



PROCEDURE MANUAL
Lab Name: Gates County Medical

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Procedure #:

Procedure: CLIA Complexity: WAIVED (Urine Sample)

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

Diagnostic Test Group provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

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Intended Use

The **Clarity** Urocheck U120 Urine Analyzer is intended for use in conjunction with the **Clarity** Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, and Leukocytes as well as the qualitative detection of Nitrite. The instrument is intended for professional, in vitro diagnostic use only.

The **Clarity** Urocheck 120 Urine Analyzer reads urine test strips. It stores results and prints reports without the need for special training.

The **Clarity** Urocheck 120 Urine Analyzer runs a self-test each time the power switch is turned on. An optional barcode reader records patient ID, which can be sent to a computer.

Only use **Clarity** Urinalysis Reagent Strips on the **Clarity** Urocheck 120 Urine Analyzer for proper function and accurate results. Users should read this complete test procedure before performing a test using this analyzer.

Only laboratories with a Certificate of CLIA Waiver may use this analyzer in a waived setting. Failure to adhere to these instructions for use and for performing QC testing is considered off-label use. Off-label use is categorized as high complexity and subject to all CLIA regulations.

Initial Start up

Place the analyzer on a level surface. Allow 20 cm on all sides of the analyzer for access.

Plug the power cord into a power outlet. Press the power switch (18) located on the back panel to turn the **Clarity** Urocheck 120 Urine Analyzer on. The **Clarity** Urocheck 120 Urine Analyzer will run a Self-Test and display "Optical Sensor Failed" due to lack of Strip Holder. Then the Strip Holder Mount will extend for Strip Holder installation. Turn off the Power Switch.

Remove the plastic packaging from the provided Strip Holder. Place the Strip Holder on the Strip Holder Mount with the white Calibration Circle facing up and positioned towards the analyzer. It will slide loosely in the locating channel. Push the Strip Holder in towards the analyzer until it makes a click sound and snaps into place. It will be held firmly on the Strip Holder Mount. Ensure the Strip Holder is installed properly. If it is not locked onto the Strip Holder Mount, the Calibration Circle will not be in the correct position and the analyzer will display "Optical Sensor Failed."

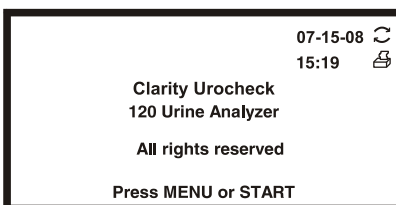




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Turn on the Power Switch, then the Self-Test will run again. If the Self-Test passes, the Initial Screen will be shown.



If the Self-Test fails, a **Failed** Screen will be displayed. The analyzer cannot be operated. Press the power switch off then on to re-test. Refer to Section 10 Troubleshooting to correct a failure.

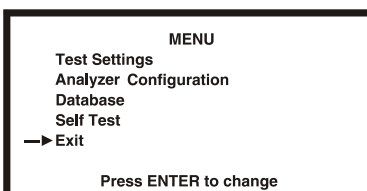
Press **MENU** to access the Test Settings, Analyzer Configuration, and Database functions and Self-Test.

Note: Use the arrow keys on the keypad to select **Exit** or press the **Cancel** key when **Exit** is not available.

Press **START** to begin strip testing.

Analyzer Setup

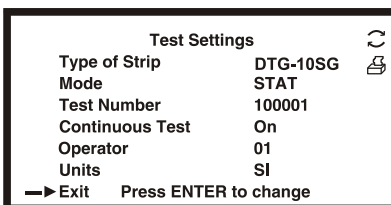
Press **Menu** from the Initial Screen to display the screen below.



Select options by pressing ▲ or ▼ until the Selection Arrow (→) is next to the option. Press **Enter** to show the options in a new screen or cycle through the settings as listed below. Select **Exit** and press **Enter** to return to the Initial Screen.

Test Settings

Selecting **Test Settings** will display the menu shown below.





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Press **▲** or **▼** until the option is selected. Press **Enter** to show the options in a new screen or cycle through the settings as listed below. Select **Exit** and press **Enter** to return to the Initial Screen.

Available settings on the **Test Settings** menu and descriptions are as follows. DTG-5OB, DTG-URO7 and DTG-10SG are examples of Type of Strips.

Type of Strip	DTG-5OB, DTG-URO7, DTG-10SG
Mode	Routine, STAT, QC
Test Number	User selected number
Continuous Test	On, Off (single test)
Operator ID	01 through 10
Units	Conventional Units or Standard International (SI)

Type of Strip

Select **Type of Strip** and press **ENTER** to change the strip type. Each strip type name defines the number of test parameters per strip.

Note: Ensure the type of strip selected corresponds with the strip to be used. If it does not an error message will be displayed.

Mode

There are three test mode options. Press **Enter** when **Mode** is selected to change the **Mode**.

Note: The Mode can be changed during normal testing for STAT tests.

Routine Test

Used for normal urine testing. The default test number ranges from 1 to 99999. It resets to 1 every day automatically if **Auto Number Reset** is set to **Yes**.

STAT Test

Used for emergency urine testing. The default test number is from 100000 to 199999. It resets to 100001 each day automatically if **Auto Number Reset** is set to **Yes**.

QC Test

Used to test Positive /Negative controls. The test number ranges from 200001 to 299999. It resets to 200001 every day automatically if **Auto Number Reset** is **Yes**.

Note: Ensure QC Test mode is used for testing positive and negative controls. Use of any other mode will cause an error.



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Continuous Test

Select **Continuous Test** and press **Enter** to cycle the settings to **off** or **on**. When the selection is correct, select **EXIT** and press **ENTER** to return to the **Main Menu**.

Continuous Test – Off (Single Test Mode)

Test one strip at a time. **Single Test** Mode performs 60 tests / hour.

Continuous Test - On

Test strips one after another. **Continuous Test** Mode performs up to 120 tests / hour. When **Continuous Test** is on, the  symbol will be displayed.

Operator ID

Select **Operator ID** and press **Enter** to increase the number by one. After **10**, it reverts back to **01**. Select **EXIT** and press **ENTER** to return to the **Main Menu**.

Units

Select **Units** and press **Enter** to cycle the units between **Conventional** or **SI** units. Select **EXIT** and press **ENTER** to return to the **Main Menu**.

Note: Arbitrary results will always be printed.

Self Test

Select **Self Test** and press **ENTER** to perform a series of self tests. A results screen will display the results of each test.

Self Test Results	
Main Control Unit	pass
Optical Sensor	pass
Test Accuracy	pass
Mechanism	fail
Excess Light	pass
Press CANCEL to exit	

After each test, a **pass** or **fail** is displayed on the screen. If any results **fail**, the unit will not operate. Refer to Section 10 Troubleshooting.

Press **CANCEL** to return to the **Main Menu** after the self tests are complete.



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Normal Operation

The Strip Holder will fully extend and the screen below will be displayed.

No. 000001DTG-10SG

Mode: Routine

Place a strip on the Holder

Press ENTER to change Mode

START to test

CANCEL to exit

Sample/Strip Preparation

Allow the strip, urine specimen, and/or controls to reach room temperature at 15-30°C (59-86°F) prior to testing.

Note: Only **Clarity** Urinalysis Reagent Strips work with the **Clarity** Urocheck 120 Urine Analyzer. Use of any other strips will cause inaccurate results.

Remove the strips from the closed canister. Use them as soon as possible. Tightly close the canister after removing the strips.

Strip Test – Single Test Mode

Press **START** when the Strip Holder is fully extended to begin the test. The following screen will be displayed. Wait for the audible triple beep to immerse the strip.

No. 000001DTG-10SG

Mode: Routine

Place a strip on the Holder

Press ENTER to change Mode

START to test

CANCEL to exit

Note: Timing is set to test a new strip every 65 seconds minimum.

Once **START** is pressed, the screen will change to the screen shown below.

No. 000001DTG-10SG

Mode: Routine

Testing . . .

Press CANCEL to exit

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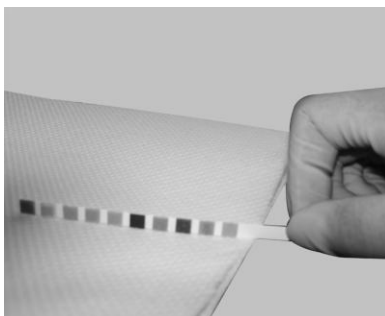
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The countdown clock is displayed on the bottom right of the screen. The clock will start to count down from **65**. The operator has 3 seconds before the triple beep sounds to immerse the strip into the urine.

Upon hearing the triple beep and/or seeing the countdown clock reach **62**, completely immerse the reagent areas of the strip in fresh, well-mixed urine. Immediately remove the strip to avoid dissolving the reagents.



Run the edge of the strip against the rim of the urine specimen container to remove excess urine. Hold the strip in a horizontal position. Bring the edge of the strip into contact with an absorbent material (e.g. a paper towel). This prevents mixing chemicals from adjacent reagent areas.



Place the strip with the reagent area facing up, onto the Strip Holder Channel. Make sure the strip end touches the Strip Holder Backstop as shown below.





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Note: When the countdown clock on the display reaches 1, the Strip Holder will carry the strip inside and begin testing.

An automatic calibration is done before each test.

The results will be displayed on the screen and stored in memory after each test. Any abnormal results will be highlighted on the screen and flagged on the print out.

If **Auto-print** is set to **on** the results will be printed. If **Auto-print** is set to **off**, press **Print** to print the results.

No. 000001	DTG-10SG	10-29-07
		15:38
ID 123456789012345		
GLU 1+	BIL 1+	KET -
SG 1.030	BLO 1+	pH 7.0
PRO 1+	URO -	NIT +
LEU -		
Press ▲▼ PRINT or CANCEL		

Remove the used strip from the Strip Holder when the strip carrier moves out. Discard the used strip according to local regulations.

Repeat the previous steps to test more urine.

Quality Control

Each lab should use its own standard and procedures for performance. Test known Positive and negative specimens/controls at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements. For obtaining accurate results, it is advised to use **Clarity** Urine/HCG liquid urine controls.

- When a new canister of strips is opened

or

- Test results seem inaccurate

or

- A new operator uses the analyzer

or

- Each new day of testing

or

- After performing maintenance or service on the analyzer



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If the QC tests do not provide expected results, perform the following checks:

- Ensure the strips used are not past their expiration date.
- Ensure strips are fresh from a new canister.
- Ensure the controls are not past their expiration date.
- Repeat the test to ensure no errors were made during the test.

If QC testing still does not provide expected results, call DTG customer service at 1-(877) 485-7877

Urine Controls QC Testing

Ensure the operating **Mode** is set to **QC**. All test numbers in QC mode will begin with **2**. This allows results to be searched for and found easily

Strip Preparation

Allow the strip and urine controls to reach room temperature at 15-30°C (59-86°F) prior to testing.

Note: Use **Clarity** Urinalysis Reagent Strips and **Clarity** Urine/HCG controls for proper functioning and accurate results.

Remove strips from the closed canister and use them as soon as possible. Close the canister tightly immediately after removing the strips.

Urine Control Test Procedures

The urine control test procedures are the same as Normal Operation, no Barcode reader, or Normal Operation, Barcode reader installed.

Compare the test results with the target values indicated in the urine control packaging insert. If there are any discrepancies, please contact Diagnostic Test Group Technical/Customer Support.

Daily Cleaning

Remove the Strip Holder

Press **Start** to fully extend the Strip Holder/Mount.

Turn off the Power Switch after the Strip Holder/Mount is fully extended.

Remove the Strip Holder from its mount by pulling out gently by the two sides as shown below.

Clean the Strip Holder

Clean the Strip Holder using a lint free/non-absorbent cotton swab/ball with distilled water. Dry with a clean, dry cotton ball.

Examine the White Calibration Circle to ensure there are no nicks or dirt present. Clean the White Calibration Circle as necessary using a cotton swab or cotton ball with distilled water. Dry with a clean, dry cotton ball.

Note: The White Calibration Circle should be replaced if any nicks or non-removable dirt are found. To replace, please contact Diagnostic Test Group Technical/Customer Support.

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Load the Strip Holder

Grasp the Strip Holder by its sides as shown below. Place the Strip Holder on the Strip Holder Mount with the white Calibration Circle facing up and positioned towards the analyzer. It will slide loosely in the locating channel. Push the Strip Holder in towards the analyzer until it makes a click sound and snaps into place. It will be held firmly on the Strip Holder Mount. Ensure the Strip Holder is installed properly. If it is not locked onto the Strip Holder Mount, the Calibration Circle will not be in the correct position and the analyzer will display “Optical Sensor Failed.”

Note: When correctly positioned, the Strip Holder will snap into and be locked in place, with the White Calibration Circle not visible. See illustration below.



Return the Strip Holder/Mount to its Internal Position

Turn the Power Switch on and wait for the Strip Holder/Mount to move inside the analyzer and stop. Turn the Power Switch off or begin testing strips.

Sample Deposit Cleaning

Remove the Strip Holder as above.

Clean the Strip Holder using lint free/non absorbent cotton swab or ball dampened with 0.1 N NaOH.

Warning: Do not allow the NaOH solution to touch the White Calibration Circle.

Clean the excess NaOH from the Strip Holder using a cloth moistened with distilled water.

Dry the Strip Holder with a clean lint free non-absorbent cotton swab or ball.

Replace the Strip Holder and return the Strip Holder/Mount it to its original position as described above.

Strip Holder Sterilization

Remove the Strip Holder and repeat Daily Cleaning above.

Clean the Strip Holder using a lint free non-absorbent cotton swab or ball with one of the following sterilizing solutions:

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1. 2% Glutaraldehyde (sufficient density): Refer to detailed instructions on the product label.
2. 0.05% Sodium Hypochlorite Solution: Add 1 mL 5% Sodium Hypochlorite into 99 mL distilled water, or prepare a 1:100 dilution ratio with appropriate final volume.
3. Isopropyl alcohol (70-80%).

Pour the sterilizing solution into a narrow vessel 10 cm (4 inches) high.

Dip the Strip Holder into the sterilizing solution

Caution: **Ensure the White Calibration Circle does not touch the solution.**

Soak the Strip Holder in the sterilizing solution for 10 minutes.

Remove the Strip Holder, clean and dry it.

Load the Strip Holder and return the Strip Holder/Mount to its original position.

Troubleshooting

Problem	Solutions
Strip Position Improper	<ul style="list-style-type: none"> Adjust the strip so the strip end is completely touching the Strip Holder Backstop and centered in the Strip Holder Channel
Strip Missing	<ul style="list-style-type: none"> Insert strip
Strip Error	<ul style="list-style-type: none"> Ensure the type of strip used matches the type of strip setting Ensure the strip brand is compatible with the analyzer Ensure all of the test pads on the strip have been immersed in the specimen Ensure the test mode selected is QC Test if a calibration strip is to be used
No display on screen	<ul style="list-style-type: none"> Turn the Power Switch on Make sure power is applied to the analyzer Examine the Fuse on the back of the analyzer to determine if it is damaged and replace if necessary
Fuse is damaged	<ul style="list-style-type: none"> Turn the Power Switch off, disconnect the plug and replace the damaged Fuse with a new 2.0A Fuse (Spare fuse is located in the fuse compartment)
Printer does not work	<ul style="list-style-type: none"> Make sure Auto-Print is set to On Refer to Printer Setup instructions Load paper if necessary and ensure Printer Setup is set for Internal when an external printer is not connected Ensure paper roll is placed correctly. If placed incorrectly, there will be no printout Clean printer with ethanol
Main Control Unit Failed	<ul style="list-style-type: none"> Turn the Power Switch off, then on and perform a Self-Test. Refer to Manual Self-Test section
Optical Sensor Failed	<ul style="list-style-type: none"> Ensure the Strip Holder is locked onto the Strip Holder Mount correctly. A click should be heard to ensure the Strip Holder is properly locked onto the Strip Holder Mount. If not, the Calibration Circle will not be in the correct position and the analyzer will display "Optical Sensor Failed." Ensure the white Calibration Circle is clean Clean the Strip Holder and refer to Daily Cleaning section

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	<ul style="list-style-type: none"> Turn the Power Switch off, then on and perform a Self-Test and refer to Manual Self-Test section
Test Accuracy Failed	<ul style="list-style-type: none"> Turn the Power Switch off, then on and perform a Self-Test and refer to Manual Self-Test section
Mechanism Failed	<ul style="list-style-type: none"> Remove any obstacles in the path of the Strip Holder Do not touch the Strip Holder when it is moving Turn the Power Switch off, then on and perform a Self-Test and refer to Manual Self-Test section
Excess Light Failed	<ul style="list-style-type: none"> Ensure the analyzer is kept away from direct light Ensure the white calibration circle is clean Ensure the Strip Holder is positioned correctly on the Strip Holder Mount and refer to Daily Cleaning section Turn the Power Switch off, then on and perform a Self-Test and refer to Manual Self-Test section

Performance Characteristics of Urinalysis Reagent Strips

The performance characteristics of the **Clarity** Urinalysis Reagent Strips have been determined in both laboratory and clinical tests. The following table indicates performance characteristics for each parameter.

Reagent	Composition	Sensitivity- Visual Reading	Sensitivity – Clarity Urocheck 120 Urine Analyzer Reading
Leukocytes (LEU)	derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients	Detects leukocytes as low as 9-15 white blood cells (Leu/ μ L) in clinical urine.	Detects leukocytes as low as 12-15 white blood cells (Leu/ μ L) in clinical urine.
Nitrite (NIT)	p-arsanilic acid; N-(1-naphthyl) ethylenediamine; non-reactive ingredients	Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.	Detects sodium nitrite as low as 0.05 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.
Urobilinogen (URO)	p-diethylaminobenzaldehyde; buffer and non-reactive ingredients	Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 μ mol/L).	Detects urobilinogen as low as 0.8-1.0 mg/dL (13.6-17 μ mol/L).
Protein (PRO)	tetrabromophenol blue; buffer and non-reactive ingredients	Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L).	Detects albumin as low as 12-15 mg/dL (0.12-0.15 g/L).
pH	methyl red sodium salt; bromthymol blue; non-reactive ingredients	Permits the quantitative differentiation of pH values within the range of 5-9.	Permits the quantitative differentiation of pH values within the range of 5-9.
Blood (BLO)	3,3',5,5'-tetramethylbenzidine (TMB); cumene hydroperoxide; buffer and non-reactive ingredients	Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/ μ L in urine specimens with ascorbic acid content of <50 mg/dL.	Detects free hemoglobin as low as 0.018-0.030 mg/dL or 5-10 Ery/ μ L in urine specimens with ascorbic acid content of <50 mg/dL.
Specific Gravity (SG)	bromthymol blue indicator; buffer and non-reactive ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide	Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ± 0.005 .	Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ± 0.005 .
Ketone (KET)	sodium nitroprusside; buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).	Detects acetoacetic acid as low as 4-5 mg/dL (0.4-0.5 mmol/L).
Bilirubin (BIL)	2, 4-dichloroaniline diazonium salt; buffer and non-reactive ingredients	Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 μ mol/L).	Detects bilirubin as low as 0.8-1.0 mg/dL (13.6-17 μ mol/L).
Glucose (GLU)	glucose oxidase; peroxidase; potassium iodide; buffer; non-reactive ingredients	Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L).	Detects glucose as low as 80-100 mg/dL (4-5 mmol/L).

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Clarity Urinalysis Reagent Strips Parameter Table

Parameter Name (Abbreviation on Display)	Arbitrary	Conventional
Leukocytes (LEU)	- ± 1+ 2+ 3+	neg 15 Leu/μL 70 Leu/μL 125 Leu/μL 500 Leu/μL
Nitrite (NIT)	- +	neg pos
Urobilinogen (URO)	- ± 1+ 2+ 3+	0.2 mg/dL 1 mg/dL 2 mg/dL 4 mg/dL 8 mg/dL
Protein (PRO)	- ± 1+ 2+ 3+	neg 15 mg/dL 30 mg/dL 100 mg/dL 300 mg/dL
pH	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0
Blood (BLO)	- ± 1+ 2+ 3+	neg 10 Ery/μL 25 Ery/μL 80 Ery/μL 200 Ery/μL
Specific Gravity (SG)	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030
Ketone (KET)	- ± 1+ 2+ 3+	neg 5 mg/dL 15 mg/dL 40 mg/dL 80 mg/dL
Bilirubin (BIL)	- 1+ 2+ 3+	neg 1 mg/dL 2 mg/dL 4 mg/dL
Glucose (GLU)	- ± 1+ 2+ 3+	neg 100 mg/dL 250 mg/dL 500 mg/dL 1000 mg/dL

Understanding the Result Print-Out

The printed results are shown below. Arbitrary units will always be printed. Either Conventional or SI unit results will also be printed depending on the units set.

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Patient ID	→	ID: 0058164578	
Date/Time	→	Date: 2008-04-19 16:54	
Operator ID	→	Operator: 01	
Test Number	→	No. 000011	
Abnormal Results	→	*GLU 1+ 250 mg/dL	←
		BIL - neg	
		KET ± 5 mg/dL	
		SG 1.030	
		BLO - neg	
Test Parameters	→	pH 5.5	
		PRO - neg	
		URO - 0.2 mg/dL	
		NIT - neg	
		LEU - neg	←

Depending on the type of strip selected, the analyzer recognizes the parameter order and automatically ranks the display and printing sequence of each parameter. Arbitrary results will always be printed automatically. Conventional or SI results will be printed based on the units selected. Abnormal results, or results of pathological significance will be marked with an *.

Arbitrary Results:

- All positive results except pH and Specific Gravity (SG) will be reported as 1+, 2+, or 3+.
- Positive results for pH and Specific Gravity (SG) will be reported with the respective data.
- Negative results for Leukocyte, Nitrite, Urobilinogen, Protein, Blood, Ketone, Bilirubin, and Glucose will be reported as “-”.

Conventional or SI:

- All positive results except Nitrite (NIT) will be reported with the respective data in front of the units. The positive results of Nitrite will be reported as “pos”
- All negative results except Urobilinogen (URO) will be reported as “neg.” The negative results of Urobilinogen (URO) will be reported with the respective data in front of the units.

IVD



Diagnostic Test Group LLC
Boca Raton, Florida
www.diagnostictestgroup.com





QUALITY CONTROL LOG FOR CLARITY UROCHECK 10SG URINANALYSIS STRIPS

Clarity Urinalysis Control Level2 Lot No: _____ Expiration Date: _____

[illegible]



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