A. Purpose
Chemstick Urine test strips are inert plastic strips to which are attached different reagent papers for determining specific indication of leukocytes, nitrite, pH, protein, glucose, ketones, urobilinogen, bilirubin, and blood in urine. The test papers are uniquely attached to the strip with a nylon mesh which holds the reagent paper in place, protects the paper and provides for rapid and even wetting on the entire test paper. To prevent urine runover, certain test papers have an inert absorbent paper located between the test area and the strip. The chemstrip urine test strips are packaged in an aluminum vial with a tightly fitting cap which contains a drying agent. Each test strip is stable and ready for use when removes from the vial. No additional instrumentation is required.

B. Principle:
Specific Gravity: In the presence of cations, protons are released by a complexing agent in test and produce a color change of the indicator bromthymol blue from blue via blue-green to yellow.

Leukocytes: Leukocytes in urine are detected by the action of esterase, preset in granulocytic leukocytes which catalyzes the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a purple color.

Nitrate: The nitrate test used in this strip is a refinement of previous methods and exhibits increased sensitivity. Nitrate, if present, reacts with an aromatic amine to give diazonium salt to produce which by coupling with a further compound, yields a pink color.

pH: The method for determining the pH (in Urine) by means of pH indicators is well known. The test strip contains the indicators methyl red bromthymol blue. These give clearly distinguishable colors over the pH range of 5-9. Colors range from orange through yellow and green to blue.
**Protein:** The detection of protein is based on the so-called “protein error of pH indicators.” The indicator 3’, 3”, 5’, 5”-tetrachlorophenol-3, 4, 5, 6-tetramethinosulfophthalein used in this test is a more recent development. Color range from yellow for “Negative” through yellow green and green to green-blue for a “Positive” reaction.

**Glucose:** Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method. The glucose test of this strip is a further development of this test principle. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. In turn, a second, enzyme, peroxidase catalyzes the reaction of hydrogen peroxide with the chromogen tetramethylbenzidine to form a green dyestuff. A positive reaction is indicated by a color change from green to a brown.

**Ketones:** Based on the principle of Legal’s test, sodium nitroferricyanide and glycine reacts with acetoacetate and acetone in an alkaline medium to form a violet dye complex. A positive result is indicated by a color change from beige to violet.

**Urobilinogen:** Urobilinogen is coupled with 4-methoxybenzene-diazonium-tetrafluoroborate in an acid medium to form a pink-red color.

**Bilirubin:** The chemical detection of bilirubin is based on the coupling reaction of a diazonium salt with bilirubin in an acid medium. The application of 2, 6 dichlorobenzene-diazonium-tetrafluoroborate, however which is used in the test strip is unique. This yields various shades of tan. Color proportional to the total bilirubin concentration.

**Blood:** This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of disopropylbenzene dihydroperoxide and 3,e’,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. POLICY:

1. A physician’s or PA’s order is required.
2. LifeBridge Health Trainers will be identified and trained by POCT Team Leader or Technical Specialist.
3. Certification as LifeBridge Health Trainers will include an in service, completion of a written examination, and will perform a test.
4. Re-certification for operators and trainers will be done yearly.
5. LifeBridge Health Certified Trainers are responsible for implementation and maintenance of certification records.
6. A record of LifeBridge Health Certified Operators and Trainers will be maintained on each nursing unit, in Staff Development, and in Pathology.
7. The Point-of-Care Testing Team Leader/Technical Specialist, designee will supply Nursing Directors with a monthly report identifying problems concerning Point-of-Care Testing.
8. Documentation of follow-up investigation and corrective actions taken will be returned to Pathology to be maintained by the Point-of-Care Team Leader/Technical Specialist.
9. Results will be recorded in Powerform or in the Patient’s Medical Record. Any data entry or corrections of data entry made by the operators will need to see Nursing Policies and Procedures for electronic entry or corrections when mistakes are made. At Sinai on some units results are entered into IVIEW where they are downloaded to Powerform. Operator must enter the lot number and expiration date for the test strips for each test performed. Normal Ranges must be included with results.
10. New bottles of strips will be distributed to each unit monthly after Quality Control using two levels of liquid controls is performed by the Bedside Testing Team Leader/Technical Specialist, or designee. Old bottles will be collected at this time and discarded. A label will be attached to each bottle of strips identifying that Quality Controls has been completed and the date that the bottle of strips was placed on the unit.
11. Extra strips can be obtained from Pathology should the bottle of strips be depleted. These bottles will be labeled as above with Quality Control performed.
12. Units will be charged to their cost code for the bottles of strips used monthly.
13. If test is not performed at the patient’s bedside, a patient label must be attached to the container.
14. The expiration date written on the bottle must be checked prior to patient testing along with the 30 day on unit expiration date.

D. Specimen:

1. Specimen Type: Urine
2. Patient Preparation:
   a. Freshly voided specimen or urine removed from indwelling catheter.
3. Collected in a clean container.
4. Handling Conditions:
   a. If the specimen cannot be tested within one hour, it should be sent to Pathology
   b. Urine should be collected in a container which will allow complete immersion of the reagent areas on the test strip.
5. Storage Requirements: N/A
6. Rejection Criteria: N/A

E. Equipment and Materials:

1. Equipment: N/A
2. Materials/ Supplies:
   a. Aluminum vial containing Chemstrip urine strips.
   b. Visual comparison color scale for reading test results (printed on side of vial).
   c. Clean specimen collection container.
   d. Watch with second hand

F. Preparation:
   Warning and Precautions: For in Vitro Diagnostic Use.
   Warning toxic: Chemstrips urine test strips contain one or more the following chemicals: phenol, diazonium salt, nitferricyanide. Avoid contact with skin and mucous membranes; flush affected areas with copious amounts of water. Get immediate medical attention for eyes or if it is ingested.
   Exercise the normal precautions requires for handling all laboratory reagents.

G. Performance Parameters:
   The performance characteristics of the Chemstrip products have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, precision, and stability. Generally, the tests at various temperatures and environmental conditions. For visually read strips, accuracy is a function of the manner in which the color blocks on the vial label are determined and the discrimination of the human eye in reading the tests.
   Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that each user is encouraged to develop his own standards for performance.

   Specific Gravity: The test determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 of the refractometric methods. In case of urines with a pH equal or greater than 6.5, 0.005 may be added to the specific gravity readings.

   Leukocytes: Studies were conducted to compare test-patch-color development from urine with values obtained by the microscopic method.

   Nitrate: Comparison of the reacted reagent area against a white background may aid in the detection of low levels of nitrite ion., which may otherwise be missed. The test is specific for nitrite and will not react with any other substance normally excreted in urine

   pH: The pH test area measures pH values generally to within 1 unit in the range of 5 to 8.5 visually and 5-9 instrumentally. pH readings are not affected by variations in the urinary buffer concentration.

   Protein: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones Protein and mucroprotein; a negative results does not rule out the presence of these other proteins.
**Glucose:** The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose nor reducing metabolites of drugs. The test is used to determine whether the reducing substance found in the urine is glucose. Reactivity may be influenced by urine specific gravity and temperature. In dilute urines containing less than 5 mg/l: ascorbic acid, as little as 40 mg/dL glucose may produce a color change that might be interpreted as positive. The test is more sensitive than the copper reduction test. If the color appears somewhat mottled at the higher glucose concentrations, match the darkest color to the color blocks.

**Ketones:** The test reacts with acetocetic acid in the urine. It does not react with acetone or B-hydroxybutyric acid. Some high specific gravity/low pH urines may give reactions up to and including Trace. Clinical judgment is needed to determine the significance of reactions up to and including Trace.

**Urobilinogen:** This test area will detect urobilinogen in concentrations as low as 0.2 EU/dL (approximately 0.2 EU/dL) in urine. The absence of urobilinogen in the specimen being tested cannot be determined.

**Bilirubin:** The test is less sensitive than ICOTOTEST Reagent Tablets.

**Blood:** The sensitivity of this test may be reduced in urines with high specific gravity. The test is equally sensitive to myoglobin as to hemoglobin. The appearance of green spots on the reacted reagent area indicates the presence of intact erythrocytes in the urine. The color chart includes examples of trace and moderate nonhemolyzed color blocks. Reactions ranging from trace to large with proportionately more numerous spots, may be observed. (Hemoglobin concentration of 0.015-0.062mg/dL is approximately equivalent to 5-20 intact red blood cells per microliter.) Because of the optical systems of urine chemistry instruments, the sensitivity to intact erythrocytes is lower than that perceived visually. Differentiation of hemoglobin from erythrocytes can be determined by the color.

**H. Storage Requirements:**
Store at room temperatures under 15-30°C (59-86°F). Do not freeze. Chemstrip urine test strips are stable in the original capped vial until the listed expiration date. In order to avoid exposure to moisture, the vial must be closed immediately after removal of a strip, using the original stopper which contains a drying agent.

**I. Calibration:**
1. **Standard Preparation:** N/A
2. **Calibration Procedure:** Calibration of the Chemstrip 10 with SG urine test strips by the user is not required.
J. **Quality Control:**

Quality Control for this procedure consists of following good laboratory techniques. Ensuring that reagents have been properly stored and specimens handled according to Instructions. The analyst should be aware of the sources of error outlined under Limitations.

See “Liquid Quality Control for Urine Dipstick” procedure for performing QC.

If the expected results are not obtained and repetition of the assay excludes errors in technique the following steps should be taken:

- a. Check expiration date stamped on the vial label.
- b. Verify that the Chemstrip urine test strip had not been exposed to heat extremes or moisture, open a new vial of strips and retest.
- c. Check for yellow label indicating that QC has been performed prior to performing test.
- d. For further help call the Bedside Testing Coordinator.

K. **Materials Used:** N/A

L. **Preparation and Handling:** N/A

M. **Frequency Run:** N/A

N. **Tolerance Limits:** N/A

O. **Corrective Action:** N/A

P. **Recording and Storage of Data:** N/A

Q. **Procedure:**

1. Written physician/PA’s order.
2. Collect freshly voided specimen into clean container. If specimen is obtained from an indwelling catheter, urine is to be obtained from catheter, not a foley bag. Specimen is to be tested as soon as obtained.
3. Don gloves.
4. Remove strip and replace cap of vial immediately.
5. Place test strip with pads facing down into the urine. Thoroughly wet test zones.
6. As you withdraw the test strip, wipe the edge against the rim of the container to remove excess urine.
7. Turn the test strip on its side an tap once on a piece of absorbent towel to remove the remaining urine, and to prevent the possible mixing of chemicals.
8. After the appropriate time read the test as follows: Hold strip close to color blocks and match carefully, ensuring that the strip is properly oriented to the color chart on the vial label.
Chemstrip 10 with SG urine test strips:

<table>
<thead>
<tr>
<th>Test</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.G. (ionic concentration)</td>
<td>45 seconds</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>120 seconds</td>
</tr>
<tr>
<td>Nitrite</td>
<td>60 seconds</td>
</tr>
<tr>
<td>pH</td>
<td>60 seconds</td>
</tr>
<tr>
<td>Protein</td>
<td>60 seconds</td>
</tr>
<tr>
<td>Glucose</td>
<td>30 seconds</td>
</tr>
<tr>
<td>Ketones</td>
<td>40 seconds</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>60 seconds</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>30 seconds</td>
</tr>
<tr>
<td>Heme</td>
<td>60 seconds</td>
</tr>
</tbody>
</table>

NOTE: All reagent’s areas except leukocytes may be read between 1 and 2 minutes for identifying negative specimens and for determination of the pH and SG. A positive reaction (Small or greater) at less than 2 minutes on the leukocyte test may be regarded as a positive indication of leukocytes in the urine. Color changes that occur after 2 minutes are of no diagnostic value.

9. Place results in Powerform or on the Point of Care Results Sheet.

S. CALCULATIONS: N/A

T. REPORTING RESULTS:
1. Results are to be charted in Powerform or on the Point-of-Care Result sheet.
2. Results are obtained by direct visual comparison with the color scale printed on the vial label. No calculations are necessary. The visual color chart is not intended to represent quantitative findings and serves only as a screening mechanism. If quantitative results are desired, it is recommended that further testing of the urine be carried out utilizing the laboratory in Pathology.
3. Results are not to be reported if quality control was not performed on strips or if the beyond the manufacturer’s expiration date or 30 day expiration date when delivered to unit.

U. Expected Values:

Specific Gravity: Random urines vary from 1.001-1.035.

Leukocytes: Normal urines should produce no color reaction. Trace indicates a possible borderline situation, and it is recommended that the test be repeated on a fresh urine specimen from the same patient. Positive and repeated findings indicate the need to further testing of the patient and/or urine sample in accordance with the medically
accepted procedures for pyuria.

**Nitrite**: A concentration as low as .05 mg/dL of nitrite will produce a slightly pink coloration of the test area. This indicates a positive result.

**pH**: Urine pH values generally range from 5 to 9 units. The most frequent pH values for the first-morning specimens in a healthy subject are between pH 5 and 6.

**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 concentrations of protein are present. Clinical judgment is needed to evaluate the significance of Trace results.

**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 positive. Results at first positive level may be significantly abnormal if found consistently.

**Ketones**: 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 is elevated. Ketone bodies should not be detected in normal urine with this test. Fasting or starvation diets may cause positive indications. If known pathological conditions such as diabetes, the presence of ketones may be useful as an index of metabolic status.

**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.

**Bilirubin**: Normally no bilirubin is detected in urine by even the most sensitive methods. Even trace amount 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 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.

**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 microscope examination.

V. Procedure Notes:
1. Reference Range
2. Critical Value (Procedure)
3. Reporting Format: Results are to be charted in Powerform or on the Point-of-Care Result sheet.
4. Hazardous Materials: Used test strips should be considered contaminated, potentially infectious and should be discarded in biohazard container.
5. Protective Equipment Requirements: Gloves

W. Limitation of Procedure: The limitations including interfering substances for each reagent are shown below:

Specific Gravity: The chemical nature of the Siemens Diagnostic SG test may cause slightly different results from those obtained with other specific gravity methods when evaluated amounts of certain urine constituents are present. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dL) of protein.

Leukocyte Test: Elevated glucose concentrations or high specific gravity may cause decrease test results. The presence of Keflex, Keflin, of high concentrations of oxalic acid may also cause decreased test results. Tetracyline may cause decreased reactivity, and high levels of the drug may cause false negative reactions.

Nitrate Test: Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrate test suggesting the presence of 10^5 or more organisms per mL, but color developments not proportional to the number of bacteria present. A negative result does not in itself prove that there is no significant bacteria. Negative results may occur when urinary tract infections are caused by organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Sensitivity of the nitrite test is reduced for urines with high specific gravity. Ascorbic acid concentrations of 25 mg/dL or greater may cause false negative results with specimens containing small amounts of nitrite ion (0.06 mg/dL or less).

pH Test: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as “runover” may occur, in which the acid buffer form the protein reagent will run over the pH area, causing a false lowering of the pH result.

Protein Test: False positive results may be obtained with highly buffered or alkaline
Contamination of the urine specimen with quaternary ammonium compounds or with skin cleaners containing chlorhexidine may also produce false positive results.

**Glucose Test:** Ascorbic acid (vitamin C) of 50 mg/dL or greater may cause false negative for specimens containing small amount of glucose (75-125 mg/dL). Ketone bodies reduce the sensitivity for the test; moderately high ketones 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 low glucose levels is metabolically improbable in screening. The reactivity of the glucose test decrease as the SG of the urine increases. Reactivity may also vary with temperature.

**Ketone Test:** False positive results (Trace or less) 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 sulfydryl groups may cause false positive results or an atypical color reaction.

**Urobilinogen Test:** The reagent area may react with substances know to interfere with Ehrich’s reagent, such as p-aminosalicylic acid and sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-aminobenzonic acid. False negative results may be obtained if formalin is present. Strip reactivity increases with temperature; the optimum temperature is 22-26°C. The test is not a reliable method for the detection of porphobilinogen. The absence of urobilinogen cannot be determined with this test.

**Bilirubin Test:** Indican can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or a positive bilirubin reading. Metabolites of Lodine may cause false positive or atypical results; ascorbic acid concentrations of 25 mg/dL or greater may cause false negatives. 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 Diagnostics Reagents Strips to bilirubin is sufficient for the intended use.

**Blood Test:** Elevated specific gravity may reduce the reactivity of the blood test. Capoten may also cause a decreased reactivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Levels of ascorbic acid normally found in urine do not interfere with this test.

**Interfering Substances:** (See Limitations)

**Chemical Interference:** N/A
AA. In vivo Interference: N/A

BB. References:


Henry, J. B. et al., Clinical Diagnosis and Management by laboratory Methods, 18th ed, Saunders, Philadelphia, 396, 397, 1991