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|  URINALYSIS TESTING  |
| **Purpose** | This procedure provides instructions for performing macroscopic Chemistry analysis of urine samples on the Aution MAX-4030 and subsequent microscopic analysis if warranted. |
| **Principle****Policy Statements****Materials****Sample** | 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. The instrument 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 specified wavelengths.This procedure applies to all laboratory technologists who are trained in the Hematology department and have been trained to operate the Aution AX-4030.

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| **Equipment** | **Reagents** | **Supplies** |
| Beckman Coulter Aution Max AX-4030 instrument | * AUTION sticks 9EB PN 73627
* 70%alcohol
* Arkray concentrated wash solution 3 PN 79053/79053-1
* SG Calibrator High PN 100672
* AUTION Check Plus Control (Low & High)
 | * Approved urine tube for IRIS workcell/AX4030
* Distilled water
* Sodium hypochlorite (bleach)
* Kim wipes
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Urine collected by catheterization or, a freshy voided clean-catch or mid-stream sample. Sample must be tested within 2 hours of collection. If testing will be delayed for more than one hour, refrigerate, stable for up to 24 hours refrigerated.* Minimum of **2 mL** of urine for Chemistry and unspun microscopic; see Notes.
* Samples **< 2 mL** must be dipped and read manually using the Siemens Multistix® 10 SG Reagent strip.

Unacceptable specimens:* Unlabeled/mislabeled
* Specimen collected in diaper or contaminated with feces
* Grossly bloody or “colored” specimens; see separate “Running Bloody/Colored Urine Sample analysis section.
* Samples not refrigerated within 1 hour of collection, or >24 hours from time of collection.

Notes: * Refrigeration provides adequate preservation for most chemical components with the exception of bilirubin and urobilinogen.
* If specimen was received refrigerated, bring to room temperature before testing.
* If urine needs to be cultured, it should be refrigerated during transit and held refrigerated until cultured.
* Samples collected in St. Paul should be sent to MPLS for culture by adding a minimum of 3.5 mL to a gray boric acid tube.
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| **Reference Range** |

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| **Analyte** | **Reference Range** |
| Color | Light yellow to amber |
| Clarity | Clear to slightly hazy |
| pH | 5 – 8  |
| Specific Gravity | 0-1 yr : 1.002 – 1.006 |
| > 1 yr : 1.001 – 1.030 |
| Glucose | Negative |
| Protein | Negative |
| Bilirubin | Negative |
| Urobilinogen | 0.1 – 1.0 Ehrlich units |
| Blood  | Negative |
| Ketones | Negative |
| Nitrate | Negative |
| Leukocytes | Negative |
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| **Limitations** |

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| **Analyte** | **Causes of false negative results** | **Causes of false positive results** |
| Glucose | Large amounts of ascorbic acid | Presence of oxidizing substances such as chlorine or hopychlorite, urine with a pH <4 |
| Protein | pH <3 | 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 |
| Nitrate | Ascorbic acid, elevated specific gravity  | N/A |
| Leukocytes | Glucose > 500 mg/dL, Protein > 300 mg/dL, Urine with low pH or elevated specific gravity | N/A |
| pH | N/A | N/A |

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| **Method Specifications****Reagents****Calibration****Quality Control****Sample Analysis****Microscopic Analysis****Numeric and Quantity Definitions****Resulting** **Reflex to Culture****Notes****Changing a Lot of Chemisty QC****References****Historical Record** | * pH is measured from 5.0 – 9.0 in 0.5 increments
* Specific gravity is measured via refractive index from 1.000 - >1.060 in 0.001 increments

**AUTION 9EB test strips** are stored at room temperatore. Open product stability is 31 days in the bottle and 3 days on the analyzer. Protect against heat, light, and moisture.* The Aution AX-4030 has two feeders. We will only use the LEFT side feeder. Load approximately one-third of one bottle onto the analyzer at a time since on-board stability is 3 days. The evening shift will routinely do this when they perform daily maintenance. \* *Additional strips may be added to analyzer at any time.*
	+ Take out the desiccant pack from the strip bottle and place it in the built-in tray on top of the feeder door. There is also a trap door under the strip feeder to place an

additional desiccant pack. Rotate the packs as you open new bottles from the trap door, to the lid, and then discard. NOTE : Replace the desiccant bags on the feeders each time a new test strip bottle is opened.* + Level the test strips into even piles. DO NOT touch the pad area on the strips.
	+ Place the test strips with the black marker to the back side of the feeder.
	+ Close the feeder cover and turn the locking lever clockwise to lock it.
* Label opened bottle with open date, and 31 day expiration date, and your initials.

**ARKRAY Concentrated Washing Solution 3** is stored at 1-30°C. Avoid direct sunlight. Open product stability is 7 months.* To prepare 10% working solution in provided container:
	+ Add 1800 mL of deionized water to the Washing Solution bottle (line is marked

on bottle).* + Pour 200 mL of Concentrated Wash solution into the Washing Solution bottle (fill

to the 2000 mL marking on the bottle).* + Seal the bottle with parafilm and invert to mix.
	+ Diluted washing solution is stable for 15 days on board the analyzer.
		- With a dry erase marker, write the date made, date expires, and your initials on the laminated card attached to the bottle.

**S.G. Cell calibration**; using low and high standards is performed once a month See Maintenance Procedure MAI 2.0 Maintenance on the Aution AX-4030 for directions.AUTION Check Plus Control (Low & High) - 25 ml/bottles* Liquid reagent;ready to use.
* Open stability 30 days.
* Store at 2-8°C

Two levels of Quality control material are run under the following circumstances:* Once every 24 hours on the evening shift.
* When a new bottle of reagent strips is opened
* In parallel with a new lot change, and documented in appropriate log book
* When test results are questionable
* Corrective Action for any failed QC should be documented on the daily QC log for Urinalysis.

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| **STEP** | **ACTION** |
| 1 | Remove AUTION Check Plus Control (Low & High) from the refrigerator and allow to come to room temperature for at least 15 minutes. |
| 2 | Gently mix by inversion several times |
| 3 | Insert clean sample tubes into ports 8 (level 1) and 9 (level 2) of the STAT/Control Rack. These ports have dark blue adapters. |
| 4 | Dispense 2 mL of QC into sample tubes (rack is marked with proper level) |
| 5 | Load rack onto sampler side (right) of analyzer |
| 6 | Press START on display screen |
| 7 | Results will automatically print and cross to the LIS. Review for acceptability. If controls fall outside stated values do not perform patient testing until resolved. Failed QC will display (--) accompanied with a specific alarm related to control failure.* Repeat test – if acceptable you are done
* Repeat with fresh test strips – if acceptable you are done
* Repeat with fresh QC material – if acceptable you are done
* If QC still does not pass, perform a Check strip calibration; repeat the QC – if acceptable you are done. If not - call Technical Support for further troubleshooting.
* Perform Visual test strip testing using Multistix® 10 SG Reagent Strip until instrument is confirmed to be in working order.
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**Running samples with Barcodes**

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| **STEP** | **ACTION** |
| **1** | Samples must be at, or brought to room temperature, before analysis. |
| **2** | Pour well mixed sample into sample tube(s) and load them into the sampler rack with the barcode showing through the opening of the rack. The tubes barcode should face the instrument.* AX-4030 mimimum volume requirement is 2 mL
* DXU-workcell (AX+iQ IRIS) minimum volume requirement is 4 mL
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| **3** | Load up to 10 samples in each rack onto sampler side (right) of analyzer |
| **4** | Press START on display screen |
| **5** | Results will automatically print and cross to the LIS. Review for acceptability. |
| **6** | When measurements of all samples are complete the message *Measurement operations ending* will appear after the entire batch of samples has been measured. |
| **7** | The instrument will proceed with flow line flushing and other end processes. When completed, the Standby screen will appear. |

 **Running samples WITHOUT Barcodes**

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| **STEP** | **ACTION** |
| **1** | Samples must be at, or brought to room temperature, before analysis. |
| **2** | Pour well mixed sample into sample tube and place into the STAT port |
| **3** | You can program the sample manually with a unique identifier by tapping the number keys multiple times to change to alpha characters. |
| **4** | Press START on display screen. Review results for acceptibility. |
| **6** | Transmit or manually enter into Sunquest when CID is available |

**Running Samples that are frankly Bloody or Colored**

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| **Sample appearance** | **ACTION** |
| Frankly Bloody samples | Grossly bloody samples should be spun down, and the supernatent dipped manually with the Siemens Multistix® 10 SG Reagent strip. Visually read the results at the allotted times. Perform microscopic. |
| Colored samples | “Colored” urines (other than bloody – e.g., orange, green, brown, etc.) should be spun down and if the color does not clear, the sample cannot be tested. Enter the code “COLU” and this will cancel the macroscopic and reflexively order a microscopic exam. |

The microscopic sediment exam should always be correlated with macroscopic results.Based on the Chemistry results of the urine sample a microscopic exam will be generated. The following criteria requires a microscopic analysis:* Turbid appearance
* Positive Protein
* Positive Blood
* Positive Leukocyte
* Positive Nitrate

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| **STEP** | **ACTION** |
| **1** | Pour 5-10 mL of well mixed urine into Kova-type centrifuge tube.  |
| **2** | Centrifuge for 5 minutes at 2200 RPM |
|  | If less than 5 mL urine volume do NOT centrifuge, an add the code “MICP” – Microscopic on uncentrifuged urine. |
| **3** | Decant sample to 1 mL  |
| **4** | Mix remaining supernatant and sediment button thoroughly with pipette |
| **5** | Transfer sample to appropriate standardized slide  |
| **6** | Exam at least 10 fields on Low Power for a general view of the sample**Quantitate under Low Power** (Identify using High power):* + epithelial cells (squamous, transitional, and renal)
	+ any yeast present
	+ any WBC clumps present.
	+ any Casts or crystals present
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| **7** | Examine at least 10 fields under high power for identification of cellular elements**Quantitate under High Power*** any RBC’s or WBC’s present
* any bacteria and mucous
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* Click on the component key that you want to enter, and the keyboard will change and

give you the keys that are available for use for those parameters.* The only *mandatory* fields are highlighted yellow: RBC and WBC, and the quantitation

of each. * For all other observations (mucous, epis, etc.) select the urine component you want

to add and then the quantity if applicable.

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| **Component** | **Code** | **Definition** |
|  **Quantitate on High Power Field** |
| RBCWBC | NSEERareNURBCNUWBCRR5RR10RR25RR50RRG1 | None SeenOne or two cells in 10 HPF’s0-3 red blood cells/HPF0-5 white blood cells/HPF5-10 cells/HPF (RBC or WBC)10-25 cells/HPF (RBC or WBC)25-50 cells/HPF (RBC or WBC)50-100 cells/HPF (RBC or WBC)Greater than 100 cells/HPF |
|  **Quantitate on Low Power Field** |
| Epithelial/Transitional/Renal cellsCastsCrystalsYeastWBC clumpsBacteria  | OccFewModerateMany | One or two elements in 10 LPF’s1-2/LPF3-25 elements/LPF>25 elements/LPF |

* All results for the urine Macroscopic will auto-file to Sunquest. If no microscopic was triggered, the result will be final.
* Microscopic results are entered using the keyboard in the GUI Sunquest.
	+ General Laboratory/Orders; enter the accession number
	+ UWBC, URBC, UTYPE (MSPU or MICP) are required results for UARC (Urine reflex to culture order)
* Available options for quantity selection will be highlighted for the specific parameters you are entering.

Reflexive testing for culture will be performed in the following situations:* Macroscopic results positive for Nitrates
* Macroscopic results positive for leukocyte esterase (trace or greater)
* Greater than 5 WBC’s/HPF on spun urine
* Greater than 10 WBC/sHPF on un-spun urine
* Microscopic positive for yeast
* Any patient less than 2 years old

\*\*Culture labels will print for Microbiology and should be delivered with the sample.* A urine pH of > 9.0 is associated with an improperly preserved sample and a new sample should be collected. Call the patient caregiver and cancel the test using code “QPH” – specimen quality questionable due to high pH, suggest recollect.”

 * Amorphous urates are seen in acid urine:
	+ add 1 drop of 10% NaOH to one drop of urine sediment to clear sample.
* Amorphous phosphates are seen in alkaline urine:
	+ add 1 drop of 25% HCl to one drop of urine sediment to clear sample.
* Reference materials (atlases, charts or photomicrographs) are available to assist in the microscopic identification of urine sediment on the shelf above the instrument.

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| **STEP** | **ACTION** |
| **1** | Select Consumables |
| **2** | Select Chemistry QC |
| **3** | Enter Strip Lot number and expiration date listed on the test strips; Next |
| **4** | Enter AUTION Check Plus Control Low lot and expiration date listed on the reagent box |
| **5** | Select Next |
| **6** | Enter AUTION Check Plus Control High lot and expiration date listed on the reagent box. Select OK |

* CLSI (Clinical and Laboratory Standards Institute) GP16-A3 Urinalysis and Collection, Transportation, and Preservation of Urine Specimen, Good Laboratory Practices and the Laboratory’s Procedure Manuals.
* Aution Max™ AX-4030 Operating Manual, 84-02160L Rev: Sep, 2022 Arkray, Inc.
* IQ Workcell Complete Urinalysis Training Guide Version 3.0 July 2019

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| Version | Written/Revised by: | Effective Date: | Summary: |
| 1 | Michele Koester | 1/30/2024 | New Instrument |
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