PACE DIAGNOSTICS

OCTOBER 2024

TECHNICAL PROCEDURE MANUAL

CLINICAL MICROSCOPY

STANDARD OPERATING PROCEDURE: MACROSCOPIC URINALYSIS

Version: 1.0

TITLE

Standard Operating Procedure: Macroscopic Urinalysis

PRINCIPLE

A macroscopic urinalysis includes an analysis of the chemical properties of urine as well as a visual assessment of color and clarity to complete the examination. The Siemens Multistix 9 or 10SG reagent strips for urinalysis comprise test pads for protein, blood, leukocytes, nitrite, glucose, ketone, pH, bilirubin, and urobilinogen. Multistix reagent strips are meant to help diagnose kidney function, urinary tract infections, carbohydrate metabolism (e.g., diabetes mellitus), and liver function. The strips also assess physical properties including acid-base balance and urine concentration. Test findings can be used with additional diagnostic information to rule out certain disease states and determine if microscopic examination is required.

SPECIMEN REQUIREMENTS

10 mL (ideal) of freshly voided and properly mixed urine. Avoid centrifuging urine. The minimum volume is 1 mL. Specimens must bear the patient's identify. If the urinalysis cannot be completed within 30 minutes, refrigerate the urine.

UNACCEPTABLE SPECIMENS

1. Any specimen kept at room temperature for longer than 2 hours.
2. Any refrigerated specimen that is more than eight hours old.
3. Substantially bloody specimens should be referred to the core lab for examination.

REAGENTS/MATERIALS

1. Multistix dipsticks
2. Urine Quality Control Level 1 and 2.

STORAGE REQUIREMENTS

Multistix 10 reagent strips should be stored at room temperature (15-30°C) and out of direct sunlight. All unused strips must be kept in their original bottle. Transferring reagent strips to another container may cause them to degrade and become non-reactive. Multistix are valid until the expiration date on the vial, unless the strips become discolored or are exposed to moisture. Do not take the desiccant out of the bottle.

QUALITY CONTROL

1. Remove two dipsticks. Take off the cap from Level 1 and invert the bottle. Squeeze the sides of the dropper bottle gently while holding the dipstick and bring the tip of the bottle into contact with it. Draw over all of the reagent pads, completely soaking each one. Avoid aspirating extra control back into the bottle. Using a tissue or paper towel, wipe the tip clean. Turn the dipstick on its side and pour the surplus control onto an absorbent cloth. Level 2: Repeat the process.

2. Read the results carefully at the stated times in good light, with the test area held close to the relevant color chart on the bottle label. **PROPER READING TIME IS ESSENTIAL FOR BEST RESULTS**.

3. Keep track of the results on the Urine QC Log sheet. Compare the levels to the tolerance values shown on the package insert (make sure the control bottles' lot numbers match the lot numbers on the tolerance value sheet). Control recaps. Record the results as Positive, Negative, or as specified on the vial.

4. If the results are not within acceptable limits, test again with a different dipstick. If the test fails again, try a new vial of Urine QC. If the test fails again, repeat it using a dipstick from a different vial of dipsticks. If the problems persist, contact the Core lab and deliver the samples to them for testing. **DO NOT PROCEED WITH PATIENT TESTING**.

5. The Urine Control Log sheet must be used to report and initial the results. The laboratory's Point-of-Care Testing office will evaluate the QC records. Each patient testing day must include quality control testing. Monthly compliance is at 95% or higher. The Medical Director signs and reviews Quality Control on a monthly basis.

6. Quality control material is stable at room temperature for one month. After this time, discard it.

STEP BY STEP INSTRUCTIONS

1. Submerge the dipstick in the urine specimen. Remove the strip immediately, running the edge against the container's rim to remove any excess pee. Hold the strip horizontally to prevent chemical mixing from neighboring locations.

2. Read the findings carefully at the prescribed times in good light, using the color scheme on the bottle label.

3. Record the result in the relevant section of the patient chart. A urine patient record is accessible, and the results may be entered immediately into the patient's file. Record the findings as positive or negative, as shown on the strip vial.

4. Values that do not match the clinical results should be validated using a clinical laboratory test procedure.

LIMITATIONS

1. Substances that cause abnormal urine color may affect readability of reagent areas on strip. The color development may be masked or a color produced that could be interpreted as a false positive. Results should include a notation of urine color and a comment about the possible false positive results.

2. **Protein**: visibly bloody urine may cause falsely elevated results.

3. **Blood**: Capoten (capropril) 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.

4. **Leukocytes**: Elevated glucose concentrations (> 3 g/dL) may cause decreased test results. The presence of ecphalexin, cephalothin, 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.

LIMITATIONS

5. **Nitrites**: Pink patches or edges should not be construed as a favorable outcome. A negative result does not rule out the presence of substantial bacteria in the urine. False negative findings may arise due to a shorter bladder incubation of the urine, the lack of dietary nitrate, or the presence of non-reductive pathogenic microorganisms.

6. **Glucose**: Ketone bodies minimize the test's sensitivity; moderately high ketone levels (40 mg/dL) may give false negatives for specimens containing minor quantities of glucose (75-125 mg/dL), however the combination of such ketone levels with low glucose levels is physiologically unlikely in screening.

7. **Ketone**: Highly pigmented urine specimens or those having high levels of levodopa metabolites might provide false trace readings. Sulfhydryl-containing compounds, such as mesna (2-mercaptoethane sulfonic acid), might provide false positive findings or an abnormal color response.

8. **Bilirubin**: Indican (indoxyl sulfate) can cause a yellow-orange to red color reaction, making it difficult to interpret a negative or positive result. Lodine metabolites might provide false positives or unusual findings. Atypical colors (colors that differ from the negative or positive color blocks given on the color chart) may suggest the presence of bilirubin-derived bile pigments in the urine sample, which might be obscuring the bilirubin response.

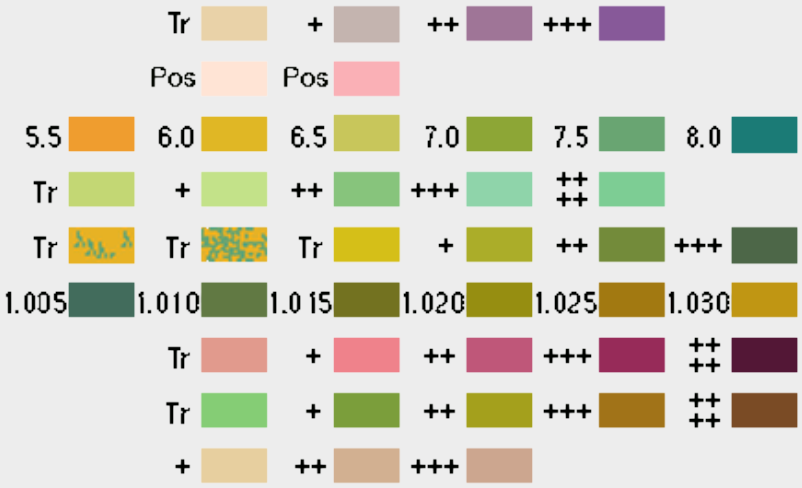
9. **Urobilinogen**: The test pad may react with interfering compounds such as p-amino salicylic acid or sulfonamides. If formalin is present, you may get atypical color responses. Strip reactivity rises with temperature; the optimal range is 22-26oC. The test does not reliably identify porphobilinogen.

10. When exposed to light, bilirubin and urobilinogen become highly unstable.

11. Urine specimen contamination with chlorhexidine-containing skin cleansers may have an effect on protein, bilirubin, and specific gravity test findings.

REPORTING RESULTS: REFERENCE RANGE

Specific gravity values normally range between 1.008 and 1.022 depending on fluid intake.



Normal values are as follows:

- **Color** – Yellow (light/pale to dark/deep amber)
- **Clarity/turbidity** – Clear or cloudy
- **pH** – 4.5-8
- **Specific gravity** – 1.005-1.025
- **Glucose** – <130 mg/d
- **Ketones** – None
- **Nitrites** – Negative
- **Leukocyte esterase** – Negative
- **Bilirubin** – Negative
- **Urobilirubin** – Small amount (0.5-1 mg/dL)
- **Blood** – <3 RBCs
- **Protein** – <150 mg/d
- **RBCs** – <2 RBCs/hpf
- **WBCs** – <2-5 WBCs/hpf
- **Squamous epithelial cells** – <15-20 squamous epithelial cells/hpf
- **Casts** – 0-5 hyaline casts/lpf
- **Crystals** – Occasionally
- **Bacteria** – None
- **Yeast** - None

REPORTING RESULTS: INTERPRETATION

Normal urine color is due to the presence of a pigment called urochrome. Urine color varies based on the urine concentration and chemical composition. Normal urine can vary from pale light yellow to a dark amber color. Highly concentrated urine has a darker yellow appearance. This may be seen in patients with diabetes insipidus, due to impaired urine concentrating ability. Urine color may vary due to certain medications, foods, and medical conditions.

Urine Color	Food	Medical Condition
Red	Beets, blackberries	Urinary tract infections (UTIs), nephrolithiasis, hemoglobinuria (rhabdomyolysis), porphyrias
Orange	Carrot, vitamin C	
Green	Asparagus	Urinary Tract Infection (UTI)
Blue		Blue diaper syndrome (also known as tryptophan malabsorption)
Purple		Bacteriuria in patients with urinary catheters (purple urine bag syndrome)
Brown	Fava beans	Gilbert syndrome, tyrosinemia, hepatobiliary disease
Black		Alkaptonuria, malignant melanoma
White		Chyluria, pyuria, phosphate crystals

Urine clarity or turbidity refers to how clear the urine is. It is determined by substances in urine, such as the amount of cellular debris, casts, crystals, bacteria, or significant proteinuria. Urine clarity is typically classified as clear, mildly cloudy, cloudy, or turbid

PROCEDURE NOTES

A complete urinalysis consists of three components or examinations: physical, chemical, and microscopical.

- Physical examination describes the volume, color, clarity, odor, and specific gravity.
- Chemical examination identifies pH, red blood cells, white blood cells, proteins, glucose, urobilinogen, bilirubin, ketone bodies, leukocyte esterase, and nitrites.
- Microscopic examination encompasses the detection of casts, cells, crystals, and microorganisms.

Urine is an unstable fluid; it changes composition as soon as it is eliminated through micturition. Accurate collection, storage, and handling are crucial to maintaining the sample's integrity. Urine samples collected from the first void or "morning urine" are considered the best representative for testing. The urine accumulated overnight in the bladder is more concentrated, thus provides an insight into the kidneys' concentrating capacities and allows for the detection of trace amounts of substances that may not be present in more diluted samples.

TROUBLESHOOTING

Contaminated Sample
Ensure sterile collection and quick analysis (within 2 hours). Request a new sample if contamination is suspected.

Incorrect Observations (Color, Clarity)
Use proper lighting and ensure observer training. Have a second person verify the observations.

Unexpected Urine Color
Review the patient's diet, medications, and history. Document and cross-check with clinical context or run additional tests.

Delayed Analysis
Analyze samples quickly or refrigerate them. Collect a new sample if the delay caused deterioration.

Equipment Issues
Calibrate equipment regularly. Use backup equipment or refer samples to another lab.

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EFFECTIVE DATE
OCTOBER 14, 2023

SIGNATURE OF LABORATORY DIRECTOR

PAIGE DEANNA FERNANDEZ
LABORATORY DIRECTOR