1. Purpose
   1.1. Siemens Multistix Urinalysis 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:
   - Carbohydrate metabolism
   - Kidney function and live function
   - Acid-base balance
   - Urinary tract infection
   NOTE: As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

2. Principle
   2.1. Urinalysis: CLINITEK Status Connect System with Siemens Multistix Reagent Strips

**Principle of the Test**

Siemens Multistix Urinalysis Strips are read instrumentally by the CLINITEK Status Connect System. Depending on the product being used, Siemens Multistix Urinalysis Strips provide tests for:

- Glucose
- Bilirubin
- Ketone (acetoacetic acid)
- Specific gravity
- Blood
### 2.2 Chemical Principles of Siemens Multistix Urinalysis Strips

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Chemical Principle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>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.</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Bilirubin couples with diazotized dichloroaniline in a strongly acid medium. Colors range through various shades of tan.</td>
</tr>
<tr>
<td>Ketone</td>
<td>Acetoacetic acid reacts with nitroprusside. Colors range from buff-pink, for a negative reading, to maroon for a positive reading.</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>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.</td>
</tr>
<tr>
<td>Blood</td>
<td>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.</td>
</tr>
<tr>
<td>pH</td>
<td>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.</td>
</tr>
<tr>
<td>Protein</td>
<td>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.</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>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.</td>
</tr>
<tr>
<td>Nitrite</td>
<td>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.</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>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.</td>
</tr>
</tbody>
</table>
3. Specimen Collection and Handling

3.1 Specimen Collection and Storage

**BIOHAZARD**

All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

- Obtain a fresh urine specimen. A first-morning specimen is preferred but random collections are acceptable. Specimens should be at room temperature for less than one hour before testing.
- Collect the urine in a clean, dry, covered container with patient’s label that includes name and date of birth.
- The urine specimen should be well mixed and un-centrifuged.
- To avoid contamination of the specimen, any cultures ordered on the same specimen should be set up before performing urinalysis.

3.2 Specimen Rejection Criteria

Do not accept the following:

- Specimens that have remained at room temperature for longer than one hour.
- Specimens with urine preservatives

4. Reagents

4.1 Storage and Stability

- Store Siemens Multistix Urinalysis Strips at room temperature, 15 - 30°C.
- 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.
- Store the unused reagent strips in the original bottle. Transferring unused reagent strips to other containers may cause the strips to deteriorate and become un-reactive.
- Do not remove desiccants from bottle.
- Do not use reagent strips beyond the expiration date.
- Initial and date the reagent bottle when you first open it.
- **Do not remove the strip from the bottle until immediately before use. Replace cap immediately and tightly after removing the strip.**
- Avoid touching the test areas of the reagent strip.
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.

Due to the nature of the urobilinogen and leukocytes reagents found on the strips, these two results may be decreased at temperatures below 22°C and increased at temperatures above 26°C.

4.2 Reagent Ingredients
Reagent ingredients for Siemens Multistix Urinalysis Strips are as follows:

<table>
<thead>
<tr>
<th>Test</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>2.2% w/w glucose oxidase (microbial, 1.3 IU); 1.0% w/w peroxidase (horseradish, 3300 IU); 8.1% w/w potassium iodide; 69.8% w/w buffer; 18.9% w/w nonreactive ingredients</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>0.4% w/w 2,4-dichloroaniline diazonium salt; 37.3% w/w buffer; 62.3% w/w nonreactive ingredients</td>
</tr>
<tr>
<td>Ketone</td>
<td>7.1% w/w sodium nitroprusside; 92.9% w/w buffer</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>2.8% w/w bromthymol blue; 68.8% w/w poly (methyl vinyl ether/maleic anhydride); 28.4% w/w sodium hydroxide</td>
</tr>
<tr>
<td>Blood</td>
<td>6.8% w/w diisopropylbenzene dihydroperoxide; 4.0% w/w 3,3',5,5'-tetramethylbenzidine; 48.0% w/w buffer; 41.2% w/w nonreactive ingredients</td>
</tr>
<tr>
<td>pH</td>
<td>0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97.0% w/w nonreactive ingredients</td>
</tr>
<tr>
<td>Protein</td>
<td>0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>0.2% w/w p-diethylaminobenzaldehyde; 99.8% w/w nonreactive ingredients</td>
</tr>
<tr>
<td>Nitrite</td>
<td>1.4% w/w p-arsanilic acid; 1.3% w/w 1,2,3,4-tetrahydrobenzo(h) quinolin-3-ol; 10.8% w/w buffer; 86.5% w/w nonreactive ingredients</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>0.4% w/w derivatized pyrrole amino acid ester; 0.2% w/w diazonium salt; 40.9% w/w buffer; 58.5% w/w nonreactive ingredients</td>
</tr>
</tbody>
</table>

The strips have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

4.3 Reagent Special Preparation
No special preparation for reagent strips is required.

5. Instrument Operation and System Description
The CLINITEK Status+Analyzer is for in vitro diagnostic use in:
• The semi-quantitative or qualitative detection of bilirubin, blood (occult), glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, protein, specific gravity and urobilinogen in urine samples. The tests reported depend on the type of Siemens Multistix 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 travels 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.

6. System Start-up

6.1 System Start-up

Power on the system 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 Select Ready screen displays after system initialization.

6.2 Calibration

The CLINITEK Status Connect System performs a “self-test” and calibration each time you power on the system. The analyzer performs an automatic calibration each time you run a test. The white calibration bar (on the test table) provides NIST traceable calibration.

6.3 Entering Urine Color and Clarity During Test Cycle (in Full Test or Custom mode only)

During a patient test, the Select Appearance-Test In Progress screen displays.

1. To choose the standard option, select Yellow and Clear. Go to Step 8. To choose a urine color and clarity, select Other. The Select Appearance-Test In Progress screen 2 of 4 displays.
2. Select a color for the urine sample from the options displayed.
3. Select Next. The Select Appearance-Test In Progress screen 3 of 4 displays.
4. If you want a different color for the urine sample, select a color from the options displayed.
5. Select Next. The Select Appearance-Test In Progress screen 4 of 4 displays.
6. Select the clarity of the urine sample.
7. Select Next. The Analyzing-In-Progress screen displays while the test is in progress followed by the Results screen.
8. Select Done to return to the Select Ready screen.
6.4  **Running liquid QC:**

1. Must be run once a week and when a new chemstrip bottle is opened. If the clinic is closed for a holiday, it would be run on the next day,
2. Must run as a patient. Label is QC 1 and QC2.
3. Results must be printed out and recorded on QC sheets. All results need to be in range before patient testing can resume.
4. QC will be reviewed weekly by the designated unit trainer and monthly by the POCC.

**Note: Troubleshooting Out-of-Range QC Values**

A QC run is acceptable when all values fall within the expected ranges.

If the QC results do not fall within the defined ranges then the run is rejected, and you must take the following corrective actions:

- Review instructions to ensure that the test was performed according to the procedures.
- Verify that the reagent strips and control materials are not expired;
- If necessary, re-run the quality control samples and contact your POCC.
7. Patient testing:

In the Full Test mode, you are prompted to enter an Operator ID, Patient Name, and/or Patient ID prior to running a test.

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. Go to step 6.
3. If you are a new operator, touch Enter New Operator ID. The Enter Operator ID screen will appear.
4. Use the keypad to enter your ID using a maximum of 7 characters.
5. Touch Enter. The Patient Information screen will appear.
6. If the test sample is from a previous patient, touch Recall Patient. A list of up to 200 patients will appear on the screen.
7. Use the up and down arrows to scroll through the patient names. Once the patient you are looking for has been highlighted, touch Select. A Prepare Test screen will appear. Go to step 13.
8. If the test sample is from a new patient, touch Enter New Patient. The Enter Patient Name screen will appear.
9. Use the keypad to enter the patient’s name using a maximum of 20 characters. Enter patients last name and first letter of patient’s first name.
10. Touch Enter. The Patient ID screen will appear. This feature may not be used for certain units.
11. Use the keypad to enter the patient’s ID which for the Wellness Center will be date of birth of the patient written as Month Day Full Year. For example for someone born on June 3, 1994, it would be 06031994.

**WARNING:** Bring the patient sample to room temperature (15 - 30°C) and mix well prior to testing.

**WARNING:** Do not remove the strip from the bottle until immediately before use. Replace cap immediately and tightly after removing the strip.

13. Follow these steps to continuing preparing the test:
   a. Make sure the test table insert has the reagent strip holder facing upward.
   b. Have the test strip, urine sample and paper towel ready.
14. Touch START. Another Prepare Test screen will appear displaying the next 4 steps:

**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.

   a. Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.
b. Drag the edge of the strip against the side of the sample container as you remove it.

c. Blot by touching the edge of the strip to the paper towel to remove excess urine.
   **WARNING:** Do not lay the pads on the paper towel or cover the pads by the paper towel.

d. 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.

e. At the end of the eight second countdown, the test table and strip will automatically be pulled into the instrument.

15. 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.

16. While the strip is being analyzed, a **Select Appearance** screen will be displayed. The urine sample must be visually observed and then the appropriate color and clarity must be selected.

   a. If the urine sample is yellow and clear, touch the **Yellow and Clear** button.

   b. If the urine sample is not yellow and clear, touch the **Other** button for more choices.

   c. If you touched the **Other** button, then select the appropriate color by touching the circle button that corresponds to the correct description.

   d. Select the clarity by touching the circle that corresponds to the correct description. Then touch Next.

17. When the analysis is complete, the **Results** screen will display the first page of results.

18. Touch **More** to display the second page of results.

19. Remove the used urinalysis strip from the test table and dispose of it according to your standard laboratory procedures.

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

21. Print the results and attach them to patient’s result sheet. Make a copy for the POCC. For the patient’s permanent record, printout will need to be copied.

22. Wipe off the test table with paper towel or chem. Wipe.

---

**8. Reporting Results**

**8.1Reference Interval**

<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Negative</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Negative</td>
</tr>
<tr>
<td>Ketone</td>
<td>Negative</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.001 – 1.035</td>
</tr>
<tr>
<td>Test</td>
<td>Reporting Unit</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Occult Blood</td>
<td>Negative</td>
</tr>
<tr>
<td>pH</td>
<td>5 – 9</td>
</tr>
<tr>
<td>Protein</td>
<td>Negative</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>≤1.0 mg/dL (E.U./dL)</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Negative</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>Negative</td>
</tr>
<tr>
<td>Color</td>
<td>Yellow or Amber</td>
</tr>
<tr>
<td>Clarity</td>
<td>Clear</td>
</tr>
</tbody>
</table>

### 8.2 Units for Reporting Results
The CLINITEK Status+ Analyzer reports results in conventional units.

<table>
<thead>
<tr>
<th>Test</th>
<th>Reporting Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>N/A</td>
</tr>
<tr>
<td>Ketone</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>≤1.005 – ≥1.030 (in 0.005 increments)</td>
</tr>
<tr>
<td>Occult Blood</td>
<td>N/A</td>
</tr>
<tr>
<td>pH</td>
<td>5.0 – ≥9.0 (in 0.5 increments)</td>
</tr>
<tr>
<td>Protein</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Nitrite</td>
<td>N/A</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>N/A</td>
</tr>
<tr>
<td>Color</td>
<td>N/A</td>
</tr>
<tr>
<td>Clarity</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Detectable Range

<table>
<thead>
<tr>
<th>Reagent Area</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>75 – 125 mg/dL glucose</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>0.4 – 0.8 mg/dL bilirubin</td>
</tr>
<tr>
<td>Ketone</td>
<td>5 – 10 mg/dL acetoacetic acid</td>
</tr>
<tr>
<td>Blood</td>
<td>0.015 – 0.062 mg/dL hemoglobin</td>
</tr>
<tr>
<td>Protein</td>
<td>15 – 30 mg/dL albumin</td>
</tr>
<tr>
<td>Nitrite</td>
<td>0.06 – 0.1 mg/dL nitrite ion</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>5 – 15 cells/hpf in clinical urine</td>
</tr>
</tbody>
</table>

Acceptable Results
Patient test results are acceptable and may be reported when:
- QC was run and acceptable for the week.
- Maintenance was performed and documented for the week.

Corrective Action
Patient test results must be repeated and corrective action taken when:
- Quality control was not run or was out of range for the week and patients were tested.
- Maintenance was not performed or not documented for the week.

9. 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 Northwest Hospital.
Method Limitations

Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. These substances include:

- Drugs containing azo dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantanol®)
- Nitrofurantoin (Macrodantin®, Furadantin®)
- Riboflavin
- Visible levels of blood or bilirubin

For additional information on method limitations and performance characteristics, see the product information in the Siemens Multistix Urinalysis Strips package insert.

10. Maintenance

10.1 Daily: Cleaning of Test Table Insert

Remove the insert and thoroughly clean. Rinse both sides of the table insert under running water. Dry and replace insert.

10.2 Weekly(as needed): Cleaning of Test Table

Remove the test table by pulling it slowly out of the analyzer. Lift the test table insert from the table, drain the drip tray if necessary. Wet a cotton-tipped stick with water and carefully clean test table(except for White Calibration Bar).

Dry the test table thoroughly(except for the White calibration bar) with a lint-free tissue. (Do not scratch the White calibration bar.)

Reinsert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer.(Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.)

Replace the test table insert.

If the white calibration bar is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or lint-free cloth wetted with distilled water. Allow the calibration bar to air dry and then inspect the surface for dust, foreign material, scratches or scuffs. If the calibration bar cannot be cleaned or is still marked, obtain a new test table.

Reinsert the test table as described earlier.
As needed: Clean the outside of the analyzer
Turn the analyzer off by pressing the on/off button for 2 seconds.
Wipe the outside(including the display) with a Sani cloth wipe.

As needed: Changing batteries
Remove the test table from the analyzer. Next, place the analyzer on its side and remove the battery cover by pressing down on the tab and pulling out. Remove current batteries. Place 6 new AA-size batteries into the analyzer. Replace the battery cover and turn the instrument back onto its base.

11. Equipment and Supplies
- Siemens Multistix Urinalysis Strips
- CLINITEK Status™ Analyzer
- Specimen collection container
- Paper towels
- Quality control level 1 and level 2 of Quantimetrix Dropper Plus urine dipstick control.
  (Controls can be kept at room temperature on the unit for 30 days.)

11. References
1. Siemens Multistix Urinalysis Strips Package Insert, AN30516F, Rev. 08/08 USA
*NCCLS is now known as: Clinical and Laboratory Standards Institute (CLSI).

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