CLARITY

Urine Drug Adulteration Test Strip

For *in vitro* use only. Read all instructions, precautions, and limitations before performing this test.

INTENDED USE

Clarity Urine Drug Adulteration test strips are a fast dip-and-read test for the determination of diluted or adulterated urine specimens. It is an important pre-screening test for any drug-testing program.

SUMMARY AND EXPLANATION

Clarity Urine drug adulteration tests are firm plastic strips to which seven different reagent areas are affixed. Clarity Urine test strips are ready-to-use and disposable. No equipment is required for its use. Only fresh and uncentrifuged urine samples without preservatives are to be used.

Clarity Urine Drug Adulteration test strips provides tests for Creatinine, Nitrite, pH, Specific Gravity, Glutaraldehyde, Oxidants, and Pyridium Chlorochromate in urine. Test results may be useful for assessing the integrity of the urine sample prior to Drugs-of-Abuse testing; for example, whether the sample is possibly diluted with water or other liquids as indicated by the creatinine and specific gravity tests. Clarity Urine Adulteration Test strips detects whether the sample contains commercially available adulterants including nitrite, glutaraldehyde, bleach, pyridinium chlorochromate and other oxidizing agents. Clarity Urine Adulteration test strips can also assess whether the sample is possibly contaminated by acidic (vinegar) or basic (ammonia solution) adulterants as indicated by the pH test.

TEST PRINCIPLE

In general, all seven tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with the corresponding pad on the container color chart label.

Creatinine: Testing for sample dilution. In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

Glutaraldehyde: Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the glutaraldehyde reacts with an indicator to form a pink/purple color complex.

Nitrite: Testing for the presence of exogenous nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink-red/purple color.

Oxidants: Testing for presence of oxidizing reagents. In this reaction, a color indicator reacts with oxidants such as hydrogen peroxide, ferricyanide, persulfate, or pyridinium chlorochromate to form a blue color complex. Other colors may indicate the presence of other oxidants.

pH: Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Specific Gravity: Testing for sample dilution. This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

Bleach: Testing for the presence of bleach in urine. In this test, the presence of bleach forms a blue-green color complex.

Pyridium Chlorochromate: Testing for the presence of chromate in urine. In this test, the presence of chromate forms a blue-green color complex.

STORAGE

1. Store at room temperature between 15 ^{o}C – 30 ^{o}C.
2. All test strips should be stored in the original container. Do not remove desiccant from bottle.
3. Do not expose to direct sunlight.
4. Remove only as many strips required for testing and immediately recap the container tightly.
5. Don't use after expiration date.

PRECAUTIONS

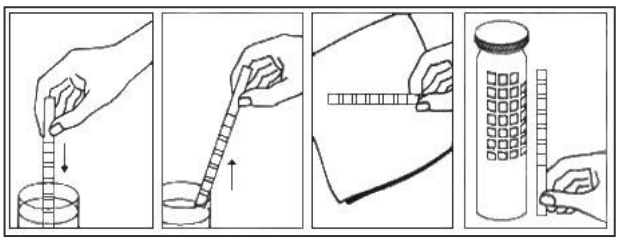
Do not touch test areas of strips.

SPECIMEN COLLECTION

1. Collect urine in a clean glass or plastic container.
2. Test urine sample as soon as possible after collection. Refrigerate urine sample immediately if the sample cannot be tested within one hour. Bring refrigerated sample to room temperature and mix thoroughly before testing.
3. Do not centrifuge or add preservatives to the urine sample.
4. Handle the urine sample as if it is potentially infectious.
5. Aliquot a small portion of the urine sample into another container for testing in order to avoid contamination of the whole urine sample. Do not dip Clarity Urine directly into the primary collection container.

PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap tightly.
2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over (contamination from adjacent reagent pads.)
4. Compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results.
5. Obtain results by direct color chart comparison.



Note: All reagent areas may be read between 1 - 2 minutes for screening positive urine from negative urine. Changes in color after 2 minutes are of no diagnostic value.

INTERPRETATION OF RESULTS

Semi-quantitative results are obtained by visually comparing the color of each pad with the corresponding test color block pictured on the container label. No equipment is required.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new test is performed or whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standard of performance, and should question handling and testing procedures if these standards are not met.

LIMITATIONS

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

Some compounds or physical properties that may affect the test result are listed below. Medications that discolor the urine may also cause abnormal results due to masking of the reactions of the reagents on the test pads.

EXPECTED VALUES

Creatinine: Daily creatinine excretion, related to muscle mass of the human body, is usually constant[6]. The DOT guideline[1] states that urine specimens with creatinine levels of less than 20 mg/dl are indications of adulteration. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution[2], sample with creatinine level of lower than 20 mg/dl should be considered adulterated.

Glutaraldehyde: Glutaraldehyde is not a natural component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, false positive may result when ketone bodies are presence in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.

Nitrite: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage.

Oxidants: The presence of oxidizing reagents in the urine is indicative of adulteration since oxidizing reagents are not normal constituents of urine. Oxidizing reagents include Hydrogen Peroxide, Ferricyanide, Persulfate, and Pyridinium Chlorochromate…etc.

pH: Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

Specific Gravity: Random urine may vary in specific gravity from 1.003 - 1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016 - 1.022[7]. Elevated urine specific gravity value may be obtained in the presence of moderate quantities of protein. DOT guidelines[1] state that a urine specimen with specific gravity level of less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.

Pyridium Chlorochromate: The presence of any chromate in urine is indicative of adulteration as chromate is not a normal constituent of urine.

REFERENCES

1. U.S. Department of Transportation, Drug Testing Procedures Handbook.
2. Young, D.S.et al, Clinical Chemistry, 21 (9), 1975.
3. Friedman, R.B. et.al. Clinical Chemistry: 26 (4), 1980.
4. Tietz, N.W. Clinical Guide to Laboratory Tests, Third Edition, W.B. Saunders Company, p566, 1995.
5. Chu, S.Y. and Sparks. Clinical Chemistry, 17, 1984.
6. Tingsrud, K.M. and Linne, J.J., Urinalysis and body Fluids A color Test and Atlas, Mosby-Year Book, Inc., 1995.
7. Henry, J.B. et al.: Clinical Diagnosis and Management by Laboratory Methods, 16th Ed. Philadelphia: Saunders; (1979).

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