# Urinalysis: Siemens MULTISTIX Family of Test Strips

# Principle of the Test

Siemens MULTISTIX® Urinalysis Strips are read visually. Depending on the product being used, Siemens MULTISTIX Urinalysis Strips provide tests for:

* Glucose
* Bilirubin
* Ketone (acetoacetic acid)
* Specific gravity
* Blood
* pH
* Protein
* Urobilinogen
* Nitrite
* Leukocytes in urine

Chemical Principles of Siemens MULTISTIX Urinalysis 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 dichloroaniline 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 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 liver 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.

# Specimen Collection and Handling

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. |

* Give the patient a sterile specimen contain that is labeled with 2 complete identifiers. Identifiers include the Full Name as it appears in CPRS, the Full Social Security Number, and the Date of Birth. The label should also have the date and time of collection on it. Note: the last four of the social security number may be useful for finding the person in CPRS but is not considered an identifier.
* If a culture is desired please collect as a midstream clean catch.
* 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 two hours before testing.
* Collect the urine in a clean, dry, sterile, covered container.
* The urine specimen should be well mixed and un-centrifuged. If the urine depth in its container is less than 3 inches pour the specimen into a narrow tube. Make sure the tube is labeld with 2 complete identifiers.
* To avoid contamination of the specimen, any cultures ordered on the same specimen should be set up before performing urinalysis. A urine culture tube should be filled from the sample cup before performing the dipstick.
* If testing is delayed (>2 hour after collection), specimen should be refrigerated (2 to 8°C) for preservation. Allow urine specimen to return to room temperature before testing. Do not hold specimen in refrigerator more than 24 hours. Do not test refrigerated samples more than 24 hours old.
* If the sample was placed in the yellow top urine transport tube and that tube was used to dip the strip in it DO NOT SEND that tube to the main lab for drug screens or microalbumin testing. It is unknown how the chemicals from the strip will react with the drug screen or other chemistry analyzer reagents.

Specimen Rejection Criteria

Do not accept the following:

* Specimens that have remained at room temperature for longer than two hours
* Specimens with urine preservatives. Only refrigerated urine may be used for this procedure. DO NOT PLACE IN PRESERVATIVE AND HOLD OVERNIGHT.
* Specimens that arrive in homemade containers (glass jars, pill bottles, etc.)
* Leaking specimen containers

If an unacceptable specimen is received, note the reason for rejection on the preanalytical error sheet 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 caregiver has been notified.

Specimen Reflex Criteria:

1. Positive Nitrite and positive leukocyte esterase results may be cultured. The sample for culture should be in the gray top urine preservative tube and filled to the minimum amount.
2. The provider should place an order for the urine culture.
3. The properly labeled gray top culture tube will be sent to the main lab in Big Spring.

**Performing a test:**

**Use Standard Precautions** For this test standard precautions should be gloves, lab coat, and face shield of some type to prevent splashes for reaching the face or eyes. The face shield may be a counter shield or one that you wear.

# Prepare a patient log sheet. Place a patient label at the top of the sheet.

1. Label a urine tube per lab protocol.
2. Pour sufficient urine in the tube to allow you to cover all pads when the dipstip is dipped into the tube.
3. Exam the urine for color and clarity.
4. Log the color and clarity.
5. Open the container and remove 1 strip.
6. Close the container tightly. Do not leave it open.
7. Dip the strip briefly in the tube tube.
8. Remove the strip and blot edge on clean absorbent material.
9. Time the tests using a timer.
10. Read the color change off the chart on the side of the bottle. Do not use color charts from other strips. Do not scan the color chart and try to print it since the colors may not match.
11. Use a calibrated timer.

Timing

Glucose 30 seconds

Bilirubin 30 seconds

Ketones 40 seconds

Specific Gravity 45 seconds

Blood 60 seconds

pH 60 seconds

Protein 60 seconds

Urobilinogen 60 seconds

Nitrite 60 seconds

Leucocyte 120 seconds

# Reagents

Storage and Stability

Dipsticks and Controls will be provided by the laboratory. There is not an excess of supplies on hand. Do not wait until you are out to request more. The lab may have to order them.

* 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.
* Never leave the strip container open. Remove 1 strip at a time and close the bottle tightly.

Reagent Ingredients

Reagent ingredients for Siemens MULTISTIX Urinalysis Strips are as follows:

| Test | Ingredients |
| --- | --- |
| Color | Visual exam for color of the urine |
| Clarity | Visual exam for clarity of urine |
| Glucose | 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 |
| Bilirubin | 0.4%w/w 2,4-dichloroaniline diazonium salt; 37.3%w/w buffer; 62.3% w/w nonreactive ingredients |
| Ketone | 7.1 % w/w sodium nitroprusside; 92.9% w/w buffer |
| Specific Gravity | 2.8% w/w bromthymol blue; 68.8% w/w poly (methyl vinyl ether/maleic anhydride); 28.4% w/w sodium hydroxide |
| Blood | 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 |
| pH | 0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97.0% w/w nonreactive ingredients |
| Protein | 0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients |
| Urobilinogen | 0.2% w/w p-diethylaminobenzaldehyde; 99.8% w/w nonreactive ingredients |
| Nitrite | 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 |
| Leukocytes | 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 |

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

Reagent Special Preparation

No special preparation for reagent strips is required.

# Quality Control (QC)

QC Materials

Use Alta DIagnostics Positive and Negative controls to monitor performance. Controls come ready to use. Follow the stability as listed on the package.

Water should not be used as a negative control.

Controls are best stored in the refrigerator. Control values may vary by lot number. Be sure you are referring to the most recent control package inset before accepting control values.

QC Frequency

Test known negative and positive specimens or controls:

1. whenever a new bottle of reagent strips is first opened,
2. whenever you have questionable test results
3. and when training new operators
4. and then daily when testing is performed.

**Proficiency Testing Materials**

Proficiency testing is part of an over all quality plan. College of American Pathologists or API Proficiency testing samples will be received a minimum of twice a year. These samples are to be run per the instructions that come with the proficiency testing survey. Results will be entered on the CAP or API website by the person running the survey. The Ancillary Testing Coordinator is not allowed to enter the results for you.

**Correlation with the main lab**

VA 1106 requires that point of care testing best be correlated with the main lab:

1. during initial validation of the test.
2. Every six months that the test is in use.

During the initial validation the Ancillary Testing Coordinator or designee will assist the testing personell at the clinic for one day to run up to 20 urines. Those urines will then go to the main lab. Results will be entered into statisitical software for analysis.

Every six months 5 urines will be run by clinic staff and sent to the main lab for repeat. These samples will then be compared to the main instrument.

Please note that specific gravity by dipstick and specific gravity by electronic meter will not provide a perfect correlation.

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 recommended by Siemens HealthCare Diagnostics;
* Verify that the reagent strips and control materials are not expired;
* If necessary, re-run the quality control samples or contact Main Lab for more assistance.

# Routine Analysis

# Reporting Results

As with all in vitro diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.

Reference Interval

|  |  |
| --- | --- |
| Glucose | Negative |
| Bilirubin | Negative |
| Ketone | Negative |
| Specific Gravity | 1.001 – 1.035 |
| Occult Blood | Negative |
| pH | 5 – 9 |
| Protein | Negative |
| Urobilinogen | ≤1.0 mg/dL (E.U./dL) |
| Nitrite | Negative |
| Leukocytes | Negative |
| Color | Lt. Yellow to Amber |
| Clarity | Clear |

Critical Values

No critical values are established for urine dipsticks.

This is a manual read test. Log results on the manual log. Log will be found after the procedure. The log will be used to enter the results into VISTA lab package. Results MUST be entered into the lab package by the person doing the test. Scan the log sheet to save it into a share drive and shred the paper copy. A second person will need to proofread the results. Proofreading will be done the next day and documented. The proofreading may be done by main lab staff if scanned results are available to the main lab. Any corrections needed to the report will be communicated to the clinic staff that performed the test. A corrected report will then need to be done. Provider must be notified of the corrected report and the notification documented under test comments.

Reporting Results

|  |  |
| --- | --- |
| Glucose | Negative, 100, 250, 500, 1000, ≥2000 |
| Bilirubin | Negative, small (1+), moderate(2+), large(3+) |
| Ketone | Negative, trace (5) 16, 40 80, 100 |
| Specific Gravity | 1.001 – 1.030 |
| Blood | Negative, trace, 1+, 2+, 3+ |
| pH | 5 – 8.5 |
| Protein | Negative, trace, 30, 100, 300, ≥2000 |
| Urobilinogen | Normal, 2, 4, 8 |
| Nitrite | Negative, Positive |
| Leukocytes | Negative, trace, small (1+), moderate(2+), large(3+) |
| Color | Yellow or Amber, other colors as seen |
| Clarity | Clear, Sl. Turbid, Turbid |

**Certain medication that turns the urine orange or green may cause difficulty in the interpretation of results. There is an over-the-counter medication for urinary tack pain that turns the urine orange.**

**If there is an abnormal color that appears to be interfering with the interpretation of the test pad note under comments:**

**“Abnormal color may be interfering with the dipstick results.”**

|  |  |
| --- | --- |
| Test | Reporting Unit |
| Glucose | mg/dL |
| Bilirubin | N/A |
| Ketone | mg/dL |
| Specific Gravity | ≤1.005 – ≥1.030 (in 0.005 increments) |
| Blood | N/A |
| pH | 5.0 – 8.5 (in 0.5 increments) |
| Protein | mg/dL |
| Urobilinogen | mg/dL |
| Nitrite | N/A |
| Leukocytes | N/A |
| Color | N/A |
| Clarity | N/A |

Detectable Range

|  |  |
| --- | --- |
| Reagent Area | Sensitivity |
| Glucose | 75 – 125 mg/dL glucose |
| Bilirubin | 0.4 – 0.8 mg/dL bilirubin |
| Ketone | 5 – 10 mg/dL acetoacetic acid |
| Blood | 0.015 – 0.062 mg/dL hemoglobin |
| Protein | 15 – 30 mg/dL albumin |
| Nitrite | 0.06 – 0.1 mg/dL nitrite ion |
| Leukocytes | 5 – 15 cells/hpf in clinical urine |

# 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

Urine may be discarded down a sink. The sink should have water run down it to prevent urine buildup in the trap that can cause oderes. This would be a sink not used to wash hands. Discard cups in the biohazard bags.

# 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). There is an over-the-counter medication that contains azo dyes sold for urinary track pain.
* NITROFURATOIN (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 Instructions for Use.

# Equipment and Supplies

* Siemens MULTISTIX 10SG Urinalysis Strips
* Color chart from side of container Do not use a printed picture of the chart since printer colors may vary
* Specimen collection container
* Paper towels

# References

1. Siemens MULTISTIX Urinalysis Strips Package Insert.
2. National Committee for Clinical Laboratory Standards (NCCLS), Clinical Laboratory Procedure Manuals, Third Edition (GP2-A3), 1996

\*NCCLS is now known as: Clinical and Laboratory Standards Institute (CLSI).

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Technical Assistance

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**Point of Care Manual Urinalysis Log**

**Sample ID: Place a patient label here with 2 identifiers or write what control this is.**

**Is this a control? Lot number\_\_\_\_\_\_\_\_\_\_\_\_\_ Level\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Time Collected:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ May place small sticker from sample label that has this information**

**Circle the results obtained.**

|  |  |
| --- | --- |
| Glucose | Negative, 100, 250, 500, 1000, ≥2000 |
| Bilirubin | Negative, small (1+), moderate(2+), large(3+) |
| Ketone | Negative, trace (5), 16, 40, 80, 100 |
| Specific Gravity | 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 |
| Blood | Negative, trace, 1+, 2+, 3+ |
| pH | 5, 6, 6.5, 7, 7.5, 8, 8.5 |
| Protein | Negative, trace, 30, 100, 300, ≥2000 |
| Urobilinogen | Normal, 2, 4, 8 |
| Nitrite | Negative, Positive |
| Leukocytes | Negative, trace, small (1+), moderate(2+), large(3+) |
| Color | Colorless, Yellow, Amber, other colors as seen\_\_\_\_\_\_\_\_\_\_  Is the color an abnormal color? Yes No If yes attach the comment “Abnormal color may be interfering with the dipstick results”. |
| Clarity | Clear, Slightly Turbid, Turbid |

**Initials of Person performing test\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of person performing test\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date/time results were entered into VISTA\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**