Drug Adulteration Test Strips

INTENDED USE
The IND 7-pad urine adulteration test is an easy and efficient test for dilution and adulteration of urine samples. The test strips are fast to operate and provide clear visual qualitative results. Its should be an essential part of drug screening test and needs to be performed prior to the actual drug test.

SUMMARY AND EXPLANATION
The addition of adulterants to urine samples can significantly affect drug-screening results. Therefore, it is very important that the urine samples are checked for adulterants prior to the drug test. Moreover, the urine tested must be fresh urine without preservatives and without centrifuging.

The IND 7-pad urine adulteration test strips are ready to use and disposable, no equipment is needed. The test strip is made with a plastic strip, and the 7 test pads are attached to the plastic strip. The 7 test pads tests for Creatinine, Nitrite, pH, Specific Gravity, Glutaraldehyde, bleach and Pyridinium Chlorochromate/ Oxidants accordingly. The results show up as a change in color and needs to be compared with the color chart on the packaging. From the different pads we can assess the presence of numerous adulterants. The Creatinine and Specific Gravity test, for example, is very efficient for determining if the sample is diluted in any way. The pH, bleach and the Pyridinium Chlorochromate/ Oxidants test, on the other hand, can screen for common household items, such as bleach, Drano, Hydrogen Peroxide, and vinegar. Moreover, our 7-pad urine adulteration test strip is capable of screening for many other adulterants, and even for commercially sold adulterants and oxidizing agents.

TEST PRINCIPLE
The principles of the IND 7-pad urine adulteration test trips are dependent upon the chemical reactions that take place between the reagents in the test pads and the components of the urine sample, including normal urine constituents, and urine adulterants. The colored results from the test strip must be compared to the color chart on the packaging.

Creatinine: This assay tests the urine sample for possible dilution. This reaction takes place in an alkaline medium between creatinine and a creatinine indicator to form a purple-brown color complex. The color intensity of the test pad is directly dependent on the concentration of creatinine in the urine.

Nitrite: This assay tests the urine sample for the presence of uncommon amounts of nitrite. The results are determined by a series of reactions, where nitrite must first react with an aromatic amine to produce a diazonium salt. Then, diazonium salt will couple with an indicator to form a pink-dark red color complex. The color intensity of the test pad is directly affected by the concentration of nitrite in the sample.

Glutaraldehyde: This assay tests for the presence of uncommon amounts of aldehyde. This reaction takes place between the aldehyde and an indicator to generate a color complex.

pH: This assay test for the presence of acidic or alkaline adulterants, and is established from the double pH indicator method to distinguish different pH levels with a large range of colors.

Specific Gravity: This assay tests for the possibility of possible dilution. In this test the indicator changes color according to the pKa of a certain pretreated polyelectrolytes, which is related to the ionic concentration. In a urine sample of low ionic concentration the colors range dark blue to green, and at a higher ionic concentration the colors will range from green to yellow.

Bleach: This assay test for the possible presence of bleach in the urine sample. This reaction occurs between bleach and its indicator. The presence of bleach will turn the test pad into a blue-green color complex.

Pyridinium Chlorochromate/ Oxidants: This assay test for the possible presence of chromate in urine. This reaction is between pyridinium chlorochromate chromate and its indicator. The presence of chromate will turn the test pad into a blue-green color complex.

WARNINGS AND PRECAUTIONS
The urine adulteration test strips are for screening only and have no diagnostic significance.

STORAGE
- The test strips are to be stored at room temperature between 15–30 °C.
- The test strips should be stored in its original packaging with desiccant in place.
- The test strip should not be exposed to direct sunlight.
- After removal of one strip from the container, recap immediately.
- The test strips must not be used after the expiration date.

SPECIMEN COLLECTION AND HANDLING
1. Collect fresh urine in a clean glass or plastic container.
2. Urine sample should be tested immediately. Refrigerate samples that cannot be tested within an hour, as the pH and Nitrite concentration may alter from a build up of bacteria in urine. For refrigerated urine mix and bring urine to room temperature before testing.
3. Preservatives should not be added to the urine, and do not centrifuge the urine.
4. The urine samples should be handled as in it is potentially infectious.
5. To avoid the contamination of the whole sample, the urine adulteration test is to be performed in a separate container with an aliquot of the original urine sample.

PROCEDURE
1. Remove the exact amount of test strips needed and immediately recap the container.
2. Mix the urine thoroughly; dip the test strip into the urine sample. Make sure all the test pads are immersed in the urine, then immediately remove the test strip to avoid the dissolving of the test pads.
3. Blot the test strip on a paper towel by gently tapping the strip on its side. This process can provide more consistent results.
4. Read by comparing to the color chart on the packaging. The results are to be read from 1-2 minutes; results past 2 minutes should be disregarded.

INTERPRETATION OF RESULTS
Visually compare the colors on the test pads to the color chart in order to obtain qualitative results. No external materials are needed.

QUALITY CONTROL
Testing of the urine adulteration test strips with known positive and negative urine samples will help to confirm the performance of the strips. These experiments are best done when a new bottle is opened, or if a new test is performed. If the negative or positive urine samples fail to produce results according to the color chart, then laboratories should question their handling and testing procedures and revise their standard of performance.

LIMITATIONS
Interpretation of the colored results is dependent on individuals, and laboratory technicians should be tested for color blindness. Like all laboratory tests, decisions should not be dependent on single test result or method. Moreover, certain compounds, physical properties, or medication that discolors urine may affect or mask test results.

EXPECTED VALUES
Creatinine: The daily creatinine excretion is usually constant, and it is consistent with the muscle mass of the human body. The DOT provides a guideline that when the urine sample has a creatinine level of less than 20mg/dL, it is likely diluted. Even though creatinine levels differs by age, sex, diet, muscle mass, and local population distribution, urine samples with creatinine levels of lower than 20mg/dL does not occur in natural urine and should be considered diluted.

Nitrite: Even though nitrite is not a normal component of urine; urinary tract infections, bacterial contaminations, or improper storage can all cause nitrite levels to be as high as 3.5mg/dL. Nonetheless, nitrite levels above 50mg/dL are abnormal and are considered adulterated by the DOT guidelines.

Glutaraldehyde: Glutaraldehyde is not present in normal urine, and many commercially sold adulterants contain glutaraldehyde. Therefore, detection of glutaraldehyde in the urine sample should indicate adulteration. False positive results can results from ketoacidosis, starvation, or other metabolic abnormalities, as the ketone bodies generated can react with the glutaraldehyde indicator to produce a positive coloration.

Bleach: The presence of bleach in the urine sample is a sign of adulteration. Other oxidative adulterants such as hydrogen peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate etc can also be detected by this test.

pH: Normal Urine pH is usually from 4.5 to 8.0. Thus, a pH below 3.0 or above 11.0 is a sign of adulteration.

Specific Gravity: Adults with a normal diet or fluid intake would have urine with a specific gravity between 1.016 and 1.022. Nonetheless, results between 1.001 and 1.035 are still considered normal. The specific gravity of the urine might be elevated by high protein concentrations. According to the DOT guidelines, a urine sample with a specific gravity of less than 1.003 should indicate adulteration. Moreover, results from both the specific gravity test and the creatinine test should be considered as a whole to decide if the sample has been adulterated.

Pyridinium Chlorochromate/ Oxidants: The presence of Pyridinium Chlorochromate in the urine sample is a sign of adulteration. Other oxidative adulterants such as hydrogen peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate etc can also be detected by this test.

REFERENCES
1. U.S Dept. of Health and Human services, Mandatory Guidelines for Federal Workplace Drug Testing Programs.
2. U.S Dept. of Transportation, Procedures for Transportation Workplace Drug and Alcohol Testing Programs. Federal Register, 1999 Dec. 64: (236); 6976
5. George, S. et.al., J. Anal. Toxicol. 1996; 20(30); 196