**purpose** To provide specific information how to operate the Siemens Urinalysis AUWI and UF 1000 instruments for urinalysis at Einstein Medical Center Philadelphia: CLINITEK AUWI TM Automated Urinalysis system.

**PRINCIPLE**

The CLINITEK AUWi™ Automated Urinalysis system is a fully automated urine chemistry analyzer (CLINITEK ATLAS® analyzer) combined with a fully automated urine sediment analyzer (Sysmex UF-1000i instrument).

The CLINITEK ATLAS® Urine Chemistry Analyzer is a fully automated reflectance

spectrophotometer. It uses CLINITEK ATLAS Reagent Paks that are made specifically for use with

this analyzer. Each Reagent Pak contains a roll of reagent strips, each containing reagent areas for

testing glucose, bilirubin, protein, pH, occult blood, ketone, urobilinogen, nitrite, and leukocytes. The

reagent roll also includes a pad for determining the color of the specimen. The analyzer determines the

specimen’s specific gravity (SG) using the refractive index method; it also determines the clarity by

measuring the transmission and scattering of light that passes through the specimen. The CLINITEK

ATLAS analyzer performs the intensity and color of the light reflected from the reagent areas and

converts the data into clinically meaningful results. Results may be recalled to the display screen or

transferred to a printer and/or host computer. The analyzer performs 12 separate tests on each urine

specimen at a rate of 16 seconds per specimen. Up to 200 routine samples can be loaded via

continuous feed in a 10-position sample rack.

**CLINICAL APPLICATION :**

Urinalysis can provide the physician with important information regarding the status of a patient’s health, and can detect metabolic disease and renal disorders. Urinalysis test results are used in at-risk patient groups to assist diagnosis in the following areas:

* kidney function
* urinary tract infections
* carbohydrate metabolism (e.g., diabetes mellitus)

**SPECIMEN COLLECTION AND HANDLING:**

* + A fresh urine specimen (<2 hours at room temperature) collected in a clean, dry, covered container without preservative.
	+ If testing is delayed (>2 hours after collection), the specimen should be refrigerated for preservation. Allow the urine specimen to return to room temperature before testing. Specimens >2 hours after collection that have not been refrigerated should be canceled. (Note: If the Dr. requests the results be released; results must be footnoted that the sample was not refrigerated and interpret results with caution.)
	+ To avoid contamination of the specimen, any culture ordered on the same specimen should be set up prior to dipping urine for urinalysis.
	+ As little as 2 mL of urine is acceptable for chemical testing only. For microscopic, manual mode requires 1ml of urine and Sampler (Auto) mode requires 4ml of urine. However, 5 mL or more is preferred for macroscopic and microscopic urinalysis.
	+ All specimens should be free from fecal and vaginal contamination.
	+ **DO NOT** centrifuge specimens until after wet testing on this system.
	+ Store specimens at 4oC. Discard after 24 hrs.

**IMPORTANT**: **DO NOT** analyze urine specimens that are visibly mucoid or bloody on this instrument. Also a large amount of foam on top of a specimen may cause inaccurate results or a dispensing error.

**REAGENT :**

**CLINITEK ATLAS :**

* CLINITEK ATLAS® Reagent Pak
* Refer to CLINITEK ATLAS Operating Manual for loading instructions. Load the reagent roll into the instrument immediately after removing it from the canister. If the reagent roll is exposed outside the sealed canister or the closed reagent compartment of the instrument for longer than 15 minutes, the reagents may not yield satisfactory results.
* Store the unopened reagent canister at room temperature 15°-30°C (59°-86°F). DO NOT store in a refrigerator.
* Use the reagent roll within 14 days after installing it into the instrument. Do not remove the packet of desiccant from the center of the reagent roll.
* When the Reagent Pak is properly stored in its sealed canister, it is stable until the expiration date. Each CLINITEK ATLAS Reagent Pak provides at least 490 profiles.
* CLINITEK ATLAS® Calibration Kit:
* Store at 2°-8°C (36°-46°F); ***do not freeze***.
* Expiration date is printed on the Calibrator bottle labels.
* CLINITEK ATLAS® Rinse Additive :
* Store at 15°-30°C (59°-86°F)
* Expiration date is printed on the rinse bottle label.
* CLINITEK ATLAS® Positive and Negative Controls :
* Prepare the CLINITEK ATLAS Control Solution(s) using CLINITEK ATLAS Positive or Negative Control Strips, as instructed in the direction insert accompanying the product.
* Store the control solutions according to the information in the control product insert.
* Household bleach (5.25% sodium hypochlorite) :
* Use household bleach with a sodium hypochlorite concentration of 5.25%. If the concentration of the sodium hypochlorite is higher than 5.25%, it must be diluted with distilled water.
* Rinse Solution
* Refer to the Rinse Additive package insert for preparation instructions.
* Prepare the Rinse solution according to the CLINTEK ATLAS Rinse Additive by adding 2 ml of Rinse Additive to 1000 ml of distilled or deionized water. Swirl gently to mix, trying to avoid producing excess bubbles.
* Store at 15°-30°C (59°-86°F)
* The expiration date is defined as two weeks from the day the solution was mixed.
* Ingredients:

|  |  |
| --- | --- |
| Test | Ingredients |
| Glucose | 3.8% w/w glucose oxidase (bacterial); 0.3% w/w peroxidase (horseradish); 19.2 % w/w 4-aminoantipyrene; 11.7% 4-methylcatechol; 26.2% w/w buffer; 38.8% w/w nonreactive ingredients |
| Bilirubin | 0.4% w/w 2,4-dichloroaniline diazonium salt; 37.3%w/w buffer; 62.3% w/w nonreactive ingredients |
| Protein | 0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients |
| pH | 0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97.0% w/w nonreactive ingredients |
| Blood | 6.8% w/w diisopropylbenzene dihydroperoxide; 4.0% w/w 3,3',5,5'-tetramethylbenzidine; 48.0% w/w buffer; 41.2% w/w non­reactive ingredients |
| Ketone | 7.1 % w/w sodium nitroprusside; 92.9% w/w buffer |
| Urobilinogen | 0.2% w/w ρ-diethylaminobenzaldehyde; 99.8% w/w nonreactive ingredients |
| Nitrite | 1.4% w/w ρ-arsanilic acid; 1.3% w/w 1,2,3,4-tetrahydro­benzo(h)-quinolin-3-ol; 10.8% w/w buffer; 86.5% w/w nonreactive ingredients |
| Leukocytes | 0.4% w/w derivatized pyrrole amino acid ester; 0.2% w/w diazonium salt; 40.9% w/w buffer; 58.5% w/w nonreactive ingredients |
| Rinse Reagents | Ingredients |
| Rinse Additive | 3.5% W/vv hexadecyltrimethylammonium hydrogen sulfate; 3.5% w/v magnesium chloride hexahydrate; surfactant |

**CLINITEK AUWi System Power-Up**

**NOTE**: The CLINITEK ATLAS Analyzer should already be powered-on because the specific

gravity (SG) well must be irrigated on a regular basis, even when the instrument is not in use. It

is at times necessary to reboot the instrument, refer to the *CLINITEK ATLAS Operating Manual*

for complete details.

1. Refill printer with paper.

2. Turn on the printer.

3. Check the waste container.

4. Remove any racks from the Track.

5. Turn on the computer.

* The Windows and UF-1000i software will load; this will take about 10 minutes.
* **NOTE**: Be sure to wait for the software to fully boot before proceeding.

6. Turn on the Main Unit (MU) of the UF-1000i using the switch located on the lower right side of the instrument.

7. Press the Start-up switch (the small green button) on the front right of the

MU.

This initiates communication between the MU and the computer.

8. Turn on the Track using the switch located at the back of the Track, where the two sections join together.

9. Verify that the UF-1000i self-checks have passed.

The results are displayed on the computer screen.

Refer to the *UF-1000i Quick Guide* for complete details.

1. **CALIBRATION:**

**A, CLINITEK ATLAS :**

1. **Calibration frequency**  : Calibration is needed when :
* A reagent roll with a different lot number is loaded.
* A reagent roll with the same lot is loaded but the system has not been calibrated within the last 24 hours.
* The system displays error messages requiring you to calibrate the system.
* The system temperature changes by more than 5oC.
	+ Temperature is monitored daily. If tech notices issues with QC material, temperature logs should be reviewed during the troubleshooting process.
* If QC materials reflect an unusual trend or shift or are outside the laboratory’s acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.
* After major maintenance or service
* When recommended by manufacture
* At least every 6 months
1. **Calibration Procedure:**

**IMPORTANT**: Before calibrating, be sure the SG well has hydrated for at least one hour if the instrument is newly installed or if the power has been off for longer than one hour.

**Prepare the tubes of calibrators and cleaning solution**

1. Pour at least 2 mL of 5.25% bleach into a properly labeled sample tube.
2. Pour each of the four Calibration Solutions (from the Calibration Kit) into properly labeled sample tubes (one tube per solution).

The tubes of Calibrator #1, #2, and #3 must each contain a minimum of 3 mL of solution to allow for duplicate testing; the tube of Calibrator #4 must contain a minimum of 5 mL of solution to allow the instrument to automatically repeat the clarity calibration sequence when needed. Allow all solutions to warm to room temperature before being used.

1. Review the previously entered lot numbers for the calibrators on the display (if numbers were entered).
2. If all the lot numbers are correct, press “CONTINUE”.

If the five-minute warming time has elapsed, the calibration sequence begins immediately. If the lamp has been *off* for longer than ten minutes, it must warm for 45 seconds before testing begins. The display shows the message “Optics Stabilizing” and a time bar indicates the time remaining.

|  |  |
| --- | --- |
| **If the lot numbers . . .**  | **Then . . .**  |
| Are incorrect or not displayed  | **a.** Press “Up or “DOWN” to move the arrow to the appropriate line. The arrow moves in a circular pattern; for example, if it is located at the bottom line (Calibrator 4) and “DOWN” is pressed, it moves to the top line (Calibrator 1).**b**. When the arrow is pointing to the calibrator lot number that you need to be change, press “↵”. The display changes to allow you to enter new numbers (up to 13 digits).**c.** Enter the new lot number.**d**. Press “↵” when the lot number has been correctly entered. **e**. Enter the lot number for the next calibrator. Repeat for each line, as needed.**f**. When all calibrator lot numbers have been correctly entered, press “CONTINUE. |

**Load the calibrators and cleaning solution**

1. Place the tube of 5.25% bleach and the four tubes of Calibrator Solution into a specimen rack in the order specified on the display.
2. Place the rack onto the right side of the Sample Handler, with the open side facing to the back as shown in Figure 6-1 of your operating manual. Align the rack along the retaining rail by pushing it to the right; then press “CONTINUE” on the Analyzer.

If the five-minute warming time has elapsed, the calibration sequence begins immediately. If the lamp has been off for longer than ten minutes, it must warm for 45 seconds before testing begins. The display shows the message “Optics Stabilizing” and a time bar indicates the time remaining.

The rack is moved into position for testing, beginning with the cleaning cycle (about 3 minutes counted down by a time bar) and dry pad calibration (about 45 seconds). When the readings are complete, the instrument rewinds the strips just read so the first strip is in position to be wetted during the wet calibration sequence.

1. Review the status on the display.

The display changes with each calibrator tested, decrementing the number of strips remaining and incrementing the tube number. Calibrator #4 is tested first, without the use of any reagent strips; Calibrators #1, #2, and #3 are then tested, each in duplicate.

After all calibrators are pipetted, and while the instrument is analyzing the results, the display shows the message “Completing Calibration Process. Please wait.”

The “Calibration Successful” screen is displayed for five seconds, after which the display returns to the Standby Mode (Ready for Testing screen).

1. **QUALITY CONTROL:**

 **A, CLINITEK ATLAS :**

1. **QC FREQUENCY :** Should be performed at the beginning of every shift using MAS I & MAS III
2. **QC PROCEDURE :**
* Pour at least 2 mL of each control into properly labeled tubes. You can run a total of three controls in a single run.
* Press “ANALYZE” to enter the Control Analyze Mode from the Standby Mode (“Ready for Testing” screen), then press the “CONTROL” softkey.

The display shows the appropriate positioning of the control solutions.

* Place up to 3 tubes of control solution into a specimen rack in positions 1, 2, and 3, as shown on the display.
* Place the rack onto the right side of the Sample Handler, with the open side facing to the back. Push the rack to the right side so it is aligned along the retaining rail.
* Press “CONTINUE” on the Analyzer.

**NOTE**: You **must** place the control tubes in the rack in the correct positions; otherwise one or more controls will not be tested.

* Review the previously entered QC lot numbers on the display (if numbers were entered).

|  |  |
| --- | --- |
| **If the lot numbers . . .**  | **Then . . .**  |
| Are incorrect or not displayed  | **a.** Press “Up or “DOWN” to move the arrow to the appropriate line. **b.** When the arrow is pointing to the control lot number that you need to change, press “↵.” The display changes to allow you to enter new numbers (up to 13 digits).**c.** Enter the new lot number, as instructed in “Procedural Notes for Entering Alpha and Numeric Data” previously.**d.** Press “↵” when the lot number has been correctly entered. **e.** Enter the lot number for the next QC sample. Repeat for each line, as needed. |

* When the lot numbers are correct, press “CONTINUE”.

The specimen rack is moved into position for testing. The instrument then searches for a tube in position 1.

* Review the status on the display.
* The display changes with each control tested, decrementing the number of strips remaining and incrementing the tube number. In addition, the message on the display changes to signify which control is being tested (1st through 3rd). Each control is tested once.

- During testing, the display continually updates the status of “Strips Remaining,” “Tray ID,” and “Tube Number” of the specimen currently being aspirated, as well as “Specimen ID” (if patient specimens are also being tested).

**-**  After all QC samples are pipetted, and while the instrument is analyzing the results, the display shows the message “Analyzer Completing Test Cycle. Please wait.”

As each set of results becomes available, they are displayed for review and printing, if needed. If entry of specimen ID, color and/or clarity is being used, and these have not yet been entered, the first screen displayed provides the opportunity to enter the information through the keyboard (see "End of Run Review" in Section 7 of your operating manual), unless this option was selected as OFF through the Set Up Analyzer routine. When all necessary information is available, the results are displayed.

The following information is also displayed:

|  |  |
| --- | --- |
| **Tray/Tube** | The sequential rack number and the tube position of the control record being displayed |
| **Test Type** | The type of Analyze Mode that was used for this specimen (Control). |
| **Seq** | The sequential number that was assigned to the record. A prefix of “C” or “CN” (depending upon the Results Format selected) is assigned to each sequence number. |
| **Time and Date** | The date and time at which the control was aspirated for testing. |
| **ID** | The identification number (if being used) of the specimens. |
| **Lot #** | The lot number that was entered at the beginning of the Control Analyze Mode for the control in the designated position. |

**10**. Review the control record, and then press “CONTINUE” to display the next record.

**NOTE**: Abnormal results are not flagged on the control records. If results for another control are available, the new record is displayed. Press “CONTIUE” after each record. If “Print Control Results” and/or “Send Control Results” have been selected as “ON” (through the Set Up Analyzer routine described in Section 4), the control results are printed and/or transmitted to a computer as soon as they are available.

1. When the last record has been displayed, the display returns to the Ready for Testing screen (Standby Mode) from which the Routine Analyze Mode can be requested.
2. Record the control results. If any results are not within the expected range, **DO NOT** test patient specimens. Troubleshoot and rerun the controls. Test and report patient specimens **ONLY** when control results are acceptable.
3. **SPECIEM PROCESSING:**
4. **Specimen processing:**
	* 1. **Routine Testing:**
5. The sample volume must be at least 5 mL to run on the AUW Track. This amount allows for the proper mixing of the sample by the UF-1000i sample probe.
6. Check that both the CLINITEK ATLAS analyzer and UF-1000i are ready. On the CLINITEK ATLAS analyzer, the **Ready for Testing** screen should appear. There are two displays on the AUW Track, one for the UF-1000i and CLINITEK ATLAS analyzer sections, respectively. The following should appear on the display units:

|  |  |
| --- | --- |
| UF → READY UFSU→ READY  | AT → READY ATSU→ READY  |

1. Set the sample tubes in the sample racks.
2. Place the rack in the sampler start rack pool of the CLINITEK ATLAS analyzer sampler unit.
3. Press the Start/Stop key on the CLINITEK ATLAS analyzer sampler unit. Do not touch the rack once it is moving.
	* 1. **Stat specimen :**

If necessary, a STAT macroscopic measurement on Clinitek Atlas analyzer can be made while the Track is in operation. The sample volume must be at least 2 mL. A STAT microscopic measurement can be made while the Track is in operation, but only if the UF-1000i instrument is not processing from the Track. The sample volume must be at least 1 mL.

**Using the STAT Holder**

* Pull the STAT holder toward you and place the STAT tube into the holder. Then push the holder back **as far as it will go**.
* Press the yellow “STAT” key on the Sample Handler.
* The STAT holder is locked into proper position for sampling, and the display shows “Stat Analyzing.” The STAT specimen is assigned a unique sequence number with a prefix of “S”; the rack number is designated as “999.”
* After the STAT sample has been analyzed, the display returns to its previous status, and the STAT holder is released.

- Pull the STAT holder forward and remove the STAT tube.

- Enter the ID number as soon as the results are available, either by scanning the bar coded label with the handheld scanner (if being used) or through the analyzer keyboard.

1. **Reports result :**

**Reference range:**

|  |  |
| --- | --- |
| Test | Report |
| Glucose | Negative  |
| Bilirubin | Negative  |
| Protein | Negative  |
| pH | 5.0 – 9.0 |
| Occult Blood | Negative  |
| Ketone | Negative  |
| Urobilinogen | 0.2-1.0 EU/dL |
| Nitrite | Negative  |
| Leukocytes | Negative  |
| Specific Gravity | 1.003 – 1.030\* |
| Color | Yellow, Straw, Dk Yellow, or Amber |
| Clarity (optional) | Clear |

1. **Abnormal Results:**

A microscopic exam is reflexed on a urinalysis sample when the reagent strip is positive for:

 Bilirubin, Blood, Ketone, Leukocyte, Nitrate, Protein

When the Clarity is other than clear

When the Color is other than yellow, dark yellow

When Glucose is >1000

1. **SYSTEM SHUTDOWN :**

**NOTE**: The CLINITEK ATLAS analyzer remains powered-on because the specific gravity (SG) well must be irrigated on a regular basis, even when the instrument is not in use. It is at times necessary to reboot the instrument, therefore, refer to the *CLINITEK ATLAS Operating Manual* for complete details.

1. **MAINTENANCE:** Refer to the *CLINITEK ATLAS Operating Manual* for complete details.
2. **Daily maintenance:**

- Clean SG well of *CLINITEK ATLAS analyzer.*

*-* Perform Shut down and check the trap chamber of UF-1000i.

1. **Monthly maintenance:**
* Check the Atlas Pipette for Leakage
* Clean Drain Spout
* Clean Detector Windows
1. **Maintenance (Every 4 Months)**
* Clean Atlas Readhead
1. **Other Maintenance**
* **Track maintenance:** Spills on the Track should be cleaned up immediately with a 5% Bleach solution and Kimwipes tissue or by using the Sani Cloth Bleach Wipes.
* **Carryover Detection:**

Carryover studies are performed as part of the initial evaluation of the instrument,

after major maintenance, repair of the pipetting assembly of instrument.

* To perform the carryover study perform the following:
	+ Spike negative urine control with a fresh blood sample to yield the highest reading for blood. The spike control will be assayed three times followed by three assays of the unspiked negative control.
	+ Pour a minimum of 4 mL of each specimen into three sample tubes labeled H1, H2, H3, L1, L2, and L3.
	+ Run the high (H1, H2, H3) specimens followed immediately by the low specimens (L1, L2, L3) in the manual or automated track mode.

**Expected Results: On the Atlas**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **H1** | **H2** | **H3** | **L1** | **L2** | **L3** |
| **Blo.** | **3+** | **3+** | **3+** | **Negative** | **Negative** | **Negative** |
| **Nit.** | **POS** | **POS** | **POS** | **Negative** | **Negative** | **Negative** |
| **Leu.** | **Small** | **Trace** | **Small** | **Negative** | **Negative** | **Negative** |

 Record results on UA01-016 Form C and submit to Supervisor for Review.

 Acceptable Limits: L1, L2 and L3 should be negative. If results are not acceptable,

 troubleshooting is necessary. Examples of troubleshooting would be to run blank samples

 through the instrument. If results continue to be unacceptable service should be called and the

 instrument should not be used until approved by the supervisor.

1. Record maintenance on Form UA01-016 Form A1.
2. **Limitation:**
* CLINITEK ATLAS Optical System: There are inherent differences between the colors that are perceived by the human eye and that are detected by any instrumental optical system. The human eye is capable of detecting minute differences in shade and very small areas of color; artificial optical systems are less sensitive to such small changes. Conversely, analyzer optics are capable of detecting certain colors that are masked by or blended with other colors to the human eye. For this reason, exact agreement between visual results and analyzer results might not be found. However, agreement is generally within one reported level and is equal to or better than the agreement between two visual readers. Agreement of urine color is generally within one step along the chromatic scale.
* Interference substances: For all tests, false positive results (increased values) and/or false negative results (decreased values) can occur when substances that cause abnormal urine color are present, such as: Visible levels of blood or bilirubin , drugs containing dyes , nitrofurantoin , riboflavin.
* Sensitivities listed in the following table depend upon the presence or absence of inhibitory and matrix factors typically found in urine, such as specific gravity and pH.

| Test Name | False Positive or Increased values | False Negative or Decreased values |
| --- | --- | --- |
| Glucose | Temperature | * Ascorbic acid (≥ 30mg/dL) may affect a 100 mg/dL glucose level
* High specific gravity
* Temperature
 |
| Bilirubin | * Metabolites of Lodine (etodolac)
 | * Ascorbic acid (≥ 15 mg/dL).
 |
| Protein | * Highly buffered or alkaline urines
* Contamination with quarternary ammonium compounds (from some antiseptics and detergents) or Chlorhexidine (found in some skin cleansers and preservatives)
 |  |
| pH |  |  |
| Occult Blood | * Oxidizing contaminants (e.g. bleach)
* Microbial peroxidase from urinary tract infections
 | * High specific gravity
* Capoten® (Captopril)
 |
| Ketone | * Highly pigmented urines
* Large amounts of levodopa (L-dopa) metabolites
* Compounds that contain sulfhydryl groups
* High specific gravity and low pH (trace reaction)
 |  |
| Urobilinogen | * Temperature > 26°C (79°F)
* ρ-aminosalicylic acid (PAS) and sulfonamides
 | * Formalin
* Temperature < 22°C (72°F)
 |
| Nitrite | * Colored precipitates
 | * Infections caused by organisms that don’t contain reductase
* Urine was not in bladder long enough (at least 4 hours)
* Absence of dietary nitrate
* Ascorbic acid (≥ 75 mg/dL)
 |
| Leukocytes |  | * Elevated glucose (≥ 3 g/dL)
* Cephalexin (Keflex®) or Cephalothin (Keflin®)
* High concentrations of oxalic acid
* Tetracycline
 |
| Specific Gravity | * Pyridium
 | * Pyridium
 |
| Color | * Concentration
* Food Pigments
* Dyes
* Blood
* Various pathological conditions
 | * These all can affect negatively as well.
 |
| Clarity |  | * Particulate matter that settles
 |

1. **TROUBLESHOOTING**

Complete UA01-016 Form B when troubleshooting is necessary.

1. **Reference:**
2. Sysmex UF-1000iTM Fully Automated Urine Particle Analyzer CLSI/NCCLS Procedure. MKT-70-1108, Oct 2008.
3. Automated Urinalysis using the CLINITEK® ATLAS Analyzer procedure,-REVA0811.
4. Clinitek AUWI Operator’s Guide, Siemens Healthcare Diagnostic INC. 10376688 Rev. B, 2012-01.

**Approval Signatures:**

|  |  |  |
| --- | --- | --- |
| Date | **Printed Name** | **Signature** |
| 12/8/2016 | Jennifer Lore, MFS, MTChemistry Supervisor  |  |
| 12/8/2016 | Nancy A. Young, M.D., FCAPMedical Director  |  |

## History Review

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| --- | --- | --- |
| **Date****Reviewed** | **Reviewed By** | **Revisions** |
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