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Area	Laboratory-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, IRICELL iChem Velocity and iQ200 System, Manual Dipstick read and Manual Microscopic. Correlation is done to look for bias in an up or down direction between the analyzers.

II. SPECIMEN COLLECTION AND HANDLING:

Fresh, well-mixed, un-centrifuged urine.

III. REAGENTS/SUPPLIES:

A. iChem Velocity Urine Chem 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. IRICELL iChem Velocity and iQ200 System #1 and #2.
    2. Clinitek Advantus #1 and #2.
    3. Manual Dipstick
    4. Manual Microscopic (Phase)

E. Record Data on the attached worksheet. Record one sample per worksheet.

F. Return worksheets to the Urinalysis Supervisor.

V. CRITERIA FOR ACCEPTABILITY:

A. The worksheets are first reviewed by the Urinalysis Supervisor 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. **Microscopic** - Comparisons between the instruments/ methods match within one reportable range. Parameters for the iQ200 and Manual Microscopic include: RBC (red blood cells), WBC (white blood cells), Bacteria, Squamous Epithelia Cell, Hyaline Cast and Bacteria.

ELEMENT (hpf = high power field) (lpf = low power field)	**REPORTABLE RANGE**
RBC/hpf	0-2, 3-5, 6-10, 11-20, >20
WBC/hpf	0-5, 6-10, 11-20, 21-50, >50
Squamous, epithelial/lpf	Negative, 1-5, 6-30, 31-50, >50
Hyaline Casts/lpf	0-2 (Negative), 3-5, 6-10, 11-20, >20
Bacteria/hpf	Negative, 1+, 2+, 3+, 4+

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

Attachments

Comparability of Urinalysis Instruments Worksheet.pdf

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	5/19/2023
Lab Chemistry Best Practice Committee	Caitlin Schein: Staff Physician	5/17/2023
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr, Division Laboratory	5/11/2023
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	5/8/2023
	Colette Kessler: Mgr, Division Laboratory	5/5/2023