PROCEDURE # **945.8035**
CLINITEK POINT OF CARE URINALYSIS TESTING

PREPARED BY	DATE ADOPTED	SUPERSEDES PROCEDURE #
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REVIEW DATE	REVISION DATE	SIGNATURE

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OPERATORS:

Registered Nurses and emergency room technicians who are properly trained on the Clinitek Status testing system perform the procedure.

All personnel must demonstrate their proficiency in performing Quality Control and patient testing activity in the annual skills lab competency or peer review. New employees will have their competency assessed six months after initial competency and annually thereafter.

EQUIPMENT AND SUPPLIES:

Equipment:

1. Siemens Reagent Strips
2. Clinitek Status Analyzer
3. Specimen collection container
4. Paper towels

Principle of the Test:

Siemens Reagent Strips for urinalysis are read instrumentally by the Clinitek Status Analyzer. Siemens Reagent Strips provide tests for:

1. Glucose
2. Bilirubin
3. Ketone (acetoacetic acid)
4. Specific gravity
5. Blood
6. pH
7. Protein
8. Urobilinogen′
9. Nitrite
10. Leukocytes in urine

Chemical Principles of the Siemens Reagent Strips

TEST NAME	CHEMICAL PRINCIPLE
Glucose	Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Peroxidase catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.
Bilirubin	Bilirubin couples with diazotized dichloraniline in a strongly acid medium. Colors range through various shades of tan.
Ketone	Acetoacetic acid reacts with nitroprusside. Colors range from buff-pink for a negative reading, to maroon for a positive reading.
Specific Gravity	pKa changes occur for 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.
Blood	Hemoglobin catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3', 5,

	5'-tetramethylbenzidine. Colors range from orange through green; very high levels of blood may cause the color development to continue to blue.
pH	The double indicator principle gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
Protein	At a constant pH, the development of any green color is due to the presence of protein (protein error-of-indicators principle). Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.
Urobilinogen	In a modified Ehrlich reaction, p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.
Nitrite	Nitrate (derived from the diet) is converted to nitrite by the action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. This diazonium compound couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.
Leukocytes	Esterases in granulocytic leukocytes 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.

Clinical Application and Usefulness:

Siemens Reagent Strips are for in vitro diagnostic use. Urinalysis can provide the physician with important information regarding the status of a patient's health. Test results may provide information regarding the status of:

1. Carbohydrate metabolism
2. Kidney function and liver function
3. Acid-base balance
4. Urinary tract infection.

NOTE: As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

Specimen Collection Storage:

Patient Identification/Preparation:

Urine Point of Care Urinalysis Testing will be performed only when ordered by a physician. Patient is identified using their identification band to verify name and date of birth. A label with the patient name, date of birth and medical record is affixed to the urine container.

Urine is the only acceptable sample type for this assay.

Collect urine into a clean, dry container.

Specimens collected at any time of day may be used.

Biohazard:

Handle all specimens, as if capable of transmitting infectious diseases. Wear appropriate facial protection, gloves and protective clothing.

1. Obtain a fresh, urine specimen. Specimens should be at room temperature for less than two hours before testing.
2. Collect the urine in a clean, dry, covered container.

3. The urine specimen should be well mixed and uncentrifuged. If the urine depth in the container is less than 3 inches (7.6 cm), pour the specimen into a narrow tube.
4. If a urine culture is required, a separate (new) specimen must be collected.
5. If testing is delayed (>2 hour after collection), specimen should be refrigerated for preservation. Allow urine specimen to return to room temperature before testing.

Specimen Rejection Criteria:

Do not accept the following:

1. Specimens that have remained at room temperature for longer than two hours.
2. Specimens with urine preservatives.
3. Specimens that arrive in homemade containers (glass jars, pill bottles, etc.)
4. Leaking specimen containers.

If an unacceptable specimen is received, note the reason for rejection in Wellsoft and request a new, acceptable specimen from the patient. Acceptable collection container and collection instructions should be provided to the patient.

WARNING: Some urine specimens may have been collected during a critical procedure or by means of an invasive procedure. Therefore, it is important to never dispose of an unacceptable specimen until the physician has been notified.

REAGENTS:

Storage and Stability:

1. Store Siemens Reagent Strips at room temperature, 15-30º C (59-86º F).
2. Do not store the reagent strips in direct sunlight. Protection from exposure to light, heat and ambient moisture is mandatory to guard against altered reagent reactivity.
3. Store the unused reagent strips in the original bottle. Transferring unused reagent strops to other containers may cause the strips to deteriorate and become unreactive.
4. Do not remove desiccants from bottle.
5. Do not use reagent strips beyond the expiration date.
6. *****Initial and date reagent bottle when you first open it.*****
7. **Do not remove the strip from the bottle until immediately before use. Replace cap immediately and tightly after removing the strip.**
8. Avoid touching the test areas of the reagent strip.
9. Discoloration or darkening of the reagent areas may indicate deterioration. If this happens, confirm the expiration date and/or check performance with known negative and positive controls. If acceptable results are not obtained, discard the deteriorated strips and retest using a new, unopened bottle of reagent strips.
10. Due to the nature of the urobilinogen and leukocytes reagents found on the strips, these two results may be decreased at temperatures below 22º C (72º F) and increased at temperatures above 26º C (79º F).
11. The strips have been determined to be non-hazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

Instrument Operation and System Description:

The Clinitek Status Analyzer is a portable instrument powered by batteries or by an electrical outlet for bench top use. It is for in vitro diagnostic use in the semi-quantitative or qualitative detection of bilirubin, blood (occult), creatinine, glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, protein,

specific gravity and urobilinogen in urine samples. The tests reported depend on the type of Siemens urinalysis strip used.

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 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.

Reagent Special Preparation:

No special preparation for reagent strips is required.

QC Materials:

Control material consists of two levels, a negative and a positive. Use MAS Level I as the negative control and MAS Level II as the positive control.

Test negative and positive liquid controls whenever a new reagent vial is first opened, at a minimum of once a month. If both controls are in range, proceed with patient testing. If a control is out of range, repeat it once. If control is in range, proceed with patient testing. If control is still out of range, forward testing to central lab. Notify Point of Care Coordinator.

For assistance, call the Siemens Diagnostics Technical Care Center (877-229-3711).

QC PROCEDURE:

1. At the main **Select** screen, touch **Strip Test.** The **Operator ID** screen will appear.
2. If you were the last operator to enter an ID on the analyzer, touch **Last Operator.** The **Patient Information** screen will appear.
3. If you are a new operator, touch **Strip Test.** The **Operator ID** screen will appear.
4. Use the keypad to enter your ID. Touch enter.
5. The **Patient Information** screen will appear. Touch the **Enter New Patient** key at the bottom right of the screen.
6. The **Patient ID** screen will appear.
7. Touch the **ABC** button in the upper left portion of the screen. Type in neg for the negative control (Level I) or pos for the positive control (Level II).
8. Touch **Enter.**

WARNING: If refrigerated, bring the qc sample to room temperature 20-30º C (68-86º F) prior to testing.

9. A **Prepare Test** screen will appear displaying the following two steps:
   a. Adjust test table insert for strip tests.
   b. Touch start to begin

10. Touch **START**. Another **Prepare Test** screen will appear displaying the next four steps:

WARNING: Once you touch the START button, you have eight seconds to dip the test strip into urine sample and place it on the test table.

   a. Dip test strip in sample.
   b. Remove excess.
   c. Blot strip by turning on edge against paper towel.

d. Place on instrument test table.

WARNING: Do not push or pull the test table.

11. At the end of the 8 second countdown, the test table and strip will automatically be pulled into the instrument.
12. The analyzer will perform an automatic calibration and finish analyzing the sample.

WARNING: Do not move or bump the table while the instrument is calibrating.

13. When analysis is complete, the **Results** screen will be displayed. Record results on the ER Multistix control log. Staple the printout to the back of the form.
14. Remove the used strip and dispose of it in biohazard container.
    Touch **Done** to complete the test and return to the main **Select** screen.

CALIBRATION:

The Clinitek Status Analyte Clinitek Status Analyzer performs a "self test" and calibration each time it is turned on. In addition, the analyzer performs an automatic calibration each time a test is run. The white calibration bar (on the test table) provides NIST traceable calibration.

SYSTEM START-UP AND MAINTENANCE:

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).

The test table insert and the test table should be kept clean if the analyzer is to operate properly.

WARNING: Do not autoclave the test table or test table insert.

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.

Refer to your Clinitek Status analyser Operator's Manual for detailed cleaning and maintenance instructions.

PROCEDURE STEPWISE

1. At the main **Select** screen, touch **Strip Test.** The **Operator ID** screen will appear.
2. If you were the last operator to enter an ID on the analyzer, touch **Last Operator.** The **Patient Information** screen will appear.
3. If you are a new operator, touch **Strip Test.** The **Operator ID** screen will appear.
4. Use the keypad to enter your ID. Touch enter.
5. The **Patient Information** screen will appear. Touch the **Enter New Patient** key at the bottom right of the screen.
6. The **Patient ID** screen will appear.
7. Use the keypad to enter the patient's ID using the 8 digit medical record number.
8. Touch **Enter.**

WARNING: If refrigerated, bring the patient sample to room temperature 20-30º C (68-86ºF) prior to testing.

9. A **Prepare Test** screen will appear displaying the following two steps:
10. Adjust the test table insert for strip tests.
11. Touch start to begin.
12. Touch **START**. Another **Prepare Test** screen will appear displaying the next four steps:

WARNING: Once you touch the START button, you have eight seconds to dip the test strip into the urine and place it on the test table.

a. Dip test strip in sample**.**
b. Remove excess.
c. Blot strip by turning on edge against paper towel.
d. Place on instrument test table.

WARNING: Do not push or pull the test table.

15. At the end of the 8 second countdown, the test table and strip will automatically be pulled into the instrument.
16. The analyzer will perform an automatic calibration and finish analyzing the sample.

WARNING: Do not move or bump the table while the instrument is calibrating.

17. When analysis is complete, the **Results** screen will be displayed.
18. Remove the used test strip and dispose of in biohazard container.
19. Touch **Done** to complete the test and return to the main **Select** screen.

RESULTS REPORTING:

Aria Health has verified the manufacturer's reference ranges as listed below as appropriate for our patient population.

REFERENCE RANGES:

Protein:

Normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. A color matching any block greater than Trace indicates significant proteinuria. For urine of high specific gravity, the test area may most closely match the Trace color block even though only normal concentration of protein are present. Clinical judgment is needed to evaluate the significance of Trace results.

Blood:

The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/myoglobin) on the reagent area within 60 seconds indicates the need for further investigation. Blood is often, but not always, found in the urine of menstruating females. This test is highly sensitive to hemoglobin and thus complements the microscopic examination.

Normal urine should produce no color reaction and is reported as negative.

Leukocytes:
Normal urine specimens generally yield negative (Ref #1) results; positive results (small or greater) are clinically significant. Individually observed Trace results may be of questionable clinical significance; however, Trace results observed repeatedly may be clinically significant. Positive and repeated Trace results indicate the need for further testing of the patient and/or urine specimen, according to medically accepted procedures for pyuria. Positive results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge

Nitrite:
Normally no nitrite is detectable in urine. The proportion of positive nitrite tests in cases of significant infection depends on how long the urine specimens were retained in the bladder prior to collection. Identification of known positive cases with the nitrite test ranges from as low as 40%, when little bladder incubation occurred, to as high as approximately 80%, when a minimum of four hours of bladder incubation occurred

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:
Normal urine specimens ordinarily yield negative results with this reagent. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine in large amounts before serum ketone concentrations are elevated.

PH:
Both the normal and abnormal urinary pH range is from 5 to 9.

Specific gravity: Reference Ranges:

Newborn	1.012
Infant	1.002-1.006
Adult	1.002-1.030

Bilirubin:
Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors that are unlike the negative or positive color blocks shown on the Color Chart) may be masking the bilirubin reaction. These colors may indicate bile pigment abnormalities and the urine specimen should be tested further (e.g., ICTOTEST Reagent Tablets).

Urobilinogen:
The normal urobilinogen range obtained with this test is 0.2 to 1.0 mg/dL (1 mg/dL is approximately equal to 1 Ehrlich Unit/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.

PROCEDURE NOTES:

Specimens used for Nitrite Testing:

Using a first morning specimen or one that has incubated in the bladder for four hours or more optimizes nitrite test results.

Specimens used for Bilirubin and Urobilinogen Testing:

It is especially important to use fresh urine to obtain optimal results with the tests for bilirubin and urobilinogen, as these compounds are very unstable when exposed to room temperature and light.

Disposal:

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner, and in compliance with all federal, state and local requirements.

METHOD LIMITATIONS AND SENSITIVITY:

PROTEIN:

Limitations: A visibly blood urine may cause falsely elevated results.

BLOOD:

Limitations: 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.

Sensitivity: 0.015-0.062 mg/dL hemoglobin

LEUKOCYTES:

Limitations: Elevated glucose concentrations ($\geq$ 3 g/dL) may cause decreased test results. The presence of cephalexin (Keflex), cephalothin (Keflin), or high concentrations 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.

Sensitivity: 5-15 white blood cells/hpf in clinical urine.

NITRITE:

Limitations: Pink spots or pink edges should not 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 non-reductive pathological microbes.

Sensitivity: 0.06-0.1 mg/dL nitrite ion.

GLUCOSE:

Limitations: Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negative for specimens containing small amounts of glucose (75-125 mg/dL) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening.

Sensitivity: 75-125 mg/dL glucose.

KETONE:

Limitations: 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.

Sensitivity: 5-10 mg/dL acetoacetic acid.

pH:

Limitations: Bacterial growth by certain organisms in a specimen may cause a marked alkaline shift (pH > 8.0), usually because of urea conversion to ammonia.

SPECIFIC GRAVITY:

Limitations: The Siemens SG test is dependent on ions in urine and results may differ from those obtained with other specific gravity methods with certain non-ionic urine constituents, such as glucose are present. Highly buffered alkaline urines may cause low readings, while the presence of moderate quantities of protein (100-750 mg/dL) may cause elevated readings.

BILIRUBIN:

Limitations: 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 (e.g., Ictotest Reagent Tablets—Contact clinical lab for additional guidance).

UROBILINOGEN:

Limitations: The test pad may react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-aminobenzoic acid. False negative results may be obtained if formalin is present. Strip reactivity increases with temperature; the optimum temperature is 22º-26º C (72º-79º F). The test is not a reliable method for the detection of porphobilinogen.

URINE POINT OF CARE DURING COMPUTER DOWNTIMES:

Point of Care testing will not be performed during computer down times. Specimens will be sent to the lab.

REFERENCES:

1. Siemens Reagent Strips Package Insert, AN30516C, Rev. 4/99.
2. Siemens Medical Solutions Diagnostics Clinitek Status Analyzer Operator's Manual, 13287. Rev. T, 2008-05.
3. National Committee for Clinical Laboratory Standards (NCCLS), Clinical Laboratory Procedure Manuals, Third Edition (GP2-A3), 1996.