

Beaumont

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Urinalysis Method Comparison

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

- A. To ensure that the patient results from each instrument/method are checked against each other for the correlation of results.
- B. At least twice annually, a minimum of five patient samples are compared between the Clinitek, the iChem Velocity instrument, refractometer, Clinitek Novus and the Sysmex UF-5000, a urine particle analyzer that is based on the flow cytometry method with a blue laser, and manual microscopy. Analysis will be conducted for the following:
 - 1. **GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, BLOOD, KETONE, NITRITE, LEUKOCYTE, CLARITY, SPECIFIC GRAVITY, COLOR, RED BLOOD CELLS, WHITE BLOOD CELLS, HYALINE CASTS, BACTERIA, SQUAMOUS EPITHELIAL CELLS OR ANY ADDITIONAL MICROSCOPIC ELEMENTS**

II. PROCEDURE:

- A. iChem Velocity, Clinitek, and Clinitek Novus, Manual Dipstick
 - 1. Five patient samples are compared.
 - 2. The five samples are tested on the Clinitek, Clinitek Novus and iChem Velocity analyzers and through the Manual Dipstick Method. See [Laboratory Manual Urinalysis Dipstick](#) procedure..
 - 3. Results are logged on the Urinalysis Instrument Comparison Chemistry worksheet and are submitted for review.
 - 4. The iChem Velocity, Clinitek, Clinitek Novus, and manual dipstick acceptability

limits are based on the level of clinical significance as determined by the reviewing pathologist.

B. Sysmex UF-5000 and Manual Microscopy

1. Five patient samples are compared.
2. The five samples are tested on the UF-5000 and a manual microscopy is performed.
3. Results are logged on the Urinalysis Instrument Comparison Microscopic worksheet and are submitted for review.
4. The UF-5000 and the manual microscopy limits are based on the level of clinical significance as determined by the reviewing pathologist.

C. iChem Velocity, Clinitek, Clinitek Novus and Refractometer

1. Five patient samples are compared.
2. The five samples are tested on the iChem Velocity, Clinitek, Clinitek Novus, and the Refractometer.
3. Results are logged on the Urinalysis Instrument Comparison to Refractometer worksheet and are submitted for review.
4. The specific gravity comparisons between the iChem Velocity, Clinitek, Clinitek Novus, and Refractometer must match within +/- 0.005 or on the level of clinical significance as determined by the reviewing pathologist.
 - a. All specific gravity results of >1.060 on the Velocity will be analyzed using the hand-held refractometer.
 - b. All specific gravity results of >1.030 on the Clinitek will be analyzed using the hand-held refractometer.

III. REFERENCE:

College of American Pathologists (CAP) Standard COM.04250 Comparability of Instruments and Methods-Nonwaived Testing

Attachments

[Urinalysis Instrument Comparison Chemistry Worksheet 042024.pdf](#)

[Urinalysis Instrument Comparison Microscopic Worksheet 042024.pdf](#)

[Urinalysis Instrument Comparison to Refractometer 042024.pdf](#)

Approval Signatures

Step Description	Approver	Date
Medical Director	Muhammad Arshad: Chief, Pathology	5/7/2024
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Applicability

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