



Clarity Diagnostics  
33 SE 8<sup>th</sup> St  
Boca Raton, Florida 33432  
877-722-6339 Customer Service  
877-485-7877 Tech Support

[www.claritydiagnostics.com](http://www.claritydiagnostics.com)  
[www.nextpap.com](http://www.nextpap.com)  
[sales@claritydiagnostics.com](mailto:sales@claritydiagnostics.com)  
[techsupport@claritydiagnostics.com](mailto:techsupport@claritydiagnostics.com)

### Corporate Description:

Diagnostic Test Group (D.B.A. Clarity Diagnostics) manufactures, markets & sells its own proprietary line of point of care rapid diagnostic tests and related medical devices for the Alternate Care, Acute Care, and Continuum of Care markets. Our number one priority is to provide our customers with the highest quality product at a fair price. DTG believes that this is accomplished through integrity, honesty and superb customer service. The **CLARITY** brand is equal or better than any named brand in the market with the exception of price. Expect to save money without compromise! Most **CLARITY** products are made here in the U.S.A. Thank you for giving us the opportunity to serve you and your patients!

### Products:

**Clarity** Urocheck 120 Urine Analyzer / **Clarity** LabLink / **Clarity** Urine Strips and Controls / **Clarity** HCG Strips, Cassettes and Combo Cassettes / **Clarity** Mono / **Clarity** Strep A / **Clarity** H Pylori / **Clarity** FSH / **Clarity** LH / **Clarity** Immuno Fecal Occult Blood (FIT) Test / **Clarity** Glucose / **Clarity** Cholesterol / **Clarity** Lancets / **Clarity** Drugs of Abuse Cups, Panels, Cassettes and Adulteration Strips / **Clarity** Cardiac Markers / **Clarity** NextPAP™

### **CLARITY** INSTRUMENTATION

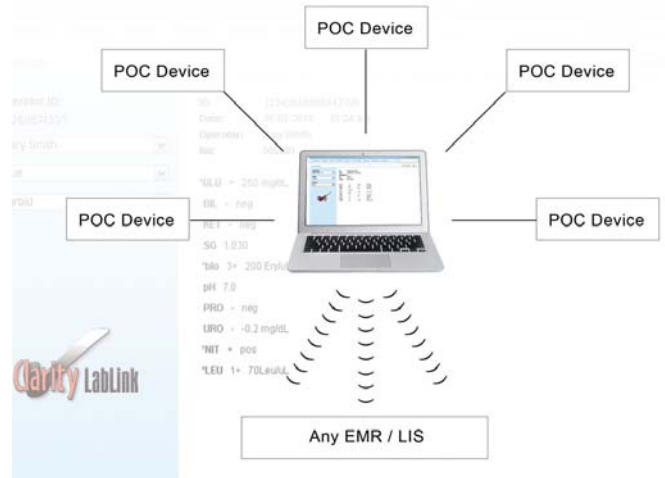
#### **CLARITY** Urocheck 120 Urine Analyzer

- CLIA Waived
- Product codes: DTG-UAM, DTG-UAPROMO and DTG-UAPROMO5
- **QC and Operator LOCKOUT**
- **Throughput of 120 tests per hour**
- **Provides automated readings for Most Clarity Urinalysis Products**
- **Compatible with ALL LIS, HIS, EMR, and EHR systems**
- **Placement program AVAILABLE**
- Auto feed mechanism for printer paper loading
- Light weight and compact-Ideal for point of care and Physicians office setup
- Accurate, Precise, Fast and Easy to use
- Large LCD Display
- Auto calibration and self check
- Flagging of abnormal patient results
- Internal Memory of last 2000 Tests
- RS 232 port or USB for connectivity
- Barcode Reader (optional)
- <http://www.claritydiagnostics.com/files/slicks/U120AnalyzerSlick.pdf>



## CLARITY LabLink Connectivity Solution

- A lab connectivity solution that provides intuitive connectivity between your EMR and the CLARITY Urocheck 120 urine Analyzer and other laboratory instruments that have HL7, unidirectional, and bi-directional data transmission capabilities
- User friendly interface and setup
- Remote management of results—anywhere internet is available
- QC tracking and auditing
- Reporting of all test results, including QC's
- Unlimited operator IDs with password protection
- HIPAA compliant
- Cost effective
- Great customer service, technical, and field support
- Increases compliance and manages accountability
- Reduces subjectivity and transcription errors (no manual result entry)
- Software Requirements: Windows XP w/ SP2 and up, .NET Framework 4 (full install), MSMQ, Microsoft Installer 2, Browser- Internet Explorer 7+ or Firefox 7+



The screenshot shows the Clarity LabLink web interface. At the top left is the Clarity LabLink logo. On the top right, there is a dropdown menu for 'Altamonte Family Clinic', a user name 'Bill Morris', and a 'Logout' link. Below the logo is a navigation bar with tabs for 'Dashboard', 'Facilities', 'Users', 'Patients', 'Devices', 'Test Results', and 'Support'. A search bar is located on the right side of the navigation bar. The main content area is titled 'Test Results' and contains a form with the following fields:

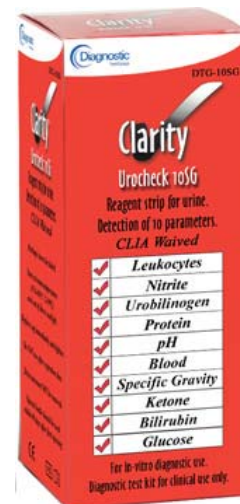
- Operator ID:** 00069874537
- Operator:** Mary Smith (dropdown menu)
- Color:** Yellow, Orange, Red, Blue, Green, Brown, Other (dropdown menu)
- ID:** 12345688966542398
- Date:** 01-01-2010 01:04 am
- Operator:** Mary Smith
- No:** 000001
- \*GLU + 250 mg/dL**
- \*BIL - neg**
- \*KET - neg**
- \*SG 1.030**
- \*blo 3+ 200 Ery/uL**
- pH 7.0**
- \*PRO - neg**
- \*URO - -0.2 mg/dL**
- \*NIT + pos**
- \*LEU 1+ 70Leu/uL**

At the bottom of the form, there are buttons for 'Accept / Verify' and 'Deny'. Below the test results, it says 'Received By: Fourth Floor' and 'Serial Number: 05669784123'. At the bottom of the page, there is a footer with the text 'All Rights Reserved © 2011 Privacy Policy Terms of Use'.

## CLARITY POINT OF CARE RAPID DIAGNOSTIC TESTS AND KITS

### Clarity Urocheck Urinalysis Strips

- Product Code (s): DTG-10SG, DTG-URO7, DTG-5OB, DTG-4OB, DTG-2GP, DTG-KET, DTG-HEM
- Tests for Leukocytes, Nitrite, Protein, pH, Blood, Specific Gravity, Ketones, Urobilinogen, Bilirubin & Glucose in urine
- Manually dipped and read or for use on the **CLARITY** Urocheck 120 Urine Analyzer
- 18 month shelf life-100 test per bottle-CLIA WAIVED
- CPT code 81000 Non automated with microscopy-\$4.48\*\*
- CPT code 81001 Automated with microscopy-\$4.48\*\*
- CPT code 81002 Non automated without microscopy-\$3.62\*\*
- CPT code 81003 Automated without microscopy-\$3.18\*\*
- Comparable to Siemens Multistix® 10SG and can be read visually, on the **CLARITY** Urocheck 120 Urine Analyzer and the Clinitek® 50/100/200/500 & Status\*\*\*
- **Strip in same reading order as the Multistix® 10SG**
- **Also available in 2, 4, 5, & 7 parameters, and Ketone only**
- <http://www.claritydiagnostics.com/files/slicks/U120AnalyzerSlick.pdf>
- [http://www.claritydiagnostics.com/files/inserts/10SG\\_insert.pdf](http://www.claritydiagnostics.com/files/inserts/10SG_insert.pdf)



\*When used on the Clinitek® device product becomes moderately complex

\*\* Based on the April 2012 Clinical Laboratory fee Schedule. Diagnostic Test Group makes no claims on reimbursement-contact your local carrier for exact rates-This disclaimer is for all reimbursement rates.

\*\*\* Multistix® and Clinitek® are registered trademarks of Siemens Healthcare Diagnostics, Inc.

	DTG-10SG	DTG-URO7	DTG-5OB	DTG-4OB	DTG-2GP	DTG-KET	DTG-HEM
Leukocytes	X	X	X	X			
Nitrite	X	X	X				
Urobilinogen	X						
Protein	X	X	X	X	X		
pH	X	X					
Blood	X	X	X	X			X
Ketone	X	X				X	
Specific Gravity	X						
Bilirubin	X						
Glucose	X	X	X	X	X		




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

- Product Code(s): DTG-UHCTLS & DTG-UHCONTROL
- For use with **CLARITY** Urocheck 10SG, Multistix® and Chemstrips®\* 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 Micro Albumin are provided for the Siemens Multistix Pro®, Clinitek Micro Albumin® and Chemstrips® Micral Micro Albumin
- 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**
- <http://www.claritydiagnostics.com/files/slicks/UHcontrolSlick.pdf>



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

## **CLARITY Urine/HCG Controls Competitive Analysis**

Parameter	<b>Clarity Urine/HCG Liquid controls</b>	<b>Bayer Chek-Stix ®- Positive/Negative control strips</b>	<b>The Dropper Urine Dipstick Control strips</b>
			
<b>Packing</b>	<b>1 x 15 ml-2 level Set –Most Economical and best pack size available in the market</b> 3 x 15 ml-2 level Set	1 x 25- 2 Level set	4 x 25 ml-2 Level set
<b>Format</b>	<b>Liquid stable –Ready to use</b>	<b>Not ready to use-</b> Requires mixing and preparation	Liquid stable –Ready to use
<b>Stability</b>	<b>24 Months from the date of manufacture-opened or unopened at 2-8°C</b>	18 Months from the date of manufacture <b>Stability of just 8 hours after reconstitution</b>	18 Months from the date of manufacture-opened or unopened at 2-8°C
<b>Tests for HCG</b>	<b>Yes</b>	<b>No</b>	Yes

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

### **CLARITY HCG/Pregnancy Strips**

- Product Code(s): DTG-HCG25, DTG-HCG50, DTG-HCG100
- Specificity 20 mIU/ml
- Sensitivity 100% - No cross reaction with FSH/LH/TSH
- 99% overall accuracy
- Available in boxes of 25, 50 & 100
- Urine dipstick—dip & read
- 18 month shelf life
- CPT Code 81025-\$8.96\*\*
- CLIA Waived
- Results as fast as 30 seconds
- <http://www.claritydiagnostics.com/files/slicks/HCGPregnancySlick.pdf>
- <http://www.claritydiagnostics.com/files/inserts/hCGStrip%20insert.pdf>



### **CLARITY HCG/Pregnancy Cassettes**

- Product Code(s): DTG-HCGPLUS25, DTG-HCGPLUS50
- Urine cassette
- Provides results in as fast as 30 seconds
- Specificity 20 mIU/ml
- Sensitivity 100% - No cross reaction with FSH/TSH/LH
- 99% overall accuracy
- Boxes of 25 & 50 available
- 18 month shelf life
- CPT Code 81025-\$8.96\*\*
- CLIA Waived
- <http://www.claritydiagnostics.com/files/slicks/HCGPregnancySlick.pdf>
- <http://www.claritydiagnostics.com/files/inserts/hCGCassette%20insert.pdf>



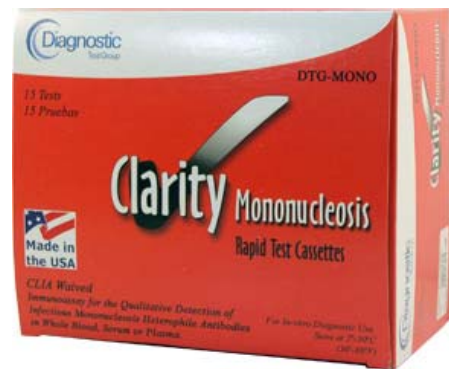
## CLARITY HCG Combo Cassettes

- Product Code(s): DTG-COMBO
- Specificity 25 mIU/ml.
- Sensitivity 100% - No cross reaction with FSH/TSH/LH
- 99% overall accuracy
- Box of 50
- 18 month shelf life
- Flexibility in sample use—combo cassette can be used with urine or serum
- CLIA waived for urine samples
- CLIA moderate for serum samples
- CPT Code 81025-\$8.96\*\*
- CPT Code 84703 for serum-\$10.64\*\*
- <http://www.claritydiagnostics.com/files/slicks/HCGPregnancySlick.pdf>
- <http://www.claritydiagnostics.com/files/inserts/hCGCombo%20insert.pdf>



## CLARITY Mononucleosis Rapid Test

- Product Code (s): DTG-MONO
- Sensitivity = 99%
- Specificity =98.6%
- 99% overall accuracy
- Results in 5 minutes
- 18 month dating
- Complete kit with Pre-Vacuumized & Pre-Calibrated pipettes
- Compact packaging with everything you need to run 15 tests
- CLIA Waived for Whole Blood
- **Approved for use on Adolescents (18 and under)**
- CPT Code 86308QW \$7.33\*\*
- **Comparable to the Genzyme OSOM Mono Test Kit**
- <http://www.claritydiagnostics.com/files/slicks/MonoSlick.pdf>
- <http://www.claritydiagnostics.com/files/inserts/Mono%20insert.pdf>



## CLARITY Strep A Strips

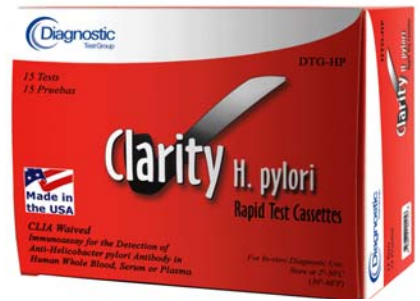
- Product Code (s): DTG-STP25; DTG-STP50
- Kit includes 25 or 50 strips respectively, swabs, extraction tubes, extraction reagent, Positive and Negative controls.
- 95% overall accuracy in Rare and 1+ colonies vs. Culture (Gold Standard).
- Specificity of 99%
- Easy to read results within five minutes or less.
- CLIA waived with 24 month dating from Manufacturing
- Room Temperature storage
- CPT Code 87880QW \$16.99\*\*
- 25 or 50 test kits available for Strep Strips
- Flip cassettes available DTG-STPFLIP Box 25
- <http://www.claritydiagnostics.com/files/slicks/StrepSlick.pdf>
- <http://www.claritydiagnostics.com/files/inserts/Strep%20insert.pdf>



\*\*Based on the April 2012 Clinical Laboratory fee Schedule. Diagnostic Test Group makes no claims on reimbursement-contact your local carrier for exact rates-This disclaimer is for all reimbursement rates.

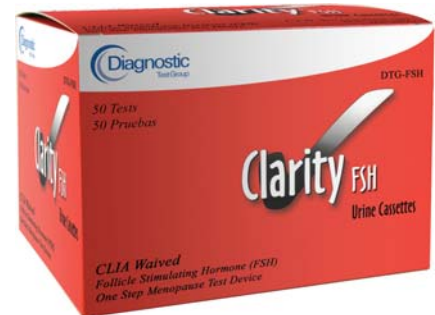
## CLARITY H Pylori Test Cassettes

- Product Code: DTG-HP
- Kit includes 15 test cassettes reagent, package insert, and external controls
- **Sensitivity > 89%**
- **Specificity > 89%**
- **Easy to read results within five minutes or less.**
- CLIA waived with 24 month dating from Manufacturing
- Room Temperature storage
- CPT Code 86318QW \$18.34\*\*
- <http://www.claritydiagnostics.com/files/slicks/HpyloriSlick.pdf>



## CLARITY FSH Test Cassettes

- Product Code: DTG-FSH
- Fast, Simple and Easy—only requires three (3) drops of urine
- **Sensitivity 100%**
- **Specificity 25 µg/ML**
- **Easy to read results within five minutes or less**
- CLIA waived with 24 month dating from Manufacturing
- Room Temperature storage/Box 50 test cassettes
- CPT Code 83001QW \$26.32\*\*
- <http://www.claritydiagnostics.com/files/slicks/FSHSlick.pdf>
- <http://www.claritydiagnostics.com/files/inserts/FSH%20insert.pdf>



## CLARITY LH Test Cassettes

- Product Code: DTG-LH
- **Sensitivity 100%**
- **Specificity 20 µg/ML**
- **Easy to read results within four to seven minutes**
- CLIA waived with 24 month dating from Manufacturing
- Room Temperature storage
- Box=50 test cassettes
- Fast, Simple and Easy—only requires four (4) drops of urine
- CPT Code 83002QW \$26.23\*\*

## CLARITY IFOBT Rapid Test Cassette (FIT Test)

- Product Code (s): DTG-FOB1
- No food or vitamin restrictions
- Increased patient compliance
- Detects human hemoglobin only
- Includes room temperature controls
- Greater reliability vs. traditional Guaiac tests (Higher sensitivity of 0.05 µg hHb/ml)
- CLIA Waived
- Higher reimbursement:
  - A. G0328QW-\$22.53 (Colorectal Screening)\*\*
  - B. 82274QW-\$22.53 (All other ICD-9 indicators)\*\*
- 100% Medicare FFS Reimbursement Guarantee
- Free Tubes for any unreturned Samples (No Lost Revenue)
- <http://www.claritydiagnostics.com/files/slicks/IFOBSlick.pdf>
- [http://www.claritydiagnostics.com/files/inserts/DTG\\_FOB-01\\_Package\\_Insert.pdf](http://www.claritydiagnostics.com/files/inserts/DTG_FOB-01_Package_Insert.pdf)



## CLARITY Plus Glucose Monitoring System

- Product Code (s): DTG-GL2PLUS, DTG-GL5PLUS
- **Based on latest Amperometric Biosensor Technology**
- Detects Blood Sugar (glucose) levels accurately and quickly
- NO Interference with Xylose, Maltose or Galactose
- Glucose Oxidase technology
- Small sample size (1.0µL)
- 300 test memory with Large reading range (20-600mg/dl)
- 5 year warranty with FREE Meter Placement Program
- Starter pack contains: 10 Sample Strips & Code Chip, 10 Lancets, Lancing Device, Normal Control Solution, all in an easy to carry case
- CLIA Waived and OTC approved
- ISO 15197 compliant
- CPT code 82948-\$4.48\*\*
- **Comparable to Roche Accu-Chek® and One Touch Ultra®**



## CLARITY Advanced Glucose Monitoring System

- Product Code (s): DTG-BGA1, DTG-BGA5, DTG-BGAB100
- **Based on latest Amperometric Biosensor Technology**
- Detects Blood Sugar (glucose) levels accurately and quickly—results in 6 seconds
- NO Interference with Xylose, Maltose or Galactose
- Glucose Oxidase technology
- Small sample size (10.7 µl)
- ISO15197 compliant
- 250 test memory
- 5 year warranty
- Starter kit contains: 5 test strips, 1 lancing device, 5 lancets, 1 battery, logbook, user's manual, quick start guide, and carrying case)
- CLIA Waived and OTC approved
- CPT code 82948- \$4.48\*\*
- <http://www.claritydiagnostics.com/files/slicks/GlucoseSlick.pdf>



## CLARITY // Cholesterol/Glucose Monitoring System

- Product Code (s): DTG-CHGLMETER, DTG-CHSTRIPS, DTG-GL2STRIPS
- Measures Glucose and Total Cholesterol in one easy-to-use monitor
- Measures Glucose in 15 sec and requires 2µL blood
- Measures Total Cholesterol in 30 sec and requires 10µL blood
- CPT Code 82465 for total cholesterol-\$6.16\*\*
- CPT code 82948 for Glucose-\$4.48\*\*
- All coding is internal requiring no external code chip
- Glucose Range: (50-500mg/dL)
- Cholesterol Range: (130-350mg/dL)
- Large LCD Display
- Ideal for health fairs
- High Clinical Precision and Accuracy
- Large Internal memory
- CLIA Waived and OTC approved
- **Comparable to Cardiochek® and Roche Accu-Chek Instant Plus Glucose/Cholesterol Meter**
- <http://www.claritydiagnostics.com/files/slicks/CholesterolSlick.pdf>
- [http://www.claritydiagnostics.com/files/inserts/Clarity\\_2\\_GC\\_Manual.pdf](http://www.claritydiagnostics.com/files/inserts/Clarity_2_GC_Manual.pdf)



## CLARITY Safety and Twist Top Lancets

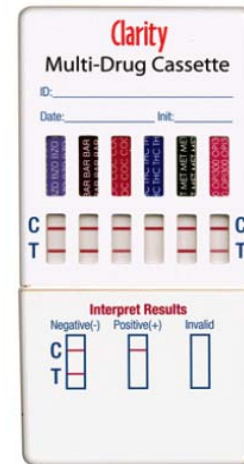
- Product Code (s): DTG-SL23100, DTG-SL23200, DTG-GL7
- Easy to use, Small and Lightweight
- Key safety features to prevent accidental finger sticks
- 23 Gauge (2.3mm depth), Box 100 or 200
- Inexpensive (opportunity to save money)
- Custom Configurations available
- <http://www.claritydiagnostics.com/files/slicks/SafetyLancetSlick.pdf>



## CLARITY DRUGS OF ABUSE TESTS

### CLARITY Drugs of Abuse Test Panel

- Product Code(s): DTG-DOA5P, DTG-DOA10P, DTG-DOA12P, and additional codes
- Standard panel Tests for Cocaine, Amphetamines, Methamphetamines, Marijuana, Methadone, Opiates, PCP, Barbiturates, Benzodiazepines, MDMA, Oxycodone, and Tricyclic Antidepressants in urine
- Easy to use test panels- 25 Tests per box
- CPT Code G0434QW \$20.60 per panel\*\*
- CLIA Waived & CLIA Moderate configurations available
- With Adulteration parameter- Adulteration kit included and detects variance in pH, Specific Gravity, and Oxidants for error proof testing
- <http://www.claritydiagnostics.com/files/slicks/DOASlick.pdf>



### CLARITY Drugs of Abuse 5 & 10 Drug Test Drug Cup

- Product Code: DTG-DOA5CP, DTG-DOA10CP, DTG-DOA12P, and additional codes
- Standard cup Tests for Cocaine, Amphetamines, Methamphetamines, Marijuana, Methadone, Opiates, PCP, Barbiturates, Benzodiazepines, MDMA, Oxycodone, and Tricyclic Antidepressants in urine
- Integrates drug panel and testing cup in one
- Easy-to-use tamper proof test cup with key activation
- 25 tests per kit with 18 Month Shelf-Life
- CPT code G0434QW-\$ 20.60 per cup\*\*
- CLIA Waived
- CUSTOMIZATION AVAILABLE
- (With Adulteration parameter) Adulteration kit included and detects variance in pH, Specific Gravity, and Oxidants
- <http://www.claritydiagnostics.com/files/slicks/DOASlick.pdf>



### CLARITY Drugs of Abuse Cassettes

- Individual test cassettes
- Single drug tests for AMP, BAR, BUP, BZD, COC, MAMP, MDMA, MTD, OPI, OXY, PCP, PPX, TCA, and THC
- Easy-to-use—three drops of urine and read
- 25 tests per kit with 18 Month Shelf-Life
- CPT code G0434QW \$20.60\*\* per Cassette
- <http://www.claritydiagnostics.com/files/slicks/DOASlick.pdf>



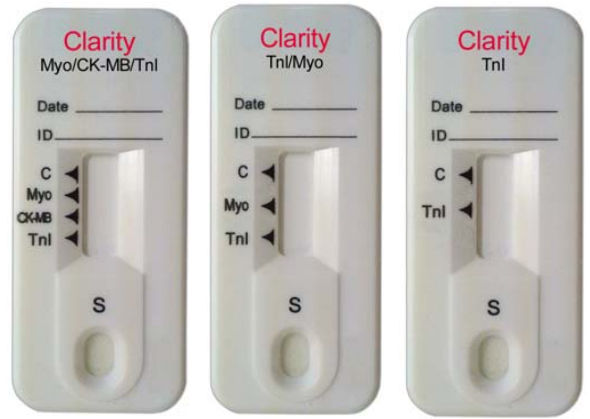


**CLIA MODERATE- CLARITY RAPID TEST KITS**

**CLARITY Cardiac Markers**

**CLARITY Rapid Cardiac Panels**

- Product Code (s): DTG-TRO; DTG-MYOTRO; DTG-CKMYOTRO
- 20 tests per box
- 15 month dating
- CLIA Moderate for Whole Blood, Plasma, or Serum
- **Results in 15 minutes**
- **Price Competitive**
- CPT code(s): (qualitative) per test\*\*  
Troponin I: CPT 84512 \$ 10.91  
Myoglobin,: CPT 83874 \$ 18.29  
CK-MB: CPT 82553 \$ 16.35



- **Comparable to the Triage® Profiler Shortness of Breath Panel (S.O.B) & Triage® Cardiac Panel\***
- <http://www.claritydiagnostics.com/files/slicks/RapidCardiacPanelsSlick.pdf>

\*Triage® is a registered trademark of Biosite an Inverness Medical Company

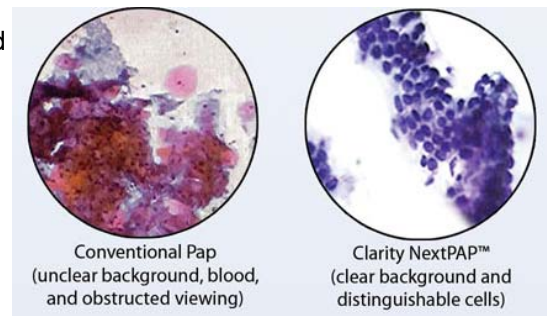
\*\*Based on the April 2012 Clinical Laboratory fee Schedule. Diagnostic Test Group makes no claims on reimbursement-contact your local carrier for exact rates-This disclaimer is for all reimbursement rates.

**OTHER PRODUCTS - CLARITY WOMEN'S HEALTH**



**CLARITY NextPAP™**

- **“The Next Generation of Pap testing with benefits of Liquid based cytology”**
- 55% more Sensitive than Conventional Pap.
- User friendly.
- Supplied in a kit format which provides standardization of each component (contains cell preservative vials, all reagents- CellPREP, Orange OG-6, EA-50, Hematoxylin, Rovers® Cervex-Brush® Combi brushes, Liquid Cover Slip, glass slides, product insert, and quick start guide)
- Most advanced cervical cell sampler—Rovers® Cervex-Brush® Combi (only one brush required; simultaneously collects both Endocervical and Ectocervical cells from patient).
- Requires only 2 rotations.
- No bleeding or inflammation reported.
- 100% cell recovery on the slide.
- Monolayer cell arrangement (no reprocessing).
- Samples can be processed up to 18 months from the date of collection.
- **Cytotech can view at least 20 slides/hour (high throughput).**
- **“Xylene Free” staining technology.**
- **3 patented technologies: Cell Preservative Vial, CellPREP Reagent, Liquid Cover Slip**



- **The cell pellet obtained using the CLARITY NextPAP™ system may be used to perform HPV and CT/NG testing**
- Product code(s): DTG-NP50 sample kit with 50 tests (everything included), DTG-NP500 kit with 500 tests (everything included)

• [www.nextpap.com](http://www.nextpap.com)

