

CERA-STAT™ 4000 | HbA1c · CRP

Smart Diagnostics for Point-of-Care!

Fast · Reliable · Cost-Effective



Features

- 3.5" Full Color Touch Screen
- Voice Guide & Instruction
- Built-in Thermal Printer
- Automatic Tray loading
- USB, RS-232 interface

Specifications

| | |
|----------------------------|---------------------------------|
| Display and User Interface | Touch Screen (3.5 inch) |
| Detection Methodology | Optical Reflectance |
| Temperature Range | 10 ~ 40 °C / 50 ~ 104 °F |
| Memory | 300 Tests |
| Operation Condition | Temp.: 20~25 °C / Humi.: 15~75% |
| Dimension | 178 X 195 X 77(mm) |
| Weight | 730g (instrument only) |

Key Features of Analyzer



Touch screen
High resolution, full color LCD touch screen. Easy access to operation.



Voice Guide
Easy access with simple GUI and clear multilingual voice guide.



Patient ID / Operator ID
Retrieve Patient ID (PID) and Operation ID (OID) with key-in and bar-code scanner.



Loading
Eliminate erroneous results by simple cartridge insert on auto-loading tray.



Built-in Thermal Printer
No need to purchase printer separately.



IT Connectivity
- USB / RS-232C
- LIS Compatible
- Software Update

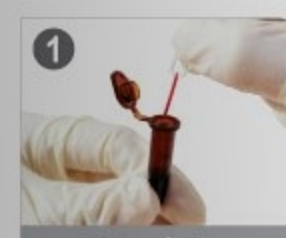


Quality Management
Easy quality control with control solution.



Pipette Guide
Easy and safe handling of samples by simple pipetting guide.

HbA1c Test Procedure



R1 Incubation
Mix well 5uL whole blood with R1 reagent and incubate for 2 minutes.



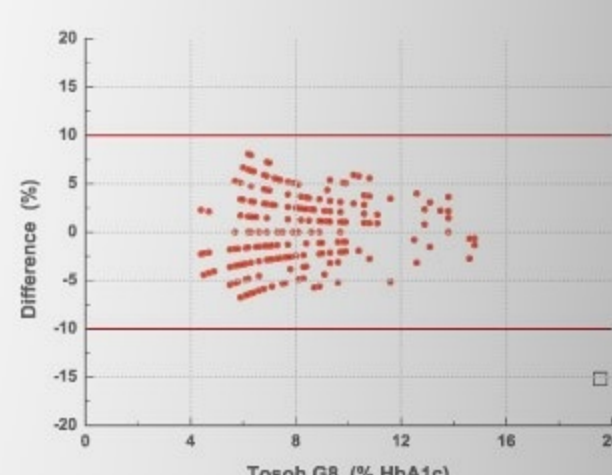
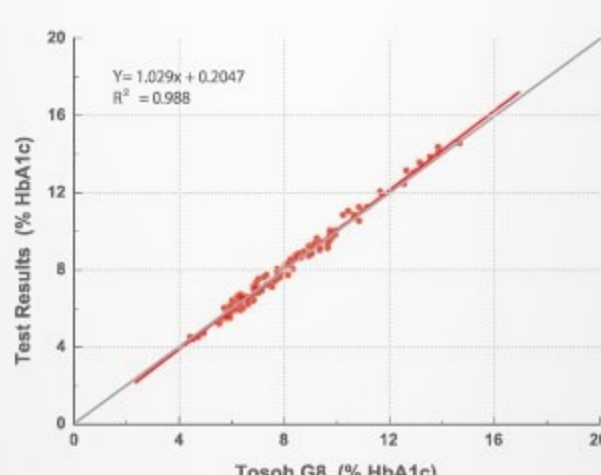
R1 mixture dropping
Apply 25uL of R1 mixture to the test device.



R2 Dropping
Apply 25uL washing solution to the Test Device (TD).



Insert the test device
Read the result within 7 seconds.



CRP Test Procedure



Sample Dilution
Mix well 5uL blood with R1 reagent.



R1 mixture dropping
Apply 25uL of R1 mixture to the test device.



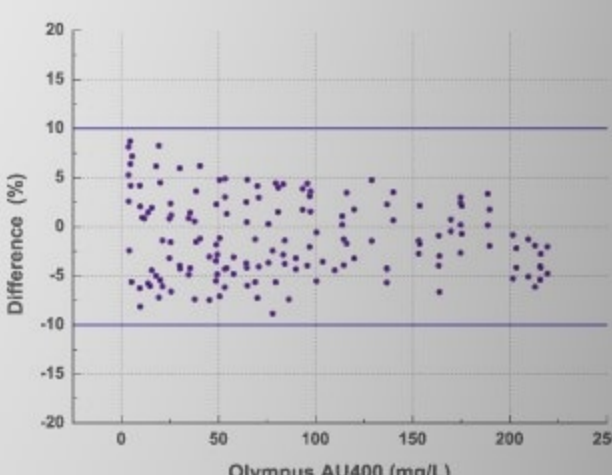
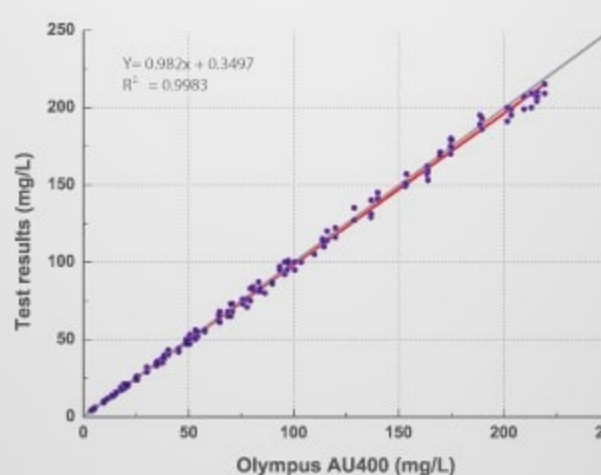
R2 Dropping
Apply 25uL of R2 reagent to the test device.



R3 Dropping
Apply 1 drop of R3 reagent to the test device.



Insert the test device
Read the result in 10 seconds.



Certificate

Certificate

Traceability of Manufacturers to the IFCC Reference Measurement Procedure for HbA1c

This certifies that **GREEN CROSS MEDIS Corp.**, using **CERA-STAT 4000 Analyzer and Merilyzer MeriCheck Analyzer**, participates in the Monitoring Programme to demonstrate traceability. In the Monitoring Programme of 2014 the following performance was seen:

| | | |
|---|---------------------------|--------|
| Deviation from IFCC-target | at 30 mmol HbA1c/mol Hb : | 2.4 |
| | at 60 mmol HbA1c/mol Hb : | 0.4 |
| | at 90 mmol HbA1c/mol Hb : | -1.7 |
| Reproducibility, coefficient of variation | | 3.37% |
| Linearity, correlation coefficient | | 0.9948 |

Date of issue: 10 December 2014 Certification expires: 31 December 2015

Alf
IFCC Network Coordinator

Certificate of Traceability

Manufacturer Certification

This certifies that **Green Cross Medis Corp.**, using **CERA-STAT 4000, Merilyzer MeriCheck Analyzer** has participated in and successfully completed the NGSP certification for manufacturers and is traceable to the **Diabetes Control and Complications Trial Reference method**. The comparison was performed with: **University of Missouri SRL#9**

The system evaluated was:

| | |
|--------------|--|
| Instrument: | CERA-STAT 4000, Merilyzer MeriCheck Analyzer |
| Reagent Lot: | H04L091, H04L092, HC433AP9EW |

Date of Certification: February 1, 2015 Certification Expires: February 1, 2016

David Smith *Randee R. Little PhD* *Shawn Amalfi*
NGSP Steering Committee Chair NGSP Network Coordinator SRL director/supervisor