

**Beaumont**

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Chemistry  
Applicability Royal Oak

## Comparability of Urinalysis Instruments and Methods - Royal Oak

Document Type: Procedure

### I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide technical staff with policies and rules for performing comparisons of patient urinalysis samples across the instruments and methods used within the Urinalysis section of the lab. The instruments and methods involved in this comparison are the Clinitek Advantus, UN9000 including two Novus Chemistry Analyzers and two UF5000 Automated Microscopic Analyzers, Manual Dipstick read and Manual Microscopy. Correlation is done to look for positive/negative bias between the analyzers.

### II. SPECIMEN COLLECTION AND HANDLING:

Fresh, well-mixed, un-centrifuged urine.

### III. REAGENTS/SUPPLIES:

- A. Novus 10SG Reagent Strips
- B. Siemens Multistix 10 SG

### IV. PROCEDURE:

- A. The comparisons of the instruments and methods within the Urinalysis section are performed biannually (2 times per year).
- B. A total of five random patient urine samples are analyzed.
- C. Note: Make sure there is sufficient urine to test in all areas.

- D. Using fresh urine samples, analyze each specimen across each of the following platforms:
1. UN9000--Novus #1 and #2, UF5000 #1 and #2
  2. Clinitek Advantus #1 and 2.
  3. Manual Dipstick
  4. Manual Microscopy (Phase)
- E. Record Data on the attached worksheet. Record one sample per worksheet.
- F. Return worksheets to the Urinalysis Lead.

## V. CRITERIA FOR ACCEPTABILITY:

- A. The worksheets are first reviewed by the Urinalysis Lead and then passed to the Medical Director for final review and sign-off.
- B. Criteria for acceptability:
1. **Dipstick** - Comparisons between the instruments/ methods match within +/- one color block for each analyte. Dipstick analytes include Color, Clarity, Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte Esterase.
  2. **Microscopy** - Comparisons between the instruments/ methods match within one reportable range. Parameters for the UF 5000's and Manual Microscopy include: RBC (red blood cells), WBC (white blood cells), Bacteria, Squamous Epithelial Cell, Hyaline Cast and Bacteria.

| <b>ELEMENT</b><br>(hpf = high power field)<br>(lpf = low power field) | <b>REPORTABLE RANGE</b>               |
|---|---------------------------------------|
| RBC/hpf   | 0-2, 3-5, 6-10, 11-20, >20            |
| WBC/hpf   | 0-5, 6-10, 11-20, 21-50, 51-100, >100 |
| Squamous, epithelial/hpf  | 0-2, 3-5, 6-10, 11-20, >20            |
| Hyaline Casts/lpf   | 0-2, 3-5, 6-10, 11-20, >20            |
| Bacteria/hpf  | Negative, Occ, 1+, 2+, 3+, 4+         |

- C. All data is reviewed for positive or negative bias in analytes/parameters across platforms.

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## Attachments

[Comparability of Urinalysis Instruments Worksheet](#)

## Approval Signatures

| Step Description   | Approver                                     | Date      |
|--|--|-----------|
| CLIA Directors   | Ann Marie Blenc: System Med Dir, Hematopath  | 7/23/2024 |
| System Medical Director                                  | Caitlin Schein: Staff Physician              | 7/18/2024 |
| Medical Director   | Subhashree Mallika Krishnan: Staff Physician | 7/16/2024 |
| Technical Director                                       | Qian Sun: Tech Dir, Clin Chemistry, Path     | 7/16/2024 |
| Policy and Forms Steering Committee Approval (if needed) | Kelly Walewski: Supv, Laboratory             | 7/16/2024 |
| Lab Manager  | Leah Korodan: Mgr, Division Laboratory       | 7/16/2024 |
|  | Kelly Walewski: Supv, Laboratory             | 7/15/2024 |

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## Applicability

Royal Oak