



**CLARITY DIAGNOSTICS  
PRODUCT LINE**



- ✓ Economically Priced
- ✓ FDA EUA Approved, CLIA Waived And POCT Approved
- ✓ Relative Sensitivity 87.5%
- ✓ Relative Specificity >98.9%
- ✓ Test Naso-Pharyngeal Swab  
(immediately or store at room temperature and test within 1 hour)
- ✓ Naso-Pharyngeal Swab stored in dry tube  
(at 2-8 degrees C can be tested within 24 hours)
- ✓ Fast & Easy  
(positive results as fast as 5 minutes)



**Product Code: CLA-COV19AG-VIS**

## Clarity's COVIBLOCK Antibody Test



- ✓ Positive Results in under 10 minutes
- ✓ Usable with Whole Blood, Plasma, or Serum
- ✓ Tests for two types of antibodies: IgG and IgM
- ✓ No special equipment necessary for use
- ✓ No special storage or transportation conditions required



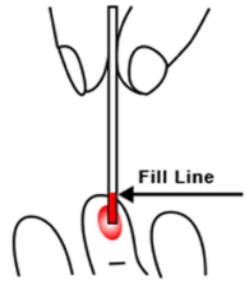
Product Code: CD-COV19

93.3% Sensitivity

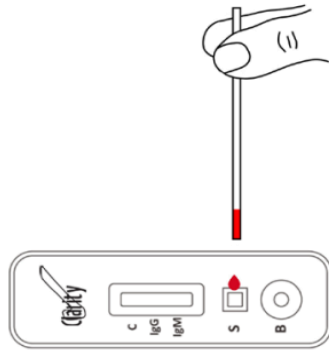
98.8% Specificity

95% Accuracy

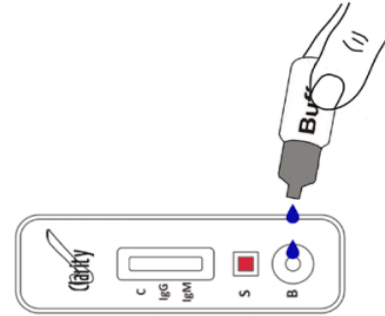
## Fingerstick Whole Blood



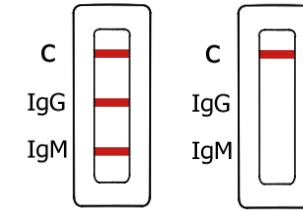
**Step 1.**  
Take 10 ul of blood from the patient



**Step 2.**  
One drop of Fingerstick Whole Blood

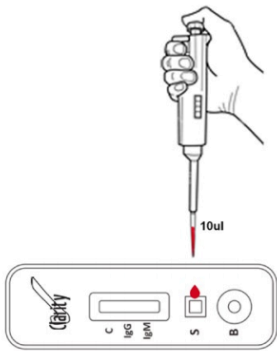


**Step 3.**  
Two drops of Buffer

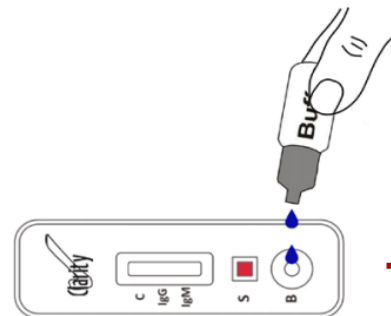


**Step 4.**  
Read Results

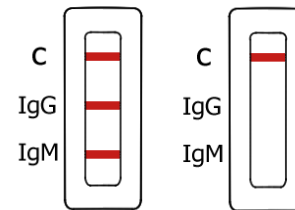
## Venous Whole Blood, Plasma or Serum



**Step 1.**  
One drop of Venous Whole Blood, Plasma, or Serum



**Step 2.**  
Two drops of Buffer



**Step 3.**  
Read Results

- ✓ 1 ml Negative and 1 ml Positive Combo (IgM + IgG) Controls
- ✓ Ready to use Liquid Controls  
No need for Freezing and Thawing
- ✓ Refrigeration Storage (2-8°C)  
Good for 6 Months after Opening
- ✓ Recombinant DNA Technology
- ✓ Proudly Manufactured in USA
- ✓ Universal Serology Test Controls  
For use with Clarity COVIBLOCK™ COVID19 IgG/IgM Rapid Test Cassettes  
and other commercially available FDA EUA approved Antibody Test Kits



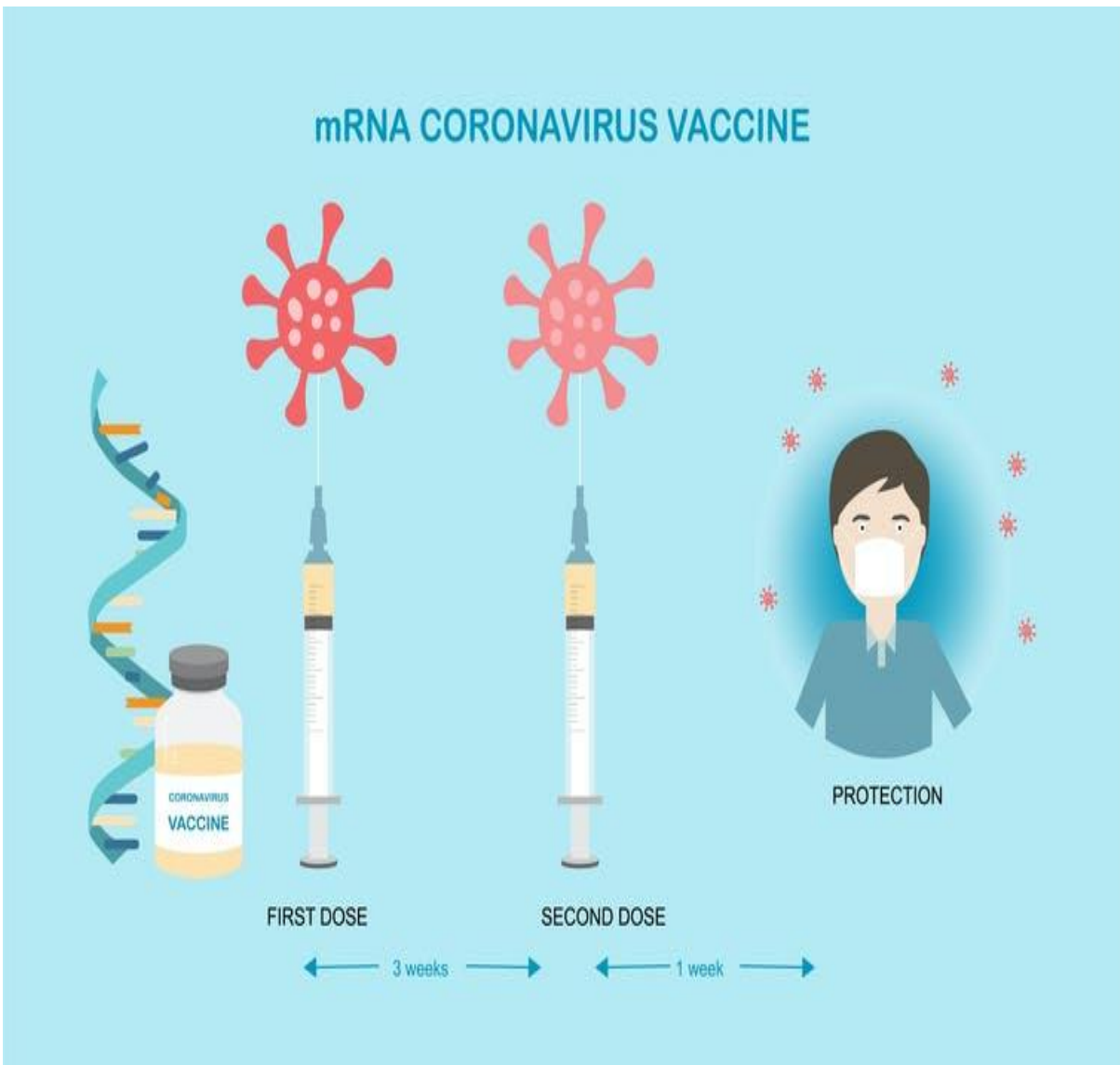
Product Code: CD-COV19-GMCTL

**Pre-test before vaccination recommended: Think of antibody tests for post-vaccination as a companion diagnostic**

"Any validation study should include a test of the individual prior to vaccination, which will go toward demonstrating the test is not subject to a problematic level of false negatives. The validation study should depict the number of days that typically elapse before the vaccine generates a sufficient level of antibodies to confer immunity."

**Tim Stenzel, FDA's Office of In Vitro Diagnostics and Radiological Health (OIR) 2/10/2021 FDA Testing Town Hall**

<https://www.bioworld.com/articles/503467-fdas-stenzel-think-of-antibody-tests-for-post-vaccination-as-a-companion-diagnostic>



**Tests on staff to track how well COVID-19 vaccines are working**

"A Department of Health and Social Care official said: "Taking antibody tests at regular intervals allows researchers to monitor antibody waning to determine the length of vaccinated immunity."

This requires the appropriate test to monitor antibody levels for the first several months after vaccinations, coupled with using different types of tests to give a better understanding of the long-term protection offered by the vaccine."

**The United Kingdom Department of Health and Social care 1/13/2021**

<https://www.hsj.co.uk/patient-safety/revealed-tests-on-staff-to-track-how-well-covid-vaccines-are-working-/7029294.article>



## Clarity Urocheck Urine Analyzer







- ✓ Performs up to 120 tests per hour
- ✓ 2000 test internal memory
- ✓ Automatic calibration and self-check
- ✓ FDA Cleared and CLIA Waived
- ✓ JCAHO Compliant: Hardware lockout if QC fails
- ✓ Flags for abnormal results

**Product Code: CLA-120C**



# URINE ANALYZER COMPETITIVE ANALYSIS

Parameter	Bayer Clinitek 50	Bayer Clinitek Status	Roche Urisys 1100	Clarity Urocheck 120C
Analyzer Image				
Tests per hour/Throughput	50 Tests /Hour	50 Tests/Hour	50 Tests/Hour	<b>120 Tests / hour</b>
Technology	Reflectance Photometer	Reflectance Photometer	Reflectance Photometer	Reflectance Photometer
Auto Feeder Paper	No	No	Yes	<b>Yes</b>
Flagging of positive results	Yes	Yes	Yes	Yes
Bar Code reader	Yes (Optional)	Yes (Optional)	Yes (Optional)	Yes (Optional)
PC connectivity	Yes	Yes	Yes	Yes
Thermal printer paper roll with sticky labels	No	No	No	<b>Yes- Easy peel-off Label style</b>
Auto calibration for every test	Yes	Yes	No	Yes
Preprogrammed Multiple Prints of the same patient report	No	No	No	<b>Yes- Ability to program for 1 Copy/2 Copies/3 Copies</b>
Results Memory	100 Results	950 Results	100 Results	<b>2000 Results</b>
LCD Display	Small	Large	Small	<b>Large</b>
Strip options	2 options	5 options	3 options	<b>6 options: 2GP / 4OB / 5OB / URO7 / 10SG /CD- MAC25</b>
Accessories supplied with the Analyzer	1 Thermal Paper roll 1 Strip tray	1 Thermal Paper roll 1 Strip tray	1 Thermal Paper roll 1 Strip tray	<b>2 Thermal Paper rolls 2 Strip trays</b>
Strip tray configuration	Requires 1 Strip Tray	Requires 1 Strip Tray	Requires 2 Strip Trays	Requires 1 Strip Tray

## CLARITY Urine Liquid Controls for Semiquantitative (Dipstick) Assay

- Product Code: CD-UCTL30.
- For use with **CLARITY** Urinalysis Strips and all **CLARITY** Urine Analyzers **ONLY**.
- Values for all analytes, including Creatinine and Microalbumin are provided.
- Available in convenient 3 x 10 mL Positive 3 x 10mL Negative box.
- 2 Year shelf life.
- Easy dispensing dropper bottles.
- Ready to use liquid reagents.
- Economically priced.



## CLARITY Urine/hCG Liquid Controls for Semi quantitative (Dipstick) Assay





- Product Code(s): DTG-UHCTLS & DTG-UHCONTROL.
- For use with **CLARITY** Urocheck 10SG, Multistix<sup>®</sup> and Chemstrips<sup>®\*</sup> for both visual and automated readers.
- Can also be used for qualitative results in rapid early detection. HCG (pregnancy tests).
- Values for Analytes, including Creatinine and Microalbumin are provided for the Siemens Multistix Pro<sup>®</sup>, Clinitek Microalbumin<sup>®</sup> and Chemstrips<sup>®</sup> Micral Microalbumin.
- Available in 2 convenient pack sizes of 1 x 15 ml and 3 x 15 ml.
- 2 Year shelf life.
- Easy dispensing dropper bottles.
- Ready to use liquid reagents.



\*Chemstrip is a registered trademark of Roche Point of Care Diagnostics

\*Chek-Stix is a registered trademark of Siemens Healthcare Diagnostics, Inc.

# CLARITY URINE/HCG CONTROLS COMPETITIVE ANALYSIS

Parameter	Clarity Urine Liquid Controls	Clarity hCG/Urine Liquid Controls	Bayer Check-Stix® - Positive/Negative Control Strips	The Dropper Urine Dipstick Control
				
Packing	3 x 10 mL 2 level set Economically priced	1 x 15 ml-2 level Set – Most Economical and best pack size available in the market 3 x 15 ml-2 level Set	1 x 25- 2 Level set	4 x 25 ml-2 Level set
Format	Liquid stable –Ready to use	Liquid stable –Ready to use	Not ready to use- Requires mixing and preparation	Liquid stable –Ready to use
Stability	24 Months from the date of manufacture- opened or unopened at 2-8°C	24 Months from the date of manufacture- opened or unopened at 2-8°C	18 Months from the date of manufacture Stability of just 8 hours after reconstitution	18 Months from the date of manufacture- opened or unopened at 2-8°C
Test for hCG	No	Yes	No	Yes

**CLARITY** Strep A Strips *in pouch*

- Product Code: CD-STP25
- Kit includes strips, swabs, extraction tubes, extraction reagents, positive and negative controls.
- Sensitivity 95%.
- Specificity 98.4%.
- Results within five minutes or less.
- CLIA waived.
- Room temperature storage.

**CLARITY** Strep A Strips *in vial*

- Product Codes: CD-STP25V, CD-STP50V
- Kit includes 25 or 50 strips respectively, swabs, extraction tubes, extraction reagent, Positive and Negative controls.
- 95% overall accuracy in Rare and 1+ colonies vs. Culture (Gold Standard).
- Specificity of 99%.
- Results within five minutes or less.
- CLIA waived.
- 18 months dating.
- Room temperature storage.

# STREP A COMPETITIVE ANALYSIS



Parameter	Clarity Strep A Test Kit	Quidel Dipstick Strep A test
Product Image		
Format	Easy to use Test Strips	Easy to use Test Strips
Pack Size	<b>25 &amp; 50 Tests</b>	50 Tests
Sensitivity	<b>96%</b>	92%
Specificity	<b>99 %</b>	98%
Shelf life	18 Months	18 Months

Product Code:  
DTG-MONO



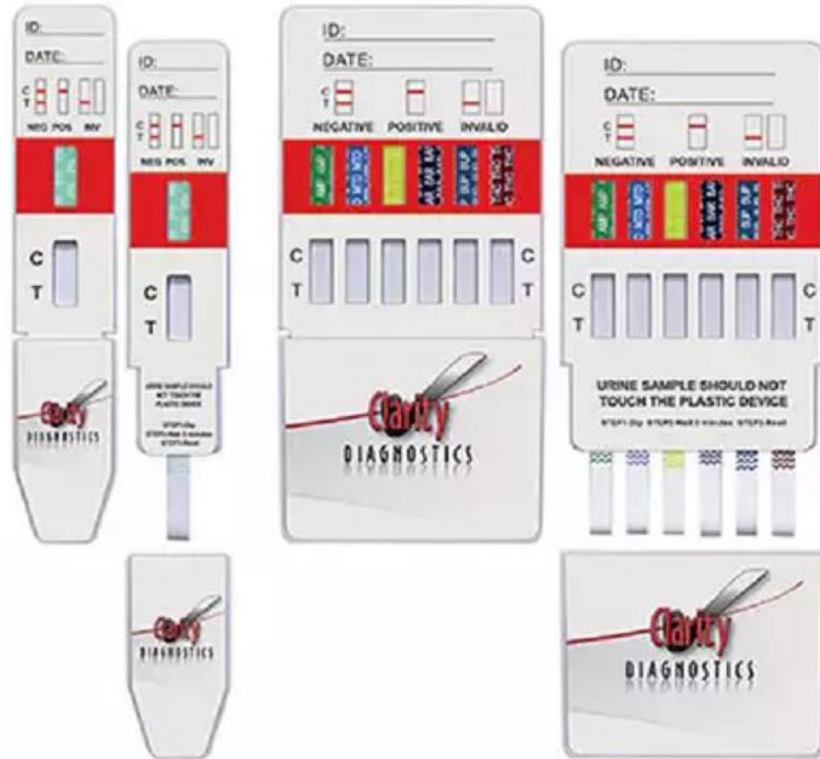
### CLARITY Mononucleosis Rapid Test

- Product Code: DTG-MONO
- Sensitivity  $\geq$  99%.
- Specificity 98.6%.
- 99% Overall accuracy.
- Fast & easy, results in 5 minutes.
- Room temperature storage.
- Pre-vacuumized, pre-calibrated pipettes.
- Everything you need to run 15 tests.
- CLIA Waived for Whole Blood.
- Approved for use on Adolescents (18 and under).
- Comparable to the Genzyme OSOM Mono Test Kit.

Parameter	Clarity Mono Test Kit	Sekisui OSOM Mono Test Kit
Product Image		
Format	Easy to use Test Cassettes	Test strips
Pack Size	15 Tests	25 Tests
Ease of Use	Easy to use Pre-Calibrated and Pre-Vacuumized disposable plastic Pipettes	Difficult and cumbersome glass capillaries with rubber bulb
Sensitivity	99%	100%
Specificity	98.6%	99%
Shelf life	16 Months	12 Months
FDA approval for use on Adolescents (18 and Under)	Yes	Yes

## Clarity Drugs of Abuse Urine Test Panels

- ✓ Easy-to-use test panels
- ✓ CLIA Waived and CLIA Moderate custom configurations available
- ✓ Room Temperature Storage
- ✓ 24 Month Dating
- ✓ 25 tests per box for all options
- ✓ Test for: AMP, BAR, BUP, BZD, COC and many more



Product Codes:

CD-DOA-154, CD-DOA-254,  
CD-DOA-1104, CD-DOA-1115  
CD-DOA-6125

## Clarity Drugs of Abuse Urine Test Cups

- ✓ Integrated drug panel and testing cup in one
- ✓ CLIA waived and CLIA Moderate custom configurations available
- ✓ Simple one-step procedure
- ✓ Automatic split- with no urine contamination
- ✓ Screw lid for no leak cup
- ✓ Test for: AMP, BAR, BUP, BZD, COC and many more



### Product Codes:

CD-CDOA-4104

CD-CDOA-7115

CD-CDOA-7125

CD-CDOA-6124

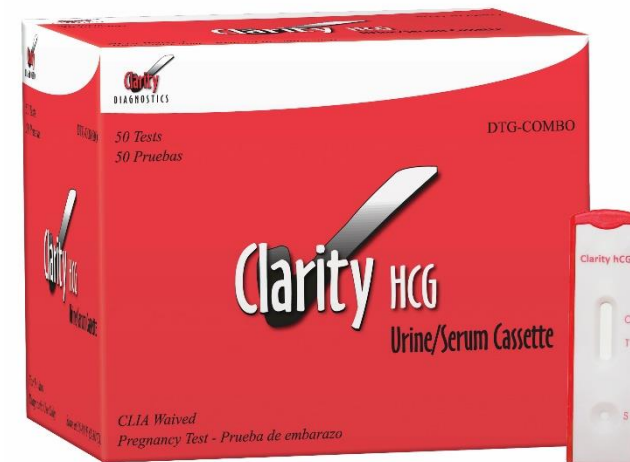
CD-CDOA-6125





### CLARITY hCG/Pregnancy Strips

- Product Codes: DTG-HCG25, DTG-HCG50, DTG-HCG100.
- Sensitivity 25 mIU/ml.
- Specificity 100% - No cross reaction with FSH/LH/TSH.
- 99% Overall accuracy.
- Available in boxes of 25, 50 & 100.
- Urine Dipstick - Dip & Read.
- CLIA Waived.
- Room temperature storage.



### CLARITY hCG Combo Cassettes

- Product Codes: DTG-COMBO
- Urine/Serum cassette.
- Three drops of sample.
- Built in quality control.
- Sensitivity 20 mIU/ml, 10 mIU/ml serum
- Specificity 100% - No cross reaction with FSH/TSH/LH.
- 99% Overall accuracy.
- Box of 50 cassettes.
- 24 Month dating.
- Flexibility in use—combo cassette can be used with urine or serum.
- CLIA waived for urine samples.
- CLIA moderate for serum samples.





### CLARITY hCG/Pregnancy Cassettes

- Product Codes: DTG-PLUS25, DTG-HCGPLUS50.
- Urine cassette.
- Three drops of sample.
- Room temperature storage.
- Built in quality control.
- Sensitivity 25 mIU/ml.
- Specificity 100% - No cross reaction with FSH/TSH/LH.
- 99% overall accuracy.
- Boxes of 25 & 50 cassettes available.
- CLIA Waived.

### Clarity Immuno Fecal Occult Blood Test Kit

Product Code:  
DTG-FOB01

Parameter	<b>Clarity IFOBT Rapid Test Cassette</b>	Hemocult® Sensa®
Product Image		
Format	<b>Easy to use Test Cassettes</b>	Cumbersome and Messy to use Test Cards
Technology	<b>Based on the superior lateral Flow Immunochromatographic (ICT) Technology</b>	Based on the old Guaiac Methodology
Tests performed for Confirmation	<b>1 Test</b>	3 Tests
Sensitivity	<b>0.05µghHB/ml</b>	0.5µghHB/ml
Specificity	<b>100%</b>	98%
Shelf life	<b>28 Months</b>	16 Months
Diet Restrictions	<b>No</b>	Yes
Specific to Only Human Hemoglobin	<b>Yes</b>	No
External QC Reagents supplied with the kit	<b>Yes, Free of cost</b>	No



#### CLARITY IFOBT Rapid Test Cassette (FIT Test)

- Product Code: DTG-FOB01
- No food, IRON, or vitamin restrictions.
- Increased patient compliance.
- Room temperature storage.
- Includes room temperature controls.
- Greater reliability vs. traditional Guaiac tests (Higher sensitivity of 0.05 µg hHb/ml).
- CLIA Waived.
- 100% Medicare FFS Reimbursement Guarantee.
- Free Tubes for any unreturned Samples (No Lost Revenue).



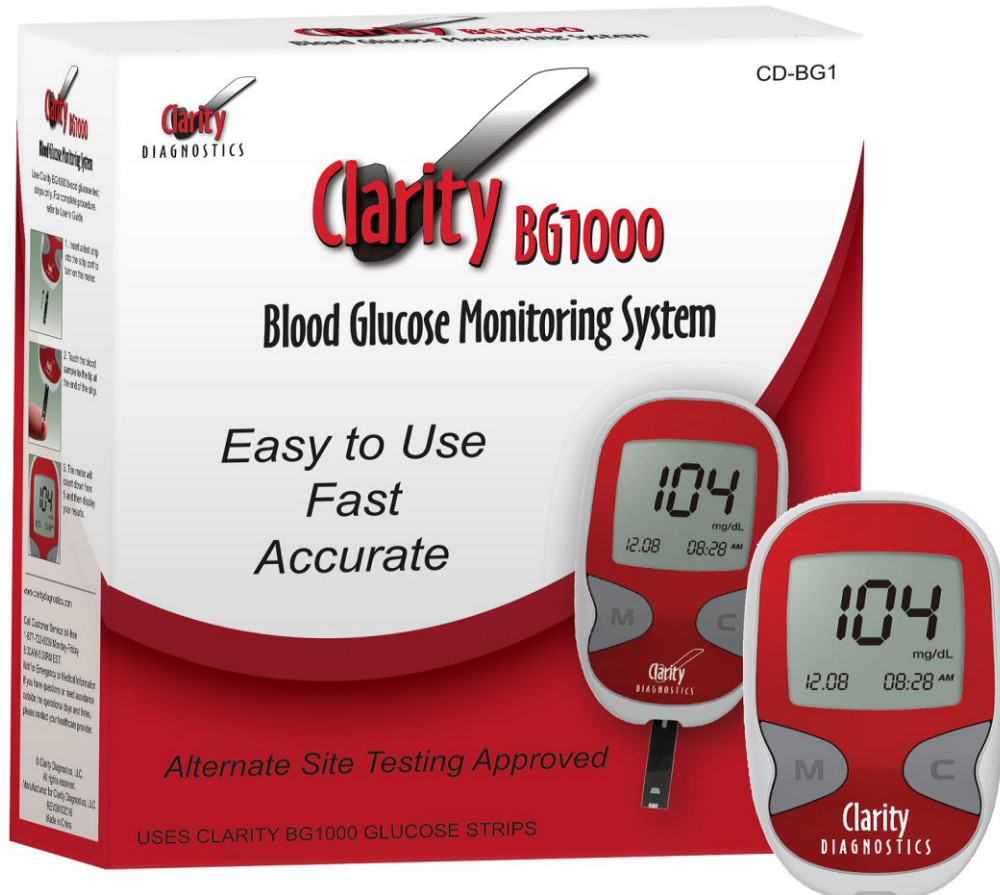
## Clarity Hemoglobin System

- ✓ Easy-to-use - Large Visual Display
- ✓ Fast and accurate - Results in just 15 seconds
- ✓ Small 10ul sample size
- ✓ Minimal Maintenance
- ✓ 90 days open vial stability of test cartridge
- ✓ For testing hemoglobin and calculated hematocrit in blood

Product Codes:

CLA-HB2, CLA-HBPROMO1, CLA-HBS50

## Clarity BG1000 Blood Glucose Monitoring System



- ✓ Meter for single and multi-patient use
- ✓ No Coding
- ✓ OTC Approved, AST Approved, and ISO 15197 Compliant
- ✓ 300 Test memory
- ✓ Use with Capillary Whole Blood Samples
- ✓ Electrochemical Biosensor Technology

Product Codes:

CD-BG1,  
CD-BG4,  
CD-BG5