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, Clinitek Status Plus SGAH.U948 v1

Clinitek Status Plus QC Log AG.F370.1

Description of change(s):

SOP: Note change to QC form (specific to this instrument)

Section	Reason
16	Deleted UA QC form F133, Added microscopic QC fields to form F370
Add B	Correct reference to screen shot

Log:

- Added columns to record microscopic QC results

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™

Clinitek Status Plus QC Log

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

Month: _____ Year : _____ Serial Number: _____

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

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

Day			Glu	Bili	Ket	SG	Blood	PH	Pro	Urob	Nit	Leuk	Color	Clarity	RBCs	WBCs	TechCode
√ to verify lot ↓		Range:															
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Note: Reconstitute with 15 mL distilled H20. Once reconstituted stable for 7 days.

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

Quest Diagnostics™

Clinitek Status Plus QC Log

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

Month: _____ Year : _____ Serial Number: _____

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

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

Day			Glu	Bili	Ket	SG	Blood	PH	Pro	Urob	Nit	Leuk	Color	Clarity	RBCs	WBCs	TechCode
√ to verify lot ↓		Range:															
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Note: Reconstitute with 60 mL distilled H20. Once reconstituted stable for 7 days.

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

Quest Diagnostics

Clinitek Status Plus QC Log

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

Month: _____ Year : _____ Serial Number: _____

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

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

Day			Glu	Bili	Ket	SG	Blood	PH	Pro	Urob	Nit	Leuk	Color	Clarity	RBCs	WBCs	TechCode
√ to verify lot ↓		Range:															
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Note: Reconstitute with 60 mL distilled H20. Once reconstituted stable for 7 days.

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

Technical SOP

Title	**Urinalysis, Clinitek Status Plus**	
Prepared by	Ashkan Chini	Date: 1/3/2017
Owner	Robert SanLuis	Date: 1/3/2017

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
Urinalysis	Clinitek Status Plus	UMAC

Synonyms/Abbreviations
Urine Macroscopic, UA

Department
Urinalysis

2. ANALYTICAL PRINCIPLE

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 hydrogen 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

Component	Special Notations
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	Samples submitted in cups will be held until the next successful QC performance and then discarded.	

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

Reagents / Kits	Supplier & Catalog Number
Multistix 10 SG Reagent Strips	Siemens Reagent Strips Cat. No. 2161

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

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

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, the controls remain 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, the controls remain stable for 7 days at 2-8°C in its original capped vial.

Note: Some constituents are labile and will degrade if shaken roughly or exposed to air, light or room temperature for excessive amounts of time. Following reconstitution, keep the KOVA-Trol stoppered and refrigerated except when aliquoting the test samples.

6.3 Frequency

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

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits
- 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. • Inspect the instrument status, do maintenance and troubleshoot. • Repeat the QC test. • Notify the Supervisor if these results are not acceptable.

B. Criteria for Acceptable QC
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

C. Corrective Action
- All rejected runs must be effectively addressed and include the following documentation:
  - Control(s) that failed (e.g. positive control with negative result) and/or atypical or unexpected patient results
  - Actions taken
  - Statement of what was done with the patient samples from the affected run/batch,
  - Date and initials of the person recording the information.
- Patient samples in failed analytical runs must be reanalyzed.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

- Save the instrument printed paper. Print results on "Clinitek Status Plus QC Log", 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

Clinitek Status Plus

7.2 Equipment

- Centrifuge, 400g
- Refractometer

7.3 Supplies

- Disposable pipettes
- 16 x 100 mm test tubes
- Microscope slide
- Cover glass

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.	Turn the instrument on.
2.	Select **Strip Test** and then select **Enter New Patient**.
3.	Scan or enter patient's information. Then press **Start**.
4.	Dip all the test pads of the strip into the urine and immediately remove the strip.
5.	Drag the edge of the strip against the container rim to remove excess urine and blot the edge on a Kim-Wipe or gauze.
6.	Place the reagent strip to the end of the channel with the test pads facing up.
7.	Slide or push the strip to the end of the channel. Do not touch the pads on the strip.
8.	After the 8 second count down ends, the analyzer pulls in the test table and strip.

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

8.2	Color Interference
1.	Run the strip through the Clinitek Status Plus.
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 Status Plus can be reported as negative.

8.2	Color Interference
4.	Report the Color and Clarity as you see it.
5.	In the LIS for the remainder of the tests, report the comment COLINT which expands out to "Results not reported due to color interference".
6.	Perform a microscopic exam on all abnormally colored urines.

8.3	Bloody Urines
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 Status Plus.
5.	Report the remaining results of the supernatant from the Clinitek Status Plus (GLU, BIL, KET, PH, PRO, URO, NIT, and LEU).
6.	Perform a microscopic exam on the sediment.

8.4	Instrument Maintenance
1.	Refer to Addenda A for weekly maintenance instructions.
2.	Record maintenance on the appropriate log.

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

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Test	Report As
Color	Yellow, Orange, Pink, Green, Amber, Brown, Bloody, Dark Yellow, Straw
Appearance	Clear, Cloudy, Slightly Cloudy, Turbid
Specific Gravity	1.000 – 1.030 (in increments of 0.005)
pH	5.0 – 9.0 (in increments of 0.5)
Glucose	Negative, Trace, 1+, 2+, 3+, 4+

Test	Report As
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

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

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 B "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: Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment of some calculi.

Specific Gravity: 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

A precision study is performed as part of the validation plan.

14.3 Interfering Substances

Bloody urine and color interference are 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.

Test Name	False Positive or Increased Value	False Negative or Decreased Value
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

Test Name	False Positive or Increased Value	False Negative or Decreased Value
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	N/A
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
Protein	▪ Highly buffered or alkaline urines ▪ Contamination with quarternary ammonium compounds (from some antiseptics and detergents) or Chlorhexidine (found in some skin cleansers)	N/A
Urobilinogen	▪ Temperature > 26°C ▪ ρ-aminosalicylic acid (PAS) and sulfonamides ▪ ρ-aminobenzoic acid (PABA) may cause atypical color development	▪ Temperature < 22°C ▪ Formalin
Nitrite	N/A	▪ 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	▪ Elevated glucose (≥ 3,000 mg/dL) ▪ High specific gravity ▪ Cephalexin (Keflex®) or Cephalothin (Keflin®) ▪ High concentrations of oxalic acid ▪ Tetracycline ▪ Temperature <22°C
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. Specific Gravity Using the Refractometer, Urinalysis procedure
6. Microscopic Examination of Urine, Urinalysis procedure
7. ~~Urinalysis QC form (AG.F133)~~
8. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
9. Current package insert Multistix 10 SG
10. Clinitek Status Plus QC Log (AG.F370)
11. Clinitek Status Plus Maintenance Log (AG.F371)

17. REFERENCES

1. Operator's Guide, Siemens Clinitek Status Plus, Siemens Healthcare Diagnostics, Inc., revised 12/2011.
2. Package Insert, Siemens Multistix 10 SG, Siemens Healthcare Diagnostics, Inc. revised 06/2010.
3. Package Insert, KOVA-Trol™ HYCOR, P/N 91017-09, 10/2015.
4. 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
0	2/13/18	16	Deleted UA QC form F133, added microscopic QC fields to form F370	L Barrett	R SanLuis
0	2/13/18	Add B	Correct reference to screen shot	L Barrett	R SanLuis

19. ADDENDA

Addendum	Title
A	Clinitek Status Plus Maintenance Procedure
B	Urinalysis Keyboard: Macroscopic and Microscopic Result Entry

Addenda A

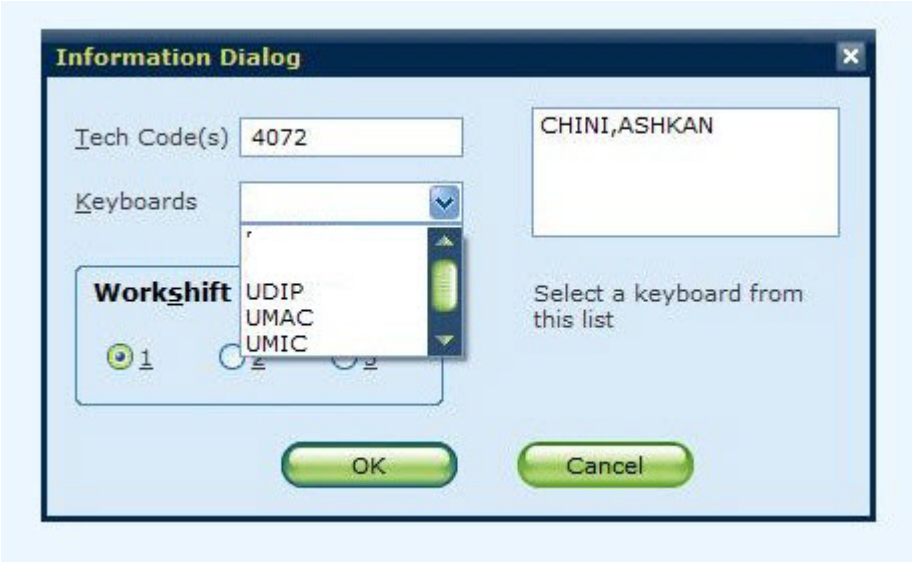
Clinitek Status Plus Maintenance Procedure

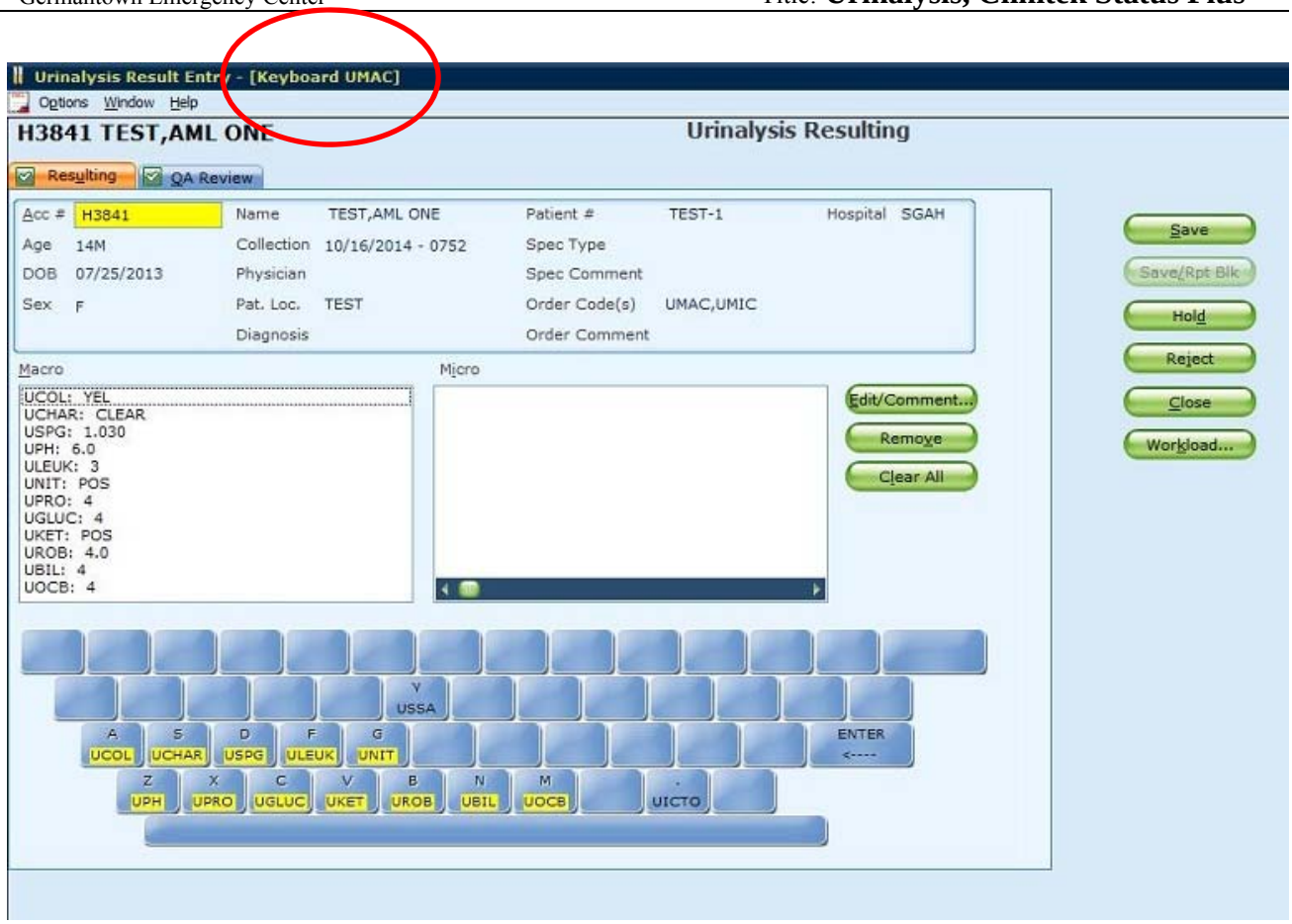
1. Remove the test table by pulling it slowly out of the analyzer.
2. Lift the table insert to remove it from the test table.
3. Drain the drip tray, if necessary.
4. Wet a cotton swab with water and thoroughly scrub the test table and table insert, except for the white calibration bar.
5. Rinse both sides of the table insert and test table under running water.
6. Dry the test table thoroughly using a Kim-Wipe or gauze.
   Note: Do not scratch the white calibration bar.
7. Examine the white calibration bar on the test table for dirt or discoloration. If it appears dirty or discolored, perform the following steps:
   a. Wet a new cotton swab with reagent grade water and gently wipe and clean the calibrator bar.
      Note: Do not touch the calibration bar while examining or cleaning it.
   b. Allow the calibration bar to air dry.
   c. Inspect the surface of dust, foreign material, scratches, or scuffs. If the calibration bar cannot be completely cleaned or if the bar has scratches order a new test table.
8. Insert the test table, pushing it in more than halfway into the analyzer.
   Note: Do not push the table fully into the analyzer. The test table might jam if pushed in all the way.
9. Insert the table insert.
10. Clean the outside of the instrument.
11. Turn the instrument off and then back on so it will reset and recalibrate automatically.

Addenda B

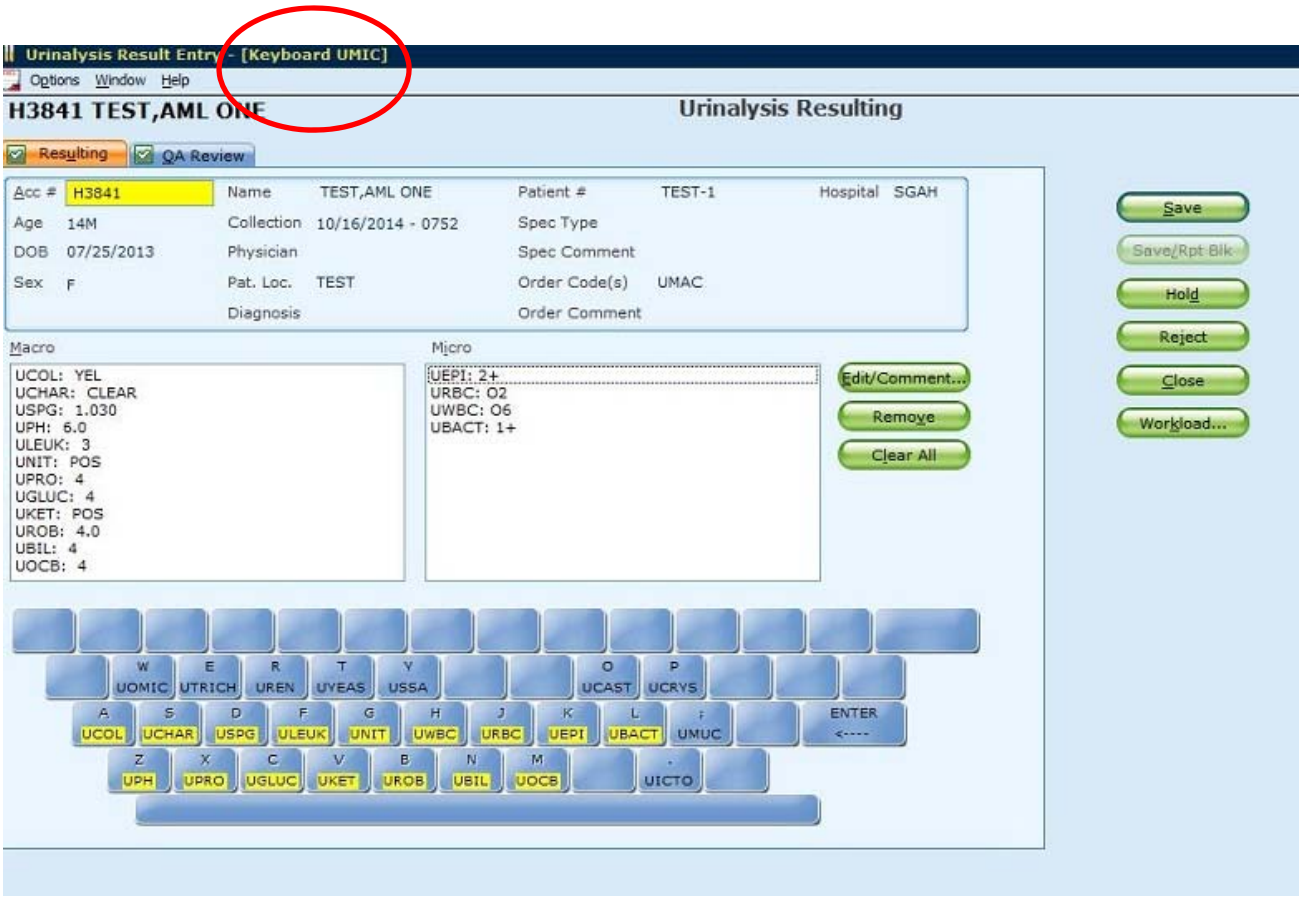
Urinalysis Keyboard: Macroscopic and Microscopic Result Entry

1. Log into Sunquest, select the **Urinalysis Result Entry**. The following information dialog box will be displayed demonstrating the different keyboards. Choose **UMAC** or **UMIC.**





2. **To result the macroscopic urinalysis**, select the **UMAC** keyboard, type in the Accession # and press **ENTER**.
   - The automated analyzer results for the macroscopic dipstick will be displayed (see above ~~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.
   - There are four (4) components that are required for each microscopic analysis:
     - White blood cells
     - Red blood cells
     - Epithelial cells
     - Bacteria



3. **To result the urine microscopic**, select the **UMIC** keyboard, type in the Accession # and then press **ENTER.** The urine macroscopic results will show up along with the keyboard to result 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.