CERA-STAT™

Smart Diagnostics for Point-of-Care!

HbA1c · CRP

CERA-STAT™ 4000

- The one special multi-parameter Point-of-Care (POC) instrument that covers the constantly expanding range of applications with the highest precision.
- Designed for HbA1c and CRP measurement

녹십자 GREEN CROSS

GREEN CROSS MEDICAL SCIENCE

The high accuracy POC analyzer that delivers lab. quality results!

Fast

Results in less than 3 minutes only

Reliable

Lab. quality accuracy and precision
Certification - NGSP, IFCC, ISO

Cost-Effective

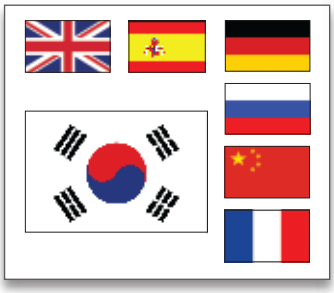
Minimum running cost

Touch screen

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

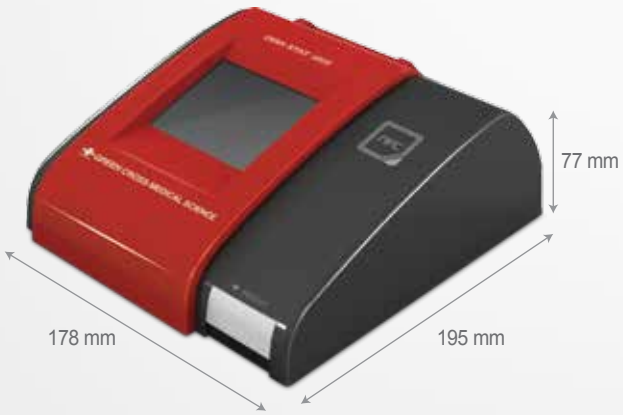
Loading

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



Voice Guide

Easy access with simple GUI and clear multilingual voice guide.



Specifications

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

▶ IT Connectivity

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

▶ Built-in Thermal Printer

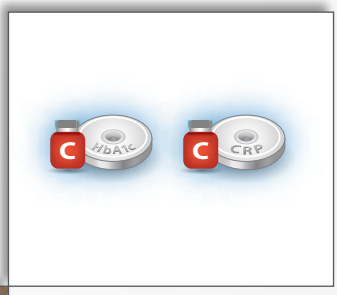
No need to purchase printer separately.

Patient ID / Operator ID ◀

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

Quality Management ◀

Easy quality control with control solution.



▶ Pipette Guide

Easy and safe handling of samples by simple pipetting guide.

CERA-STAT™ HbA1c Test Kit

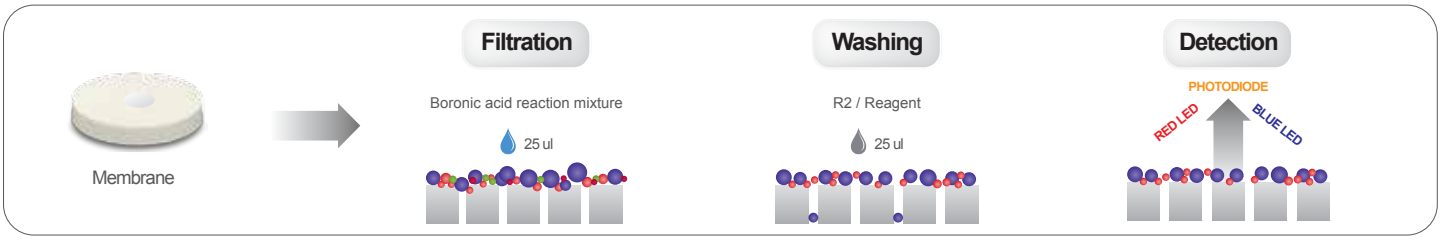
Features & Benefits

- **Gold Standard!**
  - Boronate Affinity Principle
  - HPLC (Tosoh G8) Calibrated
  - NGSP (DCCT-traceable) and IFCC certified
- **Fast & Cost-Effective!**
  - Total assay time less than 3 minutes
  - High througput - more than 50 tests/hour
  - Minimal running cost
- **Accurate & Reliable!**
  - Precision CV(%) < 3% (Guideline: < 5%)
  - More than 50 countries' market proven performance
- **Wide Measurement Range!**
  - 3 ~ 15 % (9~140mmol/mol)
  - Hematocrit compensation

Test Kit Specifications	
Principle	Boronate Affinity Chromatography
Total Assay Time	Less than 3 minutes
Test Range	3 ~ 15% (9~140 mmol/mol)
Sample Type	Whole Blood (Capillary or Venous)
Sample Volume	5㎕
Storage Condition	2 ~ 8 ℃

Test Principle

- The CERA-STAT™ HbA1c Test Kit utilizes a boronate affinity assay.



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

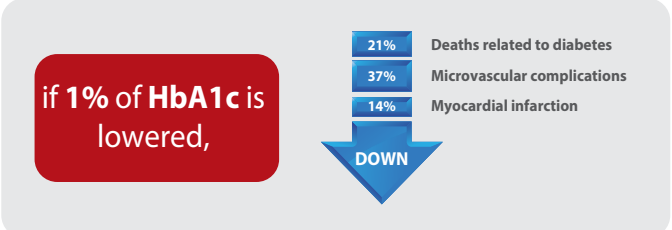
Apply 25uL washing solution to the Test Device (TD).

Insert the test device

Read the result within 7 seconds.

The Importance of HbA1c

HbA1c test is an important blood test used to determine how well the diabetes is being controlled. (Development and progression of diabetes complications, admissions to hospital, quality of life, mortality.)



CERA-STAT™ CRP Test Kit

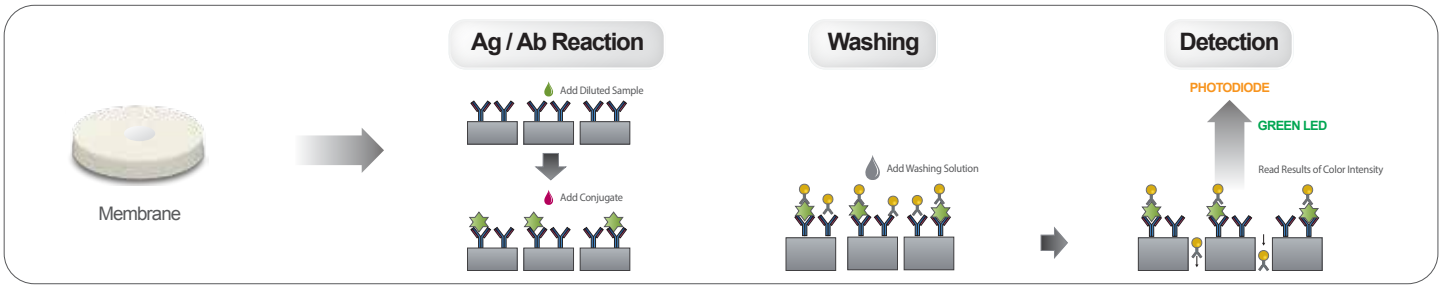
Features & Benefits

- **Lab. Instrument Calibrated!**
  - Olympus AU 400
  - Standardized against the IFCC/BRC/CAP protein reference material ERM-DA470 (CRM 470)
- **Sample Type Free!**
  - No need to select sample type
  - Whole blood / Plasma / Serum
- **Fast & Easy!**
  - Total assay time less than 1 minute
  - Immediate test result feedback
- **Cost-Effective!**
  - Implemented with HbA1c in 1 analyzer
  - Minimum running cost

Test Kit Specifications	
Principle	Immunoassay (Optical Reflectance)
Total Assay Time	Less than 1 minute
Test Range	3 ~ 220 mg/L
Sample Type	Whole blood, Serum, Plasma
Sample Volume	5㎕
Storage Condition	2 ~ 8 ℃

Test Principle

- The CERA-STAT™ CRP Test Kit is based on an immunoassy (membrane flow-through method).



Test Procedure

Sampale 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 the test device.

R3 Dropping

Apply 1 drop of R3 reagent the test tevice.

Insert the test device

Read the result in 10 seconds.

The Importance of CRP

As elevated CRP levels are always associated with photological change, the CRP assay provides information for the diagnosis, therapy and monitoring of inflammatory disease.

Importantly from a diagnostic point of view, high readings are usually seen in bacterial infection, but only low to moderate levels in viral. CRP levels reflect inflammatory activity during treatment, remission and recurrence of the disease. With follow-up CRP Testing, the course of the illness and the efficacy of any antibiotic can therefore be monitored.

Diagnosis Using CRP

CRP

lower than 10 mg/L
Men : < 5.2 mg/L
Women : < 4.6 mg/L

- **10 ~ 40mg/L** — Late pregnant women, mild inflammation and viral infection
- **40 ~ 200mg/L** — Active inflammation, bacterial infection
- **> 200mg/L** — Severe bacterial infections and burns, trauma etc.

CERA-STAT™ HbA1c Test Kit

• Within-Run Precision Testing (Venous Blood)

- Each of the samples was measured 30 times per each for precision

Value	Mean HbA1c (%)	CV (%)
Normal	5.5	2.1
Intermediate	8.6	2.2
Elevated	11.3	1.8

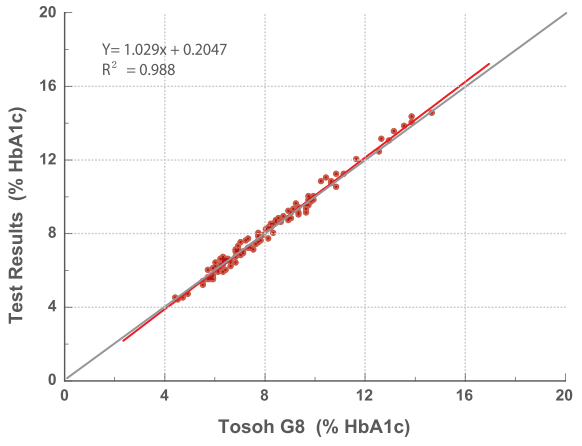
• Day-to-day Precision Testing (Control Solution)

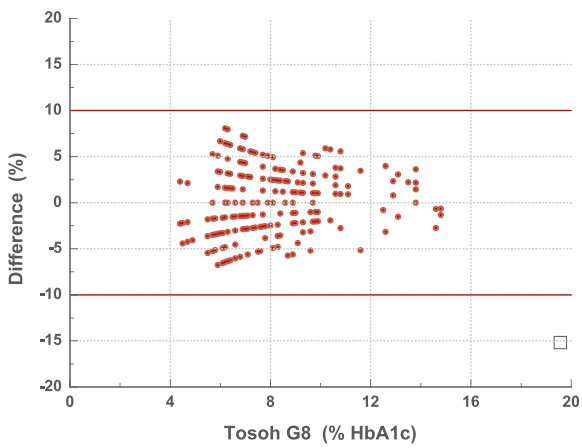
- Each sample was measured 10 times a day for 20 days using 3 meters across multiple lots.

Value	Mean HbA1c (%)	CV (%)
Normal	5.5	2.4
Intermediate	8.5	2.1
Elevated	11.5	2.2

• Accuracy

- The CERA-STAT™ 4000 system was evaluated at three clinical sites from 120 patients.
- The results show high accuracy and excellent correlation.





CERA-STAT™ CRP Test Kit

• Within-Run Precision Testing (Venous Blood)

- Each of the samples was measured 30 times per each for precision

Value	Mean CRP (%)	CV (%)
Normal	9.5	5.4
Intermediate	50.1	4.9
Elevated	99.7	3.6

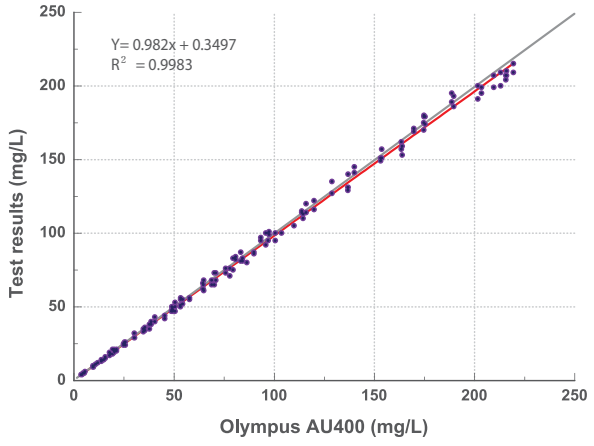
• Day-to-day Precision Testing (Control Solution)

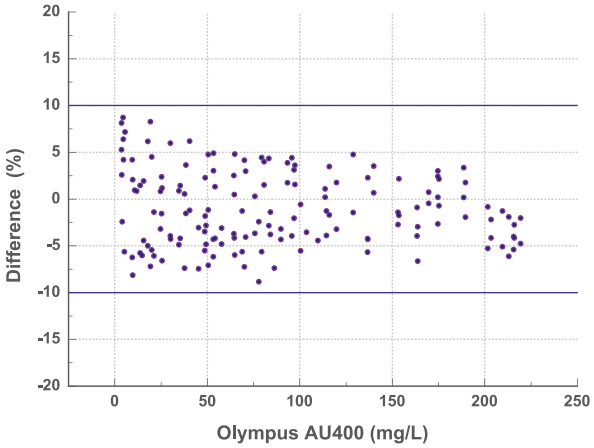
- Each sample was measured 10 times a day for 20 days using 3 meters across multiple lots.

Value	Mean CRP (%)	CV (%)
Normal	9.7	5.9
Intermediate	50.3	4.8
Elevated	98.8	5.1

• Accuracy

- The CERA-STAT™ 4000 system was evaluated at three clinical sites from 86 patients.
- The results show high accuracy and excellent correlation.





Cost Effective • Reliable • Accurate

CERA-STAT™ 4000

- The one special multi-parameter Point-of-Care (POC) instrument that covers the constantly expanding range of applications with the highest precision.
- Designed for HbA1c and CRP measurement.

Upcoming Parameters

• U-Albumin

U-Albumin test is used to to detect early kidney disease in those with diabetes or other risk factors, such as high blood pressure (hypertension).

Specification	Contents
• Principle : immunoassay(Optical Reflectance) • Total assay Time : Less than 3minute • Test range : 5~200mg/L • Sample Type : urine of human • Sample volume : 25ul • Storage Condition : 2~8℃	• 24 tubes R1 reagent • 24 units Test device • 1 vial R2 reagent • 1 vial R3 reagent

• D-Dimer

D-Dimer tests are used to help rule out the presence of an inappropriate blood clot (thrombus). Some of the conditions that the D-dimer test is used to help rule out include Deep vein thrombosis (DVT), Pulmonary embolism (PE) and Stroke.

Specification	Contents
• Principle: immunoassay(optical reflectance) • Total assay time: less than 3minute • Test range: 100~2000ng/ml • Sample type: plasma, serum • Sample volume: 25ul • Storage condition: 2~8℃	• 24 tubes R1 reagent • 24 units Test device • 1 vial R2 reagent • 1 vial R3 reagent

CERA-STAT™ 4000

▶ CERA-STAT™ 4000 Analyzer

Product Name	Contents
CERA-STAT™4000 Analyzer	1 analyzer 1 power adaptor 1 printer paper roll 1 user manual

▶ CERA-STAT™ HbA1c Test Kit

Product Name	Contents
CERA-STAT™ HbA1c Test Kit	32 tubes R1 reagent 30 units Test Device 1 vial R2 reagent

▶ CERA-STAT™ CRP Test Kit

Product Name	Contents
CERA-STAT™ CRP Test Kit	32 tubes R1 reagent 30 units Test Device 1 vial R2 reagent 1 vial R3 reagent

▶ CERA-STAT™ 4000 Control solution

Product Name	Contents
CERA-STAT™ HbA1c Control Solution	2 levels x 0.5 ml/box
CERA-STAT™ CRP Control Solution	2 levels x 0.5 ml/box

▶ CERA-STAT™ 4000 Accessories and Spare parts

Product Name	Contents
Pipette	1ea (25 uL)
Capillary Tube	1 vial (200 pcs, 5uL)
Capillary Tube Holder	1 ea
Pipette Tip	1 box (96 tips)
Printer Paper	1 roll
Lancet	1 box (200 pcs)
Lancing Device	1 ea
Pipetting Guide	3 ea

녹십자 GREEN CROSS

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