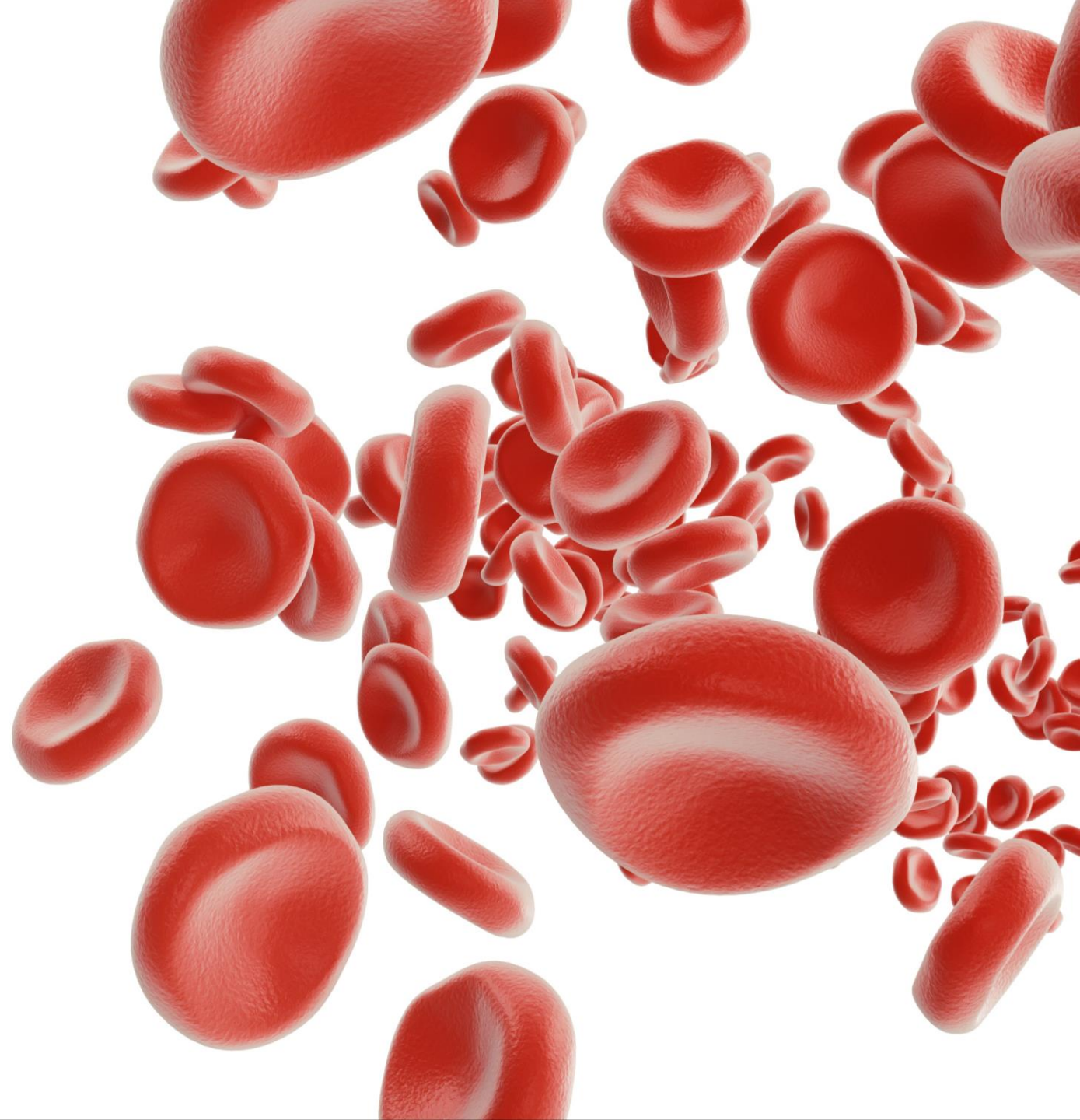




## Designing Revolutionary Blood Testing Diagnostics

Overview March 2024



## Revolutionizing Complete Blood Count (CBC)



CBC is the **most common** blood test. The market size is estimated at **\$5B**, typically performed in central laboratories.



Healthcare professionals shortage, decreasing budgets and decentralization have accelerated the shift towards POC testing, but the lack of suitable analyzer technology, **ease of use**, and **laboratory-grade** diagnostic quality are urgently needed.



**30%** of all CBCs are performed at the **point of care** on simplified laboratory equipment and POC devices with limited functionality.

## Blood testing standard of practice



Low-throughput  
benchtop analyzers



High-throughput  
automated lab

Complex to operate, requiring  
technical expertise

Frequent laborious maintenance  
and calibration procedures

Reagent management makes it  
uneconomical for small clinics

# HemoScreen Transforming POC Blood Testing

Features	Benefits
Requires a Single Drop of Blood	Simplified collection improves patient comfort and compliance
Disposable Cartridge	No maintenance or calibration required
Simple to Operate	Fully automated, eliminating the need for a lab technician
Rapid Turnaround Time	Results in five minutes significantly streamlines workflow
Lab-accurate Results	Accuracy on par with major laboratory analyzers
In-visit Results	Enables immediate intervention and improves outcomes
Low Cost	Increases patient and market access
Small Footprint	Portable and easily deployed in any clinical setting



HemoScreen Analyzer

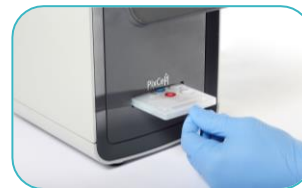
## An Elegantly Simple Workflow with Groundbreaking Ease-of-Use Providing Rapid and Actionable Results



Simple finger prick to extract one drop of blood



Insertion of sampler into modular cartridge integrated with reagents



Insertion of cartridge into fully automated analyzer



Lab-accurate, in-visit results in five minutes

[Watch movie](#)

# Internal QC (IQC)

## On-board, built-in self-tests Internal Quality Control (IQC)



Test #	Test name
1	Hemolysis, RBC integrity
2	WBC integrity
3	PLT clumps
4	Valves opening
5	Capillary filling
6	Measurement chamber
7	Flow
8	Stains' function
9	RBC sphering agent
10	Cleanliness/contaminants
11	RBC lysis
12	Optics integrity
13	Spectral stability
14	Focus motor function
15	Manipulator motor function
16	Vacuum system integrity

IQC Export

10.07.24 4:26 PM

Internal Controls Test Results

Date Range 03.07.24 to 10.07.24

Number of measurements 0

PreAnalytical

Hemolysis, RBC integrity

Pass

WBC integrity

Pass

PLT clumps

Pass

Cartridge

Valves opening

Pass

Capillary filling

Pass

Measurement chamber

Pass

Flow

Pass

Stains' function

Pass

RBC sphering agent

Pass

Cleanliness/contaminants

Pass

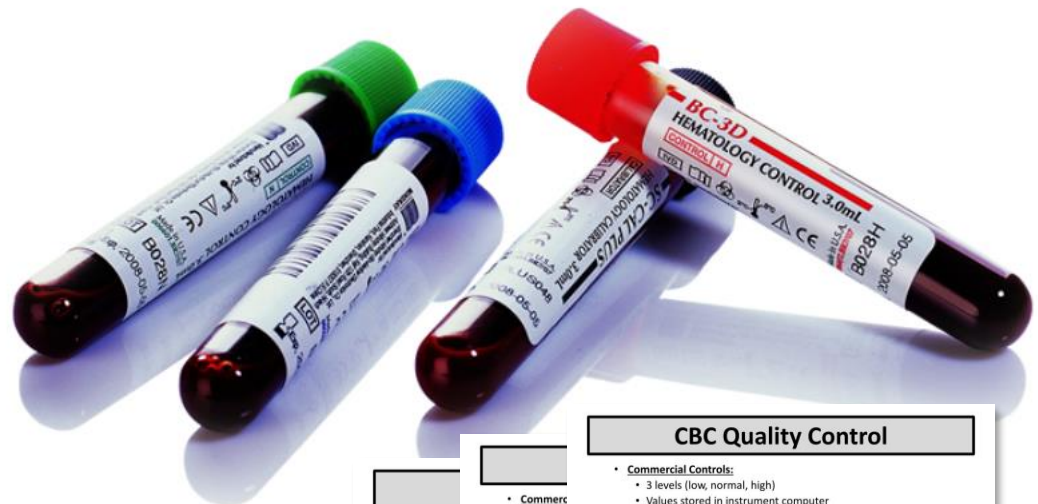
Export

Print

Back

## Liquid Quality Controls (LQC)

PIX-CBC Catalog #PIX002, R&D Systems (Bio-Techne), MN, USA



CBC Quality Control

Commercial Controls

3 levels (low, normal, high)

Values stored in instrument computer

Levey-Jennings graph generated and stored for each parameter

Mode to Mode QC

Most automated hematology instruments have a primary and secondary mode of sample aspiration. Controls must be run on BOTH and correlate.

Primary=Automated or Closed

Secondary=Manual or Open

Delta Checks

When the Laboratory Information System (LIS) and the instrument are interfaced (connected) delta checks are conducted by the LIS on select parameters.

Current values compared to most previous result

Differences greater than the limits set within the LIS are flagged

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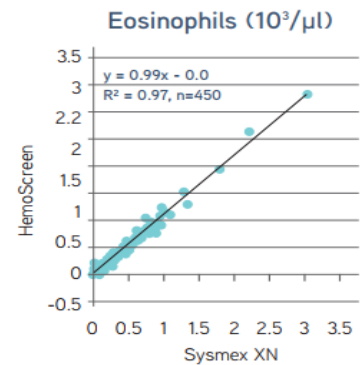
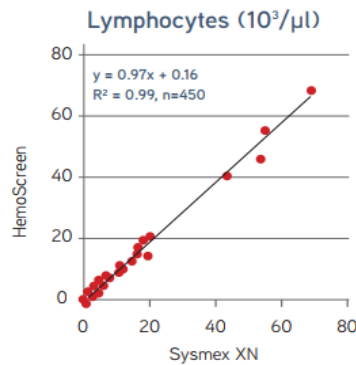
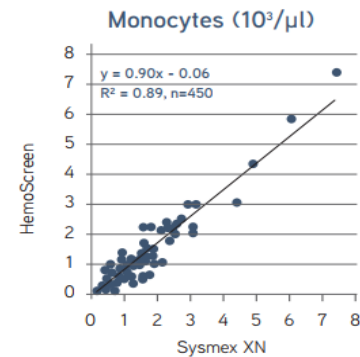
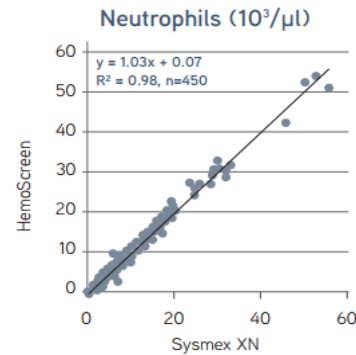
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# Performance validation

HemoScreen is the only **point-of-care CBC** testing device with a laboratory-quality 5-part differential WBC test



Parameters	Criteria
WBC ( $\times 10^3/\mu\text{l}$ )	$\leq 4\%$ CV
RBC ( $\times 10^6/\mu\text{l}$ )	$\leq 2\%$ CV
HGB (g/dl)	$\leq 2\%$ CV
HCT (%)	$\leq 2\%$ CV
MCV (fl)	$\leq 1\%$ CV
MCH (pg)	$\leq 1.5\%$ CV
MCHC (g/dL)	$\leq 1.5\%$ CV
RDW (%)	$\leq 2\%$ CV
PLT ( $\times 10^3/\mu\text{l}$ )	$\leq 4\%$ CV
NEUT (%)	$\leq 8\%$ CV
LYMPH (%)	$\leq 8\%$ CV
MONO (%)	$\leq 15\%$ CV
EOS (%)	$\leq 1$ SD
BASO (%)	$\leq 1.5$ SD



In Process:



独立行政法人 医薬品医療機器総合機構  
Pharmaceuticals and Medical Devices Agency



# True Point of Care device, Potential Users

**Small Footprint**, Fits in any spot and is easily integrated into anywhere from a central lab to a remote field clinic



## PRIMARY CARE

Lab-quality diagnostics for a wide range of pathologies, improved patient experience



## ONCOLOGY

Streamlining treatment, Superior patient experience freeing resources



## PEDIATRICS

Enhancing access to CBC for children, utilizing in-clinic capillary sampling



## FIELD HOSPITALS, SHIPS, MILITARY SETTINGS

Availing access to CBC for various DoD and MFA embassies globally



## ICU & SURGERY

ICU/OR patients suffering from Hemorrhage, Blood Transfusion constituents



## EMERGENCY MEDICINE

Real-time CBC in time-sensitive treatment, where every minute matters.



## PSYCHIATRIC CLINICS

Clozapine patients required to perform CBC and seek a simple solution



## Sample of key global **users**



**+2.5M** CBC tests annually in **+43** countries





Thank you  
Ariel Linker  
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[HEMOSCREEN CLIP](#)

