

StatStrip[®]
LAC/Hb/Hct

Fingerstick Capillary Blood Testing for Lactate, Hb, and Hct



StatStrip Xpress[®]2 Meter
with Data Storage

StatStrip[®] Hospital Meter
with Data Storage plus
Full Data Transmission
and Connectivity

**Two pre-calibrated, disposable biosensors:
Lactate and Haemoglobin/Haematocrit**

Capillary fingerstick blood samples as small as 0.6 μ L

Results as fast as 13 seconds

Lab-like accuracy

nova[®]
biomedical

Fingerstick Capillary Blood Testing for Lactate, Haemoglobin, and Haematocrit

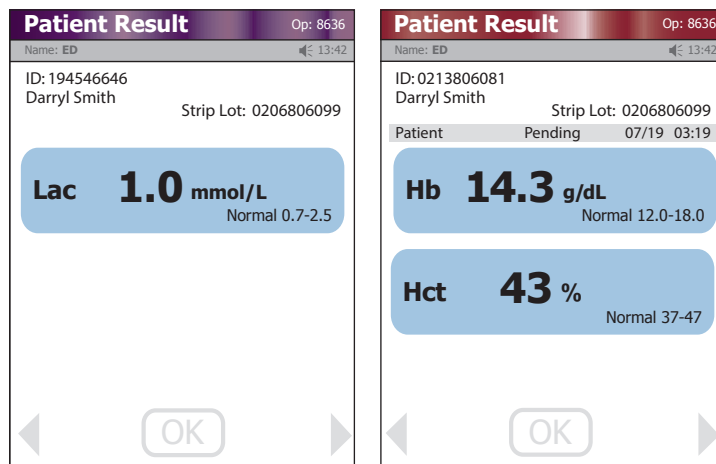
The StatStrip Lactate and Haemoglobin/Haematocrit Meter system (StatStrip LAC/Hb/Hct) is a handheld, easy-to-use meter system that measures LAC, Hb and Hct at the point-of-care using two disposable biosensors and tiny capillary blood samples for all tests. StatStrip's lactate biosensor provides lab-like accuracy in just 13 seconds from 0.6 microliters of capillary blood. StatStrip's Hb/Hct biosensor accurately measures - not calculates - both Hb and Hct in 40 seconds from a 1.6 microliter capillary sample.

StatStrip LAC/Hb/Hct testing is as easy as hospital bedside glucose testing performed by medical and nursing staff. Simply insert a lactate or Hb/Hct biosensor into the meter and touch the biosensor to a drop of capillary blood. Test results are rapidly displayed on a bright color screen, stored, and transmitted to an electronic medical record.

Choice of Two Meters



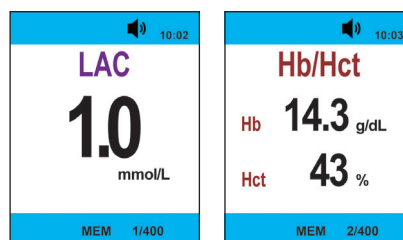
StatStrip LAC/Hb/Hct Connectivity Meter



- Color touchscreen operation and result display
- Onboard storage of 1000 patient results with positive patient ID
- Wired or wireless connectivity to NovaNet middleware, third party middleware, and electronic medical records

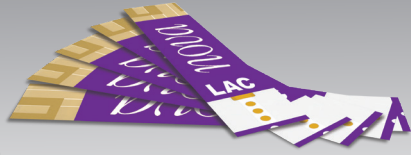


StatStrip LAC/Hb/Hct Xpress 2 Meter



- Bright color results screen and touch sensitive buttons for operation
- First in/first out storage of up to 400 test results
- Date, time, and sequential numbering for sample identification, no data transmission

LAC



Lactate Biosensors

Lactate Testing Bedside

StatStrip LAC/Hb/Hct is a point-of-care (POC) system that enables rapid and timely trending of lactate in sepsis (or other conditions of hypoperfusion) for assessment of resuscitation or treatment efforts. Compared to testing with blood gas analyzers which require arterial samples, large samples volumes (up to 95 microliters), and long analysis times (up to 2.5 minutes); StatStrip's single-use biosensor provides the fastest turnaround time (13 seconds) on the smallest whole blood sample (0.6 μ L) with excellent correlation to central laboratory reference methods.

Solves Lactate Pre-Analytical issues

Lactate is not stable in whole blood samples. Blood lactate levels rise steeply in less than 5 minutes if samples are transported or kept at room temperature.¹ StatStrip point-of-care testing ensures rapid, accurate results by eliminating sample transport preanalytical effects.

Hb/Hct



Haemoglobin/Haematocrit Biosensors

Haemoglobin and Haematocrit Testing Bedside

StatStrip LAC/Hb/Hct is the only POC system to provide anaemia screening and monitoring with measured, not calculated, Hb and Hct tests. This important breakthrough is possible because of new, patented biosensor technologies developed by Nova Biomedical.*

Accurate Assessment of Anaemia

Accurate anaemia evaluation requires both measured Hct and measured Hb. However, current POC Hb meters only provide a calculated estimate of Hct.

Calculated estimates of Hct are inaccurate in many conditions including red cell structural abnormalities, hemolysis, haemoglobinopathies, and other conditions. These conditions necessitate measured Hct because calculated results can negatively impact treatment.

Simple and safe testing

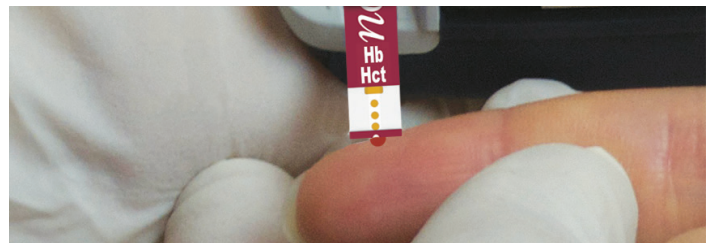
Similar to glucose self-testing, StatStrip single-use biosensors do not require calibration or coding. A biosensor ejector allows for touch-free disposal and eliminates a potential biohazard. Testing takes three simple steps:



1. Insert a Lactate or Hb/Hct biosensor into meter.



2. Lance finger to obtain blood drop.



3. Touch biosensor to blood drop.

Complete Data Connectivity with NovaNet

NovaNet is a single, economical solution for bidirectional interface of StatStrip LAC/Hb/Hct connectivity meters to the LIS/HIS/EMR. Over 70% of U.S. hospitals currently use NovaNet for connectivity and management of either Nova's StatStrip Glucose meters or Stat Profile Prime blood gas analyzers. Features include:

- Industry standard POCT1a-2, ASTM or HL7 interface formats
- Positive patient ID with 3 or more patient identifiers
- Complete data security and encryption

Small Blood Sample

StatStrip biosensors use a fraction of the blood required by other point-of-care devices that measure only lactate or haemoglobin, allowing patient screening or monitoring with minimal blood loss.

LAC 0.6 microliters **Hb/Hct** 1.6 microliters

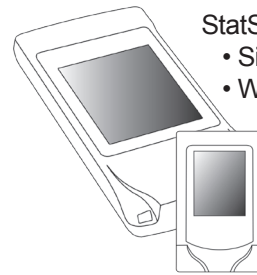
Fastest Turnaround Time

StatStrip provides the fastest turnaround time for lactate, haemoglobin and haematocrit, enabling rapid decision-making concerning tissue hypoxia, sepsis, and anaemia.

LAC 13 Seconds **Hb/Hct** 40 seconds

Small and Light Meters

StatStrip LAC/Hb/Hct meters are smaller and lighter than other POC devices that measure lactate or haemoglobin only. StatStrip lightweight, small meters enable testing at the bedside or patient-side.





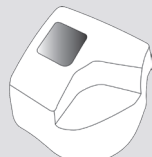

StatStrip LAC/Hb/Hct Connectivity Meter:

- Size: 147 mm x 79 mm
- Weight: 220 g

StatStrip Xpress 2 LAC/Hb/Hct Meter:

- Size: 98.0 mm x 61.0 mm
- Weight: 78.5 g

StatStrip LAC/Hb/Hct Connectivity Meter Feature Comparison

Instrument					
Tests	LAC	Yes	Yes	No	No
	Hct	Yes	No	No	No
	Hb	Yes	No	Yes	Yes
Sample Size	LAC	0.6 µL	95 µL	No	No
	Hct	1.6 µL	No	No	No
	Hb		No	10 µL	10 µL
Turn Around Time	LAC	13 seconds	2 minutes	No	No
	Hct	40 seconds	No	No	No
	Hb		No	10 seconds	10 seconds
Size		147 mm x 79 mm (5.8 in x 3.1 in)	256 mm x 143 mm (10.1 in x 5.6 in)	160 mm x 140 mm (6.3 in x 5.5 in)	170 mm x 93 mm (6.7 in x 3.6 in)
Weight		220 g (.49 lbs)	840 g (1.85 lbs)	500 g (1.1 lbs)	250 g (.55 lb)

Clinical Applications



Hospital Sepsis Monitoring Surviving Sepsis Campaign (SSC) Recommends Early Lactate Testing

The SSC Hour-1 Bundle includes the following recommendations for early sepsis recognition and management:

- Measure lactate within the first hour of sepsis recognition
- Re-measure lactate if the initial result is > 2 mmol/L
- Guide resuscitation to normalize lactate in patients with elevated levels, which is a marker of tissue hypoperfusion²

Anaemia is common in hospitalized patients, especially among critically ill patients. With StatStrip, hospital departments can:

- Obtain real-time Hb and Hct status from a small fingerstick sample
- Monitor anaemia at-risk groups, including critically ill patients, surgical patients, cancer patients, and others

Pre-Hospital and Emergency Triage

StatStrip LAC/Hb/Hct provides real-time, accurate results when every second counts:

- Rapid evaluation of anaemia (due to chronic illness, injury or other blood loss); dehydration
- Rapid evaluation of signs of infection and sepsis; abdominal pain; internal injury; trauma

Prenatal and OB/GYN

In prenatal care, nearly 42% of pregnant women experience anaemia. If left untreated, anaemia can become severe, which increases risk of premature birth and low birthweight for the baby.^{3,4} StatStrip helps clinicians:

- Prevent and monitor anaemia in pregnant women
- Adjust treatment including nutrition and supplements
- Measure cord or scalp lactate for detecting or ruling-out fetal distress during labor and delivery

Blood Bank

StatStrip provides the accuracy needed to safely and effectively screen blood donors and avoid false deferrals:

- Accurate over the entire measurement range of 6.5-22 g/dL Hb and 20s-65% Hct
- Portable for use in mobile or temporary blood collection locations

Dialysis

Anaemia is a common co-morbidity in patients undergoing dialysis. Maintaining individual and facility level Hb/Hct guidelines is associated with increased survival rates and reduced hospitalization in this population.^{5,6} StatStrip point of care testing:

- Helps maintain patients in clinically appropriate ranges
- Provides quantitative data for anaemia, EPO and iron therapy decisions



Oncology

Chemotherapy-induced anaemia (CIA) affects approximately 83% of cancer patients.⁷ StatStrip provides real time Hb/Hct status needed to proactively identify high risk patients for CIA and provide timely treatment.



Specifications



StatStrip® LAC/Hb/Hct Meter

Weight:220 g (0.49 lb)
Size:147 mm x 79 mm x 30 mm
(5.8 in x 3.1 in x 1.18 in)

Data Storage:

Patient Tests:..... 1,000 tests
QC Tests:.....200 tests
Users:..... 8,000 users

Connectivity:

Meter Docking Station:..... RJ-45 Ethernet Port
Protocol:TCP/IP Ethernet 10/100 Mbit
Standard:..... POCT1-A Compliant

Battery Information:

Type:3.7V Li Polymer
Rechargeable Battery

Operating Ranges:

Temperature:.....1°C-40°C (34°F-104°F)
Altitude:Up to 4,572 m (15,000 ft)
Humidity:10%-90% relative humidity

Barcode Laser Warning:



StatStrip Xpress® 2 LAC/Hb/Hct

Weight:78.5 g (2.77 oz)
Size:98.0 mm x 61.0 mm x 22.9 mm
(3.9 in x 2.4 in x 0.9 in)

Data Storage:

Patient & QC Tests:.....400 tests total (FIFO)

Battery Information:

Type: 2 AAA batteries
Features:Replaceable
Life:Minimum 600 tests

Operating Ranges:

Temperature:.....1°C-40°C (34°F-104°F)
Altitude:Up to 4,572 m (15,000 ft)
Humidity:10%-90% relative humidity

Additional Features:

- LCD color display
- Large numeric display (30 mm)
- Traditional QC with target values assigned to QC materials
- Units of measure based on meter ordered (mg/dL or mmol/L models)
- Automatic shut-off when not in use
- Automatic sample detection and analysis
- Automatic sample counting with date/time stamp for data tracking



StatStrip Lactate Test Strips

Test Measured: Blood Lactate
Test Strip Volume: 0.6 µL
Test Methodology: Electrochemistry
Test Time:13 seconds

Sample Types:

Whole Blood: Capillary, Arterial, Venous

Measurement Range:

Lactate3-180 mg/dL
(0.3-20.0 mmol/L)



StatStrip Hb/Hct Test Strips

Test Measured:Haemoglobin & Haematocrit
Test Strip Volume: 1.6 µL
Test Methodology: Electrochemistry
Test Time:40 seconds

Sample Types:

Whole Blood: Capillary, Venous

Measurement Range:

Haemoglobin5.0-22 g/dL
(50-220 g/L) (3.1-13.7 mmol/L)
Haematocrit15-65% (0.15-0.65 L/L)

Operating Ranges and Use Life:

Temperature: 15°C-40°C
(59°F-104°F)

Altitude:Up to 4,572 m (15,000 ft)

Humidity:10%-90% relative humidity

Test Strip Use Life:24 months from date of manufacture 3 months open-vial stability

References:

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3. Mayo Clinic. Iron deficiency anaemia during pregnancy: Prevention tips. 15 Feb 2017.
4. Townsley DM. Hematologic complications of pregnancy. *Semin Hematol* 2013;50(3):222-231.
5. Hung S-C et al. Erythropoiesis-stimulating agents in chronic kidney disease: What have we learned in 25 years? *J Formos Med Assoc* 2014;113:3-10.
6. Jing Z et al. Haemoglobin targets for chronic kidney disease patients with Anaemia: A systematic review and meta-analysis. *PLoS ONE* 2012;7:e43655.
7. Hwasoon R. Chemotherapy-induced anaemia in cancer patients. *Oncolink*: 17 Jan 2012.

Certifications and Compliance:

Nova Biomedical is certified to FDA Quality System Regulations and ISO 13485:2016.

Complies to IVDD Tested According to: EN 61010-1:2010, EN 61010-2-101:2015, EN 60825-1/A1:2007

*Nova Biomedical Patent Numbers: CA2846887A1 EP2568281A1 US8603309 JP5812957 US9535053B1 US8603309B2 US9638686B1

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