



# CERA-STAT™ 4000

SMART DIAGNOSTICS FOR  
POINT OF CARE!

HbA1c · CRP



# CERA-STAT™ HbA1c Test Kit

## FEATURES & BENEFITS



### • Gold Standard!

- Boronate Affinity Principle
- HPLC (Tosoh G7) Calibrated
- NGSP (DCCT-traceable) and IFCC certified



### • Fast & Cost-Effective!

- Total assay time less than 3 minutes
- High throughput - more than 50 tests/hour
- Minimal running cost



### • Accurate & Reliable!

- More than 50 countries' market proven performance



### • Wide Measurement Range!

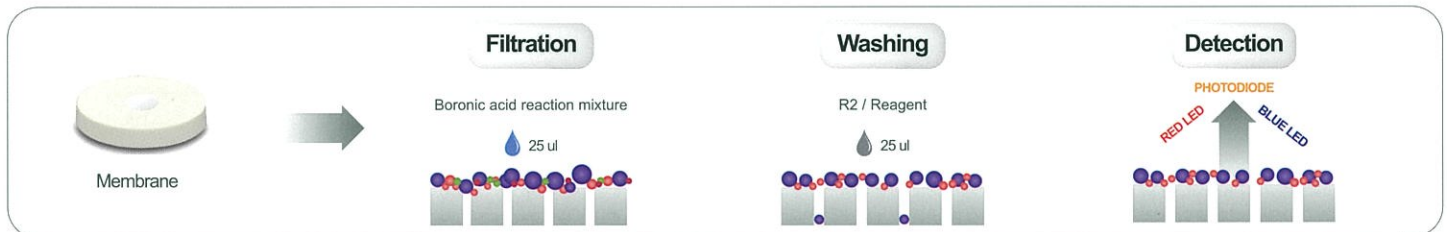
- 3 ~ 15 % (9~140mmol/mol)
- Hematocrit compensation



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 $\mu$ l
Storage Condition	2 ~ 8 °C

## 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.



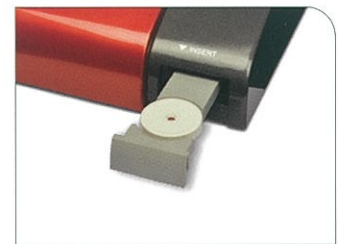
**R1 mixture dropping**

Apply 25uL of R1 mixture to the test device.



**R2 Dropping**

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



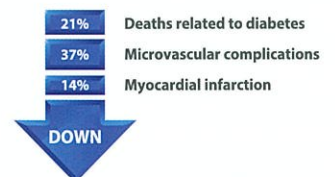
**Insert the test device**

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.)

if 1% of HbA1c is lowered,





# CERA-STAT™ CRP Test Kit

## FEATURES & BENEFITS



- **Lab. Instrument Calibrated!**  
- Olympus AU 400



- **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



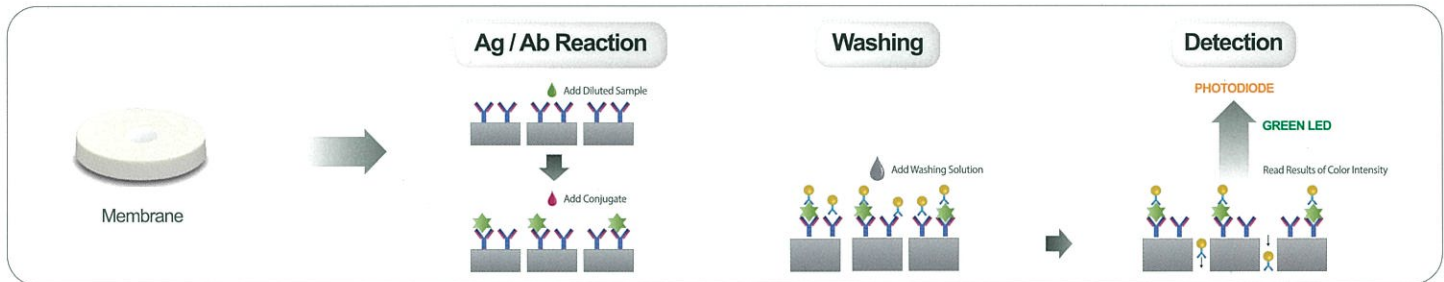
- **Cost-Effective!**  
- Implemented with HbA1c in 1 analyzer  
- Minimum running cost



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 $\mu$ l
Storage Condition	2 ~ 8 °C

## TEST PRINCIPLE

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

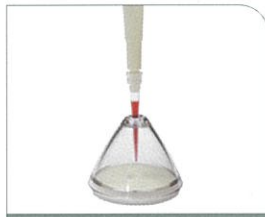


## TEST PROCEDURE



**Sample Dilution**

Mix well 5 $\mu$ L blood with R1 reagent.



**R1 mixture dropping**

Apply 25 $\mu$ L of R1 mixture to the test device.



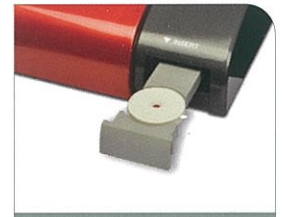
**R2 Dropping**

Apply 25 $\mu$ L of R2 reagent the test device.



**R3 Dropping**

Apply 1 drop of R3 reagent the test device.



**Insert the test device**

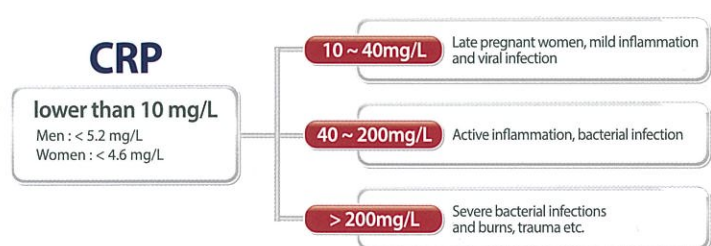
Read the result in 10 seconds.

## The Importance of CRP

As elevated CRP levels are always associated with pathological 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



## 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	2.6
Intermediate	8.6	2.5
Elevated	11.7	2.1

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

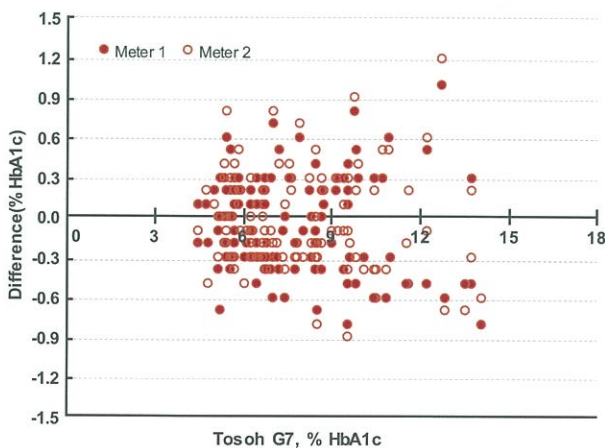
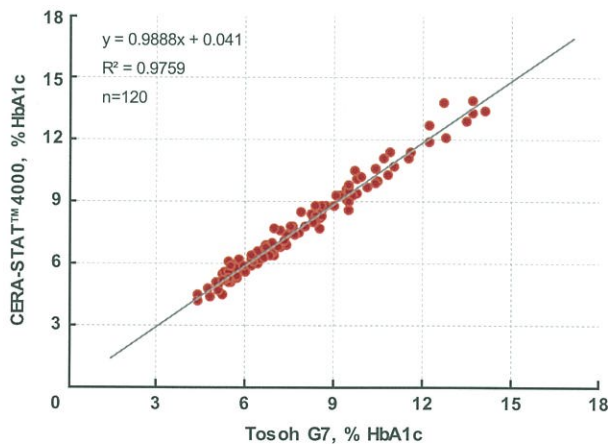
- Each sample was measured 10 times a day for 20 days using 3 meters across multiple lots.

Value	Mean HbA1c (%)	CV (%)
Normal	5.5	2.8
Intermediate	8.5	2.3
Elevated	11.5	2.6

### • 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)

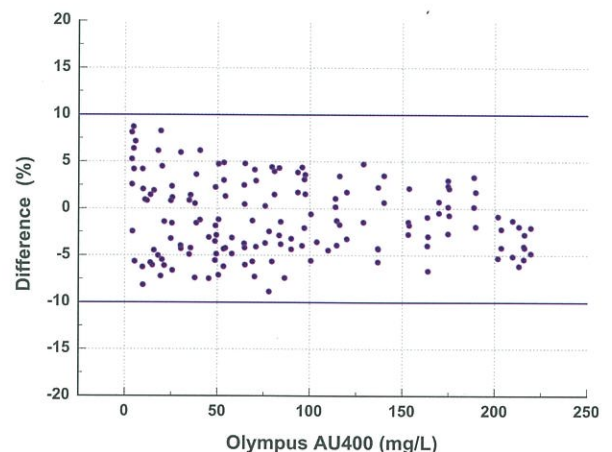
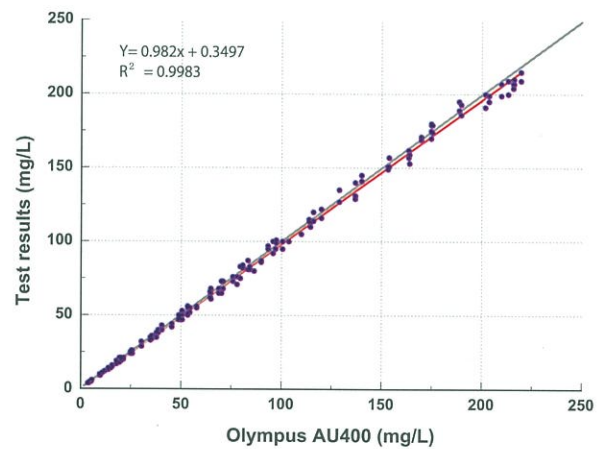
- Each sample was measured 10 times a day for 20 days using 3 meters across multiple lots.

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.





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

## Fast

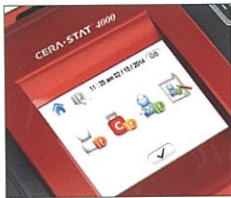
Results in less than 3 minutes only

## Reliable

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

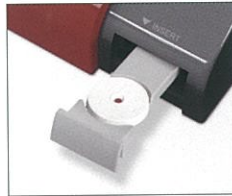
## Cost-Effective

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.



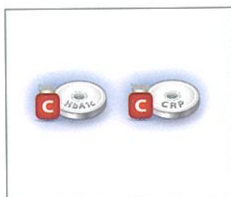
### IT CONNECTIVITY

USB / RS-232C  
LIS Compatible  
Software Update



## 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.: 15~35°C / Humi.: 15~75%
Dimension	178 X 195 X 77(mm)
Weight	730g (instrument only)



### QUALITY MANAGEMENT

Easy quality control with control solution.



### 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.



### PIPETTE GUIDE

Easy and safe handling of samples by simple pipetting guide.



# CERA-STAT™ 4000

Smart Diagnostics for Point of Care!

## 1

### CERA-STAT™ 4000 Analyzer

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

## 2

### CERA-STAT™ 4000 Control solution

Product Name	Contents
CERA-STAT™ HbA1c Control Solution	2 levels x 1.5 ml/box
CERA-STAT™ CRP Control Solution	2 levels x 1.0 ml/box

## 3

### CERA-STAT™ HbA1c Test Kit

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

## 4

### CERA-STAT™ CRP Test Kit

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

## 5

### CERA-STAT™ 4000 Accessories and Spare parts

Product Name	Contents
Pipette	1 ea (25 uL)
Capillary Tube	1 Pack (30 pc, 5uL)
Pipette Tip	1 Pack (1000 pcs)
Printer Paper	1 roll
Lancet	1 box (200 pcs)
Lancing Device	1 ea
Pipetting Guide	3 ea



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