

# 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 ~~and~~, the iChem Velocity instrument ~~as well as the iQ200 Digital Flow Morphology technology using Auto~~, refractometer, Clinitek Novus and the Sysmex UF-5000, a urine particle Recognition analyzer that is based on the flow cytometry method with a blue laser, and manual microscopy. ~~The analyzers Analysis will be checked at least every 6 months. 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 and Clinitek~~
  - 1. ~~Five patient samples are compared.~~
  - 2. ~~The five samples are tested on the Clinitek and iChem Velocity analyzers.~~
  - 3. ~~Results are logged on the Urinalysis Instrument Comparison Chemistry worksheet and will be submitted for review.~~
  - 4. ~~The iChem Velocity and Clinitek acceptability limits are based on the level of clinical~~

significance as determined by the reviewing pathologist.

B. ~~iQ 200 and Manual Microscopy~~

- ~~1. Five patient samples are compared.~~
- ~~2. The five samples are tested on the iQ200 and a manual microscopy is performed.~~
- ~~3. Results are logged on the Urinalysis Instrument Comparison Microscopic worksheet and will be submitted for review.~~
- ~~4. The iQ200 and the manual microscopy limits are based on the level of clinical significance as determined by the reviewing pathologist.~~

C. ~~iChem Velocity and Refractometer, Clinitek, and Clinitek Novus, Manual Dipstick~~

1. Five patient samples are compared.
2. ~~The five samples are tested on the iChem Velocity and the Refractometer.~~ 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 ~~iChem Velocity to Refractometer~~ Chemistry worksheet and ~~will be~~ are submitted for review.
4. The ~~iChem Velocity and Refractometer, Clinitek, Clinitek Novus, and manual dipstick~~ acceptability limits are based on the level of clinical significance as determined by the reviewing pathologist.

D. ~~iChem Velocity~~ Sysmex UF-5000 and Manual Dipstick

- ~~1. Five patient samples are compared.~~
- ~~2. The five samples are tested on the iChem Velocity analyzer and through the Manual Dipstick Method. See [Laboratory Manual Urinalysis Dipstick procedure.](#)~~
- ~~3. Results are logged on the designated Urinalysis Instrument Comparison Chemistry worksheet and will be submitted for review.~~
4. Acceptability: ~~The comparisons between The iChem Velocity and Manual Dipstick must match within +/- one color block/reportable range for each analyte or as determined by the reviewing pathologist based on the level of clinical significance. Dipstick analytes include Color, Clarity, Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte Esterase.~~
  - ~~• All specific gravity results of >1.060 on the Velocity will be analyzed using the handheld refractometer.~~

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.

- E. ~~iChem Velocity and Aution 11 (Canton Laboratory),~~ Clinitek, Clinitek Novus and Refractometer
1. Five patient samples are compared.
  2. The five samples are tested on the ~~iChem Velocity analyzer and through the Manual Dipstick Method,~~ Clinitek, Clinitek Novus, and the Refractometer.
  3. Results are logged on the ~~designated Urinalysis Instrument Comparison Chemistry~~ to Refractometer worksheet and ~~will be~~ submitted for review.
  4. ~~Acceptability: The~~ The specific gravity comparisons between ~~The~~ the iChem Velocity ~~and Aution 11, Clinitek, Clinitek Novus, and Refractometer~~ must match within +/- ~~one color block/reportable range for each analyte or~~ 0.005 or on the level of clinical significance as determined by the reviewing pathologist ~~based on the level of clinical significance.~~ Dipstick analytes include ~~Color, Clarity, Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte Esterase.~~
    - ~~• Color and clarity are evaluated visually when specimens are run on the Aution 11.~~
    - ~~• All specific gravity results of >1.060 on the Velocity will be analyzed using the handheld refractometer.~~
    - ~~• All specific gravity results of >1.030 on the Aution 11 will be analyzed using the handheld refractometer.~~
    - 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.
- F. ~~Aution 11 and Manual Dipstick (Canton Laboratory)~~
1. ~~Five patient samples are compared.~~
  2. ~~The five samples are tested on the Aution 11 analyzer and through the Manual Dipstick Method.~~
  3. ~~Results are logged on the designated Urinalysis Instrument Comparison Chemistry worksheet and will be submitted for review.~~
  4. ~~Acceptability: The Comparisons between the Aution 11 and Manual Dipstick must match within +/- one color block/reportable range for each analyte or as determined by the reviewing pathologist based on the level of clinical significance must match within one reportable range. Analytes of comparison include specific gravity, Glucose, Bilirubin, Ketone, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte Esterase.~~
    - ~~• Color and clarity are evaluated visually when specimens are run on the Aution 11.~~
    - ~~• All specific gravity results of >1.030 on the Aution 11 will be analyzed using the handheld refractometer.~~

### III. REFERENCE:

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

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#### 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	
Policy and Forms Steering Committee Approval (if needed)	Tanya Williams: Medical Technologist Lead	4/26/2024	
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#### Applicability

Taylor, Trenton, Wayne