. Divide the cell counter PLT value by the system average PLTs/HPF value for each sample to get the conversion factors.
5. Add all 30 conversion factors and divide by 30 to get the PLT estimate factor.
6. Enter the PLT estimate factor in the *PLT* tab in *Settings*.

Appendix - G Slide Preparation Guidelines

G.1 Slide Preparation for Peripheral Blood

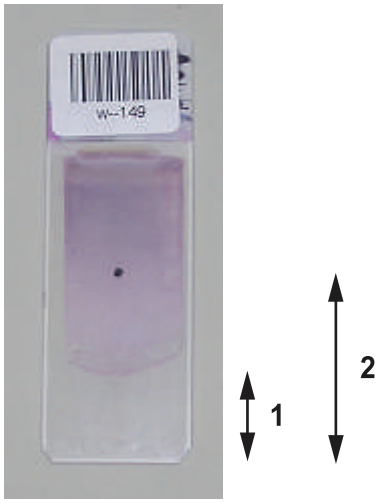
> **Warning!**
>
> Always use protective gloves when in contact with blood.

G.1.1 Sample

Collect blood from a vein or by skin puncture in an EDTA sample tube (K_2EDTA or K_3EDTA, 1.5 ± 0.15 mg/ml in liquid or powder form). Mix the sample carefully with the anticoagulant. Store the tube at room temperature. Prepare the blood films within four hours of blood collection.

G.1.2 Preparing Blood Films

1. Mix the tube (20 complete inversions by hand) before preparation.
2. Use a clean dry microscope glass slide (see Appendix - A *System Specification* for required slide types). Note that glass slides may lose their wetability on exposure to air, resulting in a poor smear.
3. Use the wedge technique performed manually or by a mechanical spreader. Manual wedge technique: Place a drop of blood near the labeled end of the slide. Narrow a spreader slide with polished edges at a 30- to 45-degree angle to the smear slide. Allow the blood to spread almost over the entire width of the slide. Then rapidly and smoothly push the spreader slide to the opposite end of the slide. There should be a gradual transition in thickness, without any grainy streaks, troughs, ridges, holes or bubbles. The blood film must be at least 30 mm in length, terminating 5-15 mm from the edge.
4. Dry the slide rapidly.
5. Stain the slide within one hour.



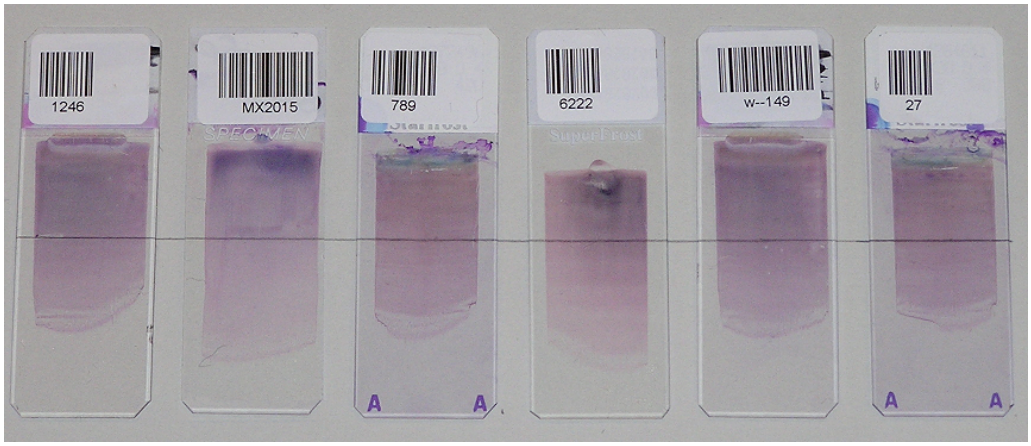
1. 5-15 mm
2. 33 mm

The dot in the image indicates the analysis starting point. The analysis proceeds from the starting point towards the thinner part of the smear.

G.2 Example Smears

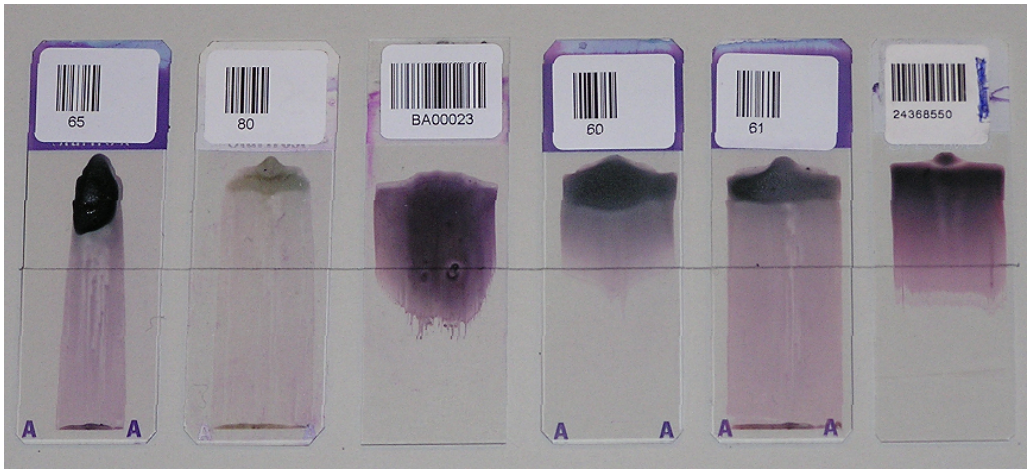
The line in the images indicates the analysis starting point.

G.2.1 Accepted



These slides are all prepared according to the specifications.

G.2.2 Not Accepted



These slides are not prepared according to the specifications and should not be analyzed in the CellaVision® DM9600.

G.3 Recommended Staining Recipes

CellaVision® DM9600 is optimized to analyze samples stained with May Grünwald Giemsa (MGG) stain, Wright stain and Wright Giemsa stain.

The staining recipes are only suggestions and may need to be adjusted according to the results of the Cell location test and level of preclassification accuracy that is achieved.

Contact the reagents provider for more information about recommended staining recipes when using a manual dip method.

Contact the vendor for recommending staining recipes when using a slide maker stainer.

Note:
Differences in staining results may be cause by alterations in pH, reagents etc. Local adjustments may be needed to achieve best results. Be aware of pH variations in water.

G.3.1 MGG Stain

	Solution	Reaction time	Change solution
1	May Grünwald stock solution a	5 min	Twice a week
2	Buffer working solution c	Quick rinsing	Every day
3	Giemsa working solution e	10 min	Every day
4	Buffer working solution c	Extensive rinsing	Every day

a	May Grünwald stain, stock solution:	Eosin-methylenblue solution, modified for microscopy (contains methanol).Store at +15 ºC to +25 ºC.
b	Buffer stock solutions 1 and 2:	1) 9.07g KH_2PO_4 (0.067M) ad 1000ml deionized water Store at +4 ºC to +8 ºC. 2) 9.45 g Na_2HPO_4 (0.067M) ad 1000ml deionized water Store at +4 ºC to +8 ºC.
c	Buffer working solution, pH 6.8	Combine 127 ml KH_2PO_4 stock solution with 123 ml Na_2HPO_4 stock solution ad 5000 ml deionized water. Adjust to pH 6.8. Store at +4 ºC to +8 ºC. Durable for a month at +4 ºC.
d	Giemsa stain, stock solution:	Azur-eosine-methylenblue solution for microscopy (contains methanol). Store at +15 ºC to +25 ºC. Durable for several months if kept in a dark bottle.
e	Giemsa working solution:	Dilute 1 part Giemsa stock solution with 19 parts buffer work solution. Stable for 8 hours.

G.3.2 Wright Stain

	Solution	Reaction time
1	Methanol	30 sec
2	Wright stain	3 min
3	Wright stain diluted 1:6 with buffer pH 7.15	6 min
4	Rinse in pH adjusted distilled water	2 min 30 sec Reuse the water 5 times only
5	Dry	5 min

G.3.3 Wright Giemsa Stain

	Solution	Reaction time
1	Methanol	30 sec
2	Wright Giemsa stain	3 min
3	Wright Giemsa stain diluted 1:10 with phosphate buffer pH 7.2	6 min
4	Rinse in pH adjusted distilled water	1 min
5	Rinse in pH adjusted distilled water	1 min
6	Dry	4 min

G.4 Slide preparation for Body Fluids

> **Warning!**
>
> Always use protective gloves when in contact with Body Fluids.

G.4.1 Sample

Quantitative assessment of cell counts and preparation of slides should be performed within 2 hours of collection.

G.4.2 Preparing the Sample

Count the WBC and RBC concentration of the fluid. For best results, dilute samples with high cell density.

Buffered saline or standard tissue culture media may be used as a diluent.

For CSF always add a drop of 30% albumin which promotes cell adhesion to the microscopy slide.

The recommendation is to have 5000-12000 cells in total on the slide

Note:
Cells are concentrated approximately 20-fold by cytocentrifugation, however the quantitative yield varies from 30-75%. The speed and time of centrifugation, the amount of sample in the chamber and the filter paper absorbance are factors that can influence both the cell yield and morphology. (ref. Body Fluid Analysis for Cellular Composition, CLSI, H56 A Vol 26, No 26)

Use a clean dry microscope glass slide (see Appendix - A *System Specification* for required slide types). Centrifuge the sample according to the manufacturer's recommendation. Dry the slide rapidly.

Note:
Do not use slides with cover slip.

G.4.3 Staining

Stain the slide using the same staining recipe as for peripheral blood samples. (See G.3 *Recommended Staining Recipes* for staining recommendations).

Appendix - H Glossary

	Description
Analysis	Starts with the loading of slides and ends with the finished report.
Confirmation	The operator approves the preclassification.
Duplicate slide differential	Two different persons sign one slide each in the order. The average result is presented.
Grid square	Sub-images of a PLT overview.
In-vitro	Outside the living body; in an artificial environment.
LIS	Laboratory Information System
Mini map	Overview image of analysis area.
Multi-slide order	An order including more than one slide from one sample.
Non-WBCs	Cells and objects identified as not being WBCs.
Not classed	Cells and objects the operator cannot identify and wants to exclude from the differential count.
Operator	The person who works with the system.
Order	The name of the ordered analyses on the slides from the same sample.
Order ID	Order identifier. There can be several slides with the same Order/Slide ID but different slide numbers.
Other	Cells that the operator identifies as WBCs, but of a type other than those listed. Will be included in the differential count.
Patient ID	Unique number identifying the patient.
Pending order	An order manually added to the database, waiting to be processed.
PLT	Platelet, thrombocyte
PLT estimate	Estimation of the PLT concentration.
PLT estimate factor	A predetermined factor to calculate the PLT estimate.
Precharacterization	The system suggests RBC morphology characteristics.
Preclassification	The system suggests a classification for a specific cell.
Processing slides	The sequence of events from when the system starts working with a slide until it is finished.
Quick scans	Quickly scanned slides for cell counter verification. The results are not sent to the LIS.

	Description
RBC	Red blood cell, erythrocyte
Reclassification	The operator changes the preclassification.
Reference cells	Cells with typical characteristics available in the 2nd and 3rd galleries.
Region of interest	Part of the BF or Scan overview image tagged by the operator.
Signing	Finally confirming analysis results before locking and reporting them.
Slide ID	The barcode number on the slide (PID). Same as Order ID.
Slide number	A number that uniquely identifies slides within the same order.
Slide position	The position of a slide in the magazine.
Unidentified	Cells and objects which the system cannot preclassify.
Verification	The operator's review of WBC, RBC and PLT, e.g. reclassification and confirmation of WBCs.
WBC	White blood cell, leukocyte

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