

## TRAINING UPDATE

Lab Location: GEC  
Department: Core

Date Distributed: 9/23/2015  
Due Date: 10/14/2015  
**Implementation: 10/14/2015**

### DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

**Urinalysis, Clinitek 500 GEC.U08 v3**

Description of change(s):

Section	Reason
3.2	Add stability for preservative tube
4.1, 8.2, 8.3	Remove 3% SSA
10.5	Change pH criteria and follow up, edit Clinitest to perform when ordered by physician ( <i>to match actual practice</i> )
16	Remove 3% Sulfosalicylic Acid SOP
App A	Remove Potomac Ridge keyboards

#### Notes:

- The 3% SSA SOP is being **discontinued**. The LIS will automatically replace the urine protein result with the English text code UAMUP (*Unable to accurately measure urine protein when pH is >8.0*) when appropriate.
- LIS screen shots are included after the SOP. These show the process when resulting from the Clinitek

**This revised SOP will be implemented on October 14, 2015**

**Document your compliance with this training update by taking the quiz in the MTS system.**

Approved draft for training (version 3)

Technical SOP

<b>Title</b>	<b>Urinalysis, Clinitek 500</b>	
<b>Prepared by</b>	Ashkan Chini	Date: 9/20/2011
<b>Owner</b>	Robert SanLuis	Date: 3/25/2013

<b>Laboratory Approval</b>		<b>Local Effective Date:</b>
<b>Print Name and Title</b>	<b>Signature</b>	<b>Date</b>
<i>Refer to the electronic signature page for approval and approval dates.</i>		

<b>Review</b>		
<b>Print Name</b>	<b>Signature</b>	<b>Date</b>

**TABLE OF CONTENTS**

1. Test Information.....2

2. Analytical Principle .....3

3. Specimen Requirements.....3

4. Reagents .....4

5. Calibrators/Standards .....5

6. Quality Control .....5

7. Equipment And Supplies .....7

8. Procedure .....8

9. Calculations.....9

10. Reporting Results And Repeat Criteria.....9

11. Expected Values.....11

12. Clinical Significance .....12

13. Procedure Notes .....13

14. Limitations Of Method .....13

15. Safety .....15

16. Related Documents .....16

17. References.....16

18. Revision History .....16

19. Addenda .....17

**1. TEST INFORMATION**

<b>Assay</b>	<b>Method/Instrument</b>	<b>Local Code</b>
Urinalysis	Clinitek 500	UMAC

<b>Synonyms/Abbreviations</b>
Urine Macroscopic

<b>Department</b>
Urinalysis

Form revised 2/02/2007

## 2. ANALYTICAL PRINCIPLE

The Clinitek 500 is a reflectance spectrophotometer that analyzes color and intensity of light reflected from the reagent areas on the Multistix 10 SG and prints out the results.

- a. Protein: This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reaction.
- b. Blood: This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.
- c. Leukocytes: Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.
- d. Nitrite: This test depends upon the conversion of nitrate to nitrite to by action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with  $\rho$ -arsanilic acid to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydrbenzo(h)quinolin-3ol to produce a pink color.
- e. Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.
- f. Ketone: This test is based on the development of colors ranging from buff-pink, for a negative reading, to maroon when acetoacetic acid reacts with nitroprusside.
- g. pH: The test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
- h. Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.
- i. Bilirubin: This test is based on the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The color ranges through various shades of tan.
- j. Urobilinogen: This test is based on a modified Ehrlich reaction in which  $\rho$ -diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

## 3. SPECIMEN REQUIREMENTS

### 3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A

Component	Special Notations
<b>Specimen Collection and/or Timing</b>	Normal procedures for collecting urine may be used for samples to be analyzed by this method. Transfer contents to Urine Collection Kit to better preserve the sample.
<b>Special Collection Procedures</b>	A first-morning specimen is preferred but random collections are acceptable.
<b>Other</b>	If Urine Collection Kit is not used, submit to Laboratory within 2 hours of collection.

### 3.2 Specimen Type & Handling

Criteria	
<b>Type</b> -Preferred -Other Acceptable	Urine, freshly voided None
<b>Collection Container</b>	Clean or sterile container
<b>Volume</b> - Optimum - Minimum	12 mL 1 mL
<b>Transport Container and Temperature</b>	Urine Collection Kit ( <a href="#">Urine Analysis Preservative Tube</a> preferred) or container at room temperature.
<b>Stability &amp; Storage Requirements</b>	Room Temperature: <a href="#">24 hours in Urine Analysis Preservative Tube</a> <a href="#">2 hours for other containers</a>
	Refrigerated: 24 hours
	Frozen: Unacceptable
<b>Timing Considerations</b>	Test the urine within two hours after voiding, sooner if testing for bilirubin or urobilinogen.
<b>Unacceptable Specimens &amp; Actions to Take</b>	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for “test not performed” message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
<b>Compromising Physical Characteristics</b>	If specimen refrigerated, let it return to room temperature before testing. The container should allow for complete dipping of all reagent strip areas.
<b>Other Considerations</b>	After testing, samples will be held until the next successful QC performance.

## 4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering “SAFETY” for additional information.

#### 4.1 Reagent Summary

Primary Reagent	Supplier & Catalog Number	Quantity
Multistix 10 SG Reagent Strips	Siemens Reagent Strips Cat. No. 2161	100 strips

Confirmatory Testing Reagents, used if needed *	Supplier & Catalog Number
CLINITEST Reagent Tablet	Bayer Corporation Cat. No. 2126
<del>3% Sulfosalicylic Acid</del>	<del>Ricca Chemical Company Cat. No. 8115-32</del>

\* Refer to specific SOP if required

#### 4.2 Reagent Preparation and Storage

**NOTES:** Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.

Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

<b>Reagent</b>	Multistix 10 SG Reagent Strips
<b>Container</b>	Plastic Bottle
<b>Storage &amp; Stability</b>	Store at temperatures between 15-30° C. <ul style="list-style-type: none"> <li>• All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become un-reactive.</li> <li>• Do not use strips after the expiration date printed on the original bottle.</li> <li>• Do not store the bottle in direct sunlight and do not remove the desiccant from the bottle.</li> <li>• Never leave the container uncapped.</li> </ul>
<b>Preparation</b>	None

#### 5. CALIBRATORS/STANDARDS

Calibration is performed automatically each time a Reagent Strip is analyzed.

#### 6. QUALITY CONTROL

### 6.1 Controls Used

Controls	Supplier and Catalog Number
Human Urinalysis Control level I	KOVA-Trol™ HYCOR® Cat. No. 91017
Human Urinalysis Control level II	KOVA-Trol™ HYCOR® Cat. No. 87128
Human Urinalysis Control Level III	KOVA-Trol™ HYCOR® Cat. No. 87328

### 6.2 Control Preparation and Storage

**NOTE:** Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	Level I Urine control
<b>Preparation</b>	Reconstitute the vial of control with exactly 15 mL of Reagent Grade water. Allow the reconstituted material to stand at room temperature for 15 minutes and gently rotate the bottle intermittently until all of the material has dissolved.
<b>Storage/Stability</b>	Once reconstituted, the controls remain stable for 7 days at 2-8° C in its original capped vial.

Control	Level II and Level III Urine controls
<b>Preparation</b>	Reconstitute each vial of control with exactly 60 mL of Reagent Grade water. Allow the reconstituted material to stand at room temperature for 15 minutes and gently rotate the bottle intermittently until all of the material has dissolved.
<b>Storage/Stability</b>	Once reconstituted, the controls remain stable for 7 days at 2-8° C in its original capped vial.

### 6.3 Frequency

All three levels of Human Urinalysis Control are tested once per day.

### 6.4 Tolerance Limits

All QC Values must be within acceptable limits listed in manufacture's package insert.

IF the result is ...	THEN...
not acceptable	<ul style="list-style-type: none"> <li>• Verify it is the correct control/reagent.</li> <li>• Verify the control/reagent has not expired.</li> <li>• Check for technical/clerical errors.</li> <li>• Visually inspect the condition of the control/reagent.</li> </ul>

	<ul style="list-style-type: none"><li>• Inspect the instrument status, do maintenance and troubleshoot.</li><li>• Repeat the QC test.</li><li>• Notify the Supervisor if these results are not acceptable.</li></ul>
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### **6.5 Review Patient Data**

Technologist must check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports. Repeat patient samples with other methodologies if necessary.

### **6.6 Documentation**

- Save the instrument printed paper. Print results on “Urinalysis Quality Control” sheet, located in Urinalysis Quality Control binder.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

### **6.7 Quality Assurance Program**

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Consult the Laboratory QC program for complete details.

## **7. EQUIPMENT and SUPPLIES**

### **7.1 Assay Platform**

Clinitek 500

### **7.2 Equipment**

- Centrifuge, 400g
- Refractometer



### 7.3 Supplies

- Disposable pipettes
- 16 x 100 mm test tubes

## 8. PROCEDURE

**NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.**

**The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.**

8.1	Test Run
1.	Scan or enter patient's accession number.
2.	Select the color and clarity description for each specimen.
3.	Completely immerse all reagent areas of a Multistix 10 SG Reagent Strip in fresh, well-mixed, un-centrifuged urine.
4.	Immediately remove the Reagent Strip. While removing, slowly run the edge of the entire length of the Reagent Strip against the side of the urine container to remove excess urine. <b>Do not blot the edge of the strip against a paper towel.</b>
5.	Place the Reagent Strip, <b>with reagent areas facing up</b> , onto the strip supports of the strip loading station.
6.	The presence of the reagent strip is detected as soon as it is placed on the loading station. The push bar moves the strip along the loading station to the read area.

Some medications cause urine to become abnormally colored (GREEN, AMBER, ORANGE or PINK) and the Clinitek 500 will report false positive results. For urines that are abnormally colored:

8.2	Color Interference
1.	Run the strip through the Clinitek 500
2.	Verify the specific gravity by manual refractometer (rounding to the nearest .005). Report the results of the manual refractometer.
3.	Tests that are NEGATIVE on the Clinitek 500 can be reported as negative.
4.	Perform confirmatory testing if applicable; CLINITEST performed only when ordered by physician and <del>3% Sulfosalicylic Acid</del>
5.	Report the Color and Clarity as you see it.
6.	In the LIS for the remainder of the tests, report the comment COLINT which expands out to "Results not reported due to color interference".
7.	Perform a microscopic exam on all abnormally colored urines.

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<b>8.3</b>	<b>Bloody Urines</b>
1.	Measure the specific gravity by manual refractometer (rounding to the nearest .005). Report the results of the manual refractometer.
2.	Report the Color as BLOODY and the Clarity as you see it.
3.	Centrifuge the specimen. Pour the supernatant into a 16 x 100 mm test tube.
4.	Perform dipstick testing on the supernatant and run through the Clinitek 500.
5.	Report the remaining results of the supernatant from the Clinitek 500 (GLU, BIL, KET, PH, PRO, URO, NIT, and LEU).
6.	Perform confirmatory testing if applicable; CLINITEST performed only when ordered by physician and <del>3% Sulfosalicylic Acid</del>
7.	Perform a microscopic exam on the sediment.

**9. CALCULATIONS**

Not applicable

**10. REPORTING RESULTS AND REPEAT CRITERIA**

**10.1 Interpretation of Data**

<b>Test</b>	<b>Report As</b>
<b>Color</b>	Yellow
	Orange
	Pink
	Green
	Amber
	Brown
	Bloody
	Dark Yellow
	Straw
<b>Appearance</b>	Clear
	Cloudy
	Slightly Cloudy
	Turbid
<b>Specific Gravity</b>	1.005 – 1.030
<b>pH</b>	5.0 – 9.0
<b>Glucose</b>	Negative
	Trace
	1+
	2+
	3+

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Test	Report As
	4+
<b>Bilirubin</b>	Negative
	1+
	2+
	3+
<b>Urobilinogen</b>	0.2
	1.0
	2.0
	4.0
	8.0
<b>Ketone</b>	Negative
	Trace
	1+
	2+
	3+
	4+
<b>Blood</b>	Negative
	Trace
	1+
	2+
	3+
<b>Protein</b>	Negative
	Trace
	1+
	2+
	3+
	4+
<b>Nitrite</b>	Negative
	Positive
<b>Leukocytes Esterase</b>	Negative
	Trace
	1+
	2+
	3+

**10.2 Rounding**

N/A

**10.3 Units of Measure**

N/A

**10.4 Clinically Reportable Range (CRR)**

N/A

## 10.5 Repeat Criteria and Resulting

- Perform CLINITEST Reagent Tablets test for reducing sugars **only when ordered by a physician. on pediatric urine ( $\leq 2$  years old).**
- ~~Perform the 3% Sulfosalicylic Acid testing for specimens with a positive protein and  $\text{pH} \geq 9.0$~~
- If  $\text{pH}$  is  $>8.0$ , remove urine protein result and replace with the English text code **UAMUP**. The code translates to “Unable to accurately measure urine protein when  $\text{pH}$  is  $>8.0$ ”
- If Bilirubin is positive, the comment “Presumptive positive bilirubin. Consider confirmation by serum bilirubin if clinically indicated.” will be appended to the result by the LIS.
- Microscopic Exam:
  1. Review the results and determine which specimens require a microscopic exam using the following criteria:
    - a. Blood: any positive result
    - b. Protein:  $>$  trace
    - c. Nitrite: any positive result
    - d. Leukocytes: any positive result
    - e. Clarity: any result not CLEAR
  2. Centrifuge the specimens that require a microscopic exam at 400 RCF (g) for 5 minutes.
  3. Refer to procedure “Microscopic Examination of Urine” for instructions on performing microscopic examination of urine.
- Results will upload from instrument to the LIS. Refer to Addenda A “Urinalysis Keyboard: Macroscopic and Microscopic Result Entry” for instructions to release results.

## 11. EXPECTED VALUES

### 11.1 Reference Ranges

Glucose	Negative
Bilirubin	Negative
Ketones	Negative
Specific gravity (SG)	1.005 – 1.030
Blood	Negative
pH	5.0 – 9.0
Protein	Negative
Urobilinogen (URO)	0.2 – 1.0
Nitrite	Negative
Leukocyte	Negative
Color	Yellow
Clarity	Clear

## **11.2 Critical Values**

None established

## **11.3 Priority 3 Limit(s)**

None established

## **12. CLINICAL SIGNIFICANCE**

The strips are intended for use in at-risk patient groups to assist diagnosis in the following areas: Kidney function, urinary tract infections, carbohydrate metabolism and liver function. The strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

**Protein:** In normal urine, less than 150 mg of total protein is excreted per day. Clinical proteinuria is indicated at greater than 500 mg of protein per day. Positive results may also indicate tubular or overflow proteinuria in the absence of any glomerular abnormality or proteins of renal origin that may be excreted during infection. Urinary protein excretions can be temporarily elevated in the absence of renal abnormality by strenuous exercise, orthostatic proteinuria, dehydration, urinary tract infections, and acute illness with fever.

**Blood:** Normally, no hemoglobin is detectable in urine. Occult blood occurs in urine as intact erythrocytes and hemoglobin, which can occur during urological, nephrological and bleeding disorders. Small amounts of blood are sufficiently abnormal to require further investigation. The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case.

**Leukocytes:** Normal urine specimens generally yield negative results. An increase in leukocytes is an indication of pyuria and is found in nearly all diseases of the kidney and urinary tract; however, pyuria may often be present in non-infection conditions. A strip result of small or greater is a useful indicator of infection. Trace results may be of questionable clinical significance; however, Trace results observed repeatedly may be clinically significant.

**Nitrite:** Normally no nitrite is detectable in urine. Many enteric gram-negative organisms give positive results when their number is greater than  $10^5$ /mL.

**Glucose:** Small amounts of glucose are normally excreted by the kidney. These amounts are usually below the sensitivity of this test but on occasion may produce a color between the Negative and the 100 mg/dL color blocks and that is interpreted by the instrument as a positive result. Results at the first positive level may be significantly abnormal if found consistently.

**Ketone:** Normally, no ketone is detectable in urine. In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine at levels of

10 mg/dL or higher before serum ketone levels are elevated. Clinical judgment is needed to determine the significance of trace results, which may occur during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.

pH: The normal pH of urine can range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment of some calculi.

Specific Gravity: The normal SG of urine ranges from 1.001 – 1.035. If the specific gravity of random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.

Bilirubin: Normal adult urine contains about 0.02 mg/dL of bilirubin, which is not detectable by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Since very small amounts of bilirubin may be found in the earliest phases of liver disease, the user must consider whether the sensitivity of Siemens Reagent Strips to bilirubin is sufficient for the intended use.

Urobilinogen: Urobilinogen is normally present in urine at concentrations up to 1.0 mg/dL. A result of 2.0 mg/dL represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further for hemolytic and hepatic disease.

### 13. **PROCEDURE NOTES**

- **FDA Status:** Approved/cleared
- **Validated Test Modifications:** None

### 14. **LIMITATIONS OF METHOD**

#### 14.1 **Analytical Measurement Range (AMR)**

N/A

#### 14.2 **Precision**

N/A

#### 14.3 **Interfering Substances**

Bloody urine and color interference explained in sections 8.2 and 8.3

For all tests, false positive results and/or false negative results can occur when substances that cause abnormal urine color are present, such as:

- visible levels of blood or bilirubin
- drugs containing dyes
- nitrofurantoin
- riboflavin

#### 14.4 Clinical Sensitivity/Specificity/Predictive Values

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.

<i>Test Name</i>	<i>False Positive or Increased values</i>	<i>False Negative or Decreased values</i>
Glucose	Temperature	<ul style="list-style-type: none"> <li>▪ Ascorbic acid (<math>\geq 50\text{mg/dL}</math>) may affect a 75 to 125 mg/dL glucose level</li> <li>▪ Ketones (<math>\geq 40\text{mg/dL}</math>) may affect a 75 to 125 mg/dL glucose level</li> <li>▪ High specific gravity</li> <li>▪ Temperature</li> </ul>
Bilirubin	<ul style="list-style-type: none"> <li>▪ Indican (indoxyl sulfate) may impart a yellow-orange to red color on the pad</li> <li>▪ Metabolites of Lodine (etodolac)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ascorbic acid (<math>\geq 25\text{mg/dL}</math>).</li> <li>▪ Urine specimen was more than one hour old (instability of bilirubin).</li> <li>▪ Contamination with chlorhexidine (found in some skin cleansers)</li> </ul>
Ketone	<ul style="list-style-type: none"> <li>▪ Highly pigmented urines</li> <li>▪ Large amounts of levodopa (L-dopa) metabolites</li> <li>▪ Compounds that contain sulfhydryl groups</li> </ul>	
Specific Gravity	<ul style="list-style-type: none"> <li>▪ Moderate (100 – 750 mg/dL) quantities of protein</li> <li>▪ Contamination with chlorhexidine (found in some skin cleansers)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Highly buffered/alkaline urines</li> </ul>
Occult Blood	<ul style="list-style-type: none"> <li>▪ Oxidizing contaminants (e.g. bleach)</li> <li>▪ Microbial peroxidase from urinary tract infections</li> </ul>	<ul style="list-style-type: none"> <li>▪ High specific gravity</li> <li>▪ Capoten® (Captopril)</li> </ul>
pH	<ul style="list-style-type: none"> <li>▪ Bacterial growth that converts urea to ammonia</li> </ul>	<ul style="list-style-type: none"> <li>▪ Run-over from the protein reagent pad</li> </ul>
Protein	<ul style="list-style-type: none"> <li>▪ Highly buffered or alkaline urines</li> <li>▪ Contamination with quarternary ammonium compounds (from some antiseptics and detergents) or Chlorhexidine (found in some skin cleansers)</li> </ul>	
Urobilinogen	<ul style="list-style-type: none"> <li>▪ Temperature <math>&gt; 26^{\circ}\text{C}</math> (<math>79^{\circ}\text{F}</math>)</li> <li>▪ <math>\rho</math>-aminosalicylic acid (PAS) and sulfonamides</li> <li>▪ <math>\rho</math>-aminobenzoic acid (PABA) may cause atypical color development</li> </ul>	<ul style="list-style-type: none"> <li>▪ Temperature <math>&lt; 22^{\circ}\text{C}</math> (<math>72^{\circ}\text{F}</math>)</li> <li>▪ Formalin</li> </ul>
Nitrite		<ul style="list-style-type: none"> <li>▪ Infections caused by organisms that don't contain reductase</li> </ul>

<i>Test Name</i>	<i>False Positive or Increased values</i>	<i>False Negative or Decreased values</i>
		<ul style="list-style-type: none"> <li>▪ Urine was not in bladder long enough (at least 4 hours)</li> <li>▪ Absence of dietary nitrate</li> <li>▪ High specific gravity</li> <li>▪ Ascorbic acid (<math>\geq 25</math> mg/dL) may affect a low positive nitrate level (<math>&lt; 0.06</math> mg/dL nitrate ion)</li> </ul>
Leukocytes	<ul style="list-style-type: none"> <li>▪ Formalin</li> <li>▪ Temperature <math>&gt;26^{\circ}\text{C}</math> (<math>79^{\circ}\text{F}</math>)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Elevated glucose (<math>\geq 3,000</math> mg/dL)</li> <li>▪ High specific gravity</li> <li>▪ Cephalexin (Keflex®) or Cephalothin (Keflin®)</li> <li>▪ High concentrations of oxalic acid</li> <li>▪ Tetracycline</li> <li>▪ Temperature <math>&lt;22^{\circ}\text{C}</math> (<math>72^{\circ}\text{F}</math>)</li> </ul>
Color	<ul style="list-style-type: none"> <li>▪ Concentration</li> <li>▪ Food Pigments</li> <li>▪ Dyes</li> <li>▪ Blood</li> <li>▪ Various pathological conditions</li> </ul>	<ul style="list-style-type: none"> <li>▪ These all can affect negatively as well.</li> </ul>

## 15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.



**16. RELATED DOCUMENTS**

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Material Safety Data Sheets (MSDS)
4. Quest Diagnostics Records Management Procedure
5. CLINITEK, Urinalysis procedure
- ~~6. 3% Sulfosalicylic Acid, Urinalysis procedure~~
7. Specific Gravity Using the Refractometer, Urinalysis procedure
8. Microscopic Examination of Urine, Urinalysis procedure
9. Urinalysis QC form (AG.F133)
10. Current Allowable Total Error Specifications at  
[http://questnet1.qdx.com/Business\\_Groups/Medical/qc/docs/qc\\_bpt\\_tea.xls](http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls)
11. Current package insert Multistix 10 SG

**17. REFERENCES**

1. Operator's Guide, Siemens Clinitek 500, Siemens Healthcare Diagnostics, Inc., revised 05/2001.
2. Package Insert, Siemens Multistix 10 SG, Siemens Healthcare Diagnostics, Inc. revised 03/2010.
3. Package Insert, KOVA-Trol™ HYPOR, P/N 91017-09, 03/2010.
4. CLINITEK 500 Technical Procedure, doc # 035103. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Procedure Manuals-3<sup>rd</sup> Edition (GP2-A3), 1996.

**18. REVISION HISTORY**

Version	Date	Section	Reason	Reviser	Approval
			Supersedes U004.002,U007.001		
000	3/25/2013		Update owner	L. Barrett	R. SanLuis
000	3/25/2013	3.1	Add urine collection kit	L. Barrett	R. SanLuis
000	3/25/2013	10.5	Add process if reagent unavailable	A. Chini	R. SanLuis
001	6/18/2013	4.1	Remove Ictotest Reagent Tablet	L. Barrett	R. SanLuis
001	6/18/2013	8.2, 8.3, 12, 14.4	Remove Ictotest as confirmatory or alternate test	L. Barrett	R. SanLuis
001	6/18/2013	10.5	Remove confirmatory test for bilirubin and process if reagent unavailable, add message for positive result	L. Barrett	R. SanLuis
001	6/18/2013	16	Remove Ictotest SOP, add QC form	L. Barrett	R. SanLuis
001	6/18/2013	19	Remove QC form	L. Barrett	R. SanLuis
002	8/21/2015	3.2	Add stability for preservative tube	L. Barrett	R. SanLuis
002	8/21/2015	4.1, 8.2, 8.3	Remove 3% SSA, add Clinitest performed only if physician orders	L. Barrett	R. SanLuis

002	8/21/2015	10.5	Change pH criteria and follow up, edit Clinitest to perform when ordered by physician	L. Barrett	R. SanLuis
002	8/21/2015	16	Remove 3% Sulfosalicylic Acid SOP	L. Barrett	R. SanLuis
002	8/21/2015	App A	Remove Potomac Ridge keyboards	L. Barrett	R. SanLuis
002	8/21/2015	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. SanLuis

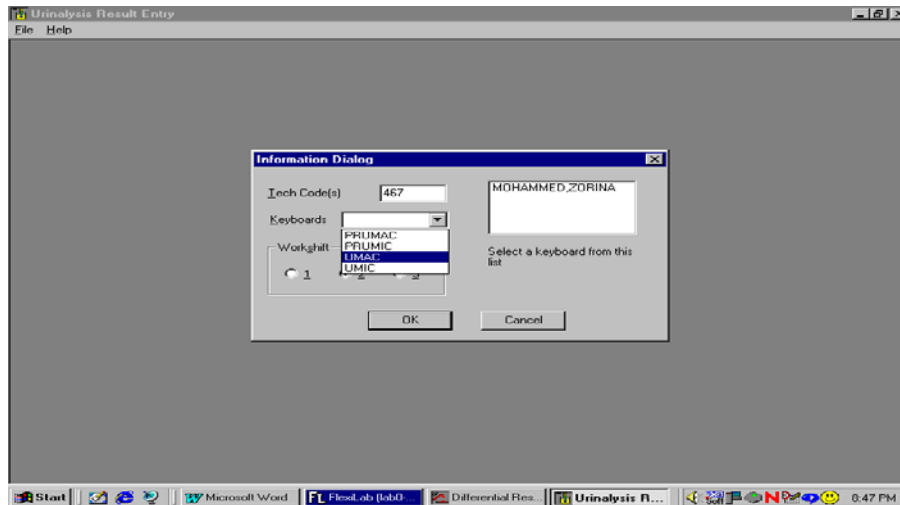
**19. ADDENDA**

## A. Urinalysis Keyboard: Macroscopic and Microscopic Result Entry

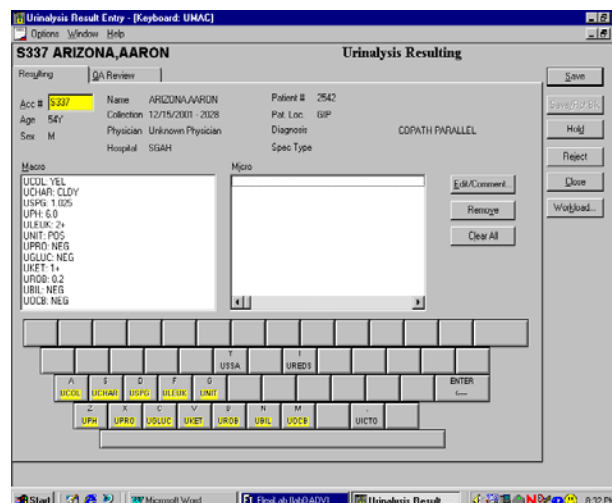
## Addenda A

### Urinalysis Keyboard: Macroscopic and Microscopic Result Entry

1. Using GUI application, select the **Urinalysis Keyboard**. The following information dialog box will be displayed ~~demonstrating the different keyboards. Two of these keyboards are for Potomac Ridge samples only PRUMAC and PRUMIC. Otherwise~~ Use the drop down box to choose **UMAC** or **UMIC** as appropriate.



2. To result the macroscopic urinalysis, select the **UMAC** keyboard, type in the Accession # and press ENTER. The Clinitek results for the macroscopic dipstick will be displayed (see below).
  - Select **QA Review** to review the results and click on the **SAVE** button to save and file the results. Orders for urine microscopic test will be automatically ordered if necessary.
  - If resulting manually depress the urine component key and select the appropriate result for the urine component. Select ENTER and continue resulting other urine components.



3. To result the urine microscopic, **click on options then keyboard select, an information dialog box will appear and from dropdown box** select the urine microscopic keyboard (UMIC), type in the Accession # then press **ENTER**. The urine macroscopic results will appear along with the keyboard for resulting the urine microscopic.
4. The urine microscopic may be resulted by clicking on the keyboard displayed on the screen with the mouse or by using the corresponding keys on the keyboard.

5. To append a comment, select the test code, click on the **EDIT/COMMENT** button and enter free text and/or an English text code in the Comment box.
6. A Quality Assurance check must be performed before saving the results. To save and file the urine microscopic click on the **SAVE** button.

## Resulting Urine Protein on a UA performed on the Clinitek 500 when pH>8.0

[Note: this same logic is applicable if manually entering results via Sunquest GUI Urinalysis Result Entry]

1. Select **Urinalysis Result Entry in GUI Sunquest**, select either the UMIC or UMAC keyboard.
2. Type in the **Accession #** and press **ENTER**
3. Screen shows that data from the instrument is loading.  
Click on **OK** to load data.

The screenshot displays the Sunquest GUI for Urinalysis Result Entry. The main window is titled "Urinalysis Resulting" and shows patient information for accession # M36749. A dialog box titled "Urinalysis Resulting" is open, displaying a warning icon and the message "Loaded online instrument data" with an "OK" button. A red arrow points from the "OK" button in the dialog box to the "OK" button in the main window's right-hand sidebar.

Acc #	Name	Patient #	Hospital
M36749	TEST,INSTRUMENT	TEST-17	SGAH

Age	Collection	Spec Type
6Y	07/21/2015 - 0852	

DOB	Physician	Spec Comment
01/01/2009	TEST MD, TEST M...	

Sex	Pat. Loc.	Order Code(s)
F	TEST	

Diagnosis	Order Comment

Buttons on the right side of the main window: Save, Save/Rpt Blk, Hold, Reject, Close, Workload...

Buttons below the Macro and Micro sections: Edit/Comment..., Remove, Clear All

4. Below is an example of data that has been loaded into Sunquest.
  - a. Note the results for the UPH (pH) and UPRO (urine protein). The pH is >8.0 therefore the UPRO needs to be resulted with UAMUP.

5. It is **ONLY once you click on the QA Review tab that the logic rule to replace the urine protein value with UAMUP occurs.**

6. Below is the outcome when the QA Review tab is selected. Click on **OK**.

7. Note that the urine protein result has been changed.

Urinalysis Result Entry - [Keyboard UMAC]

Options Window Help

M36749 TEST, INSTRUMENT Urinalysis Resulting

Resulting QA Review

Macro		
UCOL	YEL	Yellow
UCHAR	CLER	Clear
USPG	1.020	
UPH	8.5	
ULEUK	NEG	Negative
UNIT	NEG	Negative
UPRO	UAMUP	Unable to accurately measure urine protein when pH is >8.0 FAILED NORMAL [NEG]
UGLUC	NEG	Negative
UKET	NEG	Negative
UROB	1.0	
UBIL	NEG	Negative
UOCB	NEG	Negative

Order Priority Codes and Comments

Appended		Filed	
Order	Code/Comment	Order	Code/Comment
	<input type="text"/>		<input type="text"/>

Order Code

Code

Comment   Dept codes only

Save  
Save/Rpt Blk  
Hold  
Reject  
Close  
Workload...