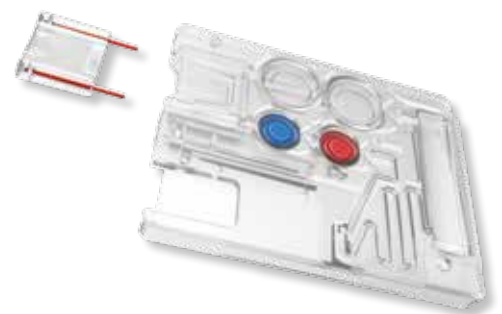




HemoScreen - Transforming blood testing at the Point of Care

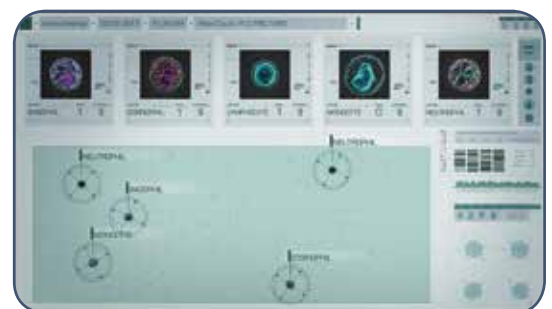
Overview

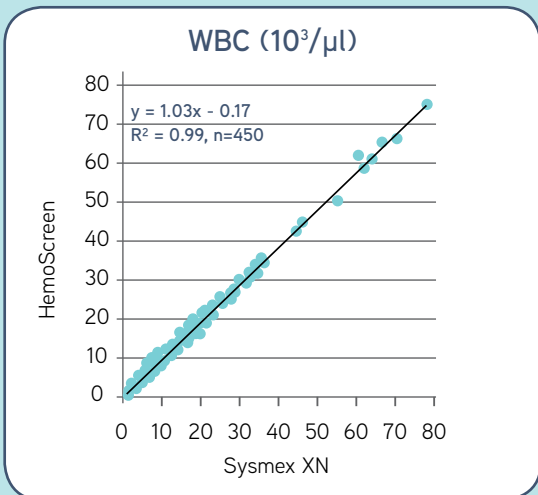
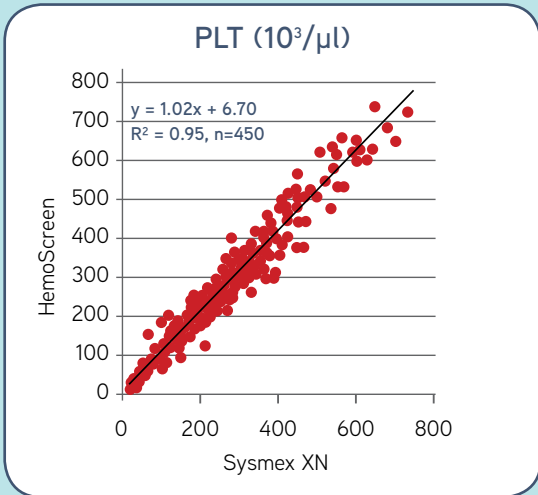
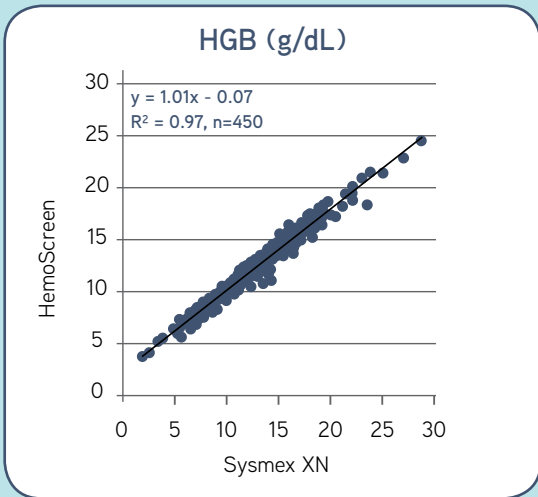
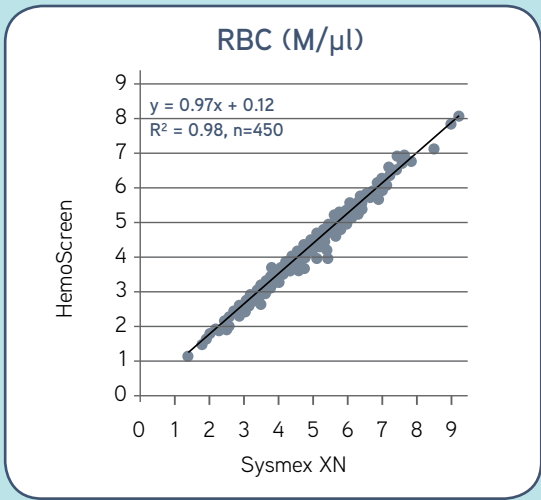
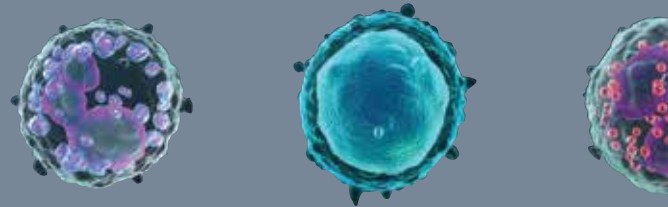
The **HemoScreen** is a miniature portable hematology analyzer that uses disposable cartridges. Each cartridge includes all necessary reagents and is designed to accept a single drop of blood. Once the cartridge is inserted into the reader, the sample is automatically processed and analyzed.



Technology

The HemoScreen employs a breakthrough technology based on **Microfluidics**, **Machine Vision** and **Artificial Intelligence**. Cells are flow focused into a single layer plane within a microfluidic chamber which facilitates their optical analysis. Thousands of images of the flowing cells are analyzed on-the-fly by cutting edge AI algorithms providing unparalleled differentiation and clarity.





Measured parameters

The HemoScreen provides 20 parameters: RBC, WBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW, MPV and percentage and absolute counts of NEUT, LYMP, MONO, EOS, BASO.

The HemoScreen flags for the presence of abnormal cells including IG, nRBC and Blasts as well as PLT aggregates.

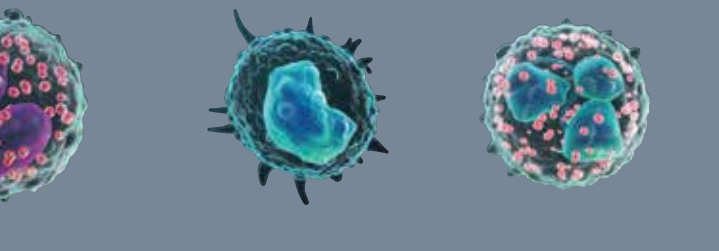
Sample specification

Each test requires 2X20 μ l whole blood from venous or capillary source with or without K2EDTA.

Performance specification

The HemoScreen performance has been validated in numerous clinical studies in the US and EU and in different settings such as oncology, ICU, primary care and ER.



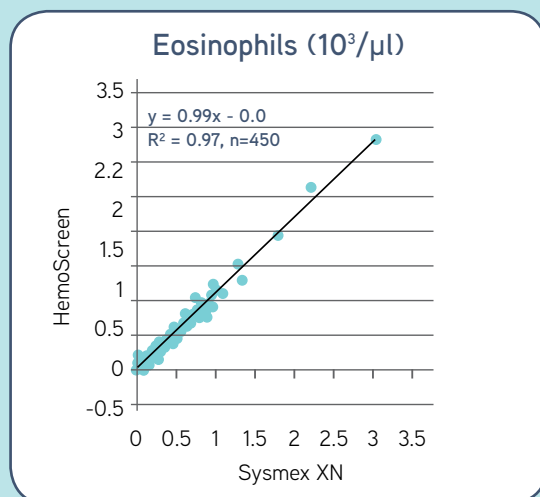
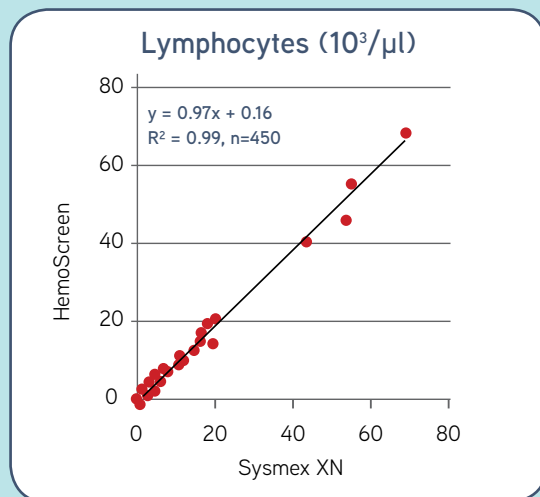
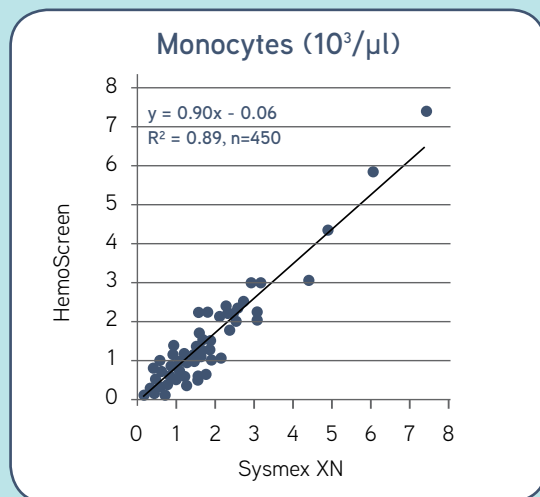
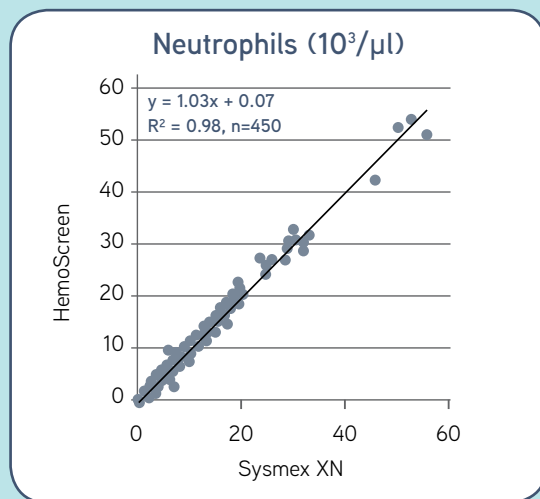


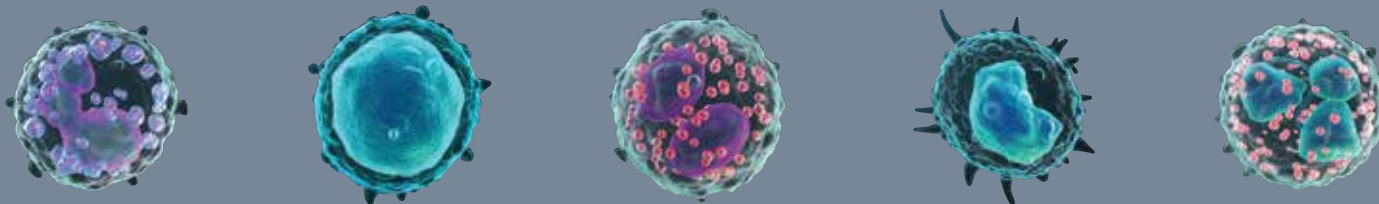
Precision

| Parameter | Criteria |
|----------------------------|----------|
| WBC (x10 ³ /μl) | ≤4% CV |
| RBC (x10 ⁶ /μl) | ≤2% CV |
| HGB (g/dL) | ≤2% CV |
| HCT (%) | ≤2% CV |
| MCV (fl) | ≤1% CV |
| MCH (pg) | ≤1.5% CV |
| MCHC (g/dL) | ≤1.5% CV |
| RDW (%) | ≤2.0% CV |
| PLT (x10 ³ /μl) | ≤4% CV |
| NEUT (%) | ≤8.0% CV |
| LYMPH (%) | ≤8.0% CV |
| MONO (%) | ≤15% CV |
| EOS (%) | ≤1 SD |
| BASO (%) | ≤1.5 SD |

Accuracy

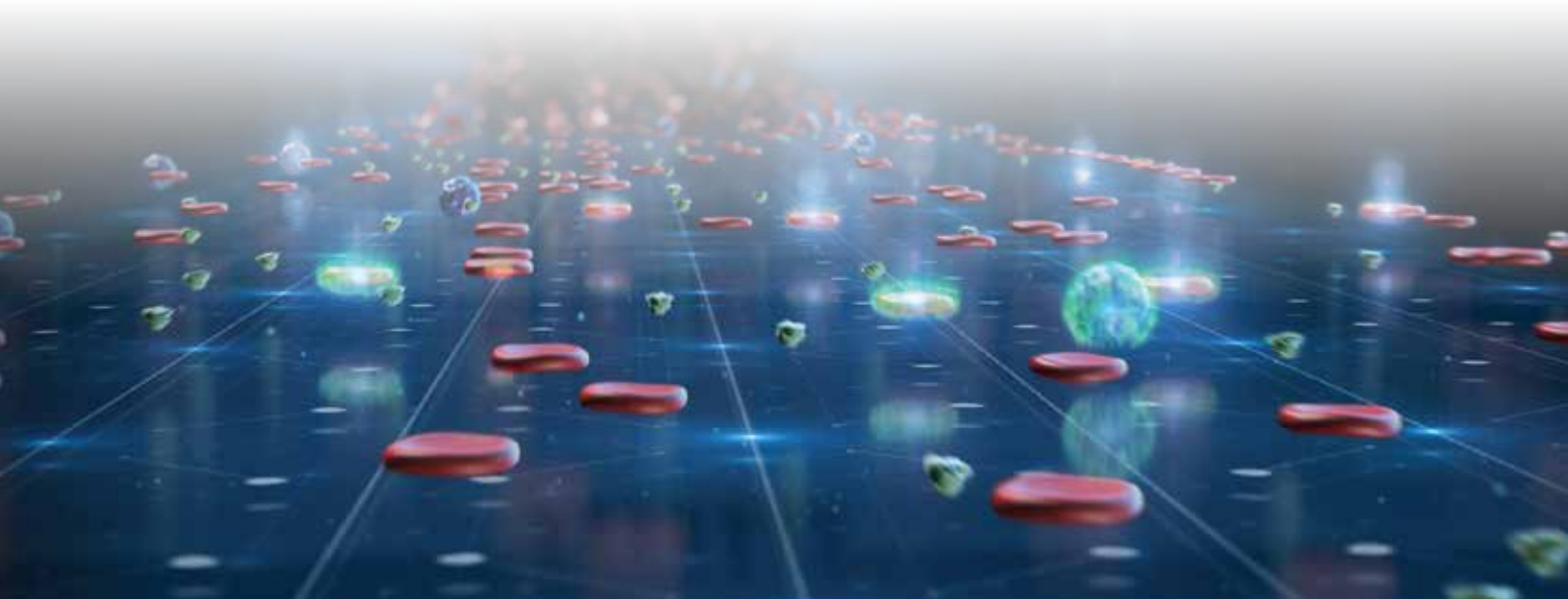
| Parameter | Correlation | Bias/Difference (Whichever is greater) |
|-----------------------------|-------------|-------------------------------------------|
| WBC (x10 ³ /μl) | r≥0.98 | ±0.3 or ±7.0% |
| RBC (x10 ⁶ /μl) | r≥0.98 | ±0.07 or ±3.0% |
| HGB (g/dL) | r≥0.98 | ±0.3 or ±3.0% |
| HCT (%) | r≥0.98 | ±2 or ±5.0% |
| MCV (fl) | r≥0.95 | ±2.5 fL or ±3.0% |
| MCH (pg) | r≥0.9 | ±5.00% |
| MCHC (g/dL) | r≥0.7 | ±5.00% |
| RDW (%) | r≥0.9 | ±1.5 or ±10.0% |
| PLT(x10 ³ /μl) | r≥0.95 | ±10.0 or ±10.0% |
| MPV (fL) | r≥0.8 | ±1.0 or ±10.0% |
| NEUT (x10 ³ /μl) | r≥0.95 | ±0.3 or ±10.0% |
| LYMP (x10 ³ /μl) | r≥0.95 | ±0.2 or ±10.0% |
| MONO (x10 ³ /μl) | r≥0.8 | ±0.2 or ±10.0% |
| EOS (x10 ³ /μl) | r≥0.95 | ±0.1 or ±10.0% |
| BASO (x10 ³ /μl) | NA | ±0.05 or ±10.0% |





Analyzer specification

| Parameter | Specification |
|-----------------------|-------------------------------------------|
| Test duration | 6 minutes |
| Operating temperature | 17°C - 27°C |
| Approvals | CE, under FDA review |
| Operating voltage | 12 VDC, 5A |
| Power supply | 100 – 240 VAC, 4 – 2 A, 50/60 Hz |
| Power consumption | Approx. 60W |
| Dimensions (LxWxH) | Device: 26cm X 17.5cm X 30cm |
| Weight | Approx. 5.5 Kg |
| Peripherals | Optional printer and barcode reader (USB) |



POCD

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See instructions for use

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