PixCell MEDICAL

Katalyst DIAGNOSTICS

HemoScreen

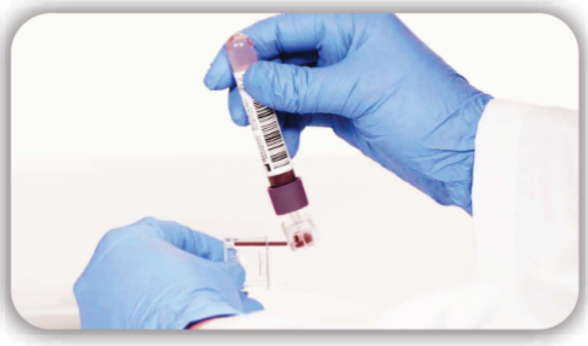
True point-of-care hematology

Katalyst Diagnostics Limited **Phone:** +44 771 051 6799 **Email**: Info@katalystdiagnostics.com

Simplifying real-time blood testing for everyone, anywhere.

Simple

The HemoScreen™ analyzer makes blood testing exceptionally simple, using a disposable cartridge that includes all necessary reagents and requires no maintenance or calibration.

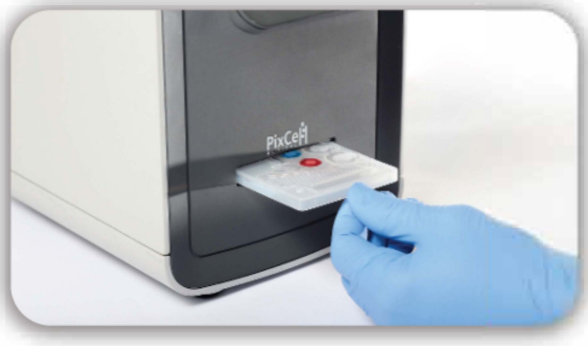


1

Draw blood sample

2

Insert sample into cartridge



3

Insert cartridge into analyzer

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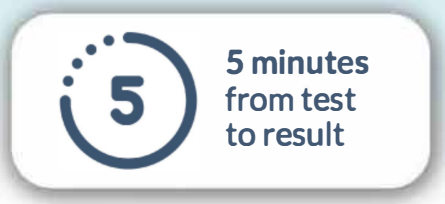
Rapid

The HemoScreen™ analyzer shortens turnaround time significantly by providing CBC results within 5 minutes, anywhere, anytime, enabling health care professionals to make immediate treatment decisions.

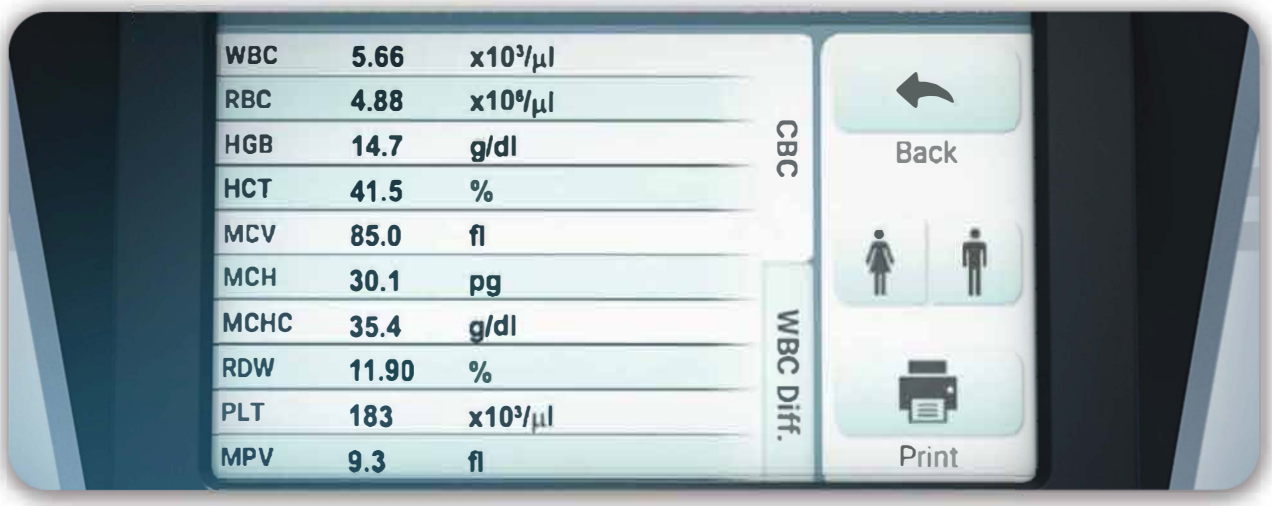


Accurate

HemoScreen™ measures 20 standard CBC parameters, including 5-part leukocyte differential, with the accuracy and precision of the most advanced central lab analyzers.

Its performance has been validated in multiple scientific peer-reviewed studies*. The analyzer is **FDA**-cleared and **CE**-marked for both venous and capillary blood samples. HemoScreen™ also offers a comprehensive flagging panel for the presence of WBC, RBC, and PLT distributional and morphological abnormalities.

* see www.pixcell-medical.com/evidence



Robust

HemoScreen™ has been specifically designed to withstand the demanding point-of-care environment and maintain performance no matter the operator's experience level.

Manufactured according to the highest quality standards, HemoScreen™ uses the most durable components. No maintenance and minimum downtime is guaranteed due to the analyzer's liquid-free design, as liquid reagents and blood samples reside in the cartridge throughout the process and can not possibly come into contact with the analyzer's internals.

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Physical Specifications

Analyzer dimensions & weight

Height	Width	Depth	Weight
30cm	17.5cm	26cm	5.5kg
11.8in	6.9in	10.2in	12.1lb

Throughput: ~10 samples/hour

Operating temperature & humidity:
+17°C (+63°F) to +27°C (+81°F)
Relative humidity of 10%- 90% maximum (without condensation)

Specimen volume:
CBC mode: 20µl | Diff mode: 20µl

Power requirements:
Power supply: 100–240VAC, 2-4 A, 50/60Hz
Power consumption: Approx. 60W

Software Specifications

Data Processing

- LCD display and touch panel
- Operating System: Windows 10
- Connection: Ethernet, USB
- Connectivity to LIS: HL7 & POCT1-A
- Optional: Barcode reader, printer

Quality Control

- PIX002 PIX-CBC 3-levels liquid control (R&D Systems, MN, USA, a Bio-Techne company)
- Target values download (USB, 2D barcode reader)

Parameters & Performance Data

20 parameters:

WBC	RBC	PLT
NEU# & NEU%	HGB	MPV
LYM# & LYM%	HCT	
MON# & MON%	MCV	
EOS# & EOS%	MCH	
BAS# & BAS%	MCHC	
	RDW-CV	

Including flagging of immature granulocytes (IG), nucleated RBC, blasts and atypical lymphocytes.

Linearity:

Parameters	Units	Linearity Limits
WBC	10^3/µL	0.5-80
RBC	10^6/µL	1.0-8.8
HGB	g/dL	3.0-25.0
HCT	%	9.0-78.0
PLT	10^3/µL	20-800

Precision (repeatability):

Parameters	Units	CV (%)
WBC	10^3/µL	≤5.0
RBC	10^6/µL	≤2.2
HGB	g/dL	≤2.2
HCT	%	≤2.3
PLT	10^3/µL	≤3.5

Measurement Principles

HemoScreen™ uses a patented technique called viscoelastic focusing, which causes the cells to perfectly align into a single plane. High resolution microscopic images are taken of the flowing cells. Each image is then analyzed using machine vision and AI algorithms, and the various cell types are differentiated and counted. WBCs are stained prior to analysis to enable differentiation between their sub-types and abnormal cells. HGB is calculated based on the optical density measured on individual, intact cells.

The HemoScreen analyzer is factory calibrated. No further calibration is required.

Standards

- IVDD 98/79/EC
- EN ISO 13485
- IEC 61010
- IEC 61010-2-101:2019
- EN 60601

Approvals

- CE (IVDD Directive 98/79/EC Annex III)
- FDA Clearance Number: K180020
- ETL Mark (US & Canada): Listing Number 5012972
- TGA Approval (Australia)
- AMAR Certificate (Israel)

CE ⚠ See instructions for use

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