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Owner	Jeanna Begay
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Manual Dipstick Urinalysis Procedure

PURPOSE

To establish policy & procedures for performing manual urine dipstick testing for point of care testing and as a source to utilize as a back-up in event the urinalysis analyzer is unavailable.

SUMMARY AND INTENDED USE

Siemens Reagent Strips are for professional use in point of care and centralized laboratory locations. The strips are intended for use in at-risk patient groups to assist diagnosis in the following areas:

1. Kidney function
2. Urinary tract infections
3. Carbohydrate metabolism (e.g. diabetes mellitus)
4. Liver function

The strips also measure physical characteristics including acid-base balance and urine concentration.

Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

These tests are CLIA waived when read visually and when run on the CLINITEK Status systems.

SPECIMEN COLLECTION

Patient Preparation

1. Female preparation for a Clean Catch Urine specimen:
    a. Separate the folds of the urinary opening.

b. Using a towelette, wipe one side of the inner fold with a downward stroke.
c. With another towelette, wipe the other inner fold with a downward stroke.
d. Using the last towelette, wipe the center area with a downward stroke.

2. Male preparation for a Clean Catch Urine specimen:
    a. Clean the head of the penis with a towelette.
    b. If not circumcised, pull the foreskin back when urinating into the container.
3. After the above procedures are performed, collect the urine in a properly labeled container by midstream method.
    a. Begin by voiding the urine in the toilet.
    b. Move the container into the "midstream" to interrupt flowing urine.
    c. Fill only half of the container with urine.
4. The specimen of choice for analysis is a clean catch collection of the first morning urine specimen.
5. Random, supra-pubic, catheterized and midstream specimens are also acceptable for testing.
6. Urine must be collected in a clean screw cap container.

SPECIMEN PRESERVATION

1. If the specimen cannot be tested within two hours after collection, it can be refrigerated for up to 24 hours after collection.
2. It is especially important to use fresh urine to obtain optimal results when testing for bilirubin and urobilinogen as these compounds are unstable when exposed to room temperature and light.

STORAGE & HANDLING

1. All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive.
2. Test strips must be stored at room temperature (15-30°C).
3. **Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip.**
4. Do not touch test areas of the reagent strip.
5. Work areas and specimen containers should be free of detergents and other contaminating substances.
6. Do not use the strips after their expiration date.
7. Do not remove desiccant from the bottle.
8. Protection against exposure to light, heat and ambient moisture is mandatory to guard against altered reagent reactivity.

QUALITY CONTROL

1. Two levels of external quality control need to be tested, negative and positive.
    a. Quantimetrix - Level 1

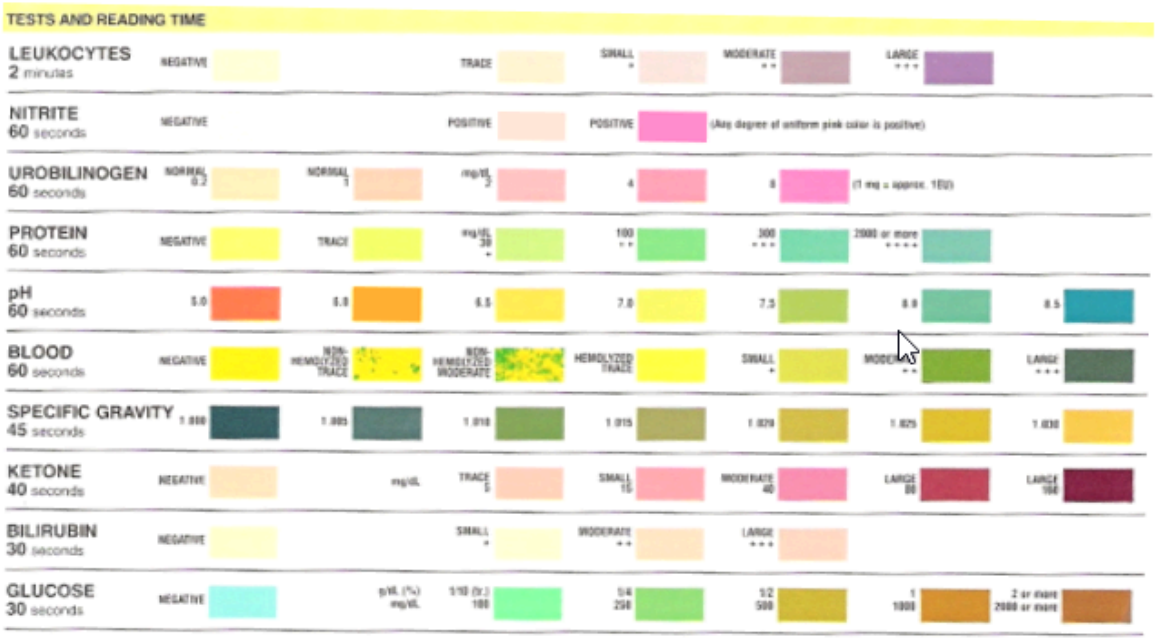
b. Quantimetrix - Level 2

2. Compare QC results to the Quantimetrix Quality Control Results Package Insert.
3. The performance of the reagent strips **MUST** be confirmed by testing with Negative and Positive urine QC material when a new bottle is first opened, and each new lot number.
4. Thereafter, QC must be performed monthly if stored for more than 30 days**.**
5. Water should NOT be used as a negative control.
6. Corrective action must be taken if the QC results are unacceptable. Do not test patient specimens. Repeat QC tests until you have acceptable results.
7. Corrective action must be documented on the QC sheet.

PROCEDURE

Note: This must be followed exactly to achieve reliable test results.

1. Follow hospital policy for the proper identification of the patient to be tested and proper specimen labeling. Specimen accession labels contain the first and last name of the patient, medical record number, date of birth, and date of patient collection. Document collection time and initials of whomever collected the specimen.
2. Mix urine sample well before testing. If urine is refrigerated, let it return to room temperature (between 15-30°C) before testing.
3. Remove one strip from the Multistix 10 SG bottle and recap immediately.
4. Dip all the test pads of the strip completely in the urine. Remove immediately to avoid dissolving out reagent. Note: The ID band can be dipped into urine and control solutions.
5. Start timing.
6. While removing, run the strip edge against the rim of the urine container to remove excess urine.
7. Hold the strip in horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
8. Visually read test results carefully, compare each test pad to the corresponding row of color blocks. Read each pad at the time shown on the label (starting with Glucose at 30 seconds). Hold the strip close to the color blocks and match carefully. Read the pads in a good light.
9. Proper read time is critical for optimal results. Read as follows and match carefully:
    a. Glucose and Bilirubin pad read at 30 seconds after dipping.
    b. Ketone pad read at 40 seconds.
    c. Specific gravity pad read at 45 seconds.
    d. Blood, pH, Protein, Urobilinogen, and Nitrite pad read at 60 seconds.
    e. Leukocytes pad read at 2 minutes.
10. Do not read any test pad after 2 minutes. Color changes that occur after 2 minutes are of no diagnostic value.
11. Avoid laying the strip directly on the Color Chart as this will result in the urine soiling the chart.



REFERENCE RANGES

1. Leukocytes: Negative
2. Nitrate: Negative
3. Urobilinogen: 0.2 – 1.0 mg/dL
4. Protein: Negative
5. pH: 4.6 – 8.0
6. Blood: Negative
7. Specific Gravity: 1.001 – 1.035
8. Ketone: Negative
9. Bilirubin: Negative
10. Glucose: Negative

DOCUMENTATION OF RESULTS

Manual dipstick results must be documented along with the initials of personnel performing the test and the date the test was performed. A functional audit trail must be maintained that allows retrieval of results.

1. Results are to be recorded on the patient and/or QC log.
2. Document date and time the test was performed, sign or symptom, provider, and two patient identifiers.
3. The initials of point of care testing personnel performing the test must be documented on log.
4. Results must be entered into EHR using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

LIMITATION OF PROCEDURE

1. Substances that cause abnormal urine color may affect the readability of the test pads on urinalysis reagent strips. Substances include, visible levels of blood or bilirubin, drugs containing dye (e.g. Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Macrodantin, Furadantin), or riboflavin. The intense color development may cause false positive results.
2. Discoloration or darkening of the test pads may indicate deterioration. If test results are questionable or inconsistent with expected findings, confirm the test strip is within the expiration date, check performance against external quality control, and/or retest with fresh test strips.
3. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent specific gravity and bilirubin) test results.
4. Protein: A visibly bloody urine may cause falsely elevated results.
5. Blood: Capoten may reduce the sensitivity. Certain oxidizing contaminants and microbial peroxidase may produce false positive results.
6. Leukocytes: Elevated glucose concentrations, presence of cephalexin, cephalothin, or high concentrations of oxalic acid may cause decreased test results. High levels of tetracycline may cause a false negative reaction. Vaginal discharge may cause positive results.
7. Nitrite: Pink spots or pink edges should not be interpreted as positive result. A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine.
8. Glucose: Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL).
9. Ketone: False trace result may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites.
10. pH: Bacterial growth by certain organisms in a specimen may cause a marked alkaline shift (pH > 8.0) usually because of urea conversion to ammonia.
11. Specific Gravity: Highly buffered alkaline urines may cause low readings. The presence of moderate quantities of protein (100-750 mg/dL) may cause elevated readings.
12. Bilirubin: Indican may interfere with the interpretation of a negative or positive reading. Atypical colors may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction.
13. Urobilinogen: May react with interfering substances known to react with Ehrlich's reagent such as p-aminosalicylic acid and sulfonamides. The presence of formalin may cause a false negative result.

REFERENCES

1. Siemens Package Insert, Siemens Healthcare Diagnostics Inc., Rev. 7/2017.
2. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS). Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline – Second Edition. Vol. 21. No. 19. Document GP-16A2. Wayne, PA 2001.

Approval Signatures

Step Description	Approver	Date
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Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	02/2024
Director of Quality Management	Jose Burgos: Public Health Nurse Director	02/2024
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	Jeanna Begay	02/2024

Applicability

Hopi Health Center

References

DC.02.01.01, WT.01.01.01.01, WT.04.01.01, WT.05.01.01