I. PRINCIPLE:

Clinitek Atlas 1000 is a highly automated system for performing macroscopic urinalysis. Fresh urine is examined for color, clarity, specific gravity, PH, glucose, protein, blood, bilirubin, nitrites, leukocyte esterase, and ketones

II. SPECIMEN REQUIREMENTS:

Specimen requirements defined in macroscopic (general) procedure. Urines with small volumes (<2.0ml), mucoid, markedly turbid or grossly bloody must be tested manually or on the Clinitek 500.

III. REQUIRED MATERIALS:

A. Clinitek Atlas 1000 Urine Chemistry Analyzer, Siemens Healthcare Diagnostics
B. Clinitek Atlas Reagent Pak, Siemens Healthcare Diagnostics
C. Count -10 Trol I, Myers-Stevens Group, Montebello, California
D. Count -10 Trol III, Myers-Stevens Group, Montebello, California
E. Clinitek Atlas Calibrator Set, Siemens Healthcare Diagnostics
F. Distilled Water
G. 15 ml conical plastic tubes
H. Bleach
I. Clinitek Atlas Rinse Additive, Siemens Healthcare Diagnostics

IV. REAGENTS:

A. Rinse solution: Make up daily and discard old rinse solution.
2ml Clinitek Atlas Rinse Additive into 1000 ml of distilled water.
Mix and place on instrument.
Rinse the old container with distilled water and let air dry.

V. OPERATION:

A. Daily Maintenance:
1. Clean the sample wheel and handle on the carousel with a mild detergent and a damp cloth.

2. Prepare fresh diluted bleach

Na hypochlorite concentration	ml of bleach	ml of water	Final concentration
6.0%	10	1.5	5.22%
6.15%	10	1.8	5.21%
7.35%	7.5	3.0	5.25%
8.25%	7.5	4.5	5.16%

3. Clean the SG well (3 minute process): **Performed beginning of each shift.**
   a. Main Menu, press "6"
   b. Place tube of fresh diluted bleach in position 43
   c. Press "Begin".

4. Replace the rinse bottle and empty waste:
   a. open left door of instrument
   b. check volume of rinse container, discard any remaining reagent if less than ½ full.
   c. remove waste container and dump contents
   d. rinse waste container with water and discard
   e. add a small amount of bleach to empty waste container
   f. reinstall waste container
   g. install full rinse container
   h. close instrument doors

B. Daily Quality Control:

1. Verify lot numbers, expiration date and open stability valid on control bottles (Count-10 Trol I and III, stable through expiration date, open stability 5 days)
2. Order Q.C. for Atlas being used that day in Soft Total Q.C per shift. Q.C. for confirmatory tests-order MUA per shift in Soft Total Q.C.
3. Verify at least 2 ml of control in bar-coded conical urine tubes
4. Bring urine control to room temperature
5. Place tubes in any position (not 43) on instrument wheel
6. Press Analyze, then 40 tray / routine
7. Post Q.C. from Instrument menu. If out of range, repeat control, new order will be generated. If still unacceptable, do not run instrument and notify supervisor. Patient samples are not processed when Q.C. is not acceptable.

Note: any instrument unresolved qc problems must be recorded in problem log in addition to informing a supervisor.

VI. PATIENT SPECIMEN ANALYSIS:

Note: specimens with <2ml, mucoid, or grossly bloody are run on Clinitek 500 or done manually.

A. Thoroughly mix each specimen (plastic conical or preservative tube).
B. Allow any refrigerated specimens to warm to room temperature
C. Remove foam from any foamy specimens; analyze any extremely mucoid or blood urines specimens on Clinitek 500. Grossly bloody samples are spun and done manually or run on Clinitek 500.
D. Place specimens in white sample positions (1-40) in sample tray with barcodes facing outward:
E. Stat specimens should be positioned in red sample positions or placed before routine specimens
F. Press ANALYZE, then 40 / TRAY ROUTINE
G. At end of run, resolve any specimens that did not sample, unread barcode or other problems.

VII. RESULTS VERIFICATION:

A. Refer to specific procedures for confirmatory testing directions.
1. All colored urines auto release.
2. Specific Gravity : >1.035 – need to do Clinitest and enter results.
3. Protein: alkaline urine and positive protein confirm with SSA.
4. Urines with positive protein, blood, nitrite, leukocyte esterase, atypical color and cloudy opacity reflex to a microscopic.

VIII. TRANSLATION OF ATLAS RESULTS TO LABORATORY REPORTING:

A. Reported results are not always the same as the values indicated on the color chart.

Use the table below to determine the values to report.

Test	Color Chart Value	YNHH Report
pH	5.0 - 8.5	5.0 - 8.5 (same)
Protein	Negative	Negative
	Trace	Negative
	30 mg/dl (+)	1+
	100 mg/dl (++)	2+
	300 mg/dl (+++)	3+
	2000 or more mg/dl (++++)	3+
Glucose	Negative	Negative
	100 mg/dl	Trace
	250 mg/dl	1+
	500 mg/dl	2+
	1000 mg/dl	3+
	2000 or more mg/dl	3+
Ketones	Negative	Negative
	5 mg/dl (trace)	Negative
	15 mg/dl (small)	Small
	40 mg/dl (moderate)	Moderate
	80 mg/dl (large)	Large
	160mg/dl (large)	Large
Blood	Negative	Negative
	Trace (Non-hemolyzed)	Small
	Moderate (Non-hemolyzed)	Moderate
	Trace (Hemolyzed)	Small
	Small (+)	Small

	Moderate (++)	Moderate
	Large (+++)	Large
Leuk Esterase	Negative	Negative
	Trace	Positive
	Small	Positive
	Moderate	Positive
	Large	Positive
Nitrite	Negative	Negative
	Positive	Positive
Bilirubin	Negative	Negative
	Small (+)	Small
	Moderate (++)	Moderate
	Large (+++)	Large
Urobilinogen	0.2 E.U./dl	0.2 E.U./dl
	1.0 E.U./dl	1.0 E.U./dl

IX. CHANGING REAGENT:

A. Refer to Clinitek Atlas operating manual (Section 5 5.1-5.6) and Macroscopic Urinalysis procedure; IV. Quality Control, Section C.

B. Each time calibration is performed on the Atlas, new tubes must be poured with Calibrator #1, #2, #3 (minimum volume of 3 ml) and Calibrator #4 (minimum volume of 5 ml). Calibrators of different lot#s are never to be used for instrument calibration. Following the calibration process, the tubes are then discarded.

X. CALIBRATION:

A. Refer to Clinitek Atlas operating manual (Section 6 6.1-6.5)
B. Calibration may need to be performed also after QC fails and troubleshooting complete. Calibration is generally done after PM and/or service. Recalibration may be required due to dry or wet calibration failure. All problems with calibration are logged in Problem Section of maintenance logs for Atlases.

XI. TROUBLESHOOTING:

A. Refer to Clinitek Atlas operating manual (Section 10 10.2-8, Section 11 11.1-11.6
B. Section 12 12.1-12.11)
C. Refer to troubleshooting section in Atlas "A" logbook.
D. ALL instrument problems must be logged in problem log and a supervisor notified if problem cannot be resolved. The instrument can not be run until problem resolved and calibration and controls validated.
E. Atlases are scheduled for PM annually.

XII. PROCEDURAL NOTES:

A. Atlas "A" and "B" are used on alternate days. Atlas "A" (SN #110005) is generally used on even days. Atlas "B" (SN #110830) is generally used on odd days .Daily set-up, maintenance and quality control are the same for both instruments.

Note: The carousel sample holder is not interchanged between Atlases.

XII. REFERENCES:

1. Schersten, B. and Fritz, H.: Subnormal Levels of Glucose in Urine. *JAMA* 201:129-132; 1967.
2. Kark, RM. et al.: *A Primer of Urinalysis,* 2nd ed. New York: Harper and Row; 1963.
3. McGarry, J.D.: Lilly Lecture, 1978: New Perspectives in the Regulation of Ketogenesis *Diabetes* 28:517-523; May, 1978.
4. Henry, J.B. et a1.: *Clinical Diagnosis and Management by Laboratory Methods,* 18th ed. Philadelphia: Saunders; 1991; pp. 396-397,415.
5. Siemens Healthcare Diagnostics, Elkhart, IN. Multistix 8 SG. 1994
6. Graff, Sister Laurine, A Handbook of Routine Urinalysis, J. B. Lippinctt, Philadelphia 1983.
7. Instructions for Use and Care PAL Digital Refractometer
8. Count-trol system package insert, Myers-Stevens Group, Montebello, Calif
9. Atlas Clinitek operating manual 5/1998

XIII. HISTORY:

H-1 This procedure was written by N. Ortoli-Drew on 10-05-03.
H-2 This procedure was revised by D. Fico on 12-20-10.
H-3 This procedure was revised by D. Fico on 3/2011.
H-4 This procedure was revised by D. Fico on 12/2011.
H-5 This procedure was revised by D.Fico on 11/2012.
H-6 This procedure was revised by D.Fico on 11/2013.