

# Perceptronix Medical Inc.

*Early diagnosis, better outcomes™*

## ClearCyte™

### ClearCyte™ Feature Summary

The ClearCyte system is a combination of a microscope and hardware that enables semi-automated analysis of DNA content in slide-based cytology specimens. The system is very user friendly, easy to maintain and has a high throughput capacity due to fully automated scanning process. The systems have been designed under ISO and FDA development requirements.

Utilizing proprietary automated image cytometry technology, ClearCyte™ captures, measures and sorts imaged cell nuclei according to DNA ploidy and other nuclear features. The presence of an abnormal DNA content (aneuploidy) reflects extensive DNA changes (gross genomic aberrations) usually indicating the presence of malignancy, correlating with tumor progression and poor survival.

ClearCyte™ is configurable and can be applied to any cytological specimen. Any lab with the correct staining and lab set-up can test and run any liquid based cytology on the microscopes, such as catheterized and voided urine, oral brushings, bronchial washings, etc. The system is optimized for use with Clear2C™ Feulgen-Thionin quantitative staining kit (product of Perceptronix Medical Inc.), however any Feuglen- type staining can be used with the device.

### Expanded Slide Capacity

ClearCyte™ includes two 25 slide cassettes for a total capacity of 50 slides. Depending on the sample deposition, each slide will take between 20 minutes of scanning time for cytospin preparation to 30 minutes for ThinPrep preparation. Each machine can scan over 12,000 slides per year. Scanning can be pre-set for a shorter time if desired, e.g. for a target number of cells to be collected.

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## ClearCyte™ Hardware

ClearCyte™ devices incorporate readily available high quality off the shelf components from well established and reliable manufacturers: Zeiss microscope, Ludl stage and slide handling system, QImaging camera (see below):



## Calibration and Quality Control

ClearCyte™ devices are calibrated using a universal coordinate system to record positions of imaged cell nuclei allowing for interchangeable scan/revisit capability. Any ClearCyte™ device can be used to review nuclei acquired on any other ClearCyte™ device.

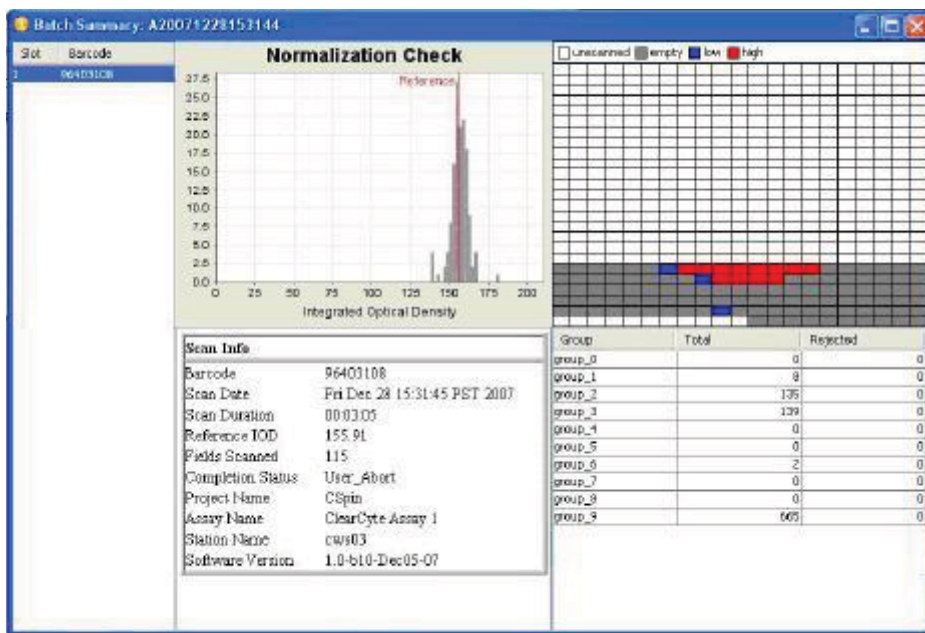
ClearCyte™ includes improved brightfield image calibration which reduces noise/artifacts in the acquired images.

ClearCyte™ includes QC tool (special slide with software) which measures various system parameters to ensure the system is operating within specification. The QC tool is designed to detect deviations in xy-stage accuracy, magnification, focus drive performance, camera performance and illumination uniformity.

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## Improved Acquisition and Review Software

Batch summary screen (see below) allows operator to review status of current scan batch at a glance.



Searchable database of scan results allows for quick access to scans at any point in the review workflow.

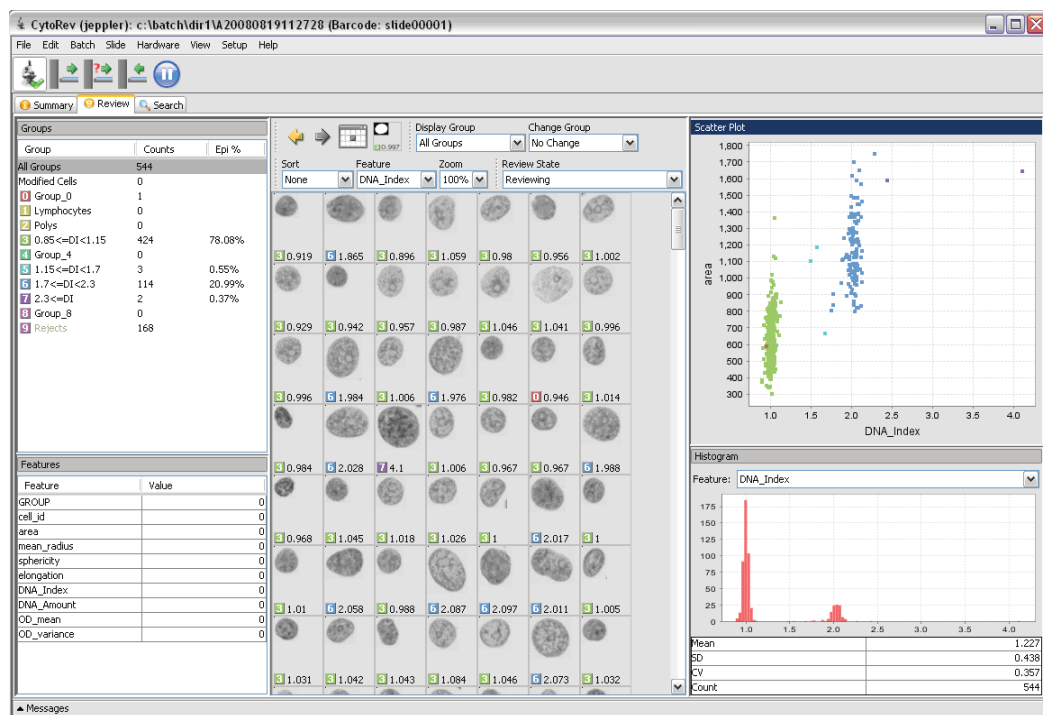
During review process the operator can select a cell on the screen with the "mouse"; clicking on that cell commands the automated stage to bring the cell in the center of the visual field review under microscope, if necessary.

The system includes integrated report generation and data export.

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## Integrated Report Generation

Data review screen (see below) includes customizable image gallery, scatter plot and histograms views.



## Quality System and Regulatory Compliance

System designed and manufactured in accordance with ISO 9001/13485 standards and with FDA QSR regulations.