

The Complete Urinalysis with Automation



Points: Points are awarded for Admission Ticket (AT), Skills, including general lab requirements, as well as successful and timely completion of Study Questions.

Objectives: **Note: The Siemens Clinitek Status+ instrument is brand new to this lab. Students working with these instruments must, under the direction of their instructor(s), follow the manufacturer's written directions for maintenance and operation. Any information presented in this lab is subject to change based on the requirements of the newer instruments.**

1. According to the standards set by the instructor, the student will be able to perform routine maintenance and quality control on a automated urine analyzer prior to analyzing three (in first lab session) and five (in second lab) urine specimens producing dipstick results within ± 1 pad reading of the instructor's results and matching microscopic results $\pm 20\%$ as outlined in the Microscopic Lab.
2. Following class demonstration, each student will, in turn 'mentor' and evaluate one or more classmates and, in-turn, be similarly evaluated for the maintenance and operation of the Siemens Clinitek Status+ OR Clinitek 50 Urine Chemistry Analyzer (as applicable).
3. Use appropriate recording format to report results as established in previous UA labs.
4. Use quality control results to determine the acceptability of test results. (One set of controls per instrument will be performed and all students who use that instrument will record and utilize the information.)
5. Answer all pre-test and study questions *using related information found in the textbook, lecture guide, and this lab's procedure as well as ALL course lab procedures covered previously.*

Equipment:

1. Centrifuge
2. Microscope
3. Test tubes, racks, marking pencils, Kim-wipes
4. Siemens Diagnostics Clinitek Status+ OR Clinitek 50 Urine Chemistry Analyzer

Supplies:

1. Siemens Clinitek Status+ OR Clinitek 50 Urine Chemistry Analyzer
2. Centrifuge tubes
3. Five (5) urine specimens, appropriate urine controls.
4. Multistix 10 SG reagent strips
5. 3% SSA, Acetest tablets, Ictotest tablets (with color charts)
6. Microscope slides and cover glasses
7. Color pictures of urinary sediment

References:

1. Siemens/Bayer Siemens Clinitek Status+ OR Clinitek 50 Urine Chemistry Analyzer User's Guide
2. Current course textbook - **Mundt & Shanahan Ch. 15**
3. Strasinger, S.K., Di Lorenzo, M.S., Urinalysis and Body Fluids, 5th ed., Appendix A: Urinalysis Automation
4. Bayer Multistix Package Insert
5. Package insert from quality control specimens.

- Agenda:**
1. Review of this lab, related textbook readings, and techniques from previous UA lab exercises.
 2. Review instrument routine maintenance, quality control and operation procedures outlined in this document. Observe demonstration(s) / powerpoint presentation.
 3. Perform maintenance and quality control procedures required in preparation of performing routine UA. Students will work in pairs, coaching and monitoring these procedures. Each of the student pair must perform the activity.
 3. Perform complete urinalysis on five (5) specimens including color, transparency, UA chemical analysis and microscopic exams.
 4. Clean work area, restock supplies if needed.
 5. Utilize lecture, textbook and other resources to work on study questions.

Principles and Related Information:

The biggest preventable variable in urinalysis results comes from the mis-reading / mis-interpreting of the dipstick results. The solution to this problem is utilization of an automated urine dipstick reading instrument. Advantages to use of such instrumentation includes: increased efficiency, improved precision, accuracy and reproducibility.

Within these instruments, light passes through a filter to reach the dipstick pad where, depending on the depth of color, some of it is absorbed and the remainder is bounced / reflected to a photocell - detector. The signal created is sent to the instrument's on-board computer which compares the amount of reflected light detected to that of known concentrations of the analyte / substance being measured and displays the appropriate concentration for the amount of light detected from this analysis.

Instruments vary greatly in the tasks they perform. Strip readers evaluate the reactions on the dipstick at specified times. Their accuracy depends on the operator's skill and accuracy in appropriately identifying the sample, mixing, dipping, blotting, getting the strip onto the tray and activating the timer appropriately. Higher end instruments add the urine to the strip and automatically activate the timing mechanism. There are also instruments capable of performing the complete UA from evaluating the physical and chemical properties through the microscopic.

See reference listings for sources of additional / general information on automated urinalysis. Addition information on the CLINITEK 50 is available on the *CLINITEK 50 Urine Chemistry Analyzer* document that accompanies this lab. Additional information on the Clinitek Status is available in the Operator's Manual that accompanies the instrument.

Laboratory informatics

Where the CLINITEC 50 or Clinitek Status Analyzer is a suitable instrument for low volume clinics, educational settings and doctor's offices; the larger and more automated urinalysis analyzers with on-board computers capable of interfacing with the laboratory mainframe computer is standard equipment in the modern hospital laboratory.

In today's modern laboratory a system of computers and software programs exchange data about patients, test requests and test results. Collectively this is known as a Laboratory Information System or LIS. The LIS is interfaced with the Hospital Information System. This system enables the hospital and lab to order the correct test requests for each patient, keep track of individual patient or specimen histories, and help guarantee a better quality of results as well as printing hard copies of the results for patient charts and apply appropriate billing.

Principle of Instrument:

Virtually all urine dipstick readers, such as the Siemens Clinitek Status+ OR Clinitek 50 operate on the principle of reflectance photometry which analyze the color and intensity of the light reflected from the reagent area of the dipstick and display the results in a clinically meaningful units. (Reflectance photometry)

Results are reported with semi quantitative values, e.g. Protein is expressed as 5 mg/dl, 10 mg/dl, but not in between values. Instrument programming allows reporting in either traditional or SI system units according to the protocol of the institution.

Purposes

Routine urinalysis is done for a number of reasons:

1. Screen for asymptomatic, congenital, and inherited diseases such as diabetes mellitus, galactosemia, renal and liver disease.

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Urinalysis

2. To aid in diagnosis of diseases such as urinary tract infections, diabetes, and types of jaundice.
3. To determine the progress of a disease and the effectiveness of treatment.

Principle of Reactions

See Multistix 10 SG produce insert for complete explanation of reaction principles. Parameters analyzed are as follows:

Glucose: Glucose Oxidase-peroxidase method.	(Negative for normal samples)
Bilirubin: Diazotized dichloroaniline method.	(Negative for normal samples)
Ketone: Nitroprusside test.	(Negative for normal samples)
Specific gravity: By indicator dye.	(Range: 1.016-1.022)
Blood: Peroxidase like activity of hemoglobin.	(Negative for normal samples)
pH: By double indicator.	(Dipstick range: 5 to 9; normal patient 4.5 - 8.0)
Protein: Protein-error-of-indicators principle.	(Negative for normal samples)
Urobilinogen: A modified Ehrlich reaction.	(0.2 - 1 mg/dL reported as "Normal")
Nitrite: Reaction of nitrite with p-arsanilic acid.	(Negative for normal samples)
Leucocytes: By leucocyte esterase detection.	(Negative for normal samples)

Specimen Collection / Handling Processing and Testing Points:

1. Accept only fresh urine samples collected in a clean, disposable plastic container, properly labeled. Ideally, at least 30 mL of the first-morning specimen is provided. Clean catch is preferred, especially from female patients, whose specimens may have increased WBCs from genital contamination. Other collection methods and techniques may be used, but test result outcomes may be compromised. Nitrite results are optimized by using a first morning specimen or one that has incubated in the bladder for four hours or more.
2. If sample is to be cultured, follow the protocol of the institution. Example instructions: mix the sample well and pour off an aliquot into a sterile tube and send to the Microbiology department ASAP.
3. If testing cannot be done within an hour after voiding, refrigerate the tightly capped specimen immediately. Because the majority of the dipstick reactions are enzyme driven rate reactions, the refrigerated urine samples must be allowed to return to room temperature before testing.
4. Prolonged exposure of the specimen to room temperature before testing may result in microbial proliferation. The effects of microbial proliferation include:
 - a. Increase in pH due to bacterial action on urea resulting in the formation of ammonia.
 - b. Increased chance of false positive results with the protein test area due to the increasing alkaline pH overriding the buffer on the pad.
 - c. Decrease in glucose levels due to bacterial utilization.
 - d. Decrease or loss of ketones due to evaporation of acetone.
 - e. Decrease or loss of bilirubin and urobilinogen due to photo oxidation to non-reactive products.
 - f. Increased nitrate results.
 - g. Proliferation of organisms (such as E. coli) that produce enzyme 'peroxidase' may give false increase in blood reaction.
 - h. Reduced numbers of RBCs, WBCs, and casts due to disintegration in alkaline pH.

Quality Control:

- * Review specific manufacturer's recommendations.
1. Store controls at 2-8C. Do not freeze. If properly handled, the controls are stable until the expiration date stated on the label.
 2. On initial use, the controls must be labeled date / time and initials of tech. Expiration date must be noted on the control bottle when it is opened..
 3. After removing the controls from the refrigerator, they must be allowed to come to room temperature (25 - 25 C), about 15 to 30 minutes. Control (and patient samples) must be tested at room temperature to obtain accurate results.
 4. Control (and patient samples) should be protected from direct sunlight and never subjected to a heat source.
 5. Positive and Negative Controls will be analyzed during each laboratory. Calibration is performed internally by the instrument before each strip.
 6. Control results must be placed on the student report sheet. Any discrepancies must be brought to the instructor's attention.

Equipment The Siemens Clinitek Status+

Maintenance: Students working with these instruments must, under the direction of their instructor(s), follow the manufacturer's written directions for maintenance and operation. Any information presented in this lab is subject to change based on the requirements of the newer instruments.

Though students will work in pairs, each student must independently perform the instrument's basic maintenance (tray cleaning) as follows.

1. Tray cleaning - The tray should be cleaned daily or more often if buildup is seen.
 - a. Remove table by simply pulling it out; be careful that the white bar at the top of the tray is not damaged.
 - b. Clean strip area using a cotton-tipped applicator wetted with distilled water. Rinse both sides of table.
 - c. Dry carefully and thoroughly.
2. Disinfect the table. If the table is in need of disinfection, one of several solutions is safe to use: Cidex®, Theracide®, Amphyl®, 5% household bleach and Isopropyl alcohol (70-80%). Most area laboratories use 5% household bleach or 70% Isopropyl alcohol. Rinse the table with distilled water; dry thoroughly.

Again, do not touch the white bar as it is used by the instrument for calibration. Periodically, check the white bar to insure that it is free of dust, scratches or other marks. If it is scratched or has other marks on it, it may need to be replaced!
3. Changing the paper roll (discussed, not performed unless needed)
 - a. Pull out the remainder of the paper **from the existing roll**
 - b. Open cover and remove the paper core.
 - c. Insert new paper roll so that paper unrolls from underneath
 - d. Trim insert end to resemble a large "V" shape.
 - e. Insert paper under printer roller until the paper comes through other side of roller. Pull paper towards the back. Do not pull paper up or to the front as it may damage the printer.
 - f. Feed paper through printer cover and snap cover into position

Instrument Start-Up and Operation See specific instrument's procedure document.

CLINITEK 50 Urine Chemistry Analyzer



Introduction

The CLINITEK 50 Urine Chemistry Analyzer is a semiautomated, benchtop instrument designed to read Bayer Reagent Strips for Urinalysis. The Program Module for the Multistix 10 SG Reagent Strips contains programming information necessary to read the reagent strip areas for testing of glucose, bilirubin, ketone (acetoacetic acid), blood, pH, protein, urobilinogen, nitrite, and leukocytes.

Principle

The CLINITEK 50 is a reflectance photometer that analyzes the color and intensity of the light reflected from the reagent area and displays the results in a clinically meaningful units. All programming for the instrument is contained in a replaceable Program Module located below the instrument surface on the left side. The module is programmed with such information as wavelengths, error messages, operating sequence, and algorithms needed to convert reflectance into clinically meaningful results. A white plastic chip located at the end of the feed table insert, provides a reflectance surface for the internal calibration of the instrument's optical system. Calibration is accomplished automatically by the measurement of reflected light from the calibration chip surface. The calibration chip (aka - the white bar) must be kept clean for proper instrument calibration.

Start - Up Procedure

1. Ensure that the Program Card is in place and appropriately seated. (Program Card is below the instrument surface on the left side. Our 'card' is for the Multistix 10 SG.)
2. Turn the CLINITEK 50 instrument on by switching the toggle at the rear of the instrument.
 1. Adjust display screen in an upright position, adjusting contrast (if necessary with dial on right side of screen.)
 2. Tray table automatically moves out to "load" position.
 3. Calibration and self-test procedure will be in progress. Upon successful completion of self-test, the screen will change to Main Menu.
 4. Inspect feed table for cleanliness and correct positioning. If feed table is dirty, gently clean with absorbent tissue dampened with deionized water. Wipe dry with clean absorbent tissue. CAUTION: The round white "calibration chip" at the end of the feed table insert should be free of dirt, debris or stains. If it is discolored or appears damaged, notify instructor.

Performance Check

1. Frequency
 1. At start of day's run.
 2. With each new bottle of reagent strips.
 3. With each change of instrument operators.
 4. Whenever test results are in doubt.
2. Prepare CHEK-STIX solution according to manufacture's directions.
3. Analyze control sample in the same manner as patient samples (see below). Compare results to expected results sheet. If unexpected results are obtained, contact instructor.
4. Over for Sample Analysis

Sample Analysis

Note: The "←" is the "ENTER" KEY/BUTTON.

1. Obtain Main Menu (if not already displayed) by depressing the blue square button. This button is marked:

1. _____
2. _____
3. _____

2. **Selecting sequence number:** Choose appropriate sequence number. (Used to identify a series of runs or specimens analyzed on a shift, etc. This function will not be necessary for our purposes and can be by-passed by pushing the ← button.
3. Using appropriate dipstick technique, completely immerse all reagent areas of the dipstick into the specimen (either control or specimen). Immediately remove the strip while running the edge along the specimen container's side.
4. With your free hand, immediately depress the green oval button - thereby activating the instrument's timing mechanism.
5. Keeping the strip horizontal, touch its side to a clean paper towel to remove excess specimen and *immediately** place it onto the strip holder of the instrument, pads side up and as forward as possible and flat against the holder. This technique should be demonstrated by instructor.

(* NOTE: THE STRIP MUST BE PLACED ON THE HOLDER WITHIN 10 SECONDS OF ACTIVATION OF THE INSTRUMENT'S TIMING MECHANISM.)

6. Instrument will move the strip into the reading area automatically. Do not interfere with the instrument including the dipstick holder during this time.
7. Entering physical properties & obtaining print-out of results.
 1. After the instrument displays dipstick results (@ 2 minutes), enter the patient ID number followed by pressing the ← button,
 2. Enter the specimen color by selecting the appropriate color (use yellow - orange up/down arrows to choose color) followed by pressing the ← button,
 3. Select the appropriate clarity term by, again, using the yellow / orange arrows and again press the ← button.
 4. At this time the instrument will print the results.
 5. OR - You may by-pass the entering of ID, color and clarity, and obtain a printout of the dipstick's reading by pressing the ← button 3 times.
 6. Dispose of the used dipstick in an appropriate container and proceed with the next sample.
8. At the end of the run, gently cleanse the tray using deionized water and an absorbent tissue.

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Urinalysis

Name _____
/ 25 points

Date _____

1st AUTOMATED URINALYSIS LAB REPORT FORM

Specimen # Name / ID		Control 1 -----	Control 2 -----	1 -----	2 -----	3 -----
Physical Properties:	Color					
	Transparency					
	*SG- refract					
Dipstick:	Glucose					
	Bilirubin					
	Ketones					
	Spec. Gravity					
	Blood					
	pH					
	Protein					
	Urobilinogen					
	Nitrite					
	Leuk Esterase					
Microscopic	Mucous					
	Casts					
	Epithelial cells					
	RBCs					
	WBCs					
	Crystals					
	Bacteria					
	Other					

Note: Circle any control results that do not give expected results & notify instructor.

/ 30 points

Mentoring Check-Off Sheet

Student Name _____ Date _____

Student mentor's name _____

This sheet will be provided to the student mentor named above and who is responsible for its completion. The student named above is responsible for turning this sheet in along with their lab report. For acceptable completion of this exercise, the student can have no more than two (2) "Needs Improvement" checkmarks. 3 - 5 point deduction taken for "Needs Improvement" checkmarks.

Items marked with (*) are critical items, worth more points and must be performed acceptably.

Skill / Activity	Acceptable	Needs Improvement
1. Describes purpose of test		
2. * Demonstrates compliance with Standard Precautions; ie. wears gloves (Others? _____)		
3. Cleans / disinfects the test strip table		
4. *Removes one strip from the container and immediately replaces the cap.		
5. Removes the strip immediately after dipping in sample and presses START key.		
6. Draws edge of strip along container rim or blots on paper towel, to remove excess urine.		
7. Places the reagent strip, with test pads facing up, into the middle trough of the test strip table. The strip must touch the end of the trough.		
8. *Does not move or bump the table.		
9. Obtains the printed results in one minute.		
10. *Discards used strip in proper container		
11. *Following manufacturer's recommendations, wipes table clean of residue		
12. Reports the result in the appropriate log or record.		
13. Allows refrigerated controls to reach room temp prior to testing.		
12. Mixes controls & samples before dipping.		
13. Successfully runs and evaluates two levels of controls prior to turning out patient sample results.		
14. Checks to see that lot numbers on the QC bottles match the expected results sheet.		
15. Takes appropriate action if QC results are out of range. (repeats test/refers to troubleshooting chart in manual) **IF this situation does not occur, student MUST explain the appropriate action to the mentor!		

*** Student mentor's signature _____

___/45 points

Name _____

Date _____

Complete UA with Automation Study Questions

Instructions: Unless otherwise noted, each question is worth one point. The following study questions are to review you on previously covered information as well as the current lab material. Using lecture notes, reading assignments and information presented in this and previous UA labs, answer the following questions.

(3 points)

1. What would be the immediate and long term effects (on the Siemens Clinitek Status+ OR Clinitek 50 instrument) of not blotting the urine strips before placing them in the tray /table? (Note this is a 3 point question, I am looking for some thought and substance in your answer.)
2. Name at least two (2) instruments that automatically read dipstix.

(2 points)

3. A well mixed fresh urine specimen is divided into 2 samples. Sample "A" is tightly capped and refrigerated for 4 hours, while Sample "B" is left on the bench-top near a sunny window. If complete UA s are performed on each sample, explain *how & why* the results could be different. (Assume: Sample A is brought to room temp before testing.)

(2 points)

4. What are oval fat bodies, and what are their significance?
5. What is indicated in a urine sample that demonstrates a positive glucose dipstick and a negative Clinitest?
6. What is indicated in a urine sample that demonstrates a negative glucose dipstick and a positive Clinitest result?
7. Explain the expression "protein error of indicators."
8. List at least two causes for false positive results in the protein area of the dipstix?
9. Which serum protein is most likely to be found in the urine?
10. Testing for ketones has been proven useful in the monitoring of what disease condition?
11. Distinguish between hematuria and hemoglobinuria.

12. What gelatinous - like substance makes up the matrix of casts?
13. What is the most frequently found cast?
14. Finding WBC casts is primarily associated with what condition?
15. What type of epithelial cell is found in a epithelial cell cast?
16. List two (2) structures that usually accompany a fatty cast?
17. What two (2) types of casts are most often associated with 'chronic renal failure'?
18. Which of the following abnormal crystals is NOT associated with severe liver disease?
 - A. Leucine
 - B. Tyrosine
 - C. Cystine
 - D. Bilirubin

(2 points)

19. List at least two (2) normal crystals found in *acid* urine.
 1. _____
 2. _____

(2 points)

20. List at least two (2) normal crystals found in *alkaline* urine.
 1. _____
 2. _____

(2 points)

21. List four (4) crystals considered to be pathological, regardless of the number or amount found.
 1. _____
 2. _____
 3. _____
 4. _____
22. I am a substance that on rare occasions precipitate in the urine of a patient who has recently undergone kidney x-rays. I cause the specific gravity to be incredibly high when measured by the refractometer. I cause a huge amount of sediment to form as the urine cools off. I am not pathological, but my structural appearance is sometimes confused with a pathological crystal. Who am I?

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Urinalysis

(3 points)

23. Match the following abnormal crystals with their description.

Crystal's name	description
___ Bilirubin	1. Colorless hexagonal plates
___ Cystine	2. Rectangular plates with notched corners usually of 90° angles, associated with very high specific gravity.
___ Leucine	3. Short, brilliant yellow - orange needles often attached to cellular products.
___ Tyrosine	4. Dark, oily, highly retractile, yellow-brown spheres with concentric circles and radial striations.
___ Ampicillin	5. Dark, very fine retractile needles with sharp points occurring in sheaves.
___ Cholesterol	6. Long thin, colorless needles, form after refrigeration - rarely seen.

24. What is 'orthostatic proteinuria'?

25. Give at least two (2) clinical conditions / reasons why a person may have ketones in their urine.

(3 points)

26. Describe the classical macroscopic and microscopic characteristics of a urine from an out of control diabetic. Put your results in the table below.

Physical properties	Chemical properties	Microscopic properties
color & clarity _____		
specific gravity level (low, normal, high?) _____		

(3 points)

27. List three different substances /structures that are detectable on the blood portion of the dipstick.

28. Explain how the 'nitrite' portion of the dipstick can be negative for a patient with a UTI.

29. Explain how you can have a positive nitrite test and a negative leukocyte esterase result.

(2 points)

30. Compare and contrast 'diabetes mellitus' and diabetes insipidus' by completing the following table.

	diabetes mellitus	diabetes insipidus
deficient hormone		
specific gravity level		