**Beaumont Laboratory**
**Royal Oak**

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Related Documents: RC.CH.UA.IRIS.PR.001, RC,CH,UA,C5,PR,001, RC.CH.UA.MT.PR.007, RC.CH.UA.MT.PR.006, RC.CH.UA.MT.PR.002

# ROUTINE URINALYSIS

RC.CH.UA.MT.PR.001r05

## Principle

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 and 2) aid in the detection of metabolic or systemic diseases not directly related to the kidney.

## Specimen Collection and Handling

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

## Reagents

For Iris Velocity: iChem Velocity Urine Chemistry Strips are ordered from Beckman Coulter and delievered to the Urinalysis Lab.
For Clinitek 500: **Bayer Multistix 10 SG(#2161A).** Reagent dipsticks are ordered as needed and delivered to the Urinalysis Lab.

Store reagents at 15-30$^{o}$ 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 Clinitek, do not remove strips from the Multistix vial until immediately prior to testing. Replace cap immediately.

## Calibration

See IRIS procedure (RC.CH.UA.IRIS.PR.001) or Clinitek 500 procedure (RC.CH.UA.C5.PR.001) for respective instrument requirements.

## Quality Control

Commercial urine (Kova-Trol), normal and abnormal controls are run and recorded by all shifts for Clinitek 500. Specific gravity by T.S. meter and SSA procedures are also quality control checked each day. The IRIS Velocity uses IRISpec CA/CB/CC urine controls which are run each shift. The iQ200 uses FOCUS, Positive and Negative particle controls which are run on each shift.

## Special Safety Precautions

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

## Procedure

Routine urinalysis includes a report of specimen color, clarity, specific gravity, and chemical dipstick testing. The IriCell analyzer is routinely used. The Clinitek 500 is available for the following conditions:

1. For backup.
2. When sample volume is insufficient for IRICell testing

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.

A microscopic examination of urinary sediment is performed when:

- An abnormal result (trace or greater) is found in the "dipstick" testing for any of the following seven chemistries:

| | | |
|---|---|---|
| 1. Glucose | 4. Blood | 7. Leukocyte Esterase |
| 2. Bilirubin | 5. Protein | |
| 3. Ketone | 6. Nitrite | |

- A microscopic exam is specifically ordered.
- The urine is highly colored so as to interfere with dipstick reading of the color blocks.
- The clarity of the urine is anything other than clear.

I. <u>Physical/Chemical Examination of the Urine:</u>

1. 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 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 IRIS Procedure (RC.CH.UA.IRIS.PR.001)

For Clinitek 500:

a. COLOR: Record the color. Accepted descriptive terms:
   i. Yellow
   ii. Red
   iii. Blue
   iv. 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. meter procedure RC.CH.UA.MT.PR.007). The **CLINITEK 500** s.g. result is reported **unless**:
   i. Clinitek result of s.g. $\leq$ 1.005 or s.g. $\geq$ 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 Clinitek is inoperable.
   In event of the above, specific gravity is reported by refractometry (T.S. meter). **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. See Clinitek 500 protocol for instrument read.

**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 10 SG**

| TEST | TIME | REPORT |
|---|---|---|
| Glucose | 30 sec | Negative, Trace (100), 1+ (250), 2+ (500), 3+ (>=1000) |
| Bilirubin | 30 sec | Negative, 1+ (Positive), 2+ (Positive), 3+ (Positive) |
| Ketone | 40 sec | Negative, Trace (5), 1+ (15), 2+ (40), 3+ (>=80) |
| Specific Gravity | ------ | Use refractometer result |
| Blood | 60 sec | Negative, Trace, 1+, 2+, 3+ |
| pH | 60 sec | 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 |
| Protein | 60 sec | Negative, Trace (15), 1+ (30), 2+ (100), 3+ (>=300) |
| Urobilinogen | 60 sec | 0.2, 1, 2, 4, ≥8 |
| Nitrite | 60 sec | Negative, Positive |
| Leukocytes | 2 min | Negative, Trace, 1+, 2+, 3+ |

When the urine is highly colored so as to interfere with dipstick reading of the color blocks:

1. Attempt to visually read the strip. **DO NOT ACCEPT IRIS OR CLINITEK 500 RESULTS!**
2. Attempt alternate tests for protein (3% SSA). This dipstick pad is reported as "color interference".
3. Microscopic examination of sediment is required.

II. Additional Chemical Testing:
   1. If the IRIS, Clinitek 500 or Visual Read indicates PROTEIN, report this amount. If urine has a pH >8.0 test then report results with 3% SSA test. (See SSA procedure, RC.CH.UA.MT.PR.006).
   2. If the IRIS, Clinitek 500 or Visual Read indicates a positive BILIRUBIN then an ICTOTEST needs to be performed (See Ictotest Procedure CH.UA.MT.
   3. Reporting the Physical/Chemical Results:
      a. Verify entry of the interfaced (IRIS, Clinitek) results before 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 p. A3.)

III. Microscopic Examination of the Urine Sediment:
   See procedure RC.CH.UA.MT.PR.002 if examination of the sediment is required.

IV. Verification of Unusual Laboratory Results:
The "top" of the urine is 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 Tech 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 tech may expect to find in a microscopic with positive dipstick findings.

| If result is positive: | Then consider these findings in micro: |
|---|---|
| Blood | RBC's |
| Leukocytes Esterase | WBC's & Bacteria |
| Protein | Casts |
| Nitrite | Bacteria |
| High Specific Gravity (> 1.035) | Radiographic (X-RAY) crystals |

**Reportable Range**

See pages in the respective IRIS/ Clinitek 500 Manual applicable to the given Urinalysis procedure

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**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 Routine Urinalysis Dipstick section that follows. See page applicable to the given Multistix chemistry testpad procedure for specific limitations.

**AUTOMATION DOWTIME**

1) In the event of IRICELL system downtime, the Clinitek 500 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.
2) In the event that both IRICELL systems and the Clinitek 500 are not functional:

a) 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.
b) Routine and outpatient testing will be refrigerated and stored on-site until automated testing is available.
    i) In the event that automation downtime is expected to exceed specimen stability, samples will be sent to Beaumont Health – Troy Hematology for automated testing.

**Interpretation**

See page applicable to the given IRIS or Clinitek Multistix 10 SG procedure.

**References**

1. Iris iChem Velocity Operators Manual, 301-7146 English Rev B 11/2/2011.
2. Multistix 10 SG package insert, Bayer Corp. Inc. Diagnostics Division, Elkhart, IN, rev.
3. Henry, J.B., Clinical Diagnosis and Management by Laboratory Methods, 23rd ed., Philadelphia, W.B. Saunders, 2017, pp 422-480.

**Authorized Reviewers**

Section Medical or Technical Director

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## Document Control

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## Document History

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| Elizabeth Sykes, MD | 01/03/2011 | | | |
| Elizabeth Sykes, MD | 02/16/2012 | | | |
| Elizabeth Sykes, MD | 06/24/2014 | r01 | Removed Ictotest protocol | |
| Elizabeth Sykes, MD | 10/21/2015 | | | |
| Elizabeth Sykes, MD | 12/01/2015 | r02 | Removed all references to Clinitest tablets | |
| Elizabeth Sykes, MD | 10/24/2017 | r03 | Changes reported ranges for Glucose, Protein, Ketone and Bilirubin. Updated logo | |
| Elizabeth Sykes, M.D. | 12/10/19 | r04 | Updated to Iris Information | |
| Elizabeth Sykes, M.D. | 12/20/2019 | r05 | All automation downtime | |

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