TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	2/22/2018
Department:	Core Lab	**Due Date:**	3/1/2018
		Implementation:	**3/1/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Urinalysis, Multistix 10 SG Reagent Strips SGAH.U11 v5

This has been converted to a system SOP

Manual Urinalysis QC Form AG.F133.1

Description of change(s):

SOP: Most changes are format updates, note change to QC frequency

Section	Reason
Header	Add other sites
4,6	Remove individual section labeling instructions and add general one
6.3	Change QC from daily to days of testing
10.5	Move patient review from section 6
15	Update to new standard wording
17	Update package insert date

Log:

- Name changed to reflect only used for manual testing
- Format updated to allow for recording all levels on single page
- Frequency changed to only days on which patients are tested by this method

This revised SOP and form will be implemented on March 1, 2018

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

Quest Diagnostics

MANUAL URINALYSIS QUALITY CONTROL

All QC levels are tested each day of patient testing

☐ Germantown Emergency Center
☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

Control Level: I - High Abnormal Lot #: _____ Exp Date: _____

Reagent Strip: Bayer Multistix 10 SG Lot #: _____ Exp Date: _____

Date			Glu	Bili	Ket	SG	Blood	PH	Pro	Urob	Nit	Leuk	Color	Clarity	RBCs	WBCs	Code
√ to verify lot ↓		Range:															

Control Level: II - Low Abnormal Lot #: _____ Exp Date: _____

Reagent Strip: Bayer Multistix 10 SG Lot #: _____ Exp Date: _____

Date			Glu	Bili	Ket	SG	Blood	PH	Pro	Urob	Nit	Leuk	Color	Clarity	RBCs	WBCs	Code
√ to verify lot ↓		Range:															

Control Level: III - Normal Lot #: _____ Exp Date: _____

Reagent Strip: Bayer Multistix 10 SG Lot #: _____ Exp Date: _____

Date			Glu	Bili	Ket	SG	Blood	PH	Pro	Urob	Nit	Leuk	Color	Clarity	RBCs	WBCs	Code
√ to verify lot ↓		Range:															

Note: Reconstitute Level I with 15 mls distilled H20. Reconstitute Levels II & III with 60 mls distilled H20. Once reconstituted stable for 7 days.

Weekly Review:	Weekly Review:	Weekly Review:
Weekly Review:	Weekly Review:	Monthly Review:

Technical SOP

Title	**Urinalysis, Multistix 10 SG Reagent Strips**
Prepared by	Ashkan Chini Date: 9/20/2011
Owner	Robert SanLuis Date: 3/25/2013

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Multistix 10 SG Reagent Strips for Urinalysis	Manual Reading	UMAC

Synonyms/Abbreviations
Manual Reagent Strip reading

Department
Urinalysis

2. ANALYTICAL PRINCIPLE

The Multistix 10 SG Reagent Strips for Urinalysis include test pads for protein, blood, leukocytes, nitrite, glucose, ketone (acetoacetic acid), pH, specific gravity, bilirubin and urobilinogen.

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 ρ-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 fluconic acid and dydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidze 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 ρ-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
Specimen Collection and/or Timing	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.
Special Collection Procedures	A first-morning specimen is preferred but random collections are acceptable.
Other	If Urine Collection Kit is not used, submit to Laboratory within 2 hours of collection.

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Urine, freshly voided None	
Collection Container	Clean or sterile container	
Volume - Optimum **- Minimum**	12 mL 1 mL	
Transport Container and Temperature	Urine Collection Kit (Urine Analysis Preservative Tube preferred) or container at room temperature.	
Stability & Storage Requirements	Room Temperature:	24 hours in Urine Analysis Preservative Tube 2 hours for other containers
	Refrigerated:	24 hours
	Frozen:	Unacceptable
Timing Considerations	Test the urine within two hours after voiding, sooner if testing for bilirubin or urobilinogen.	
Unacceptable Specimens & Actions to Take	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.	
Compromising Physical Characteristics	If specimen refrigerated, let it return to room temperature before testing. The container should allow for complete dipping of all reagent strip areas.	
Other Considerations	After testing, samples will be held until the next successful QC performance.	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

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.

4.1 Reagent Summary

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

4.2 Reagent Preparation and Storage

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

5. CALIBRATORS/STANDARDS

Not applicable

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

Control	**Level I Urine control**
Preparation	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.
Storage/Stability	Once reconstituted: stable for 7 days at 2-8°C in its original capped vial.

Control	**Level II and Level III Urine controls**
Preparation	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.
Storage/Stability	Once reconstituted: stable for 7 days at 2-8°C in its original capped vial.

6.3 Frequency

All three QC levels are tested each day of patient testing ~~of Human Urinalysis Control are tested once per day~~.

6.4 Tolerance Limits and Criteria for Acceptable QC

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

IF the result is …	**THEN…**
not acceptable	• Verify it is the correct control/reagent. • Verify the control/reagent has not expired. • Check for technical/clerical errors. • Visually inspect the condition of the control/reagent • Repeat the QC test. • Notify the Supervisor if these results are not acceptable.

6.5 Documentation

- 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.

6.6 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

Not Applicable

7.2 Equipment

Centrifuge, 400g
Timer

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.

8.1	Test Run
1	Use a fresh urine specimen in a clean, dry container. Mix well immediately before testing.
2	Remove one strip from bottle and replace cap. Do not remove the strip from the bottle until immediately before it is to be used for testing.
3	Completely immerse reagent areas of the strip in urine and remove immediately to avoid dissolving out reagents.
4	While removing, run the edge of the entire length of the strip against the rim of the urine container to remove excess urine.
5	Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas and/or contaminating the hands with urine.

8.2	Reading
1	Do not read any test pad after 2 minutes.
2	Visually compare the reagent areas to corresponding Color Chart on the bottle label. Read the pads in good light. **Note**: Avoid laying the strip directly on the Color Chart, as this will result in the urine soiling the chart.
3	Proper read time is critical to optimal results. Visually read each test as follows:

Test	after dipping, read at
glucose and bilirubin	30 seconds
ketone	40 seconds
specific gravity	45 seconds
pH, protein, urobilinogen, blood and nitrite	60 seconds
leukocytes	2 minutes

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Compare test pad to corresponding color blocks on bottle label to read the strip.

Test	Report As
Color	Yellow
	Orange
	Pink
	Green
	Amber
	Brown
	Bloody
	Dark Yellow
	Straw
Appearance	Clear
	Cloudy
	Slightly Cloudy
	Turbid

Test	Report As
Specific Gravity	1.005 – 1.030
pH	5.0 – 9.0
Glucose	Negative
	Trace
	1+
	2+
	3+
	4+
Bilirubin	Negative
	1+
	2+
	3+
Urobilinogen	0.2
	1.0
	2.0
	4.0
	8.0
Ketone	Negative
	Trace
	1+
	2+
	3+
	4+
Blood	Negative
	Trace
	1+
	2+
	3+
Protein	Negative
	Trace
	1+
	2+
	3+
	4+
Nitrite	Negative
	Positive
Leukocytes Esterase	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 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.

10.6 Repeat Criteria and Resulting

- If 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 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.
- 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 Standard Required Messages

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 of 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:** Exempt
- **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

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.

Test Name	***False Positive or Increased values***	***False Negative or Decreased values***
Glucose	Temperature	▪ Ascorbic acid (≥ 50mg/dL) may affect a 75 to 125 mg/dL glucose level ▪ Ketones (≥ 40mg/dL) may affect a 75 to 125 mg/dL glucose level ▪ High specific gravity ▪ Temperature
Bilirubin	▪ Indican (indoxyl sulfate) may impart a yellow-orange to red color on the pad ▪ Metabolites of Lodine (etodolac)	▪ Ascorbic acid (≥ 25mg/dL). ▪ Urine specimen was more than one hour old (instability of bilirubin). ▪ Contamination with chlorhexidine (found in some skin cleansers)
Ketone	▪ Highly pigmented urines ▪ Large amounts of levodopa (L-dopa) metabolites ▪ Compounds that contain sulfhydryl groups	
Specific Gravity	▪ Moderate (100 – 750 mg/dL) quantities of protein ▪ Contamination with chlorhexidine (found in some skin cleansers)	▪ Highly buffered/alkaline urines
Occult Blood	▪ Oxidizing contaminants (e.g. bleach) ▪ Microbial peroxidase from urinary tract infections	▪ High specific gravity ▪ Capoten® (Captopril)
pH	▪ Bacterial growth that converts urea to ammonia	▪ Run-over from the protein reagent pad

Test Name	*False Positive or Increased values*	*False Negative or Decreased values*
Protein	▪ Highly buffered or alkaline urines ▪ Contamination with quarternary ammonium compounds (from some antiseptics and detergents) or Chlorhexidine (found in some skin cleansers)	
Urobilinogen	▪ Temperature > 26°C (79°F) ▪ ρ-aminosalicylic acid (PAS) and sulfonamides ▪ ρ-aminobenzoic acid (PABA) may cause atypical color development	▪ Temperature < 22°C (72°F) ▪ Formalin
Nitrite		▪ Infections caused by organisms that don't contain reductase ▪ Urine was not in bladder long enough (at least 4 hours) ▪ Absence of dietary nitrate ▪ High specific gravity ▪ Ascorbic acid (≥ 25 mg/dL) may affect a low positive nitrate level (< 0.06 mg/dL nitrate ion)
Leukocytes	▪ Formalin ▪ Temperature >26°C (79°F)	▪ Elevated glucose (≥ 3,000 mg/dL) ▪ High specific gravity ▪ Cephalexin (Keflex®) or Cephalothin (Keflin®) ▪ High concentrations of oxalic acid ▪ Tetracycline ▪ Temperature <22°C (72°F)
Color	▪ Concentration ▪ Food Pigments ▪ Dyes ▪ Blood ▪ Various pathological conditions	▪ These all can affect negatively as well.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual

3. Safety Data Sheets (SDS)
4. Quest Diagnostics Records Management Procedure
5. Microscopic Examination of Urine, Urinalysis procedure
6. Urinalysis QC form (AG.F133)
7. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
8. Current package insert Multistix 10 SG

17. REFERENCES

1. Package Insert, KOVA-Trol™ HYCOR, P/N 91017-18, 10/2016.
2. Package Insert, Siemens Multistix 10 SG, Siemens Healthcare Diagnostics, Inc. revised 06/2010.
3. CLINITEK 500 Technical Procedure, doc # 035103. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Procedure Manuals-3rd Edition (GP2-A3), 1996.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes U017.002, 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	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	12, 14.4	Remove Ictotest as alternate test	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	8/19/2015	3.2	Add stability for preservative tube	L. Barrett	R. SanLuis
002	8/19/2015	4.1	Remove 3% SSA	L. Barrett	R. SanLuis
002	8/19/2015	10.5	Change pH criteria and follow up, edit Clinitest to perform when ordered by physician	L. Barrett	R. SanLuis
002	8/19/2015	16	Remove 3% Sulfosalicylic Acid SOP	L. Barrett	R. SanLuis
002	8/19/2015	App A	Remove Potomac Ridge keyboards	L. Barrett	R. SanLuis
002	8/19/2015	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. SanLuis
3	12/9/2015	4.1, 10.5	Remove Clinitest	L. Barrett	R. SanLuis

Version	Date	Section	Reason	Reviser	Approval
3	12/9/2015	16	Remove Clinitest SOP	L. Barrett	R. SanLuis
4	2/6/18	Header	Add other sites	L Barrett	R SanLuis
4	2/6/18	4,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
4	2/6/18	6.3	Change from daily to days of testing	L Barrett	R SanLuis
4	2/6/18	10.5	Review data moved from section 6	L Barrett	R SanLuis
4	2/6/18	15	Update to new standard wording	L Barrett	R SanLuis
4	2/6/18	17	Update package insert date	L Barrett	R SanLuis

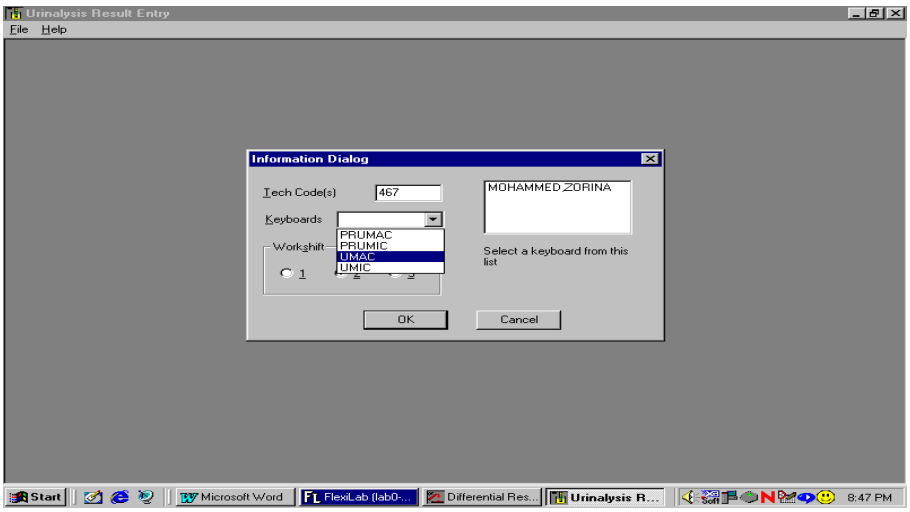
19. ADDENDA

A. Urinalysis Keyboard: Macroscopic and Microscopic Result Entry

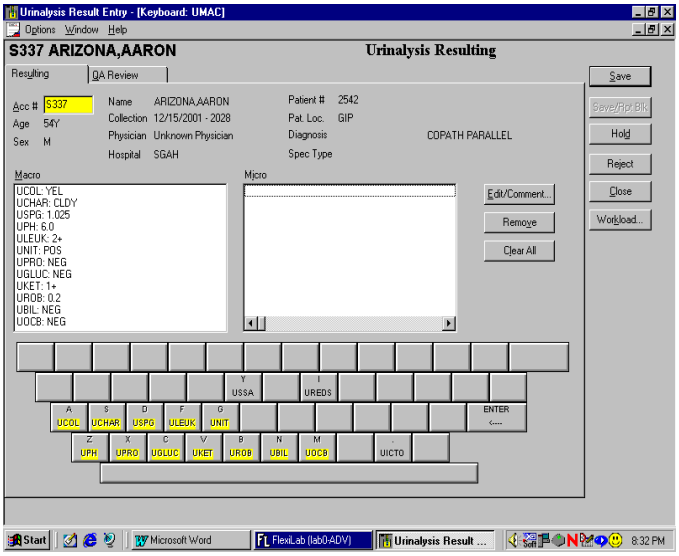
Addenda A

Urinalysis Keyboard: Macroscopic and Microscopic Result Entry

1. Using GUI application, select the **Urinalysis Keyboard**. The following information dialog box will be displayed. Use the drop down box to choose **UMAC** or **UMIC** as appropriate.

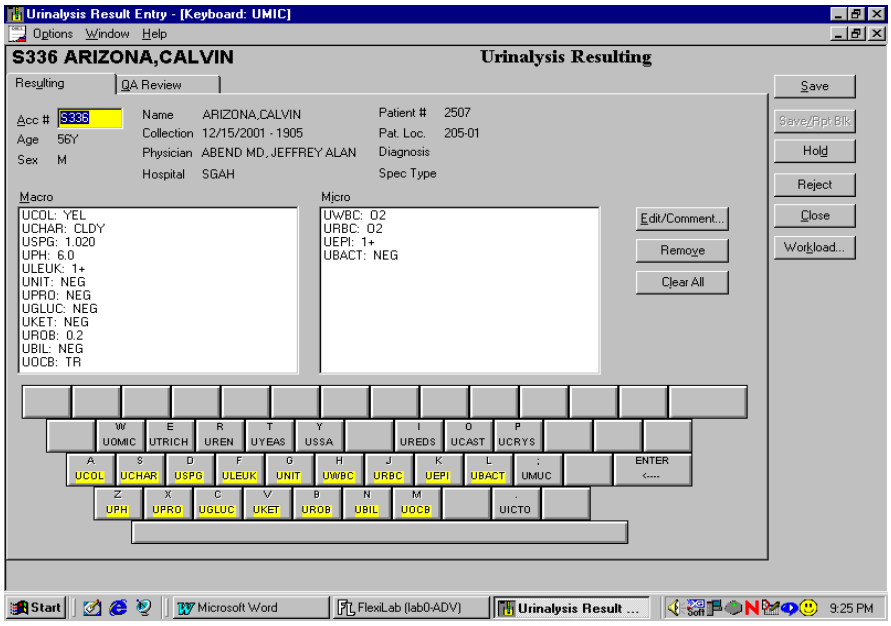


2. To result the macroscopic urinalysis, select the **UMAC** keyboard, type in the Accession # and press **ENTER**.
   Manually result by depressing the urine component key and select the appropriate result for the urine component. Select ENTER and continue resulting other urine components.



3. To result the urine microscopic, click on **Options,** then keyboard select, and an information dialog box will appear. From dropdown box, select the urine microscopic keyboard (UMIC), type in the Accession # and 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.