**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 Sysmex UF-1000*i* is a fully automated urine particle analyzer intended for *in vitro* diagnostic in urinalysis. The instrument is a medical device to replace microscopic testing of normal and abnormal urine specimens and to flag samples containing certain abnormal formed elements. The UF-1000*i* is intended to screen patients for urine abnormalities that indicate the need for further assessment. The analyzer automatically mixes, aspirates and analyzes formed elements in urine using flow cytometry measurements of forward scatter of light (Fsc) and fluorescence (Fl). The UF-1000*i* displays and enumerates populations of formed elements and provides flagging information for other pathological elements. The elements enumerated by the UF-1000*i* are RBC, WBC, Squamous Epithelial Cells, Hyaline Cast and Bacteria. Flagged elements are Crystals, Yeast Like Cells (YLC), Pathological Casts, Small Round Cells, Sperm and Mucus.

**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 REQUIREMENTS:**

1. Uncentrifuged urine without preservatives is the preferred sample type.
2. Manual mode analysis requires 1 mL of urine.
3. Sampler (auto) mode analysis requires 4 mL of urine.
4. Analysis should be done as soon as possible. Formed elements may disintegrate at varying rates depending on pH, osmolality and storage conditions.
5. If immediate analysis is not possible, the urine may be refrigerated. No significant interference from amorphous urates or phosphates has been demonstrated on the UF-1000*i*.

**IMPORTANT**: **DO NOT** analyze urine specimens that have fluorescent colors, large visible particles or specimens that glutaraldehyde, antibiotics or formalin have been added to after collection on the instrument.

SUPPLIES

1. Deionized water
2. Clorox™ bleach

**Note:** *Used for sample filter cleaning only. Do not aspirate.*

1. Kimwipes, gauze, or plastic lined wipes
2. Urine test tubes with a diameter of 12-15mm and a height of 95-120mm
3. Plastic squeeze bottles
4. Tweezers
5. Bi-level Commercial Control, UFII Control

REAGENT :

**SYSMEX UF-1000ITM:**

* **UFII SHEATH™ (UTS)** : is an isotonic saline solution used to form a laminar sheath flow around diluted and stained samples for flow cytometry on the UF-1000*i.*
* **UFII PACK-SED™ (UPS)** : is the diluent for RBC, WBC, Epithelial Cells and Casts on the UF-1000*i*. UFII PACK-SED can also be used to dilute urine samples prior to analysis on the UF-1000*i*. When used as a diluent, samples must be analyzed within 30 minutes.
* **UFII PACK-BAC™ (UPB) :** BAC is the diluent for Bacteria on the UF-1000*i*.
* **UFII SEARCH-SED™ (USS)** is a stain for flow cytometric measurement of RBC, WBC, Epithelial Cells and Casts on the UF-1000*i*.
* **UFII SEARCH-BAC™ (USB)** is the stain for flow cytometric measurement of Bacteria on the UF-1000*i.*
* **Clorox™ Bleach :** is a strong alkaline detergent used to clean the filter on the UF-1000*i*. Clorox bleach is recommended for use in cleaning. If Clorox is not available, generic bleach may be used but must be filtered.
* **UFII CONTROL™ Commercial Control Material** is a bi-level commercial control for *in vitro* diagnostic use with the UF-1000*i*.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reagent** | **Abbreviation** | **Active ingredient** | **Storage** | **Stability(after opened)** |
| **UFII SHEATH™** | **UTS** | **Tris Buffer 0.14%** | **2-35oC** | **60 days** |
| **UFII PACK-SED™** | **UPS** | **Buffer 1.12%** | **2-35oC** | **60 days** |
| **UFII PACK-BAC™** | **UPB** | **Buffer 1.12%** | **2-35oC** | **60 days** |
| **UFII SEARCH-SED™** | **USS** | **Polymethine Dye 0.03%**  **Ethylene Glycol 99.9%** | **2-35oC** | **60 days** |
| **Clorox™ Bleach** |  | **Sodium hypochlorite 6.0%** | **Room Temp.** | **Stable** |
| **UFII CONTROL™** |  | **Latex particle**  **UFII-L: Control particle 0.10%**  **UFII-H : Control particle : 0.40%** | **2-10oC** | 1. **days** |

REAGENT REPLACEMENT

1. When the UF-1000*i* runs out of a reagent, an alarm sounds and the instrument stops after completing analysis of the sample being processed.
2. A message indicating which reagent requires replacement is displayed in the “Help” dialog box. Click **OK**.
3. The Reagent Replacement dialog box will display.
4. Select the tab for the reagent being replaced.
5. Enter the reagent lot information by one of the following methods:
   * Using the keyboard, type the lot number and expiration date.
   * Using the handheld barcode reader, scan the barcode on the container.
   * Scan barcode on bottles of UFII Pack SED and UFII Pack BAC and on pouches of UFII Search SED and UFII Search BAC.
6. Remove the cap from the new container.
7. Remove cap and tubing from empty container and using clean technique, insert the tubing into the new container.
8. Click **RUN** in the dialog box to begin priming the reagent.
9. Dispose of empty containers according to local regulations.

**SYSMEX UF-1000ITM:**

1. **Calibration frequency :**

Calibration must be verified every six months or on an “as needed” basis to ensure accuracy of the system. Calibration is also required if one or more of the following occur:

* Critical parts are replaced such as the SRV or circuit boards.
* Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.
* When advised by Sysmex Field Service Representative (FSR) or Technical Assistance Center (TAC).

**2. 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:
  + Carry over should be performed on BACT to ensure the integrity of the system, since it has the highest linear range.
  + 3, 4-mL tubes of both a low and a high sample. The low sample is the PACK-BAC reagent. The high sample should be from 80% to 100% of the UF-1000i AMR.
  + Run the high (H1, H2, H3) specimens followed immediately by the low specimens (L1, L2, L3) in the manual or automated track mode.
  + Carryover % will be calculated from results as follows:
  + (L1-L3)/ (H3-L3) X 100
  + Where
    - L1 is the first analysis of the low specimen
    - L3 is the third analysis of the low specimen
    - H3 is the third analysis of the high specimen.
    - The expected % carryover for BACT is <0.1%
    - Record on UA01-017 Form A
* If results are not acceptable, troubleshooting is necessary. Examples of troubleshooting would be to run blank samples through the instrument, run background checks and clean the filter. If results continue to be unacceptable service should be called and the instrument should not be used until approved by the supervisor.

QUALITY CONTROL

1. **Frequency**

UFII Control-L will be run every 8 hours.

UFII Control-H will be run every 8 hours.

1. **Control Use**
2. Preparation of QC Files

Before analyzing controls, each new box of QC material regardless of lot number must be inputted into the Instrument Software Setup

* 1. Click **QC Files** on the toolbar or press **F5** on the keyboard.
  2. Click on the line for the QC lot information to be input.
  3. Open the Input dialog box by clicking **Edit** or pressing **F9** on the keyboard.
  4. Select the appropriate control level (UFII Control-L or UFII Control-H) from the drop-down box for “Material”.
  5. QC Lot information may be entered by one of the following methods:
* Using the keyboard, enter the 8-digit lot number. Using the drop-down box for the expiration date, select the date stated on the assay sheet from the calendar.
* Using the handheld barcode reader, scan the barcodes for the lot number and expiration date.
  1. Enter the target and limit values by one of the following methods:
* Using the keyboard, enter each target and limit value from the assay sheet. For UFII Control-H, enter the upper and lower limits for each of the sensitivity parameters.
* Using the handheld barcode reader, scan the barcodes for each parameter on the assay sheet.
  1. Click **OK** to save.
  2. Repeat steps **b** through **g** for remaining level.

1. Analysis of Quality Control Material

Allow control material to come to room temperature (15-30OC) for 20-30 minutes before use.

* 1. Click **Manual** on the toolbar or press **F2** on the keyboard.
  2. Click **QC** on the right side of the dialog box.
  3. Select the appropriate file from the list and click **OK**. Verify that appropriate lot and level are displayed on the QC Analysis dialog box.
  4. Mix the UFII control bottle **vigorously** (at least 20 times).
  5. Within 10 seconds after mixing, dispense 1.0 mL of UFII Control into a new test tube.
  6. Within 10 seconds after dispensing, hold the tube with dispensed control up to the aspiration pipette with the tip near the bottom of the tube, and press the green **Start** switch on the front of the Main Unit.
  7. When aspiration is complete and beeping stops, pull the tube away from aspiration pipette.
  8. Discard the test tube after measurement and do not reuse.
  9. After analysis is complete, results will display in the dialog box. Click **Accept** for points to plot or **Cancel** to end without saving. Click **Reanalyze** to process same QC level again.
  10. Repeat steps **a** through **i** for remaining QC level.

1. Review of QC Results
   1. To view the **QC Radar charts**, click **QC Files** on the toolbar on the IPU or press **F5** on the keyboard.
   2. Click on the file to be viewed (1-24). Do not open the file.
   3. The radar charts display to the right of the file selected. Date and time of analysis are displayed next to the radar charts.
   4. Most recent results are displayed on the radar chart in blue. Points outside of acceptable limits are displayed with red “X”, the name of the parameter is backlit in red and the word ERROR is displayed.
   5. To view the Levy-Jennings (L-J) chart of the selected file, open the chart by clicking **QC Charts** on the toolbar on the IPU, pressing **F11** on the keyboard or double clicking on the line for the file to be viewed.
   6. View all of the parameters on the QC chart using the scroll bar on the right side.
   7. After completion of the QC analysis, verify the RBC-S\_FSC histogram on the browser screen for each QC level is a single peak as shown on the UFII Control assay sheet.

**Quality Control Corrective Action Plan**

1. If QC is out, Check the lot number and expiration date. If lot and expiration date are acceptable re-pour fresh QC and repeat.
2. If lot number and expiration data are not correct set up the new lot number and expiration date as explained above in section Quality Control B and notify lead tech/ supervisor and record in the communication log.
3. If QC is still out after repeating using the same bottle of QC material open a new vial of QC and set it up in the Instrument the run the QC.
4. If QC is still out contact Siemens hotline for support.

**Recording/Storage of Quality Control Data**

* 1. Printing Quality Control data
     1. Click **QC Files** on the toolbar on the IPU or press **F5** on the keyboard.
     2. Click on the line for the QC file to print. Display the chart by clicking **QC Charts** on the toolbar on the IPU, pressing **F11** on the keyboard or double clicking on the line for the appropriate file.
     3. Set the range of points to be printed by clicking the cursor and dragging to the left. If all points are to be included, press **Ctrl** and **A**.
     4. Click **Report** on the toolbar on the IPU or press **F12** on the keyboard. Select: **Report (GP)(R)** for L-J charts or **Report (LP)(L)** for numeric data.

1. Sending Quality Control data to Host
   1. Click **QC Files** on the toolbar on the IPU or press **F5** on the keyboard.
   2. Click on the line for the QC file to send to the host. Display the chart by clicking **QC Charts** on the toolbar on the IPU, pressing **F11** on the keyboard or double clicking on the line for the appropriate file.
   3. Set the range of points to be sent to the host by clicking the cursor and dragging to the left. If all points are to be included, press **Ctrl** and **A.**
   4. Click **Report** on the toolbar on the IPU or press **F12** on the keyboard. Select **Host (HC)(H)**.

**MAINTENANCE:** Refer to the *CLINITEK ATLAS Operating Manual and UF-1000i*for complete details.

* **Daily maintenance:**
* Perform Shut down and check the trap chamber of UF-1000i.
* **Weekly maintenance:**
* Perform Full Shut down powering off unit.
* **Monthly maintenance :**
* Clean the Sample Rotary Value (SRV) of UF-1000i.
* **As-needed maintenance: UF-1000i :**
* Replace the waste container
* Replace the sample filter
* Replace the reagents
* Check/adjustment of pressure and vacuum
* Replace fuses
* **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.
* Record maintenance on UA01-017 Form A1.

OPERATING PROCEDURE

1. **Start-up Procedure**
2. Check physical status of the analyzer:
   1. Fill printer with paper.
   2. Remove racks from sampler.
   3. Empty waste container (if used).
3. Power on the Information Processing Unit (IPU).
4. Press the power button on the front lower right side of the IPU.
5. The UF-1000*i* log-on box displays. Using the keyboard, enter the log-on name. Press **Enter** when prompted for a password.
6. Power on the Main Unit (MU).
   1. Press the power switch on the right side of the Main Unit.

**Note:** *Power switch will remain on following a Shutdown when “Main Unit power OFF” is selected.*

* 1. Press the green Start-Up button on the front right side of the Main Unit.
* The instrument automatically performs checks on the following: microprocessor, mechanical parts, temperature and background.
* If any of the checks are outside of specifications, an error message will be displayed.
* Pressure and vacuum are monitored by the analyzer.

## Patient Sample Processing

1. SAMPLER (AUTO) MODE (1200μL aspirated volume). 4.0 mL of urine is required in sample tube for sampler mode analysis.

**Note:** *Mix specimen container by inversion before pouring into sample tube. Do not swirl contents.*

* 1. Mix and pour urine from collection container into sample tube and affix barcode label.
  2. Place the barcoded sample tubes in a rack and set the rack in the right rack pool of the sampler. The notch on the rack must be on the right side when placed on the sampler.
  3. When “Ready” LED is green, click **Sampler** on the IPU toolbar or press **F3** on the keyboard.
  4. Click **Sampler Start** on the Sampler Sample Number dialog box or press **Enter**.
  5. The UF-1000*i* will automatically turn the tube to read the barcode, mix and aspirate the sample.
  6. Results will be displayed on Explorer screen and will print if auto-output is selected.

1. MANUAL MODE ANALYSIS (800μL aspirated volume). 1.0mL is required for manual mode analysis.
   1. When “Ready” LED is green, click **Manual** on the IPU tool bar or press **F3** on the keyboard.
   2. Enter specimen ID number by one of the following methods:
      * Using the keyboard, type the sample ID number.
      * Using the handheld barcode reader, scan the barcode on the specimen tube.

**Note:** *After the first specimen, the numbers will be added sequentially.*

* 1. Specimen and Collection information may be entered if appropriate.
  2. Place the well-mixed specimen tube up to the aspiration pipette with the aspiration tip well below the meniscus of the sample.
  3. Press the green manual **Start** switch on the front of the Main Unit. Hold the tube in place until aspiration is complete (beeping stops).
  4. The next sample may be analyzed when the “Ready” LED is green.
  5. Results display in Explorer when complete and print if auto-output is selected.

## DAILY MAINTENANCE

***Perform Shutdown Sequence***

The shutdown sequence automatically cleans the aspiration pipette and internal parts of the hydraulic system. Perform shutdown at the end of each day’s analyses or at least once every 24 hours or 500 samples when the instrument is used continuously.

1. Double-click **SHUTDOWN** on the Menu screen. The Shutdown dialog box will display.
2. To automatically turn off the Main Unit after the shutdown process, click “Yes” in the shutdown dialog box.
3. Press the green “Start” switch on the front of the Main Unit. Status of the shutdown process will be displayed.
4. When the shutdown process is complete, the power to the Main Unit is turned OFF automatically if “Yes” was selected in step 2.
5. If the automatic Main Unit power off is set to “No”, manually turn off the power switch or click “Restart” to continue with analysis.
6. Record cleaning on maintenance log.

***Check* and *Remove Fluid from Trap Chamber***

At the end of the day’s analyses, check the vacuum trap chamber for fluid and discard if present.

* 1. If fluid is present, turn the Main Unit off and wait for one minute for the pressure to drop.
  2. Open the cover of the Main Unit. The trap chamber is located on the upper right side.
  3. Turn the chamber counterclockwise to remove.
  4. Discard the fluid. Rinse the ball and chamber.
  5. Replace the ball (pointed side up) in the chamber. Replace the chamber and turn clockwise to tighten finger-tight. Pressure and vacuum errors can occur if the chamber is not properly seated.
  6. If fluid accumulates on a daily basis, contact Sysmex Technical Assistance Center.
  7. Record on maintenance log.

## MONTHLY MAINTENANCE

***Clean Sample Rotor Valve (SRV) and Reset the SRV counter***

Clean the Sample Rotor Valve (SRV) monthly or every 9,000 cycles. If the SRV cycle count reaches 9000 since the last cleaning, the message “**Clean the SRV**” will be displayed when the analyzer is powered up.

1. Turn off the power to the Main Unit. Wait one minute for the pressure to drop.
2. Open the Main Unit cover.
3. Turn the fixing screw counter-clockwise and remove it from the Sample Rotor Valve (SRV) mounting shaft.
4. Remove the front fixed valve by pulling gently towards you.
5. Remove the SRV. The valves are held together by suction and may be difficult to separate. Pull the valve gently, carefully twisting it off, without separating them from each other. Take care not to lose the washer between the rotary valve and the front fixed valve.
6. Wash the surfaces of the front and rear fixed valves, the SRV, the shaft and the washer with gauze soaked in deionized water.
7. Reassemble the SRV in reverse order of disassembly. Turn the fixing screw clockwise to tighten against the shaft with a gap of about 1mm.
8. Remove, clean and dry the SRV tray, and replace.

**Note:** *Make certain that the metal knob is between the valve switching plates on the right and is touching the top one.*

1. Close the Main Unit front cover and switch the power on.
2. Verify background values are within acceptable limits.
3. Perform QC.
4. Reset the SRV counter.
5. Double-click the **Controller** icon on the main menu.
6. Double-click the **Maintenance** icon and **Counter** icon. The Counter dialog box will display.
7. Click **Reset** button next to the SRV counter to reset to zero.
8. Click **OK** to save.
9. Record the cleaning on the maintenance log.
10. **AS-NEEDED MAINTENANCE**

**Note:** *This is the only use of Clorox on the UF-1000i. Do not aspirate bleach.*

***Sample Filter Maintenance***

If a sample contains a large amount of foreign particles, clogging of the Sample Filter can occur. When this occurs, a “Short Sample” message may display even when sufficient sample is in the tube. The sample filter is cleaned or replaced on an as-needed basis.

* 1. Turn off the power to the Main Unit. Wait one minute for the pressure to drop.
  2. Open the front cover of the Main Unit.
  3. Remove the sample filter from the sample filter holder.
  4. Remove the filter fixture from the tube supporting brace by holding the tube supporting brace and turning the filter fixture counter-clockwise.
  5. Hold the tube supporting brace and turn the filter fixture counter-clockwise to remove the complete filter assembly.
  6. Carefully remove the filter and packing within the filter fixture using tweezers.
  7. Rinse the filter and packing with Clorox bleach followed by **thorough** rinsing with deionized water.

**Note:** *After disassembling sample filter, reassemble in reverse order*.

* 1. Re-install the cleaned filter **OR** replace with a new filter.
  2. Record the cleaning on the maintenance log.

1. REPORTING RESULTS

## Reference Range:

WBC 0-5 hpf

RBC 0-4 hpf

Epithelial Cells 0-5 hpf

Casts 0-8 lpf

Bacteria 0-500 cells/ul

**Review Criteria and Actions**

If any of the following parameters flag than the specimen will need to be spun down at 2000 rpm for 5 minutes and reviewed manually using the microscope.

* Path Cast, SRC, X-TAL, YLC, Sperm
* Any discrepancy flags for RBC and WBC (i.e. ??? or +++)

Upon review of results in Cerner:

Change “Path Review” to N/A

Corrective Action for Sysmex UF-1000*i* Series Messages

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter or Condition | Positive | **Review Flag** | **Limit Defaults** | Action |
| **Pathological Casts** | + | ON | 3.5/µL | Spin sediment for microscopic analysis to verify presence of path casts – identify if present |
| **SRC** | + | ON | 15.0/µL | Spin sediment for microscopic analysis to verify presence of Small Round Cells – identify if present |
| **YLC** | + | ON | 25.0/µL | Spin sediment for microscopic analysis to verify presence of Yeast Like Cells - identify if present |
| **X-TAL** | + | ON | 25.0/µL | Spin sediment for microscopic analysis to verify presence of Crystals – identify if present |
| **Sperm** | + | ON | 10.0/µL | Spin sediment for microscopic analysis to verify presence of Sperm |
| **Mucus** | N/A | OFF | N/A |  |
| **RBC** |  | OFF |  | Report as >5,000/µL or TNTC |
| **WBC** |  | OFF |  | Report as >5,000/µL or TNTC |
| **EC** |  | OFF | >200 | Report as >200/µL or TNTC |
| **Cast** |  | ON | 2.5/µL | Report as >30/µL or TNTC |
| **Bacteria** |  | OFF | 10,000/µL | Report as >10,000/µL or TNTC |
| **RBC Abnormal Cluster Errors** |  |  |  | Spin sediment and check RBC enumeration |
| **Vote Outs** |  |  |  | Spin sediment for microscopic analysis |
| **Abnormal DC Sensitivity Error** |  |  |  | Spin sediment for microscopic analysis |

Limitations of Procedure

## UF-1000*i* Series Manufacturer Stated Linearity

Range of element concentrations

|  |  |
| --- | --- |
| **Formed Element** | **Measuring Range** |
| RBC | 1.0 – 5000.0 / µL |
| WBC | 1.0 – 5000.0 / µL |
| Epithelial Cells | 1.0 – 200.0 / µL |
| Cast | 1.00 – 30.0 / µL |
| Bacteria | 5.0 – 10000.0 / µL |

Samples containing fluorescent dyes should not be analyzed due to possible interference with dyes used on the UF-1000*i*.

**TROUBLESHOOTING**

Complete UA01-016 Form B when troubleshooting is necessary.

References

* + - 1. Sysmex UF-1000*i* *Instructions for Use*, Sysmex Corporation, Kobe, Japan. March 2008.
      2. Sysmex UF-1000*i* *Software Guide*, Sysmex Corporation, Kobe, Japan. March 2008.
      3. UFII Control package insert, Sysmex Corporation, Kobe, Japan. June 2007.
      4. Material Safety Data Sheets, Sysmex America, Inc. January 2008.
      5. Product inserts and reagent packaging, Sysmex Corporation, Kobe, Japan.

**Approval Signatures:**

|  |  |  |
| --- | --- | --- |
| Date | **Printed Name** | **Signature** |
| 12/8/2016 | Jennifer Lore, MFS, MT  Chemistry Supervisor |  |
| 12/8/2016 | Nancy A. Young, M.D., FCAP  Medical Director |  |

## History Review

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