

Director's Signature: _____

Date: _____

<p style="text-align: center;">UCSF Medical Center</p> <hr/> <p style="text-align: center;">UCSF Benioff Children's Hospital</p> <p style="text-align: center;">Clinical Laboratories</p>	<p style="text-align: center;">Point of Care Testing</p>
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CLINITEK Status® + Analyzer
Multistix® 10 SG Urinalysis and Clinitek® Microalbumin 2

I. PURPOSE

Urinalysis can be used to screen for disorders or infections of the urinary tract, as well as metabolic disorders affecting the urinary excretion of certain substances. Multistix® 10 SG Reagent Strips are used to rapidly determine urine specific gravity, pH, protein, blood, glucose, ketones, bilirubin, nitrite, leukocyte esterase and urobilinogen.

Clinitek Microalbumin 2 can be used for screening samples for microalbuminuria which has been reported to be an early predictor of the development of glomerular damage in the absence of overt nephropathy.

II. SCOPE

Multistix® 10 SG urinalysis is performed on patients in both the hospital and ambulatory setting. It is used for performing urinalysis on adult and pediatric patients. Common reasons for the test include, but are not limited:

- to determine the presence of infection in patients with urinary symptoms, such as urinary urgency or dysuria
- to determine the presence of glycosuria and ketonuria in patients with known or suspected diabetes
- to determine the presence of proteinuria in patients with known or suspected nephrosis
- to determine hydration status in patients who have experienced fluid loss

Clinitek® Microalbumin 2 strips test for albumin and creatinine in urine. An albumin-to-creatinine ratio is also determined.

III. PRINCIPLE

The CLINITEK Status® Analyzer is a portable instrument powered by batteries or by an electrical outlet for bench top use. The optical system consists of six light emitting diodes, a light guide, a mirror, a lens and a detector. Light from the LEDs travel along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror. It is then directed through an aperture on the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

IV. PERSONNEL

Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the ambulatory setting, this includes Registered Nurse, Nurse Practitioners, Physician Assistants, Physicians, Medical Assistants, Licensed Vocational Nurses and other licensed Technologists.

V. REAGENTS, EQUIPMENTS, AND MATERIALS

- A. Reagents
 1. Siemens Multistix 10® SG Urinalysis Strips - Catalog #2161
 2. Siemens Microalbumin 2 Reagent Strips – Catalog #2083
 3. BIO-RAD qUantify® Plus Control Levels 1 and 2 – Catalog #995
- B. Equipments
 1. CLINITEK Status® + Analyzer
 2. Connector Board
 3. Bar Code Scanner
- C. Materials
 1. Disposable plastic pipettes
 2. Gloves
 3. Paper towels
 4. Safety glasses or goggles
 5. Specimen containers
 6. Thermal printer paper – Catalog # 5773, PMM #15581

VI. SPECIMEN REQUIREMENTS

- A. Require 20 ml (2 ml minimum) of freshly voided urine.
- B. Criteria for Acceptable specimens
 1. Clean-voided urine for culture is collected in a clean, dry, plastic cup with a non-leaking lid (non-sterile containers are OK).
 2. If testing is delayed (>2 hour after collection), specimen should be refrigerated at 2 – 8°C for preservation. Allow urine specimen to return to room temperature before testing.
 3. Sample for culture can be submitted to Microbiology after performing dipstick testing on the original urine cup.
- C. Criteria for Specimen Rejection
 1. Specimens untested more than 2 hours after voiding.
 2. Urine contaminated by skin cleansers, stool, or vaginal discharge
 3. Use of medications that cause abnormal urine color (such as Pyridium, Azo Gantrisin, Azo Gantanol, nitrofurantoin, and riboflavin), which may affect the readability of the reagent areas on the strip.
 4. Highly colored urine sample should be sent to the laboratory for testing.

VII. STORAGE AND STABILITY OF TEST STRIPS

- A. MULTISTIX® 10 SG AND CLINITEK® MICROALBUMIN 2
 1. Store at room temperature between 15°-30°C (59°-86°F).
 2. Do not use product after expiration date.
 3. Do not store the bottle in direct sunlight.
 4. All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive.
 5. Do not remove desiccant packet(s) from bottle.

6. Remove each strip from the bottle immediately before it is to be used for testing.
7. Replace cap immediately and tightly after removing reagent strip.
8. Do not touch test areas of the reagent strip
9. Dip test areas in urine completely, but briefly to avoid dissolving out the reagents.

VIII. STORAGE AND STABILITY OF CONTROLS

- A. Controls will be stable until the expiration date when stored unopened at 2° - 8°C (36° - 46°F).
- B. Once opened, Controls will be stable for 14 days at 2° - 8°C (36° - 46°F) or 8 strips immersions, whichever comes first. **For each immersion add a tally mark on each vial until done with the 8th markings- Discard Control vial with 8 markings.** Do not reuse.
- C. **DO NOT FREEZE, DO NOT STORE IN DIRECT LIGHT.**

IX. QUALITY CONTROL REQUIREMENT

- A. Test Level 1 and Level 2 controls whenever a new bottle of Multistix 10 SG or Microalbumin reagent strips is first opened and each day of patient testing.
- B. **NOTE:** At a minimum, open bottles of test strips must be re-QC'd every 30 days, when not used daily for patient testing.
- C. Write the date and your initials on the bottle when first opened and QC performed, , and thereafter every 30 days re-QC'd has been performed.
- D. BIO-RAD Quantify Plus Controls Levels 1 and 2 is a liquid base matrix prepared with human erythrocytes and leukocytes, constituents of animal origin, chemicals and preservatives
- E. These Quality Control materials should be tested in the same manner as patient specimens
- F. **IMPORTANT NOTE-whenver a new lot of control is received, please notify POCT coordinator at 4-6839 and Fax (4-6841) the new lot insert to POCT. Do not use until given instruction by POCT coordinator. New control ranges may have to be programmed in the instrument by POCT coordinator if applicable.**

X. QUALITY CONTROL PROCEDURE

- A. Before testing, allow the control to reach room temperature (18°-25°C) for 15-30 minutes. Invert the bottles several times to ensure homogeneity. **DO NOT SHAKE.**
- B. **Note:** The Clinitek Status can be programmed to read QC for one kind of strip only. QC for the 10SG will be run as a control and QC results documented on the QC log sheet. The user will be prompted to perform 10SG QC at the appropriate intervals. QC for the Microalbumin strip will be run in patient test mode, not in control mode, but these QC results will be logged as QC results on the QC log sheet. The user will not be prompted to perform Microalbumin QC.
- C. To perform a Multistix 10 SG QC:
 1. At the Select Ready screen select **QC Strip Test Due** (The Control Lot screen displays).
 2. Operator ID screen appears. Scan barcode from your ID badge or manually enter.
 3. Operator Name Screen appears. Pick one of the following options, **Last Operator** or **New Operator**.

4. Control and Level Screen appear. Pick **Enter Lot and Expiration Date** box.
 5. Manually enter the lot number, use the **ABC** key to enter text. To enter numeric text, select **123**.
 6. Select **Enter**. (The Control Expiration screen displays).
 7. Use the arrow keys to indicate the control lot expiration date.
 8. Select **Enter**. (The Strip Lot screen displays)
 9. Select **Enter New Lot and Expiration Date** box. Use the bar code scanner or to enter manually, use the ABC key to enter text and the 123 to enter numeric text.
 10. Select **Enter**. (The Strip Expiration screen displays). Use the arrow keys to indicate the strip expiration date.
 11. Select **Enter**. (The Prepare Test screen displays).
 12. Select **Start**. (The Results screen displays). **WARNING: Once you touch the START button you have eight seconds to treat the reagent strip with the QC sample and place the strip on the test table.**
 13. Dip the reagent strip into the QC sample, wetting all pads. Immediately remove the strip from the urine.
 14. Drag the edge of the strip against the side of the Control container as you remove it. Blot by touching the edge of the strip to the paper towel to remove excess urine. Do not lay the pads on the paper towel or cover the pads by the paper towel.
 15. Place the reagent strip in the channel of the test table with the test pads facing up. Slide the strip to the end of the channel. **WARNING: Do not push or pull the test table.**
 16. At the end of the eight second countdown, the test table and strip will automatically be pulled into the instrument.
 17. The analyzer will perform an automatic calibration and begin analyzing the strip. **WARNING: Do not move or bump the table while the instrument is calibrating.**
 18. When the analysis is complete, the Results screen will display the results.
 19. Select **Print** to print the results. Record Control 1 results on QC Log Sheet
 20. Remove the used urinalysis strip from the test table and dispose it properly.
 21. Select **Done**. (The Control and Level Screen displays). Repeat above steps for Level 2 control.
 22. Select **Print** to print the results. Record Control 2 results on QC Log Sheet
 23. **NOTE: Patient tests can not be run until the QC tests pass.**
 24. To repeat the failed QC test, select **Repeat failed QC test**.
 25. QC Test Results Summary screen displays. Select **Done** to return to the main Select Ready screen
- D. To perform a Microalbumin QC, use Level 1 and Level 2 controls and run as a patient sample:
1. Testing is started from the main Select Ready Screen.
 2. Press **Strip Test** box to conduct strip test
 3. Operator ID screen appears.
 4. Either press **Enter Last Operator** or **Enter New Operator Name**.
 5. Scan the barcode on your ID badge to enter New Operator ID.
 6. Patient Information screen appears.
 7. Select **New Patient** box.

8. Enter Patient Name Screen is displayed. Type in **Control 1** or **Control 2**. (Press ABC button to enter text. To enter numeric text, select 123). Press **Enter**.
 9. The next screen displayed is **Patient ID**, enter the lot number of control 1 or control 2. Press **Enter**.
 10. Strip Lot screen is displayed. Press **Use Last Lot button**
 11. Prepare Test screen is displayed. Select **Start**.
 12. Dip the reagent strip into the QC sample, wetting all pads. Immediately remove the strip from the urine.
 13. Drag the edge of the strip against the side of the Control container as you remove it. Blot by touching the edge of the strip to the paper towel to remove excess urine. Do not lay the pads on the paper towel or cover the pads by the paper towel.
 14. Place the reagent strip in the channel of the test table with the test pads facing up. Slide the strip to the end of the channel. **WARNING: Do not push or pull the test table.**
 15. At the end of the eight second countdown, the test table and strip will automatically be pulled into the instrument.
 16. The analyzer will perform an automatic calibration and begin analyzing the strip. **WARNING: Do not move or bump the table while the instrument is calibrating.**
 17. When the analysis is complete, the Results Screen will display.
 18. Results will print. Press **done**.
 19. Record Control 1 or Control 2 results on QC Log Sheet
 20. Select Ready screen appears
 21. Remove the used urinalysis strip from the test table and dispose it properly.
 22. Touch **Done** to complete the test and return to the main Select Ready screen.
- E. Documenting Quality Control
1. All quality control tests results using both Level 1 and Level 2 solutions should be recorded on the QC Log.
 2. Write the open date, and your initials on the reagent strip bottle to denote QC was done. Thereafter, date and initial the reagent strip bottle every 30 days when re-QC is performed.
 3. Write the open date, expiration date and the number of immersions (using tally markings) on the Level 1 and Level 2 control vials to document QC vial usage.

XI. SPECIMEN COLLECTION PROCEDURE

- A. Using two patient identifiers, verify patient identification, and explain urine collection procedure to patient and/or family. If sample is not obtained from the patient by the person who will perform testing, and testing is not performed **immediately**, then the specimen container (not the lid) must be labeled with two forms of patient identification in the presence of the patient.
- B. Females: While the labia are held apart, the vulva is thoroughly washed from front to back with two successive cleansing pads as supplied. Special attention should be paid to the urethral meatus - benzalkonium, chlorhexidine or hexachlorophene should not be used, as contamination of the collection with residual disinfectant can sterilize the urine sample. The patient should not halt and restart the urine stream for a "midstream" collection, but preferably should move the container into the path of the already voiding urine.

- C. Males: The process is similar to that described above. The foreskin is retracted, and the glans penis is thoroughly washed with two successive cleansing pads as supplied, special attention being paid to the urethral meatus.
- D. Analysis should be performed within 1 hour of collection or the specimen must be refrigerated. Specimen must return to room temperature before testing.
- E. **CAUTION:** Ensure that work areas and specimen containers are always free of detergents and other contaminating substances. Some substances can interfere with patient results.

XII. PATIENT TESTING PROCEDURE

- A. Required 20 mL (2 mL minimum) of freshly voided urine. If sample has been refrigerated, bring the patient sample to room temperature and mix well prior to testing.
- B. **WARNING:** Do not remove the strip from the bottle until immediately before use. Replace cap immediately and tightly after removing the strip.
- C. Put on gloves and protective eyewear.
- D. Testing is started from the main **Select Ready** screen.
- E. Press **Strip Test** box to conduct strip test.
- F. Operator ID screen appears. Enter ID number. Manually enter or Scan the barcode on your ID badge to enter New Operator ID.
- G. Operator Name Box appears. Either press **Enter Last Operator** or **Enter New Operator Name**.
- H. Patient Information screen appears. Select **New Patient** box.
- I. **Patient Name** screen is displayed. Type in patient's name. (Press ABC button to enter text. To enter numeric text, select 123). Press **Enter**.
- J. The next screen displayed is **Patient ID**, scan the patient barcode or manually enter the patient ID. Press Enter.
- K. **Strip Lot** screen is displayed. Press Use Last Lot button
- L. A **Prepare Test** screen is displayed. Select **Start**.
- M. **WARNING:** Once you touch the **START** button you have eight seconds to treat the reagent strip with the urine sample and place the strip on the test table.
- N. Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.
- O. Drag the edge of the strip against the side of the sample container as you remove it.
- P. Blot by touching the edge of the strip to the paper towel to remove excess urine.
- Q. **WARNING:** Do not lay the pads on the paper towel or cover the pads by the paper towel.
- R. Place the reagent strip in the channel of the test table with the test pads facing up. Slide the strip to the end of the channel.
- S. **WARNING:** Do not push or pull the test table.
- T. At the end of the eight second countdown, the test table and strip will automatically be pulled into the instrument. If the test strip was not placed on test table, repeat with a fresh test strip.
- U. The analyzer will perform an automatic calibration and begin analyzing the strip.
- V. **WARNING:** Do not move or bump the table while the instrument is calibrating.
- W. When the analysis is complete, the **Results** screen will display the first page of result.
- X. Results will automatically be printed.
- Y. Remove the used urinalysis strip from the test table and dispose it properly.

Z. Touch **Done** to complete the test and return to the main Select Ready screen.

XIII. RESULTS AND REPORTING

- A. Record results on the Multistix 10 SG Urinalysis and Clinitek Microalbumin 2 Patient Results Log and/or in the patient's medical record. The patient's provider should be notified according to practice guidelines or MD order.
- B. Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

XIV. INTERPRETATION

- A. Interpretation of the test results will be made by the patient's health care provider. General interpretation guidelines are provided below.

NORMAL VALUES (10® SG):

Glucose	Negative
Bilirubin	Negative
Ketone	Negative
Specific Gravity	1.002 - 1.030
Blood	Negative
pH	4.5 - 8.0
Protein	Negative
Urobilinogen	≤1.0 mg/dL
Nitrite	Negative
Leukocytes	Negative

NORMAL VALUES (Microalbumin strip):

Albumin	<20 mg/L
Creatinine	10-300 mg/dL
Albumin-to-Creatinine Ratio	<30 mg/g creatinine

ADDITIONAL INFORMATION:

1. **Glucose:** Small amounts of glucose (<30 mg/dL) are normally excreted by the kidney. These amounts are usually below the sensitivity level of this test but on occasion may produce a result between Negative and 100 mg/dL that is interpreted as a positive result. Results at the first positive level may be significantly abnormal if found consistently.
2. **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 (0.1 mg/dL or greater) 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 intended use.
3. **Ketone:** Normally, no ketone is detectable in urine (up to 2 mg/d: acetoacetic acid). 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.

4. **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 kidney can be considered normal.
5. **Blood:** Normally, no hemoglobin is detectable in urine (<0.010mg/dL or 3RBC/ μ L). Occult blood occurs in urine as intact erythrocytes and hemoglobin, which can occur during urological, nephrological and bleeding disorders. Small amounts of blood (0.030-0.065 mg/dL or a strip result of Small) 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. Blood is often, but not always, found in the urine of menstruating women.
6. **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.
7. **Protein:** Protein in urine can be the result of urological and nephrological disorders. In normal urine, less than 150 mg of total protein is excreted per day (24 hour period) (<15 mg/dL). Clinical proteinuria is indicated at greater than 500 mg of protein per day (strip result of \geq 30 mg/dL). 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 excretion can be temporarily elevated in the absence of renal abnormality by strenuous exercise, orthostatic proteinuria, dehydration, urinary tract infections, and acute illness with fever. Clinical judgment is needed to evaluate the significance of Trace results.
8. **Urobilinogen:** Urobilinogen is normally present in urine at concentrations up to 1.0 mg/dL (1 Ehrlich Units/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. Evaluation of both the bilirubin and urobilinogen results helps in the differential diagnosis of jaundice, as well as other liver and biliary disorders.
9. **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 (0.075 mg/dL nitrite ion or greater).
10. **Leukocytes:** Normal urine specimens generally yield negative results. An increase in leukocytes (\geq 10 leukocytes/ μ L) 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-infective 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.
11. **Albumin:** Albumin is normally present in urine at concentrations of less than 20 mg/L. Microalbuminuria is indicated with results of 20-200 mg/L results of >200 mg/L indicated clinical albuminuria. These levels have been found to be predictive of albumin excretion rates of 30-299 mg/24 hours and >300 mg/24

hours, respectively. Urinary albumin excretions can be temporarily elevated by exercise, urinary tract infections, and acute illness with fever.

12. **Creatinine:** Creatinine is normally present in urine at concentrations of 10-300 mg/dL (0.9 to 26.5 mmol/L).
13. **Albumin-to-Creatinine Ratio:** Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine (3.4 mg albumin/mmol creatinine). Microalbuminuria is indicated at a ratio result of 30-300 mg/g (3.4-33.9 mg/mmol) (Abnormal) and clinical albuminuria at a ratio result of >300 mg (>33.9 mg/mmol) (High Abnormal).

XV. ALTERNATIVE TEST METHODS

Freshly voided or refrigerated specimens may be sent to the Clinical Lab for testing.

XVI. LIMITATIONS/INTERFERENCES

- A. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.
- B. Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. These substances include visible levels of blood or bilirubin and drugs containing dyes (e.g., Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Macrochantin, Furadantin), or riboflavin. Highly colored urine sample should be sent to the laboratory for testing.
 - a. **Glucose:** Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL) but the combination of such ketone levels and a low glucose level is metabolically improbable in screening.
 - b. **Bilirubin:** Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or positive reading. Metabolites of Lodine (etodolac) may cause false positive or atypical results. Atypical colors (colors that are unlike the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction. These colors may indicate bile pigment abnormalities and the urine specimen should be tested further.
 - c. **Ketone:** False Trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction
 - d. **Specific Gravity:** The Siemens SG test is dependent on ions in urine and results may differ from those obtained with other specific gravity methods when certain nonionic urine constituents, such as glucose, are present. Highly buffered alkaline urines may cause low readings, while the presence of moderated quantities of protein (100-750 mg/dL) may cause elevated readings.
 - e. **Blood:** Capoten(captopril) may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.

- f. **pH:** Bacterial growth by certain organisms in a specimen may cause a marked alkaline shift (pH >8.0), usually because of urea conversion to ammonia.
- g. **Protein:** A visibly bloody urine may cause falsely elevated results.
- h. **Leukocytes:** Elevated glucose concentrations (≥ 3 g/dL) may cause decreased test results. The presence of cephalexin (Keflex), cephalothin (Keflin), or high concentration of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.
- i. **Nitrite:** Pink spots or pink edges should be interpreted as a positive result. A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathological microbes.
- j. **Urobilinogen:** The test pad may react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamide. Atypical color reactions may be obtained in the presence of high concentrations of p-minobenzoic acid. False negative results may be obtained if formalin is present. Strip reactivity increase with temperature, the optimum temperature is 22-26 C (72-79F). The test is not a reliable method for the detection of porphobilinogen.
- k. **Albumin and Creatinine:** The presence of hemoglobin or myoglobin (≥ 5 mg/dL or a visibly bloody urine) may cause falsely elevated results with both the albumin and creatinine tests. Contamination of the urine specimen with soaps, detergents, antiseptics, or skin cleansers, or the use of urine preservatives other than boric acid (1.0 g/L), may also affect test results. The presence of cimetidine (Tagamet) may cause falsely elevated results with the creatinine test.

XVII. MAINTENANCE

A. Clinitek Status Analyzer:

1. The system is turned on by pressing the **on/off button** located at the front of the instrument. The analyzer automatically runs a system diagnostic check during which it performs a series of electronic, signal and memory checks, as well as ensures there is sufficient battery voltage to operate the instrument (if powered by batteries).
2. The test table insert and the test table should be kept clean if the analyzer is to operate properly.
3. **WARNING:** Do not autoclave the test table or test table insert.
4. **WARNING:** Care should be taken not to scratch the white calibration bar. If it is scratched or scuffed, obtain a new test table. Solvents of any kind must not be used to clean the bar.
5. Refer to your CLINITEK Status® Analyzer Operator's Manual for replacing the printer paper and for detailed cleaning and maintenance instructions.

B. Bar Code Scanner- Clean the bar code scanner window whenever it appears dirty or smeared:

1. Wipe the scanner window with a soft cloth or facial tissue dampened with water, or an ethanol solution.

2. If a detergent solution is used, rinse with a soft cloth of facial tissue dampened with water only.
3. Clean the plastic case in the same manner.

Caution:

- i. Do not submerge the scanner in water. The scanner's housing is not water-tight.
- ii. Do not use laboratory wipes, because they may scratch the window.
- iii. Do not use any type of solvent, other than recommended solvents, to clean the scanner. Harsh chemicals can damage the finish or the window.

XVIII. DOCUMENTATION & RECORDS MAINTENANCE

Retired Quality Control and Test Result Logs are kept in an accessible area for three years, as required by law. Patient Test Results are also documented in the patient's medical record. Obsolete or revised procedures are removed to Discontinued Procedure binders for historical review when needed.

XIX. REFERENCES

- A. Siemens Multistix Urinalysis Strips Package Insert, AN30516F, Rev. 03/10 USA
- B. Siemens Clinitek Microalbumin 2 Strips Package Insert, AN73024J, Rev. 02/09 USA
- C. Siemens Healthcare Diagnostics CLINITEK Status® Analyzer Operator's Manual, 132387, Rev. T, 2008-05
- D. National Committee for Clinical Laboratory Standards (NCCLS), Clinical Laboratory Procedure Manuals, Third Edition (GP2-A3), 1996
- E. *Technical Assistance*
Siemens Healthcare Technical Solutions Center: 1-877-229-3711
Siemens Healthcare Diagnostics
Benedict Avenue
Tarrytown, NY 10591-6147
- F. College of American Pathologists "Laboratory General," 06/17/2010 Edition
- G. NCCLS "Clinical Laboratory Technical Procedure Manuals; Approved Guideline - Fifth Edition";
- H. GP2-A5; Volume 26, Number 12.



PROCEDURE REVIEW COVER SHEET

Clinitek STATUS Multistix® 10 SG Urinalysis and Clinitek® Microalbumin 2

Author: Sonia Moscardon, CLS Date: 04/29/2011
Director: Tim Hamill, M.D. Date: 10/03/2011
In Use Date: October 7, 2011 Discontinued Date _____

ACTION: Reviewed or Revised/Approved

Version: 1.0 Action: Approved Signature: Dr. Hamill Date: 10/9/2011
Version: 1.1 Action: Revised Signature: Alice Seid Date: 4/27/2012
Version: 1.1 Action: Approved Signature: Dr. Hamill Date: 5/1/2012
Version: 1.2 Action: Revised Signature: Alice Seid/ Kim Lee Date: 11/26/12
Version: 1.2 Action: Approved Signature: Dr. Hamill Date: 11/30/12

See Signature Manifest

Signature Manifest

Document Number: SOP-0021

Revision: 2

Title: Status Plus-Urinalysis and Albumin

All dates and times are in Pacific Standard Time.

Status Plus Urinalysis Procedure

SR Sup Review

Name/Signature	Title	Date	Meaning/Reason
Cynthia Ishizaki (024044224)	POC SR SUP	18 Jun 2013, 05:30:55 PM	Reviewed

Med Dir Apprvl

Name/Signature	Title	Date	Meaning/Reason
Tim Hamill (023335003)	PA CB MED DIRECTOR	19 Jun 2013, 09:27:53 AM	Approved