| D | 00 | 1 100 | 0.14 | 4 |
|---|-----|-------|------|----|
| D | Cai | um | .OI | LL |

Origination 4/17/2023 Document Colette Kessler: Contact Mgr, Division 4/17/2023 Last Laboratory Approved Area Laboratory-Effective 4/17/2023 Chemistry Last Revised 4/17/2023 Applicability Royal Oak Next Review 4/16/2025

Routine Urinalysis Procedure - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

- A. A random urine specimen is chemically screened for abnormal concentrations of substances. In the presence of these abnormal constituents, microscopic examination of urinary sediment follows. Examination of the urine can provide:
 - 1. Information for diagnosis and management of renal or urinary tract disease
 - 2. Aid in the detection of metabolic or systemic diseases not directly related to the kidney

II. SPECIMEN COLLECTION AND HANDLING:

- A. A freshly voided urine sample, less than two hours old, in a clean collection container. A fairly concentrated specimen, e.g., the first morning void, is preferred.
- B. Optimum specimen volume is at least 20 mL.
- C. Analyze the specimen within one-two hours of collection or refrigerate immediately at 2-8°C and return to room temperature before testing. MIX THOROUGHLY before testing.

III. REAGENTS:

- A. For Iris Velocity: iChem Velocity Urine Chemistry Strips are ordered from Beckman Coulter and delivered to the Urinalysis Lab.
- B. For Advantus: **Siemens Multistix 10 SG (#2161A)**. Reagent dipsticks are ordered as needed and delivered to the Urinalysis Lab.
- C. Store reagents at 15-30° C. Protection against ambient moisture, light, and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of reagent areas may

indicate deterioration. **DO NOT** use strips beyond expiration date stamped on iChem Velocity or Multistix vials. For Velocity, load a quantity of strips appropriate to the testing volume to be performed. Replace the desiccant as indicated on the maintenance log. Store any strips remaining in the vial on its side. For Advantus, do not remove strips from the Multistix vial until immediately prior to testing. Replace cap immediately.

IV. QUALITY CONTROL (QC):

- A. For IRIS Velocity: Use IRISpec CA/CB/CC urine controls and run each level every twelve hours.
- B. For iQ200: Use FOCUS, positive and negative particle controls and run each every twelve hours.
- C. For Advantus: Kova-Trol, commercial urine normal and abnormal controls are run and recorded by each shift.
- D. Specific gravity by T.S.Meter is a quality control check that is performed daily.

V. SPECIAL SAFETY PRECAUTIONS:

Externally contaminated specimen containers should be cleaned with 10% Clorox bleach. Gloves should be worn when specimens are tested, as per standard precautions.

VI. PROCEDURE:

- A. Routine urinalysis includes a report of specimen color, clarity, specific gravity, and chemical dipstick testing. The IriCell analyzer is routinely used. The Advantus is available for the following conditions:
 - 1. For backup
 - 2. When sample volume is insufficient for IRICell testing
- B. A visual dipstick read may be used to confirm questionable analyzer results or when the specimen is highly colored or bloody/turbid. See specific procedure below for visual reporting.
- C. A microscopic examination of urinary sediment is performed when:
 - 1. An abnormal result (trace or greater) is found in the "dipstick" testing for any of the following seven chemistries:
 - a. Glucose
 - b. Bilirubin
 - c. Ketone
 - d. Blood
 - e. Protein
 - f. Nitrite
 - g. Leukocyte Esterase
 - 2. A microscopic exam is specifically ordered.

- 3. The urine is highly colored so as to interfere with dipstick reading of the color blocks.
- 4. The clarity of the urine is anything other than clear.
- D. Physical/Chemical Examination of the Urine
 - Mix the yellow-stoppered conical BD vacutainer collection tube and destopper OR pour 8 mL of a well-mixed urine specimen into a graduated disposable centrifuge tube. Perform the following physical/chemical evaluations.

Note: Be sure to aspirate off any foam from the urine samples. Foam may cause inaccurate results because of dispensing errors.

 For Velocity: Color, Clarity and Specific Gravity are determined by the analyzer. See Macroscopic and Microscopic Examination of Urine Using the IRIS iQ200 Sprint procedure.

2. For Advantus:

- a. COLOR: Record the color. Accepted descriptive terms:
 - i. Yellow
 - ii. Amber
 - iii. Red
 - iv. Blue
 - v. Other
- b. CLARITY: Record the clarity. Accepted descriptive terms:
 - i. Clear
 - ii. Cloudy
 - iii. Turbid
- c. SPECIFIC GRAVITY: The T.S. meter is checked daily with distilled water and quality control materials. A NaCl standard (2.8%) is assayed on the T.S. meter monthly. (See T.S. Refractometer procedure). The Advantus specific gravity result is reported unless:
 - i. Advantus result of specific gravity < 1.005 or specific gravity > 1.030 is obtained.
 - ii. Urine is highly colored so as to interfere with dipstick reading.
 - iii. Physician requests specific gravity by meter.
 - iv. The Advantus is inoperable.
 - a. In event of the above, specific gravity is reported by refractometry (T.S. Refractometer). Under NO CIRCUMSTANCES IS A VISUAL READ OF SPECIFIC GRAVITY REPORTED.
- d. DIPSTICK (Multistix 10 SG): Check test strips each shift with urine controls (See specific dipstick procedures for protocol). Be sure that any refrigerated specimen has warmed to room temperature before analysis

with the dipstick. Dip the test areas briefly but completely into well-mixed, uncentrifuged urine. Remove the excess by touching the strip to the edge of the container. Hold the strip in a horizontal position to prevent possible mixing of chemicals.

i. For Visual Read of Multistix 10 SG dipstick, hold strip close to color blocks on the dipstick vial and match carefully. Proper read time is critical for optimal results. The pH and protein areas may also be read immediately, or at any time up to two minutes after dipping. After dipping the strip, check the pH area. If the color on the pad is not uniform, read the reagent area immediately, comparing the darkest color to the appropriate Color Chart.

| Visual Reporting for Multistix 10SG | | | | | | | |
|-------------------------------------|---------------|--|--|--|--|--|--|
| Test | Time | Report | | | | | |
| Glucose | 30 seconds | Negative, Trace (100), 1+ (250), 2+ (500), 3+ (>=1000) | | | | | |
| Bilirubin | 30 seconds | Negative, 1+ (Positive), 2+ (Positive), 3+ (Positive) | | | | | |
| Ketone | 40 seconds | Negative, Trace (5), 1+ (15), 2+ (40), 3+ (>=80) | | | | | |
| Specific Gravity | | Use refractometer result | | | | | |
| Blood | 60 seconds | Negative, 1+, 2+, 3+ | | | | | |
| рН | 60 seconds | 5.0, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 | | | | | |
| Protein | 60 seconds | Negative, Trace (15), 1+ (30), 2+(100), 3+ (>=300) | | | | | |
| Urobilinogen | 60 seconds | 0.2, 1, 2, 4, ≥8 | | | | | |
| Nitrite | 60 seconds | Negative, Positive | | | | | |
| Leukocytes | 2 minutes | Negative, Trace, 1+, 2+, 3+ | | | | | |

- a. When the urine is highly colored so as to interfere with dipstick reading of the color blocks:
 - Attempt to visually read the strip. DO NOT ACCEPT IRIS OR ADVANTUS RESULTS!
 - Microscopic examination of sediment is required.

E. Additional Chemical Testing:

- 1. Reporting the Physical/Chemical Results:
 - a. Verify entry of the interfaced (IRIS, Advantus) results before Laboratory Information System (LIS) acceptance. Correlate confirmatory tests with the analyzer dipstick results and available clinical information (Chart Review) to accept the dipstick and confirmatory testing together for the patient.
 - b. Document any critical value in the LIS per procedure. (See Critical Value List and Reporting Panic Procedure)
- F. Microscopic Examination of the Urine Sediment: See Examination of Urinary Sediment by Phase Microscopy procedure if examination of the sediment is required.
- G. Verification of Unusual Laboratory Results: The dipstick urine results are correlated with the microscopic findings. Any "discrepancies" are verified by repeat testing of the dipstick and/or microscopic. Any positive findings for **Bilirubin** or **Urobilinogen** should be correlated via CHART REVIEW with serum chemistries for elevated liver enzymes and bilirubin. The technologist is strongly encouraged to routinely utilize CHART

or **Urobilinogen** should be correlated via CHART REVIEW with serum chemistries for elevated liver enzymes and bilirubin. The technologist is strongly encouraged to routinely utilize CHART REVIEW prior to release of any Urinalysis Report. The table below can be used as a reference for what the technologist may expect to find in a microscopic with positive dipstick findings.

| | If test is positive: | Then consider these findings in micro: | |
|--|---------------------------------|--|--|
| | Blood | RBC's (red blood cells) | |
| Leukocyte Esterase WBC's (white blood cells) & B | | WBC's (white blood cells) & Bacteria | |
| | Protein | Casts | |
| | Nitrite | Bacteria | |
| | High Specific Gravity (> 1.035) | Radiographic (X-RAY) crystals | |

VII. INTERFERING SUBSTANCES:

Substances that cause abnormal urine color such as drugs containing azodyes (Pyridium, Azo Gantrisin, Azo Gantanol) nitrofurantoin (Macro-dantin, Furadantin) and riboflavin may affect the readability of reagent areas, mask a pad, or produce a result that is instrumentally read or visually interpreted as false positive. See procedure applicable to the given Multistix chemistry test pad for specific limitations. See page applicable to the given Multistix chemistry test pad procedure for specific limitations.

VIII. AUTOMATION DOWNTIME:

- A. In the event of IRICELL system downtime, the Advantus will be used as a backup for Urine chemical testing and phase microscopy will be used for all urine chemical results that require microscopic examination.
- B. In the event that both IRICELL systems and the Advantus are not functional:
 - STAT testing will be processed by manual dipping of the urines with the Multistix 10 SG dipsticks and all necessary microscopics will be performed manually by phase microscopy.

- 2. Routine and outpatient testing will be refrigerated and stored on-site until automated testing is available.
- C. In the event that automation downtime is expected to exceed specimen stability, samples will be sent to Corewell Health Troy Hematology for automated testing.

IX. REFERENCES:

- 1. Iris iChem Velocity Operators Manual, 301-7146 English Rev B 11/2/2011.
- 2. Multistix box. Siemens Healthcare Diagnostics Inc. Tarrytown, NY 10591
- 3. Henry, J.B., Clinical Diagnosis and Management by Laboratory Methods, 23rd ed., Philadelphia, W.B. Saunders, 2017, pp 422-480.

Approval Signatures

| Step Description | Approver | Date |
|--|--|-----------|
| Medical Director | Ann Marie Blenc: System Med Dir, Hematopath | 4/17/2023 |
| Policy and Forms Steering Committee Approval (if needed) | Colette Kessler: Mgr, Division Laboratory | 4/5/2023 |
| Policy and Forms Steering Committee Approval (if needed) | Gail Juleff: Project Mgr Policy | 4/5/2023 |
| Lab Chemistry Best Practice Committee | Caitlin Schein: Staff Physician | 4/5/2023 |
| Lab Chemistry Best Practice Committee | Qian Sun: Tech Dir, Clin Chemistry, Path | 3/28/2023 |
| | Colette Kessler: Mgr, Division Laboratory | 3/28/2023 |