

Beaumont

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Document Contact Tanya Williams:
Medical Technologist Lead
Area Laboratory-Urinalysis
Applicability Taylor + Trenton + Wayne

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, ~~and~~ 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 difference 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 difference 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 091024.pdf](#)

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

[Urinalysis Instrument Comparison to Refractometer 09102024.pdf](#)

Approval Signatures

Step Description	Approver	Date
Medical Director	Muhammad Arshad: Chief, Pathology	9/27/2024
Policy and Forms Steering Committee Approval (if needed)	Tanya Williams: Medical Technologist Lead	9/18/2024
	Christopher Ferguson: Dir, Lab Services	9/18/2024
	Kristen DiCicco: Mgr, Laboratory	9/18/2024
	Katherine Persinger: Mgr, Laboratory	9/17/2024
	Ashley Beesley: Mgr, Laboratory	9/17/2024
	Tanya Williams: Medical Technologist Lead	9/11/2024

Applicability

Taylor, Trenton, Wayne