

# New POC technology in blood counting

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## **Presentation**

1. POC overview
2. Current POC CBC/FBC technology
3. New POC devices
  - Image analysis
  - Microfluidics
4. Future potential for POC devices

## POC Overview

POC defined as any analytical test performed for a patient by a health care worker outside the laboratory setting<sup>1</sup>

Laboratory should have responsibility

Information technology

## POC Overview

- CBC/FBC parameters
- POC setting
- POC management

## Current POC technologies

- Hand held devices - convenient as portable but usually only one or two parameters
  - HemoCue® systems



The HemoCue® WBC DIFF system

## Current POC technologies

### Abbott POC® i-STAT

- Conductivity based method to calculate Haemoglobin

### Chempaq® XBC

Incorporates Coulter impedance technology, to provide Haemoglobin and 3-part differential

## Current POC technologies

Multiple parameter devices

Small bench top systems

- Sysmex® pocH-100i
- Beckman Coulter® AcT 5 Diff
- Various Blood gas analysers

# New CBC POC devices

- Free standing analytical device, sits on bench top.
- Utilises new technology incorporating a disposable self contained microcassette which contains all required reagents.
- The cassette with patient's sample feeds into the analytical device.
- Each device employs complex microfluidic systems and digital image analysis for processing the cell counts.
- Produce a total blood count including 5-part differential within 5 minutes.
- Has the potential to flag both RBC & WBC abnormalities
- Some traditional parameters may be calculated from other measured parameters



# New POC devices

## Abbott Diagnostics



W = 36cm  
H = 43cm  
D = 56cm  
Wt approx. 20Kg

## PixCell Medical



W = 17.5cm  
H = 30cm  
D = 26cm  
Wt approx. 8Kg

## Single use disposable cartridge

### Abbott POC



### PixCell



Disposable cartridge includes sampler which requires approx. 20ul blood (venous or capillary). The cartridge contains all required stains, reagents, held within a microfluidic system. This together with the analytical device enables the cell count results to be produced.

# PixCell Medical HemoScreen Technology: Disposable Cartridge

Microfluidic Technology

Integrated, simple, & accurate  
blood sample acquisition



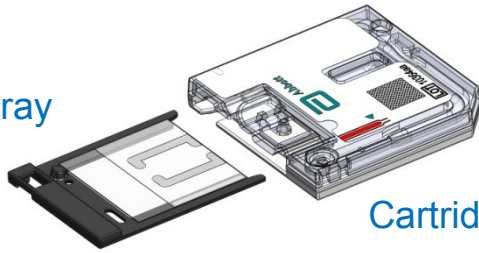
Self contained reagent  
compartment

# Abbott Image-based Technology – Blood Imaging Chamber

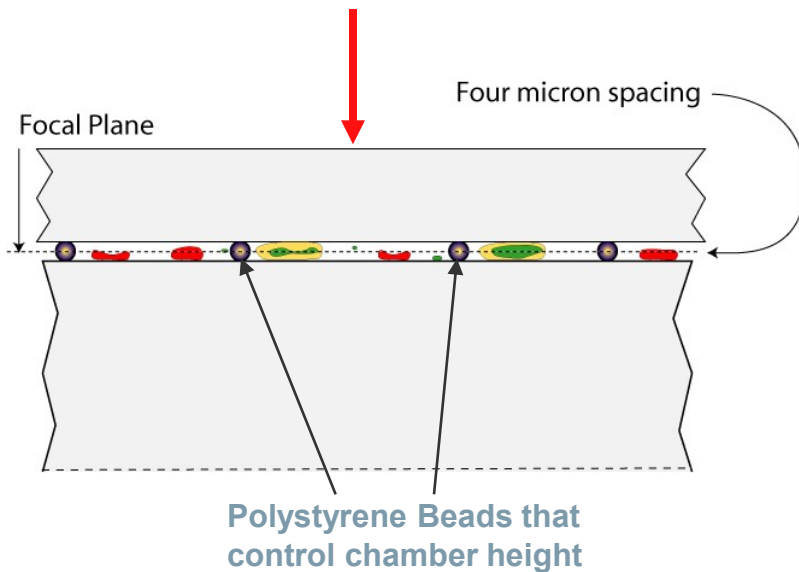
A simple solution solves two challenges:

- Monolayer cells for imaging
- Volume accurately computed

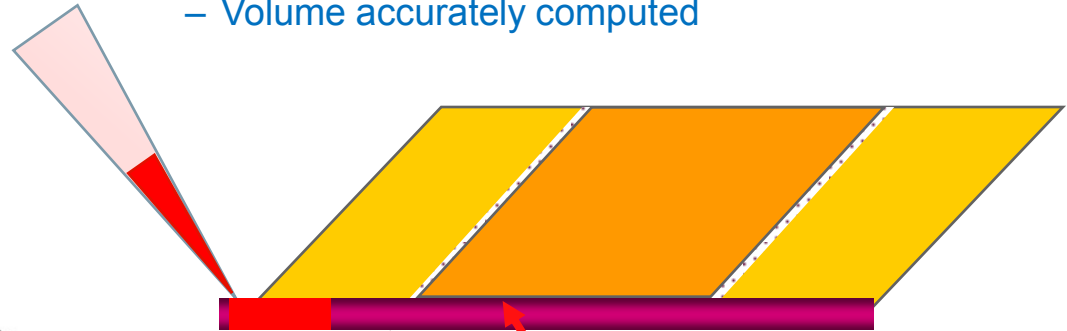
Chamber/  
chamber tray



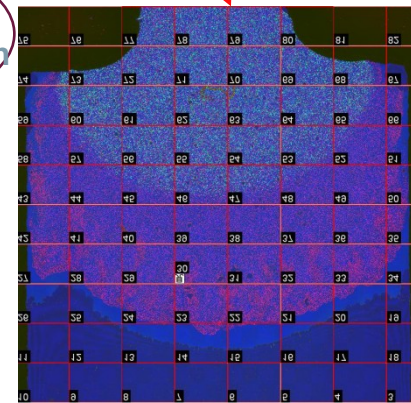
Cartridge



Monolayer of cells in the fixed height chamber



Resuspend and fluorescent stain



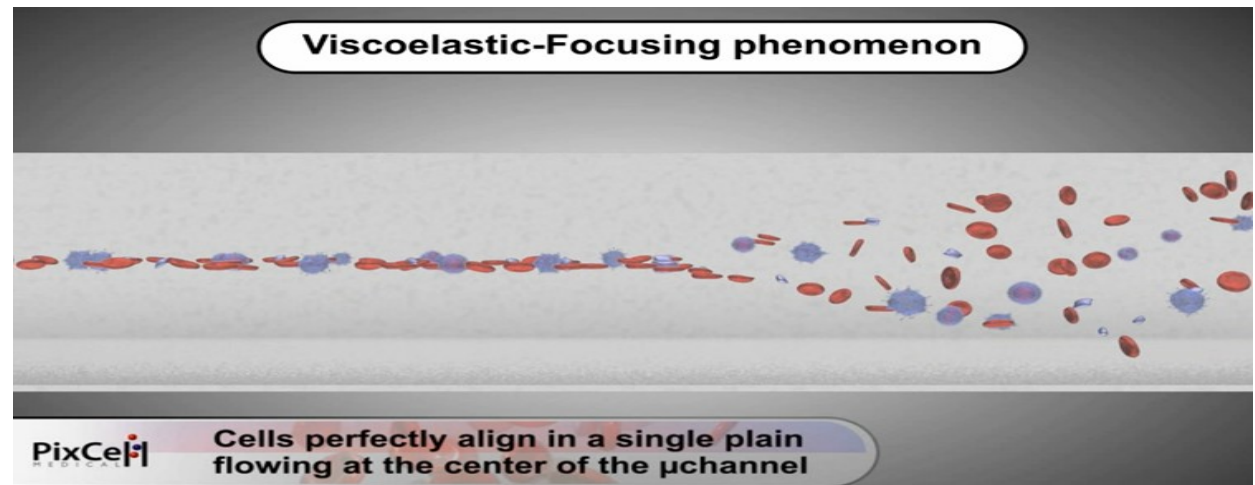
Height x area = volume

Chamber imaged using multiple wavelengths of light inside analyzer

# PixCell Medical HemoScreen Technology: Viscoelastic Focusing

- **Viscoelastic Focusing** – a new physical phenomenon Viscoelastic Focusing causes cells, which are suspended in a proprietary fluid, to perfectly align in a single column of cells to enable visualisation, and to facilitate their optical detection and analysis.
  - Simple, robust and requires no complex geometries.
  - 2D or 3D focusing is possible depending on the vessel's cross-section.
  - May be used in a variety of applications

2D focusing used in the HemoScreen cartridge enabling high throughput



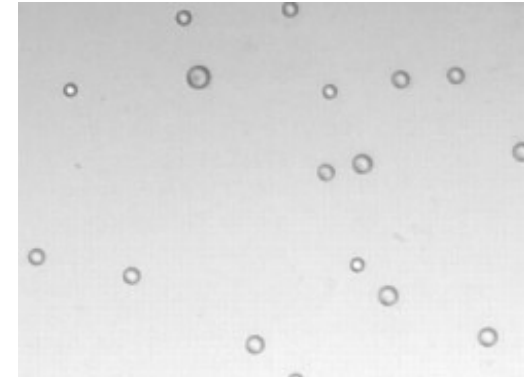
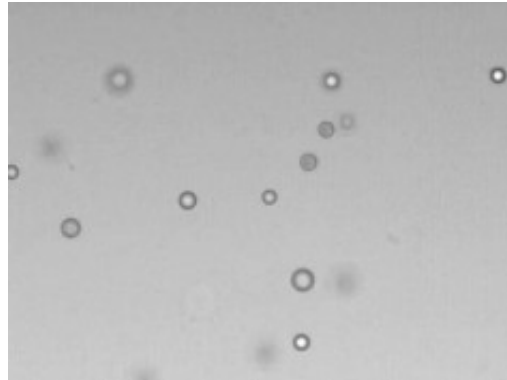
# Viscoelastic Focusing

Normal Fluid

Patented Fluid

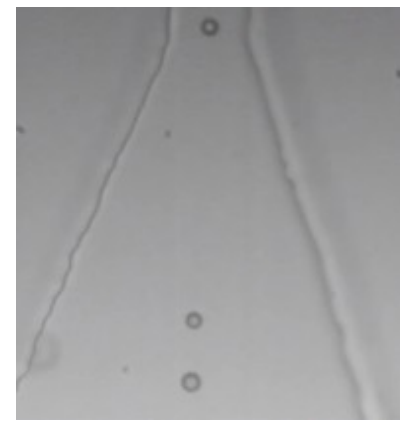
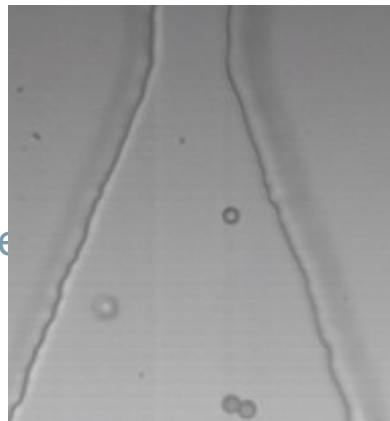
2D focusing

Applies for  
multiple cell capture



3D focusing

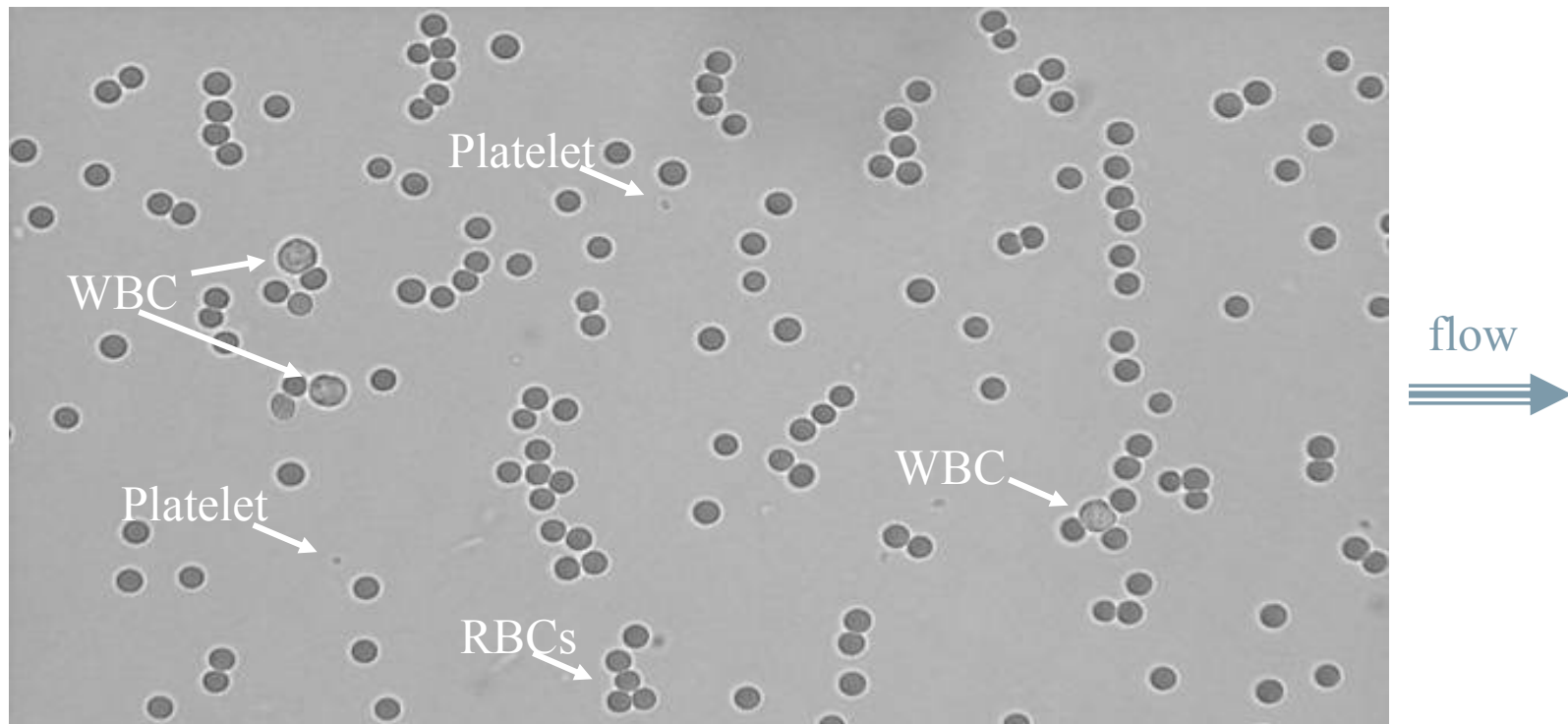
Applies for single cell/particle  
Cytometry



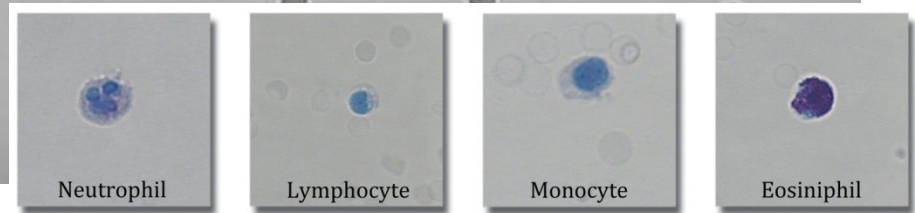
## PixCell Medical HemoScreen Technology: Complete blood count

- Microfluidic chip facilitates simultaneous multiple analysis
- Cell counts obtained by image based analysis and complex classification algorithms
- Haemoglobin measured in a separate zone using dual wavelength absorption method.
- White cell differential obtained using proprietary stain, which enables the cells to be identified by their cell size, cellular content and colour, nucleic size.

# PixCell Medical HemoScreen Technology: Cell count image capture



Use of custom staining to differentiate White Blood Cells





# **PixCell Medical HemoScreen Technology:**

## **Correlation studies**

Analytical performance of the HemoScreen system was verified against the Sysmex XE-2100 in accordance with the International Council for Standardization in Hematology (ICSH) and Clinical and Laboratory Standards Institute (CLSI) standards.

This was undertaken internally with the Haematology laboratory at Rambam Medical Center.

(presented May 2014 ISLH)

## Correlation Results

Good correlation with all parameters tested in normal subjects.

Further work needs to be undertaken with specimens in pathological ranges.

## **Results**

For the device, results are displayed on the screen. They can be printed off as a paper record or stored on the system for transfer to laboratory systems.

Format of results can be customised to user needs

## Maintenance

The device is designed to be maintenance free. It has self initiated electronic checks carried out when the device is switched on.

Internal electrical and alignment checks take place for cartridge sensors prior to analysis and during analysis.

Self checks are also undertaken each time a cassette is fed to the device between samples.

## Quality Control

Each device will be factory calibrated but will need to be validated on site to ensure it meets the needs of the user.

The device will have IQC at 3 levels.

EQA MUST be developed by independent national providers

Both have potential to be calibrated to user request for own setting depending on patient population

## **Competency and compliance**

The HemoScreen device is still in development stages but the manufacturer will ensure they work with service users to provide the required training to comply with competency testing for users.

The device will have to undergo independent evaluation according to ICSH and CLSI guidelines.

## Possible Future Applications

CRP

CD4 counts

Malaria

Platelet aggregation studies

Sickle cells

Others?

## New POC devices cont.....

Constitution medical Bloodhound technology incorporated into Roche 'Cobas system' four in one

- Slide maker
- Stainer
- Analyser
- Imaging system

Capable of 26 parameters, measures 42x56inches



## Biosurfit - Spinit®

<http://biosurfit.com/>

## Non-invasive technology

### Spectrophotometry- based methods

- Differential optical density of wavelengths of light passed through a finger, similar to pulse oximetry.
- Masimo Radical 7<sup>2</sup>

## POC vs Satellite Laboratory

### POC

- Portable
- Rapid
- At patient's bedside
- Operators may be untrained

### Satellite

- Rapid
- Expand on limited test menu available in POC
- Utilise existing technology
- QC and QA

## Summary

- Various devices now available
- Laboratory needs to assess own needs for POC service
- Important to validate the device in own setting
- Portable devices need to be carefully monitored
- EQA in development
- ‘SMART’ technology may need new ways of monitoring and tracking

## Acknowledgements

### Abbott Point of Care

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PixCell Medical  
Technologies Ltd.

[www.pixcell-  
medical.com](http://www.pixcell-medical.com)

**Thank you for your  
attention.  
Any questions?**

## References

- 1. Briggs, C., Guthrie, D., Hyde, K., Mackie, I., Parker, N., Popek, M., Porter, N. and Stephens, C. (2008), Guidelines for point-of-care testing: haematology. *British Journal of Haematology*, 142: 904–915. doi: 10.1111/j.1365-2141.2008.07274.x
- 2. Rice, M.J., Gravenstein, N., Morely. T.E., (2013) Non-invasive haemoglobin monitoring: how accurate is enough? *Anesth.analg.* 117:902-7
- Briggs, C., Carter, J., Lee, S.-H., Sandhaus, L., Simon-lopez, R., Vives Corrons, J.-L. and International Council for Standardization in Haematology (ICSH) (2008), ICSH Guideline for worldwide point-of-care testing in haematology with special reference to the complete blood count. *International Journal of Laboratory Hematology*, 30: 105–116. doi: 10.1111/j.1751-553X.2008.01050.x
- [Capillary compared to venous blood sampling in clozapine treatment: patients and healthcare practitioners experiences with a point-of-care device](#) Bogers, Jan P.A.M. ; Bui, Hong ; Herruer, Martien ; Cohen, Dan, *European Neuropsychopharmacology*, March 2015, Vol.25(3), pp.319-