**PRINCIPLE:**

The AUTION MAX AX-4030 is a fully automated urinalysis chemistry analyzer intended for the determination of glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity and color-tone. AUTION Sticks 9EB multi-parameter test strips are used with the AUTION MAX AX-4030. The AUTION Sticks 9EB consist of a plastic strip containing nine pads impregnated with chemicals specific for the determination of glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite and leukocytes. An additional correction pad is included to compensate for the natural color of urine and its effect on the color reactions of the pads. The AUTION MAX AX-4030 utilizes reflectance spectroscopy in combination with AUTION Sticks reagent chemistry to provide qualitative or semi-quantitative results. Specific gravity is determined by refractometry. The specific gravity is corrected for temperature and high concentrations of glucose and protein. Turbidity is determined using transmitted and scattered light. Twenty-three colors are analyzed simultaneously using reflectance values at specific wavelengths.

**CHEMICAL PRINCIPLES OF THE TEST STRIPS:**

Glucose: This test is based on the glucose oxidase–peroxidase-chromogen reaction, which produces a purple color.

Protein: This test is based on the protein-error reaction of pH indicator, which produces a blue color.

Bilirubin: A reddish-brown azo dye is obtained by the coupling of bilirubin with a diazonium salt.

Urobilinogen: A reddish-brown azo dye is obtained by the coupling of urobilinogen with a diazonium salt.

pH: The reagent pad contains pH indicators which give colors ranging from yellow to blue with the pH range of 5 to 9.

Blood: This test is based on the pseudoperoxidase activity of hemoglobin which catalyzes the oxidation of chromogen. The reaction produces a blue color.

Ketones: Ketones react with sodium nitroprusside to form a purple complex.

Nitrite: Nitrite reacts with sulfanilamide to form a diazo compound which couples with NEDA-2HCl to form a red azo dye.

Leukocytes: Due to esterase activity in leukocytes, indoxyl is released from the substrate. The indoxyl reacts with diazonium salt to form a purple azo dye.

**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 AX-4030 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 the doctor(s) in conjunction with the clinical condition and other examination results.

**Procedural overview:** Please note complete test instructions and analyzer operations are contained in downloaded IFU’s and Operator instructions. Please refer to the most recent copy of these to ensure correct test performance and most recent manufactures procedural updates.

**SPECIMEN Collection and preparation:**

Use freshly voided urine specimens, collected in a clean container. If analysis cannot be performed within one hour after collection, immediately refrigerate the specimen. Bring the specimen to room temperature prior to analysis. Mix the specimen well prior to analysis. Do not centrifuge the specimen until after testing is performed on the AUTION MAX AX-4030. Minimum sample level must be above 40mm from the bottom of the tube.

Causes for rejection:

*Insert laboratory-specific criteria for rejection here:*

1. Specimens improperly collected or stored.
2. Unlabeled or mislabeled specimens.
3. Specimens with urine preservatives, disinfectant or detergent added.
4. Hematuria. Residue may adhere to the SG measurement cell and cause incorrect analysis results. The color-tone of visually judged hematuria (around 10,000 RBCs/mL) may not correspond to the result with the AUTION MAX AX-4030.

**EQUIPMENT and MATERIALS:**

1. Urine centrifugation tubes, round or conical bottom. .
2. AUTION Sticks 9EB product number 73627. Store at room temperature. Open product stability is 31 days in the bottle and 3 days on the analyzer. Protect against heat, light and moisture.
3. ARKRAY Concentrated Washing Solution 3 product numbers 79053/79053-1. Store at 1°-30°C. Avoid direct sunlight. Open product stability is 7 months.
4. 10% Working Washing Solution: Pour 200 mL of Concentrated Washing Solution 3 into the Washing Solution bottle. Add 1800 mL of deionized water to the Washing Solution bottle. Seal the bottle with parafilm and invert to mix. Diluted Washing Solution is stable for 15 days.
5. Sodium hypochlorite. Dilute to a concentration of 0.5% with deionized water.
6. SG Calibrator High product number 100672. Store at 2° -10°C. Stable until expiration date on package. Use immediately after opening.
7. Quality Control materials: *Add laboratory-specific commercial controls here.*

**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.

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:**

SG Calibration is performed monthly.

1. Low Calibrator: pour more than 2 mL of deionized water into a urine centrifugation tube. Ensure the liquid level is at least 40 mm above the bottom of the tube.
2. High Calibrator: pour more than 2 mL SG Calibrator High into a urine centrifugation tube. Ensure the liquid level is at least 40 mm above the bottom of the tube.
3. In a Normal rack, place Low Calibrator tube in port 1 and High Calibrator tube in port 2.
4. Place the rack on the loading side of the sampler.
5. On the Standby screen, press S.G. Cal.
6. Enter 1.000 below Standard Solution Low and press the enter key.
7. Enter the SG High value from the package insert below Standard Solution High and press OK to save entries.
8. Press Start.
9. Evaluate the printed results:
10. SG CAL OK: results are acceptable
11. E120: SG calibration failure. See Section 5.2.2 Causes and Remedies on page 5-8 to determine cause. Repeat calibration. If the second SG calibration fails, contact Technical Support.

**QUALITY CONTROL:**

A commercially available positive and negative liquid control should be assayed on a regular basis per your laboratory protocol. Three levels of control can be analyzed simultaneously.

1. Prepare control solution according to package insert.

*Insert laboratory-specific QC preparation procedures here.*

1. Transfer more than 2 mL of control solution into a urine centrifugation tube. Ensure the liquid level is at least 40 mm above the bottom of the tube.
2. Load controls in the following position on the STAT and Control Rack:
	1. Position No. 8 Low Control
	2. Position No. 9 High Control
3. Place the rack on the loading side of the sampler.
4. Press the start button.
5. Review results: Both levels of QC must pass. Repeat QC as necessary.

**SAMPLE ANALYSIS:**

Normal analysis:

1. Transfer at least 2 mL of a well-mixed sample into a labeled urine centrifugation tube. Ensure the liquid level is above 40mm from the bottom of the tube.
2. Load samples into a Normal rack.
3. Load rack on loading side of the sampler.
4. Press the start button.

Port (single) STAT analysis:

1. Transfer at least 2 mL of mixed sample into a urine centrifugation tube. Ensure the liquid level is above 40mm from the bottom of the tube.
2. Place a sample tube in the STAT port.
3. Push the STAT port into place.
4. Press the STAT key.
5. Choose [Use Port]. Press OK.
6. Enter the sample ID.
7. If the analyzer is in Standby, press START.
8. If “STAT reserved” displays, port STAT measurement will start automatically.

Rack (group) STAT analysis:

1. Transfer at least 2 mL of mixed sample into a labeled urine centrifugation tube. Ensure the liquid level is above 40mm from the bottom of the tube.
2. Load samples in the STAT and Control rack in positions 1-7.
3. Load rack on rack loading area.
4. Press the start button.

**REPORTING RESULTS:** Results are uploaded to StratusDx LIS. Reference Ranges are set in the LIS.

AUTION Sticks 9EB Interpretation:

| GLU |  | Normal | +/- | +/- | +1 | +1 | +2 | +2 | +3 | +3 | +4 | +4 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | mg/dL |  | 30 | 50 | 70 | 100 | 150 | 200 | 300 | 500 | 1000 | OVER |
| PRO |  | - | +/- | +/- | +1 | +1 | +1 | +2 | +2 | 3+ | 3+ | 4+ |
|  | mg/dL |  | 10 | 20 | 30 | 50 | 70 | 100 | 200 | 300 | 600 | OVER |
| BIL |  | - | +1 | +1 | +2 | +2 | +2 | 3+ | 3+ | 3+ | 4+ |  |
|  | mg/dL |  | 0.5 | 1.0 | 2.0 | 3.0 | 4.0 | 6.0 | 8.0 | 10.0 | OVER |  |
| URO |  | Normal | +1 | +1 | +2 | +2 | 3+ | 3+ | 4+ |  |  |  |
|  | mg/dL |  | 2.0 | 3.0 | 4.0 | 6.0 | 8.0 | 12.0 | OVER |  |  |  |
| pH |  |  | 5.0 | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 |  |
| BLD |  | - | +/- | +1 | +1 | +2 | +2 | 3+ | 3+ |  |  |  |
|  | mg/dL |  | 0.03 | 0.06 | 0.10 | 0.20 | 0.50 | 1.0 | OVER |  |  |  |
| KET |  | - | +/- | +1 | +1 | +2 | +2 | 3+ | 3+ | 4+ | 4+ |  |
|  | mg/dL |  |  | 10 | 20 | 40 | 60 | 80 | 100 | 150 | OVER |  |
| NIT |  | - | 1+ | +2 |  |  |  |  |  |  |  |  |
| LEU/uL |  | - | 25 | 75 | 250 | 500 |  |  |  |  |  |  |

Turbidity: -, +1, +2

SG: 1.000 – 1.050

Color: Colorless

 Light Yellow, Yellow, Dark Yellow

 Light Orange, Orange, Dark Orange

 Light Brown, Brown, Dark Brown

 Light Red, Red, Dark Red

 Light Violet, Violet, Dark Violet

 Light Blue, Blue, Dark Blue

 Light Green, Green, Dark Green

**LIMITATIONS:**

| Analyte | Causes of false negative results | Causes of false positive results |
| --- | --- | --- |
|  |  |  |
| Glucose | Large amounts of ascorbic acid | Presence of oxidizing substances such as chlorineor hypochlorite, urine with a pH <4.0 |
|  |  |  |
| Protein | pH < 3.0 | Large amount of hemoglobin, contrast medium, disinfectants including quaternary ammonium compounds, urine with a pH >8.0 |
|  |  |  |
| Bilirubin | Ascorbic acid, uric acid, and nitrites | Urobilinogen, Ethodolac |
|  |  |  |
| Urobilinogen | N/A | Carbapenem |
|  |  |  |
| Blood | Elevated specific gravity or protein, large amounts of ascorbic acid | Oxidizing substances such as chlorine or hypochlorite |
|  |  |  |
| Ketones | N/A | L-DOPA, BSP, PSP, Phenylketone, Cephalosporine, Aldose reductive antienzyme |
|  |  |  |
| Nitrite | Ascorbic acid, elevated specific gravity  | N/A |
|  |  |  |
| Leukocytes | Glucose > 500 mg/dL,Protein > 300 mg/dL,Urine with low pH or elevated specific gravity | Formaldehyde |
|  |  |  |
| pH | N/A | N/A |

**Proficiency Testing:**

* Proficiency test material will be obtained from an approved source
* Proficiency test material will be handled and documented in the same manner as a patient specimen
* The Laboratory Director and Laboratory Manager will review all proficiency test results

**REFERENCES:**

AUTION MAX™ AX-4030 Operating Manual.

AUTION Sticks 9EB Package Insert.

CLSI. *Urinalysis; Approved Guideline – Third Edition*. CLSI document GP16-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.

Brunzel N. *Fundamentals of Urine and Body Fluid Analysis.* 3rd ed. St. Louis, MO: Elsevier Saunders; 2013.

**TECHNICAL ASSISTANCE:**

ARKRAY Technical Support: 1. 855.646.3108