



LUCIA Cytogenetics

In Vitro Diagnostic Medical Device



CE 2797

IVD



Table of Contents

Intended Purpose of LUCIA Cytogenetics	3
Karyotyping	5
FISH	9
Metaphase Finder	13
Database	17
Report Tool	22

Intended purpose of LUCIA Cytogenetics

LUCIA Cytogenetics is an in vitro diagnostic medical device software that helps the user to perform the chromosome analysis (digital karyotyping and FISH) by means of digital image manipulation and analysis. The device takes a digital image as the input data and helps a laboratory professional, namely a qualified cytogeneticist, bioanalyst, pathologist, medical scientist or cytogenetic technician to achieve diagnostic or analytical results in the diagnosis of chromosomal disorders or risk factors. The software provides user tools that are manual, semi-automatic or automatic; some tools provide qualitative as well as quantitative information. Namely the device assists the users to count chromosomes or cells, to arrange karyograms, to evaluate structure of chromosomes or to evaluate spatial location of fluorescent signals. LUCIA Cytogenetics allows the user of the device to draw a conclusion and provide it as a result to a medical professional. The software does not provide any diagnostic or treatment recommendation nor has any direct physical impact on a patient. LUCIA Cytogenetics is intended to be used on the input images acquired using bright field or fluorescence microscopy that show cell chromosomes or cells stained with fluorescent dyes binding to chromosomal DNA.

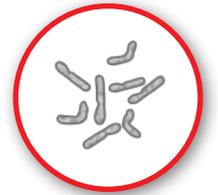
According to the section of 1.1.(c) of Annex II of the Regulation (EU) 2017/746 the manufacturer states the following:

- (i) The software is intended to assist a user to
 - Count chromosomes or cells.
 - Arrange a karyogram.
 - Evaluate chromosome structure.
 - Evaluate fluorescent signal spatial location.
- (ii) The intended function is an aid to diagnosis, to prognosis or to prediction.
- (iii) The software is intended to aid in a detection of chromosome disorders or risk factors.
- (iv) There are manual, semi-automatic and automatic tools.
- (v) The most of tools is qualitative and doesn't provide any numerical result. The exceptions are counting tools assisting user to count objects such as chromosomes or cells.
- (vi) LUCIA Cytogenetics is intended to be used on the input images acquired using bright field or fluorescence microscopy that shows
 - cell chromosomes
 - cells stained with fluorescent dyes binding to chromosomal DNA
- (vii) The testing population is not limited.
- (viii) The software is to be used by a qualified cytogeneticist, bioanalyst, pathologist, medical scientist or cytogenetic technician.
- (ix) LUCIA Cytogenetics is not a companion diagnostics and therefore this point is not applicable.

Any hardware depicted in this brochure is not subject to IVDR certification and falls outside the scope of the compliance process, which applies to the software only.

Karyotyping

LUCIA Cytogenetics



Optimized hardware configurations

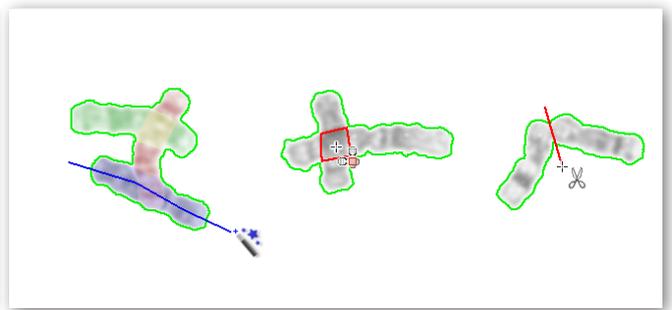
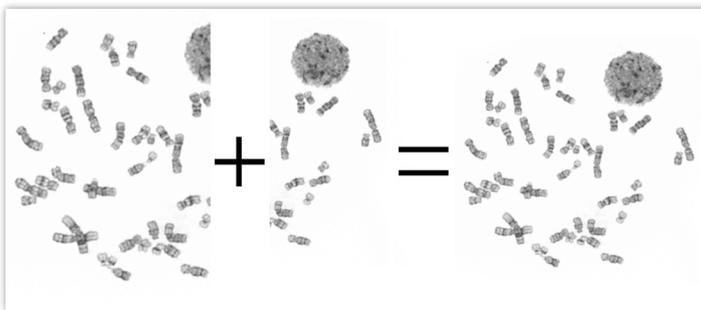
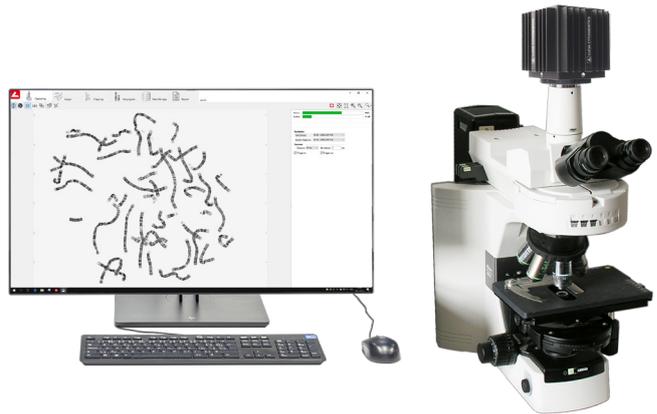
Variety of computer-controlled devices such as motorized microscopes, filter wheels, or scanning stages are available.

Carefully selected cameras

Modern camera models, cooled and highly sensitive digital cameras are available and will be recommended to you based on your requirements.

Let the system optimize the scene

The continuous auto-exposure algorithm balances intensity of the scene while the automatic image quality assessment system leads you to get the maximum of details.

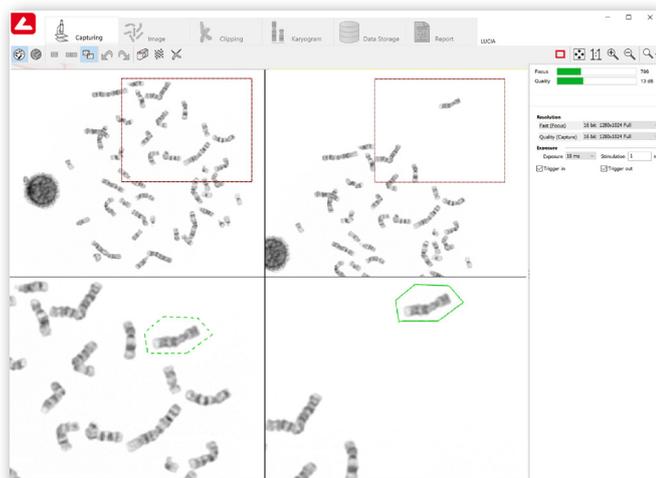


Acquire extra large scenes

The seamless image stitching algorithm enables you to merge several fields of view of the camera together.

Capture chromosomes beyond the metaphase

Chromosomes located outside the metaphase can be captured and added to the metaphase image. The Capture Chromosome feature allows retrieval of chromosomes even after the karyotyping step.

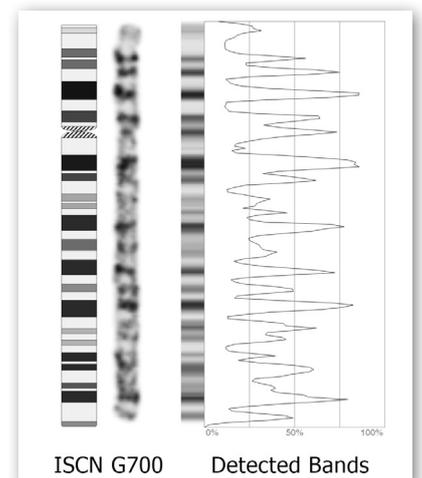


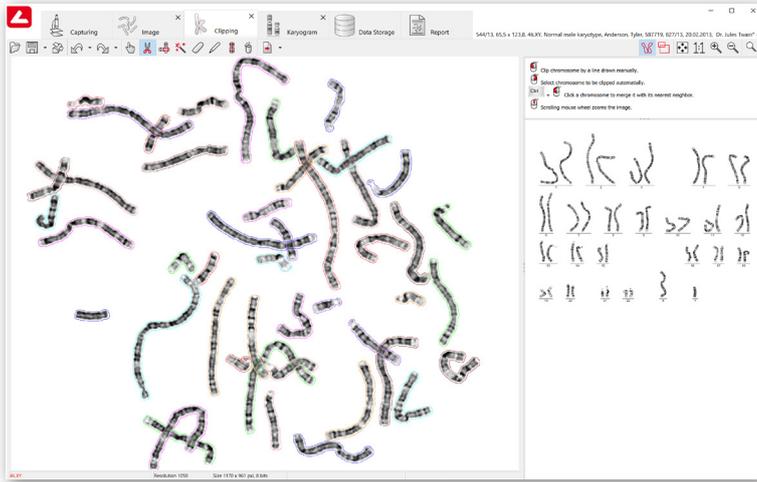
Chromosome clipping

Easy chromosome separation using automatic and semi-automatic functions. Chromosome clipping, and overlap resolving tools will help you to create karyograms fast and comfortably.

Chromosome classification

Highly efficient banding pattern classifier developed by artificial intelligence with the possibility of further training. The classifier detects bands on each chromosome for the most accurate automatic karyogram arrangement.



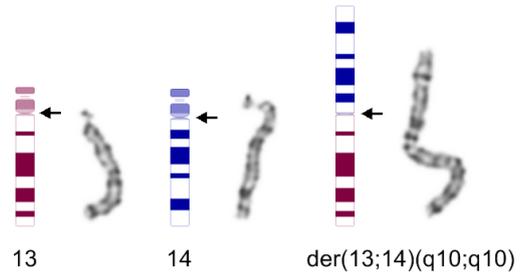
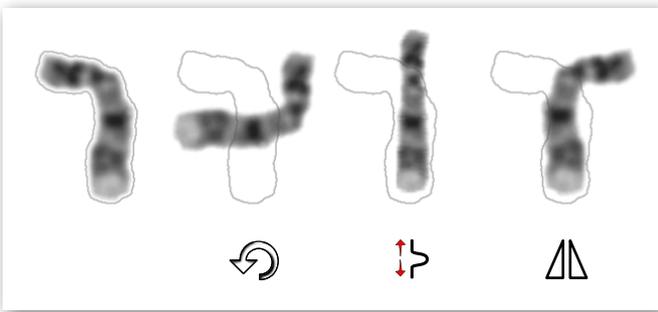


Automation

Chromosome classification and other tasks are performed automatically.

Correct imperfections of the image

Automatic zooming and panning of the image help to get an overview of the chromosomes for easier correction of details such as deletion of attached artifacts, chromosome cropping, or telomere region redefinition.



Arrange the karyogram

A variety of functions including a multifunctional tool that allows for alignment, smooth rotation, 180° chromosome flipping or chromosome alignment on the centromere.

Use predefined ideograms or create your own

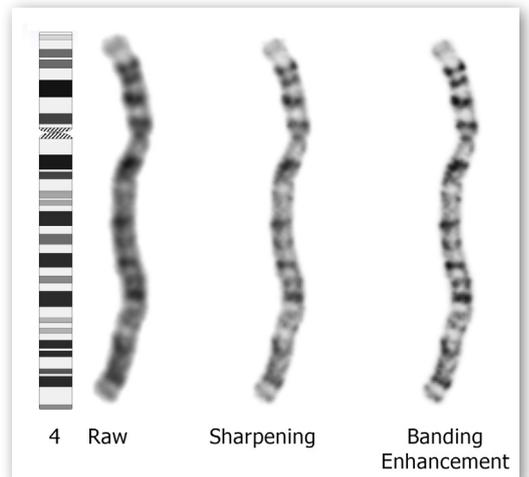
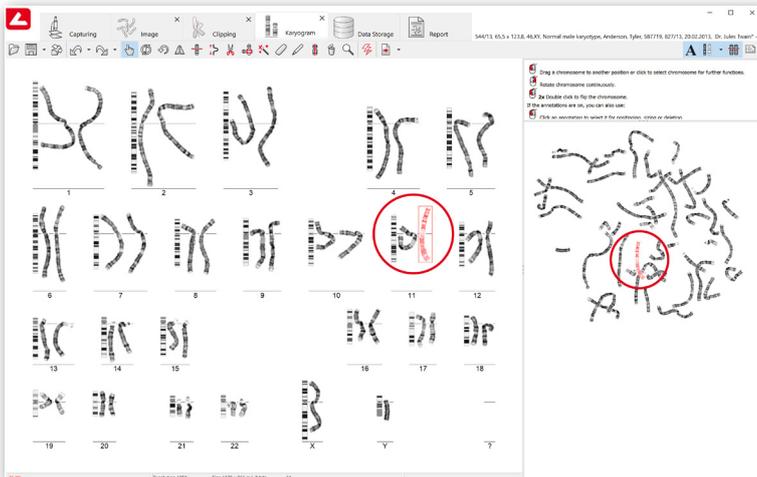
Ideograms for different techniques and banding resolutions are provided (G300, G400, G550, G700, G850, R400) according to the latest ISCN, and custom ideograms can be created as well.

See where chromosomes originate from

Simultaneous display of the karyogram and the metaphase image couples the corresponding chromosomes.

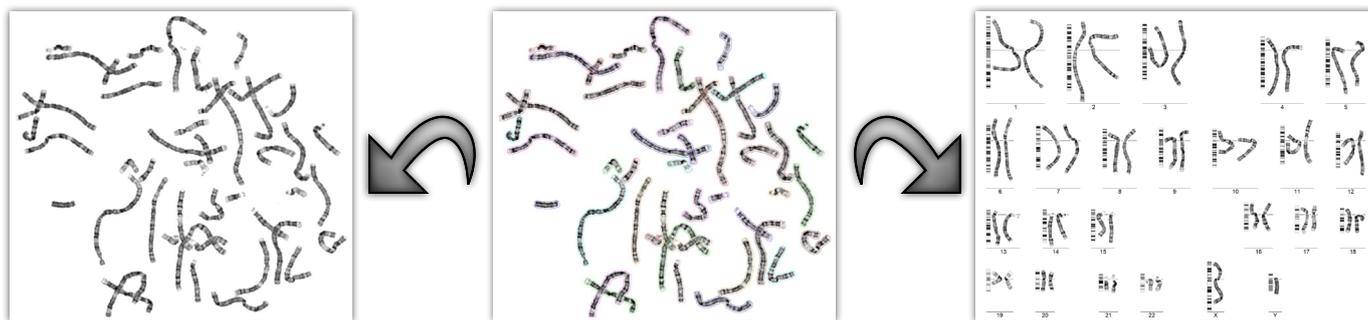
Chromosome enhancement

A selection of multiple functions to improve the quality of chromosome staining and banding pattern on the whole karyogram or a single chromosome.



Browse the history of actions comfortably

Use the multiple-step back and forth ability. The number of steps remembered is not limited and is saved into the database together with the document.



Audit trail module

Enables to fully manage document history and patient data including examinations.

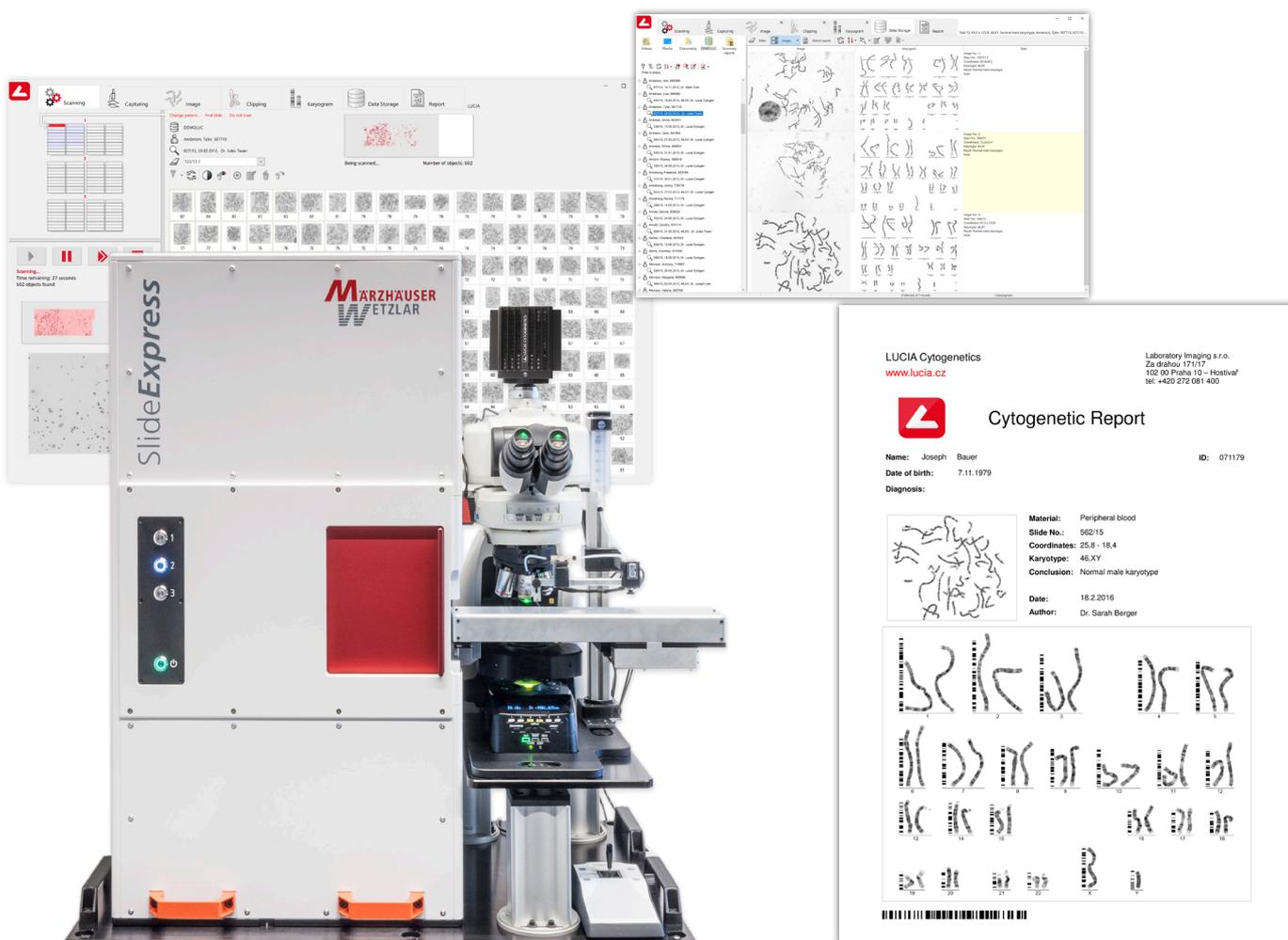
Integration with other LUCIA products

LUCIA Cytogenetics - Karyo is fully compatible and can be integrated with other LUCIA products:

LUCIA Cytogenetics - Metaphase Finder

LUCIA Cytogenetics - Database

LUCIA Cytogenetics - Report Tool



FISH

LUCIA Cytogenetics

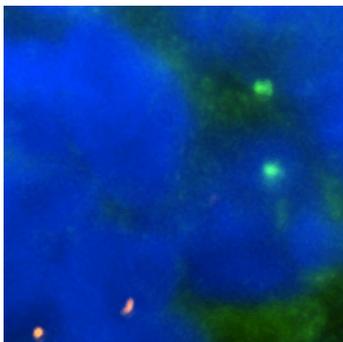




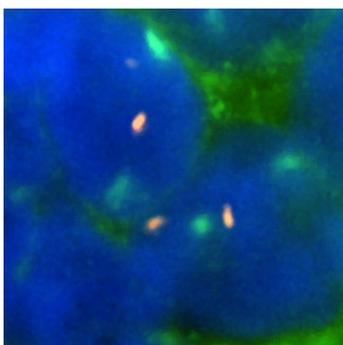
Automated Microscope Control

LUCIA Cytogenetics™ is automation-friendly:

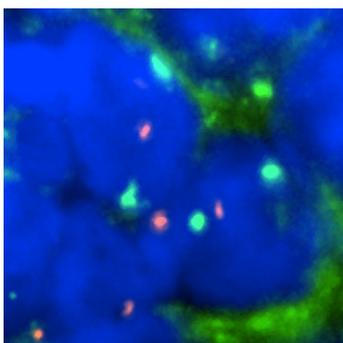
- Control of all motorized parts of a microscope.
- Control of external devices: shutter, filter turret, filter wheels, light path etc.
- Image acquisition settings per fluorescent probe set.
- Observation filter (used for eye piece) per fluorescent probe set.
- Z-axis control.



Z1



Z2



EDF



Flexible FISH Image Acquisition

- Image acquisition with different levels of user control, from fully-automatic to fully-manual.
- Separate camera settings are saved for each fluorescent probe.
- Various automatic exposure options:
 - » Continuous or single-push auto exposure.
 - » User defined target values (% of overexposed pixels, target maximum intensity).
 - » Live image speed acceleration.
 - » Reducing image to a region of interest (area probe).
- Usage of a highly sensitive CCD camera (up to 14 bits and 67 dB SNR).
- Maximum-quality or minimum-time image acquisition.
- Extended depth of focus (EDF) acquisition for thick samples such as tissue sections.
- Fully automated EDF.

Thick sample acquisition

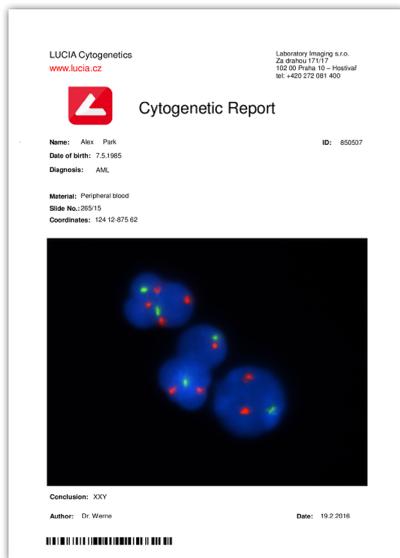
- Different objects are visible when focusing through Z axis (Z1, Z2).
- The thick sample acquisition (EDF) tool merges focused areas of the whole Z-stack and creates a single perfectly focused image.

True or False Color Display

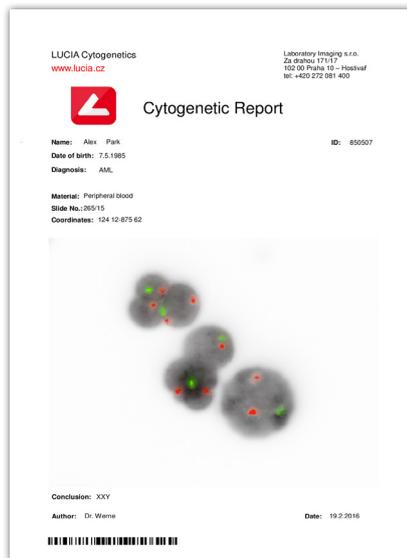
- During the acquisition, each image component is associated with a probe and obtains its name and display color.
- The name and color of the components can be changed later, the information is stored with the image.
- True (real) or false (pseudo) color display can be achieved by assigning appropriate colors to each image component.
- One component, usually DAPI, can be marked as counterstaining - this component can be displayed as inverted (black on the white background).
- Any combination of components or a single component alone can be displayed.
- The color display options can differ for on-screen display, reports and exports.



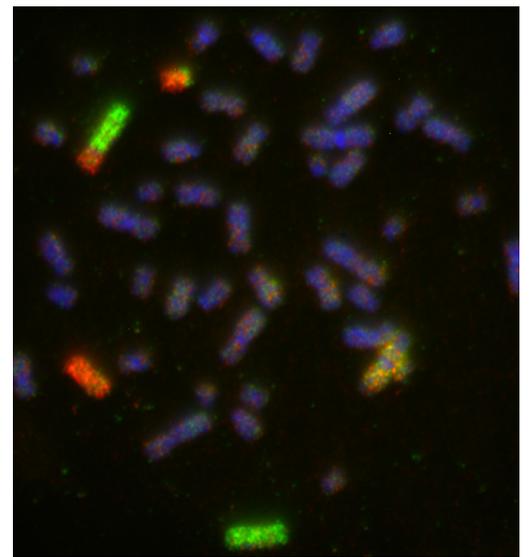
The counterstaining component displayed as inverted



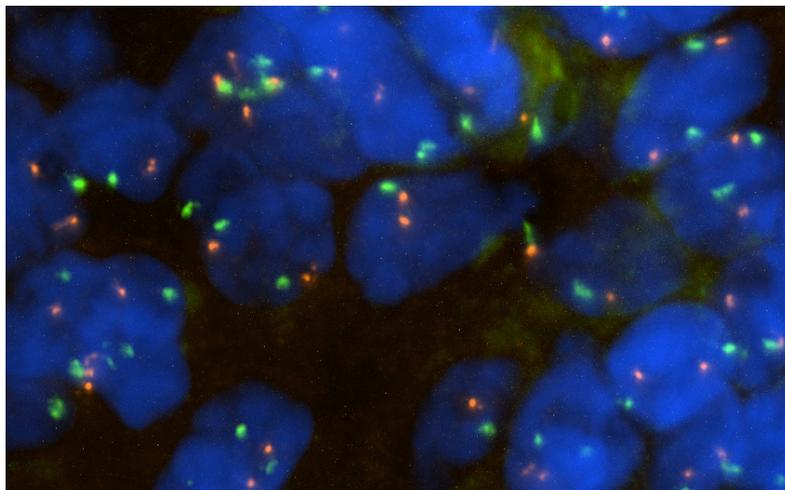
True color report



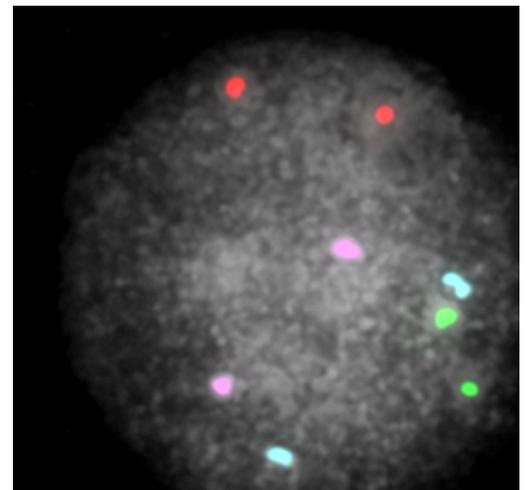
Pseudo color report



True color display



Thick sample captured with LUCIA Cytogenetics™

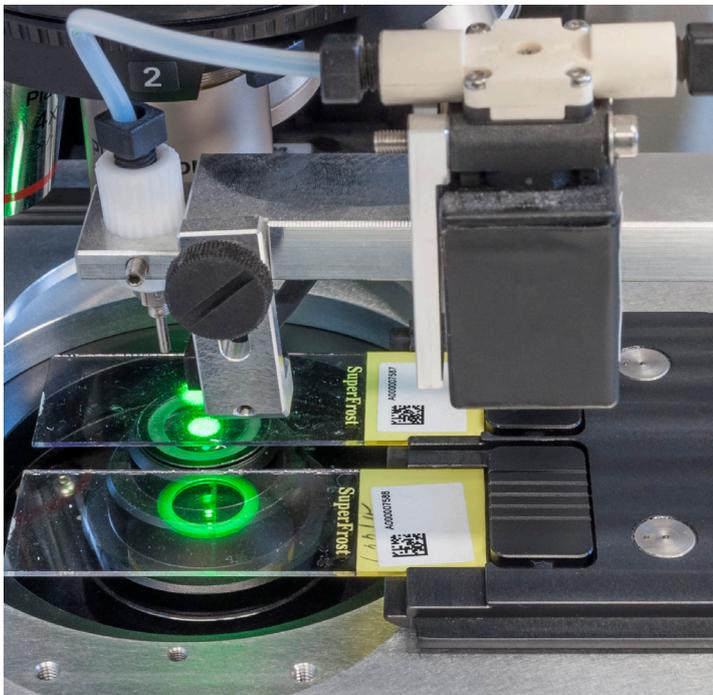


Blastomere

Metaphase Finder

LUCIA Cytogenetics





Immersion oil dispenser attached to the microscope

Flexibility

The loader with capacity of 120 slides* together with an integrated bar code reader open ways to build a highly effective system.

* Optionally, a basic 4-8 slides scanning stage can be used.

- The included metaphase classifier is fine-tuned to handle different sample types and preparation techniques.
- Thanks to the network-based database and full bar code support, the system is broadly extensible and can be adapted at any time to meet increasing demands.



System comes with three magazine containing 60 clips holding up to 120 slides.

Comfort

- **Press one button**
Once the system is adjusted by the administrator, the scanning process can be run by a single button.
- **Walk away**
The slide loader capacity of 120 slides allows about 4 hours of unattended scanning at approximate speed under 2 minutes per full slide (~90mm² using 10x objective).
- **Check on the progress anytime**
The scanning results are immediately accessible within the database.

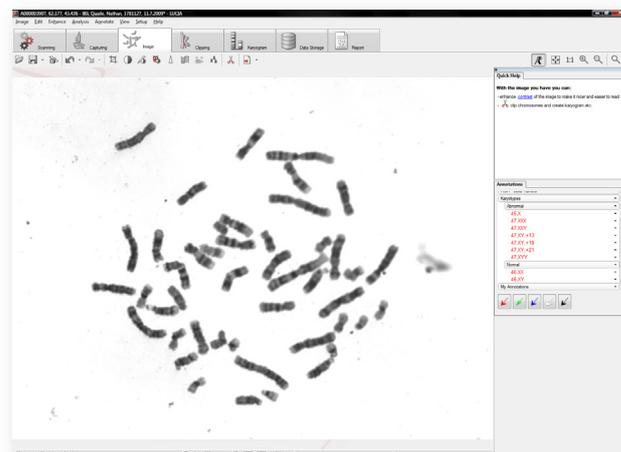
Performance

- The network-accessible database provides fast access to the metaphase galleries including the stage coordinates data.
- Metaphases can be located and reviewed on any workstation thanks to the automatic coordinates recalculation procedure.
- Metaphase images can be captured automatically using a high magnification (100x) oil immersion objective. The selection of metaphases to be scanned can be either automatic or manual.

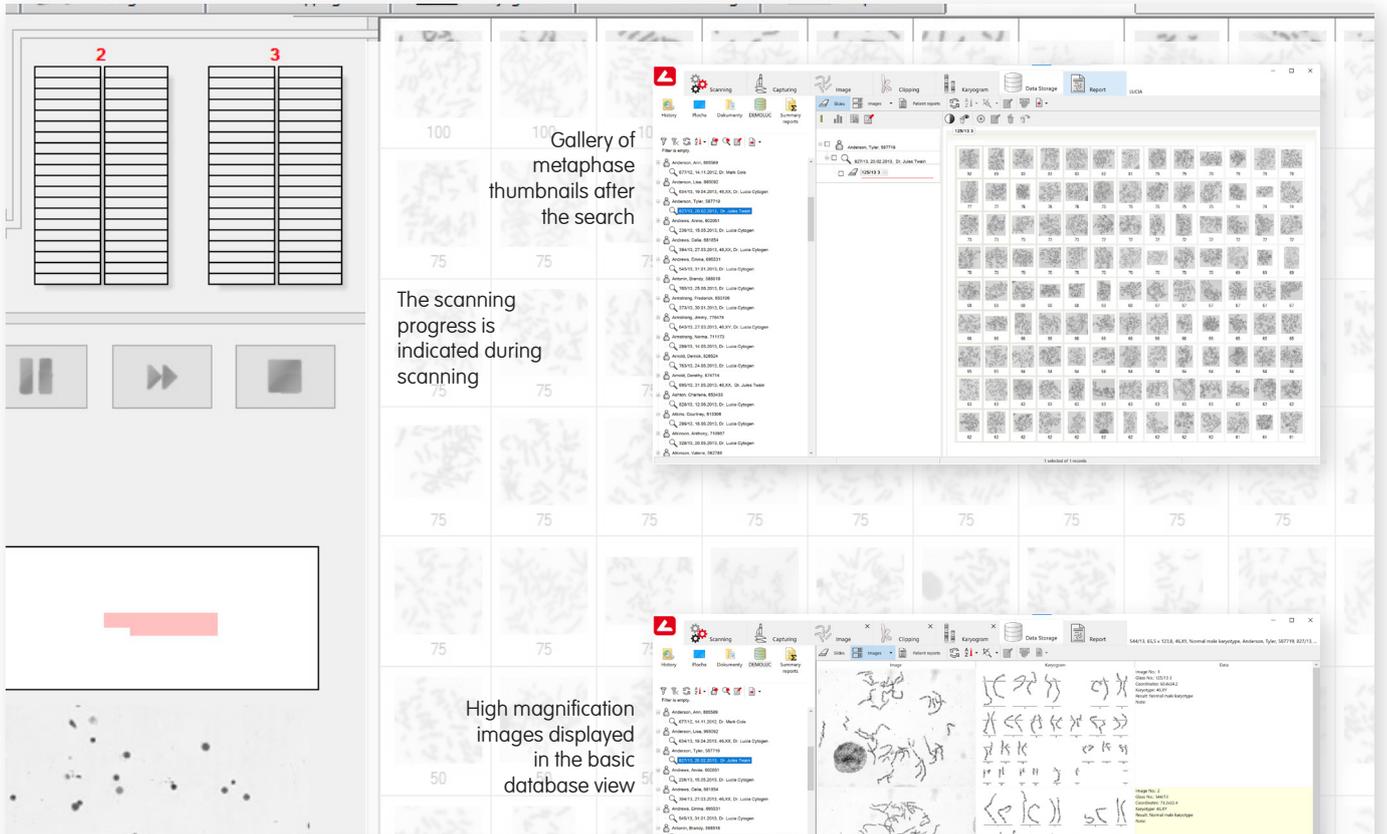
Reliability

The Metaphase Finder system consists of carefully selected top quality hardware components all produced by well-established manufacturers. In a very compact setup, you can find the following devices cooperating together:

- **Nikon Eclipse Ni-E microscope:** The computer controlled illumination ensures stable light conditions. The absolute coordinates focus control ensures reliable and fast auto focus.
- **QI825 camera:** A fast CCD camera with internal cooling.
- **Märzhäuser SCAN:** 8-position scanning stage developed especially for applications like Metaphase Finder which requires automatic, fast, and very exact precision.
- **Märzhäuser Slide Express:** Combination of the slide loader and an integrated scanning stage provides precision, speed and reliability of the scanning.
- **Lucia Immersion Oil Dispenser:** Allows automation of the high-magnification image acquisition phase, which would otherwise need human assistance.



High magnification image ready for the analysis



Märzhäuser Slide Express attached to Nikon Ni-E microscope

Database

LUCIA Cytogenetics



Complex data storage

The database server stores the following data:

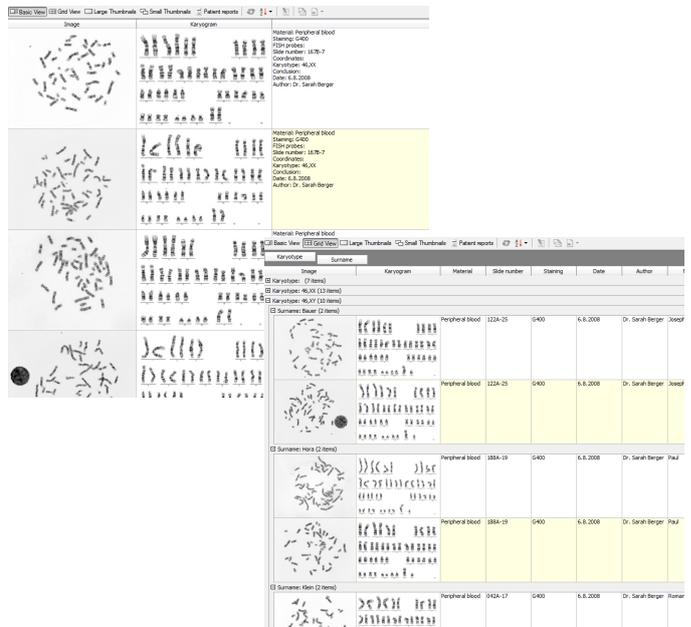
- Patient, examination, and image data.
- Case reports, summary reports and report templates.
- Information about slides and cell/metaphase coordinates within one slide.
- User settings such as history, classifiers and other.

No size limits

The number of records stored in the database is virtually unlimited so there is no need to „archive“ the old data. All the data is always fully accessible and can be easily searched for using our filter tool.

SQL - Reliable and stable platform

The database system is based on a widely accepted third party SQL database server.



Flexible database structure

Inspired by usual laboratory usage, there are three types of database records: patient, examination, and image records.

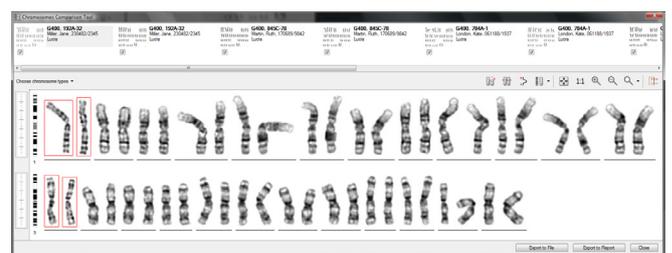
A record consists of multiple fields.

The field properties can be adjusted in order to improve the workflow and ensure the data correctness:

- The „display“ fields are used as representatives - in the database browser etc.
- The „unique“ fields prevent the records from undesirable duplication.
- The „required“ fields must be filled before the record is saved.
- A data type is assigned to each field preventing mistakes – for example „date“ fields accept valid dates only.
- You can let the system fill a field automatically e.g. insert the karyotype, the current date etc.
- Enumeration fields allow users to pick one of the pre-defined values (e.g. insurance codes).

Tools

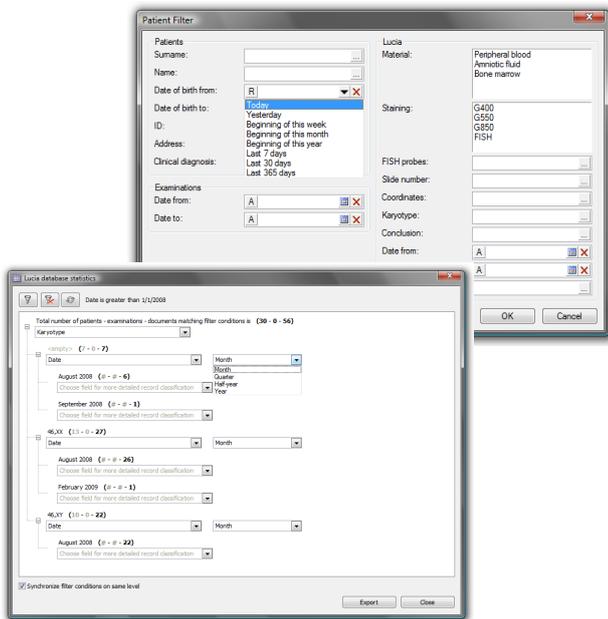
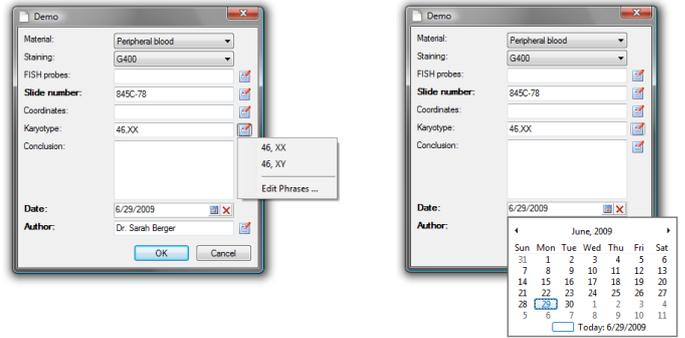
- The database browser offers:
 - » various view layouts
 - » tabular view optimized for cytogeneticist's nature
 - » variable-sized image thumbnails
 - » a grid view allowing data grouping and simple statistics
- Fast data sorting is performed on the database server with full regional-customization support.
- Complex, yet simple to use data filter.
- The LUCIA report tool is fully integrated with the database. The in-database storage of reports and report templates, the direct database-to-report data insertion and other useful features are included.
- The advanced statistics tool enables complex studies to be done easily and efficiently.
- The chromosome comparison tool.



The chromosome comparison tool

Efficient workflow, access control

- The access to the data can be controlled on different levels - database, record, field.
- The user who creates a database record becomes its owner. The owner has privileged rights to the record until a supervisor – a user with stronger user rights - takes it over and locks it for other users. However, the role of the supervisor can be omitted so that each user master his own records.
- Concurrent access to the data is resolved by the database server. Each record is locked for others while it is being used. All record changes are registered to a log file.



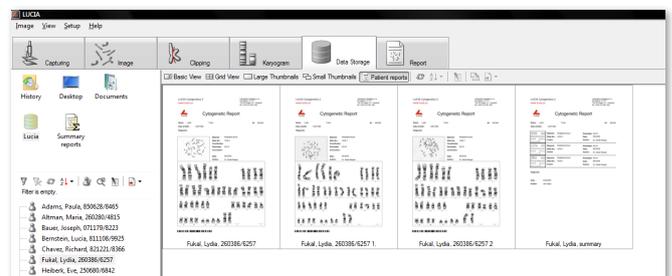
Architecture

Lucia Cytogenetics Database uses a client-server architecture. For small and simple installations, both the client and the server software runs on the same PC. However, the server can run on a standalone computer dedicated only to this purpose.

- The server software manages all data produced by clients.
- The server software guarantees data integrity and security.
- All maintenance tasks (back-ups etc.) are easier with the server.
- If the standalone server computer is supplied, its components along with the installed operating system are selected very carefully in order to provide stable and fast performance.
- Client computers access the server software via network.
- A local area network (LAN) for in-house data sharing.
- A fully secured internet connection for remote access via internet.

Easy data maintenance and security

- The LUCIA database provides a fully automated back-up system. Logging, remote reporting and remote monitoring is included.
- The database network communication is encrypted using SSL to increase the data security.



Report

LUCIA Cytogenetics



According to us, the results of your hard work deserve special treatment - to be well arranged and to look professional. For this exact purpose, LUCIA CytoGenetics comes with the mighty Report Tool, a combination of a text editor, presentation creator and an automatic data-to-print-output processor.

Effortless to Learn

- All items and information needed to create the report are arranged within one screen.
- Drag and drop text fields, images and arrows to the report page.
- A single click is enough to create the report from a predefined template.
- A single click is enough to print the report or export it to PDF.

Simple Editor

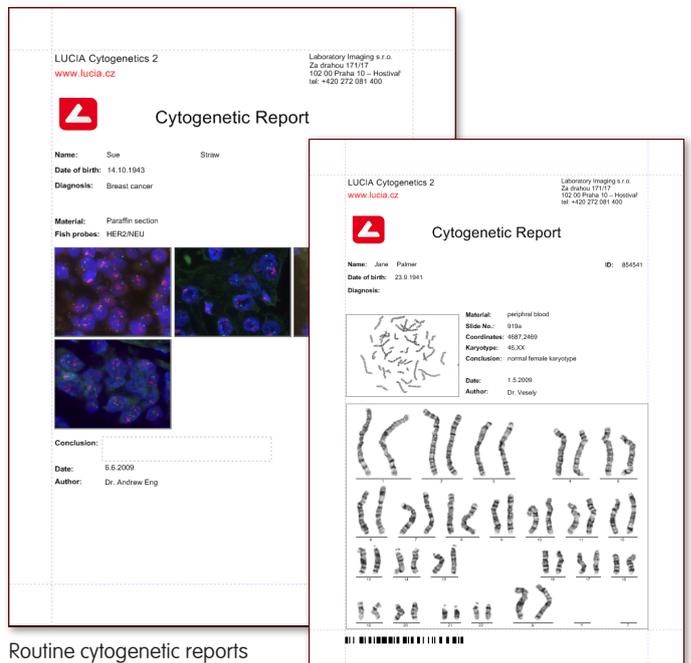
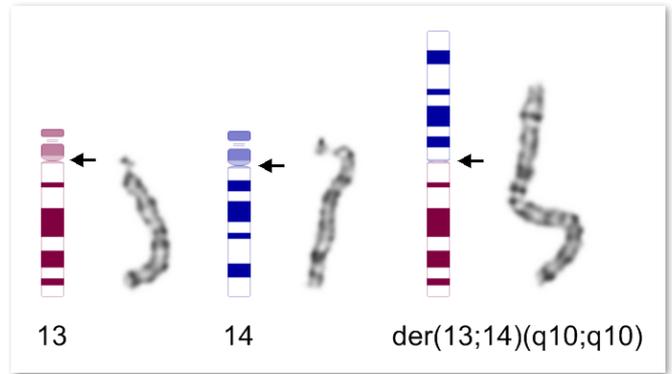
- Standard user interface common to most presentation or document writing products.
- Large scope of views - from a magnified detail to multiple page overview.
- Unlimited undo history.
- Easy formatting, multiple object alignment, distribution and order.

Variable Page Content

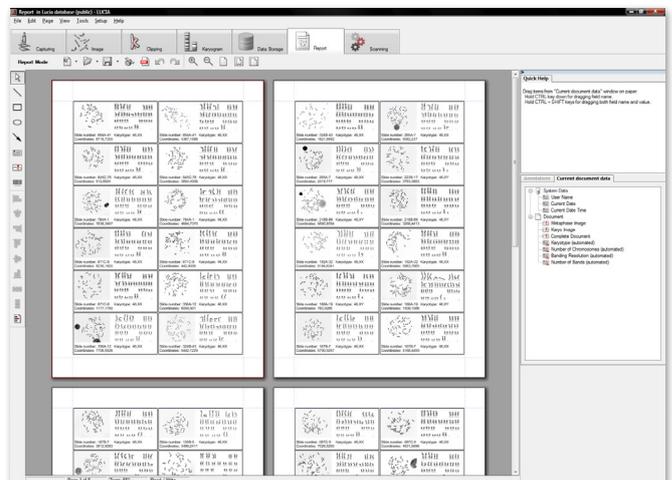
- Simple graphics is available to enrich the look of your reports.
- External images, logos, etc. can be inserted.
- Easy system data insertion (date, time, user name, etc.).
- Headers and footers repeating on each page.
- Images and patient data can be displayed in many ways. For example an image object can display a karyogram if it is available. If not available, the source image is used.
- Any patient data may be inserted in a plain form or using a bar code.

Secure Storage

- The reports and report templates can be easily saved to the database. The patients' reports are associated with the other patient data. The database access right control is applied to both reports and report templates.



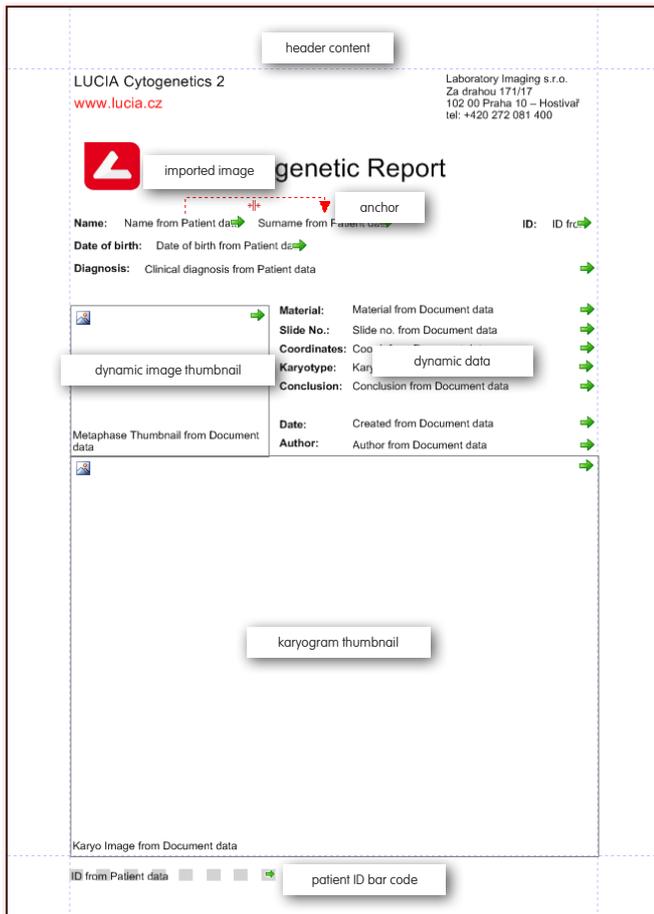
Routine cytogenetic reports



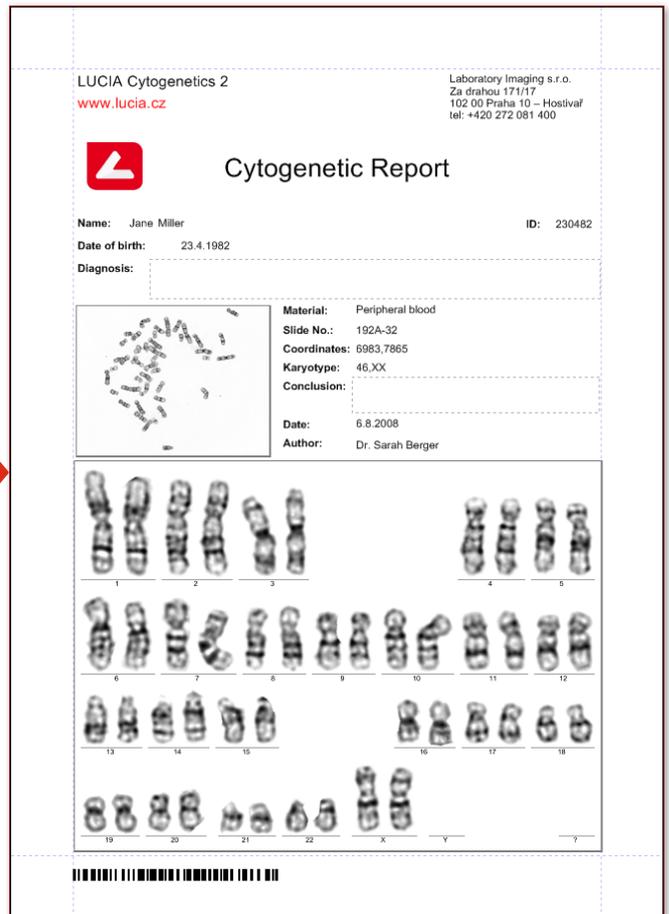
The multiple metaphase/karyogram report

Powerful Templates

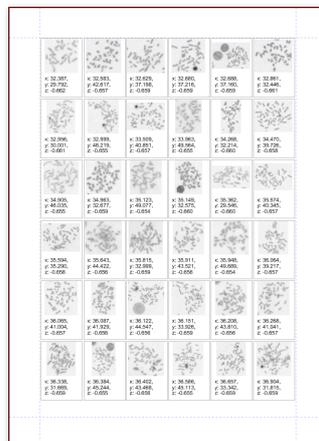
- The usage of the LUCIA database module allows the user to create reports for a single image, multiple images, multiple patients or metaphase finding results.
- A library of report templates can be used to generate varied formats from the same data.
- A dynamic text object can adapt its size to fit the actual data, the subsequent objects are shifted accordingly. This way, a well arranged continuous document is created.
- Anchoring allows you to specify an object position relative to another object. In combination with the size adaptation feature, this is a perfect tool to format for example the „Name“ and „Surname“ fields one after another.
- The usage of a general repetition object called „band“ carries a huge potential to present multiple data. The band allows you to insert an unspecified number of patients, images or other data, because it repeats itself until the number of records is reached.



Dynamic report template



Generated report



Bands have been used to create these reports

About the Bands

- The band can have a header and a footer for easy table design.
- The number of repetitions is controlled by the master "data source" assigned to the band.
- Bands can be nested one into another, each one having a different data source.
- Bands use a sophisticated page breaking control mechanism.
- For image galleries, horizontal alignment option is available.



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