**Semi-automated Urine Chemistry using AUTION ELEVEN™ AE-4022**

**Scope:** This procedure pertains to UPMC Hanover

**PRINCIPLE:**

The AUTION ELEVEN™ AE-4022 semi-automated urine chemistry analyzer provides qualitative and semi-quantitative measurement of glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrites, leukocytes, specific gravity and color tone in urine. Although Clarity is not measured by the analyzer, the operator can manually enter a Clarity result.

The AUTION Sticks 10EA consists of a plastic strip containing 10 pads impregnated with chemicals specific for the determination of each analyte. The chemical reaction produces a color change indicating the concentration of the analyte.

The AUTION ELEVEN AE-4022 measures the end product of the chemical reaction by reflectance spectroscopy. A set of LEDs direct a single wavelength for measurement at each reagent pad on the test strip. Glucose, protein, pH, specific gravity and blood all receive 635nm. Bilirubin, urobilinogen, ketone, nitrite and leukocyte receive 565nm. A reference wavelength of 760nm is directed at every pad (except blood) to mitigate variability in the cumulative factors affecting light measured. To mitigate the variability of urine color, a reagent-free pad on every strip is used as an additional reference.

**CHEMICAL PRINCIPLE OF THE TEST STRIP**:

Glucose:Glucose oxidase reaction.

Protein: Protein-error reaction.

Bilirubin: Azo coupling reaction.

Urobilinogen: Azo coupling reaction.

pH: pH indicators covering pH range of 5-9.

Specific Gravity: Cation extraction reaction with pH indicators over a specific gravity range of 1.005 – 1.030 in increments of 0.005.

Blood: Activity measurement of pseudoperoxidase in hemoglobin.

Ketones: Legal reaction.

Nitrite: Griess reaction.

Leukocytes: Measurement of leukocyte esterase activity.

Color Tone: Reflected light is measured from the reagent-free pad at differing wavelengths (430nm, 565nm, 635nm, 760nm) to calculate color tone.

**CLINICAL SIGNIFICANCE:**

Urinalysis is performed to aid in the diagnosis of disease, to monitor wellness, to monitor the progress of disease and to monitor therapy.

The AUTION ELEVEN is intended for the performance of urinalysis screening of urine samples when indicated as part of patient management activities in a clinical laboratory. The clinical judgment based on the analysis result must be decided by doctor(s) in conjunction with the clinical condition and other examination results.

**SPECIMEN:**

***WARNING: Wear Personal Protective Equipment to prevent exposure to pathogenic microbes.***

Use freshly voided urine collected in a clean container. If analysis cannot be performed within two hours after collection, immediately refrigerate the specimen. Bring the specimen to room temperature prior to analysis. Mix the specimen well prior to analysis. Do not add preservatives or centrifuge samples prior to analysis.

Causes for rejection:

*Insert laboratory-specific criteria for rejection here:*

1. Specimens improperly collected or stored.
2. Unlabeled or mislabeled specimens.
3. Specimens with preservatives, disinfectant or detergent added.
4. Specimens previously run on the iQ200
5. Specimen Tubes that have been previously dipped with the Aution Strips (Re-pour new specimen with each analysis)

**REAGENTS AND SUPPLIES:**

1. Urine centrifugation tubes, round or conical bottom.
2. AUTION Sticks 10EA product number 73591. Store at room temperature.
* **Open product stability is 31 days. Protect against heat, light and moisture.**
1. Quality Control materials: **Aution Check Plus Level 1 and 2**
2. Alcohol.
3. DI water.

**AUTION Sticks Reactive Ingredients (per 100 test strips):**

Glucose:Glucose oxidase 700 I.U., Peroxidase175 P.U., 4-aminoantipyrine 14.0 mg, 1-Naphthol-3,6-disulfonic acid, disodium salt 14.0 mg.

Protein: Tetrabromphenol blue 0.35 mg.

Bilirubin: 2-Methyl-5-nitroaniline 1.9 mg, Sodium nitrite 1.0 mg.

Urobilinogen: 3,3’-Dimethoxy-4,4’-biphenylbis (diazonium tetrafluoroborate) 0.16 mg.

pH: Bromocresol green 0.07 mg, Bromoxylenol blue 0.72 mg.

Specific Gravity: Di (2-ethylhexyl) phosphoric acid 8.0 mg., Bromthymol blue 0.7 mg.

Blood: Cumene hydroperoxide 30.0 mg, 3,3’, 5,5’-Tetramethylbenzidine 15.0 mg.

Ketones: Sodium nitroprusside 12.0 mg.

Nitrite: Sulfanilamide 3.9 mg, N-1-Naphthylethylenediamine dihydrochloride 0.3 mg.

Leukocytes: 3-(N-Toluenesulfonyl-L-alanyloxy)indole 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium 0.38 mg.

**CALIBRATION:**

Calibration is not required.

**QUALITY CONTROL:**

Commercially available control solutions should be assayed on a regular basis per laboratory protocol. Refer to the control solution package insert for expected values.

1. Remove the Aution Check Plus from the refrigerator
2. From the Standby screen, press the right arrow key to switch to Control measurement mode.
3. Set the measurement number using the numeric keys and press the Enter key.
4. Remove the required number of test strips from the bottle. Close the test strip bottle cap securely.
5. Use the beeping sounds to signal the dipping timing.



* 1. Dip strip for 2 seconds. Do not dip the black mark. Note: Beeping does not sound for the first dipping measurement.
	2. Draw the entire length of the strip along the tube to remove excess urine.
	3. Place the strip in the detection area on the test strip tray. Test strip must cross both white rails. The carrying arm will automatically move the test strip to the suction ports.
1. Use the beeping sounds to signal the dipping timing for the next control sample.
2. When control measurement is complete, the Standby screen appears. Use the arrow keys to change measurement mode.

**SAMPLE MEASUREMENT:**

1. Prepare a sufficient volume of well-mixed sample in a tube so entire test strip pad area can be dipped in a single movement.
2. Remove the required number of test strips from the bottle. **Immediately close** **the cap.**
3. **You do not have to enter Operator ID.**
4. If you do have to Enter Operator ID (if function is ON).
	1. From the Standby screen, press and hold the Menu key for approximately 3 seconds.
	2. Enter Operator ID using the numeric keys.
	3. Press the Enter key.
5. Confirm **Standby** screen displays 10EA test strip type.
6. Set measurement number (optional).
7. **Enter Patient ID:**
	1. Press the **Patient ID** key.
	2. Enter the ID using either the numeric keys **or** scan the barcoded sample with the barcode reader.
	3. **Press** the **Enter** key. Measurement number and Patient ID will display alternately on the screen.
8. **Enter Clarity** value:
	1. Press and **hold the hyphen key** for about 2 seconds.
	2. Enter the clarity value (1-5) according to table below.
	3. Press the Enter key.



1. Use the beeping sounds to signal the dipping timing.



* 1. Dip strip for 2 seconds. **Do not dip the black mark.**

Note: Beeping does not sound for the first dipping measurement.

* 1. Draw the entire length of the strip along the tube to remove excess urine.
	2. Place the strip in the detection area on the test strip tray. Test strip must cross both white rails. The carrying arm will automatically move the test strip to the suction ports.
1. Use the beeping sounds to signal the dipping timing for the next sample. Repeat steps 5-8 for additional testing

**MAINTENANCE:**

Daily Maintenance

1. **Cleaning the Feeder**
	1. Turn off the instrument.
	2. Detach the carrying arm. Pull the arm forward and lift.
	3. Open the maintenance cover.
	4. Sterilize the carrying arm using alcohol, then wash with water**. Dry** **completely.**
	5. Detach the test strip tray. Slide tray forward and lift.
	6. Detach suction ports. Pull straight up from the test strip tray.
	7. Detach test strip feed tray. Slide forward and lift.
	8. Detach feed lever. Slide white lever forward, then lift feed lever.
	9. Clean the test strip tray, suction ports, test strip feed tray and feed lever with running water.
	10. **Completely dry cleaned ports.**
	11. Clean the table before reassembly (rails, guides, strip sensor window, white plate, aligning levers and aligning arm).
	12. Reassemble the instrument:
		* Attach the feed lever: set the feed lever to align with the positioning pins. Slide the white lever back.
		* Attach the test strip feed tray.
		* Attach the suction ports to the test strip tray.
		* Attach the test strip tray.
		* Close the maintenance cover.
		* Attach the carrying arm.
	13. Clean the white plate using a clean cloth.
2. **Cleaning the Waste Box**
	1. Discard used test strips.
	2. Sterilize the waste box using alcohol, then wash with water. Dry completely.
	3. Attach the waste box.

**As-needed Maintenance**

**Replace the thermal recording paper:**

1. From the Standby screen, open the printer cover.
2. Press the Feed key to remove the remaining paper. Remove paper core from the paper holder. Note: When paper is completely removed, an error (E0004 – No paper in printer) will display. The alarm sound can be stopped and error cleared by pressing the Enter key.
3. Trim the end of a new roll of paper to make a straight end.
4. Set the roll of paper in the holder in the proper orientation so that the paper feeds from the bottom. Note: Always press the Feed key after paper replacement to verify that the paper feeds properly.
5. Close the printer cover.

**REPORTING RESULTS:**

Reference Range:

Glucose: Negative mg/dL

Protein: Negative mg/dL

Bilirubin: Negative mg/dL

Urobilinogen : < or = to 0.2

pH : 5-8

Blood: Negative mg/dL

Ketones: Negative Mg/dL

Nitrite : Negative

Leukocytes: Negative

Color : Colorless, Straw, Light yellow and Yellow

Clarity : Clear

Specific Gravity: 1.005 – 1.030

AUTION Sticks 10EA Interpretation:



**Reporting Protocol**:

***Critical Value****: Positive Ketone on a child less than 2 years old.*

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**LIMITATIONS:**

Glucose False negative: pH < 4

 False positive: Ascorbic acid >50 mg/dL

Protein False positive: Hemoglobin >20 mg/dL.

Bilirubin False positive: Urobilinogen >8 mg/dL.

Urobilinogen False positive: Bilirubin >3 mg/dL.

pH and Nitrite: NA

Specific Gravity Elevated when: pH < 4

Albumin >300 mg/dL

Ammonium chloride >200 mg/dL

Blood False negative: Substances such as MESNA that contain sulfhydryl

Ketones False positive: Substances such as MESNA that contain sulfhydryl

Leukocytes False negative:

Glucose >200 mg/dL

Albumin >300 mg/dL

pH <4

**REFERENCES:** AUTION ELEVEN™ AE-4022 Operating Manual

 AUTION Sticks 10EA Package Insert

 **Urinalysis; Approved Guideline** – Third Edition, GP16-A3, Clinical Laboratory and Standards Institute.

**Document History**

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