



Brief Instructions

(Consult the product insert for detailed instructions)

Using Intect® 7 is very easy. It involves a simple 3 step procedure.

Dip the numbered reagent end of the test strip in urine sample and remove immediately. Alternatively, the urine sample can be pipetted onto each pad of Intect® 7.

Blot the strip to remove excess urine.

After one (1) minute, read and compare the numbered test areas with corresponding panels in the color chart.

Intect® 7 is a preliminary screening test. Positive results should be sent to a laboratory of confirmatory testing.

Intect® 7 Product Insert Urine Adulteration Test Strip

Tests for Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Bleach and Pyridinium Chlorochromate Chlorochromate

ADULTERANT

Intended User

The Intect® 7 urine adulteration test strip is a plastic strip affixed with 7 chemically treated pads for assessing the integrity of the urine sample prior to Drugs-of-Abuse (DAU) testing. By visual color examination of the pads after dipping the strip into the urine sample, semi-quantitative values of creatinine, nitrite, glutaraldehyde, pH, specific gravity, bleach and pyridinium chlorochromate can be determined and the intactness of the sample can be assessed.

This test strip is intended for professional forensic/toxicology use only. It is not intended for use in the diagnosis of disease or illness.

SUMMARY AND EXPLANATION

The validity of DAU screening depends on the integrity of the urine samples. Contaminated or adulterated samples may cause erroneous results leading to significant consequences. Hence, it is important to insure that the samples are intact and not adulterated prior to DAU testing. Both the mandatory guidelines for Federal Workplace Drug Testing Program and the Department of Transportation (DOT) regulations allow integrity testing.

Intect(tm)7 test strips are plastic strips affixed with seven reagent pads. The pads are chemically treated with specific reagents to provide for semi-quantitative tests for creatinine, nitrite, glutaraldehyde, pH, specific gravity, bleach and pyridinium chlorochromate. By visual comparison of these pads with the color chart on the container label after dipping the test strip into a urine sample, the following information can be obtained which may be useful in assessing the integrity of the urine sample:

- Whether the sample is possibly diluted with water or other liquids as indicated by the creatinine and specific gravity tests.

- Whether the sample possibly contains commercially available adulterants including nitrite ("KLEAR"), glutaraldehyde ("INSTANT CLEAN ADD-IT-IVE" and "URINAID"), bleach, pyridinium chlorochromate ("URINE LUCK") and other oxidizing agents ("STEALTH").
- Whether the sample is possibly contaminated by acidic (vinegar) or basic (ammonia solution) adulterants as indicated by the pH test.

The Intect^(tm) 7 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. The samples should be handled as if they are potentially infectious. Remove only as many strips required for testing from the container and immediately recap it tightly. The test procedure should be followed exactly as directed. Test results are obtained by comparing the color of the pads with color chart on the container label.

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 numbered tested pad with the corresponding numbered pad on the container color chart label.

- Pad #1 Creatinine: In this assay, creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex. The color intensity of the tested pad is directly proportional to the concentration of creatinine in the sample.
- Pad #2 Nitrite: This test is based on the reaction of aromatic amine to yield a diazonium salt which then couples with an indicator to form a color complex ranging from pink to dark red depending on the concentration of nitrite in the sample.
- Pad #3 Glutaraldehyde: This analysis is based on the reaction of the aldehyde group on the glutaraldehyde with an indicator to generate a brown color complex.
- Pad #4 pH: This test is based on a double indicator principle that gives a broad range of colors ranging from orange (low pH) to yellow and green (pH 4 to 9) and blue (high pH).
- Pad #5 Specific Gravity: This test is based on the release of protons from a polyacid in the presence of cations in the test liquid. A colored reaction is produced when the released protons react with the indicator reagent generating color ranging from blue to blue-green and then to yellow depending on the specific gravity of the sample.
- Pad #6 Bleach: In this reaction, a color indicator reacts with bleach to form a blue color complex.
- Pad #7 Pyridinium Chlorochromate: In this assay, a color indicator reacts with pyridinium chlorochromate to form a blackish blue color complex.

REAGENTS

- Pad #1 Creatinine: 2.05% creatinine reactive indicator, 97.95% buffer and non-reactive ingredients.
- Pad #2 Nitrite: 0.81% nitrite reactive indicators and 99.19% buffer and non-reactive ingredients.
- Pad #3 Glutaraldehyde: 3.30% glutaraldehyde reactive indicator, 96.70% buffer and non-reactive ingredients.
- Pad #4 pH: 0.10% indicator reagent and 99.90% non-reactive ingredients.
- Pad # 5 Specific Gravity: 1.38% indicator reagent and 98.62% non-reactive ingredients.
- Pad #6 Bleach: 0.22% reactive indicator and 99.78% non-reactive ingredients.
- Pad #7 Pyridinium Chlorochromate: 0.22% reactive indicator and 99.78% non-reactive ingredients.

WARNINGS AND PRECAUTIONS

- Intect^(tm)7 test strip is for forensic/toxicology use only.
- Handle urine sample as if potentially infectious.
- Avoid contact of test strip with skin or mucous membrane.

STORAGE

- Store at room temperature between 15°C - 30°C. (59°F - 86°F).
- All test strips should be stored in the original container.
- Remove only as many strips required for testing and immediately recap the container tightly.
- Do not use after expiration date.

SPECIMEN COLLECTION AND HANDLING

- Collect urine in a clean glass or plastic container.
- 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.
- Do not centrifuge or add preservative to the urine sample.
- Handle the urine sample as if it is potentially infectious.
- 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 Intect(tm)7 directly into the primary collection container.

TEST PROCEDURE

1. Dip the numbered reagent end of the test strip in urine sample and remove immediately.
2. Blot the strip to remove excess urine.
3. Read and compare the numbered test areas with corresponding panels in the color chart in one (1) minute.

INTERPRETATION OF RESULTS

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

QUALITY CONTROL

The performance of the reagent strips should be confirmed by testing known negative and positive specimens or multiple analyte controls containing normal and abnormal amounts of each analyte being tested. Alternatively, quality standard set developed specifically for Intect(tm)7, brand named IntectCheck(tm), is available from the manufacturer. Please note that other commercial urine quality controls with artificial matrix may give false results due to masking of the test reactions on the reagent pads with an intense yellow color.

EXPECTED RESULTS AND LIMITATIONS

Some compounds or physical properties which 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.

- Pad #1 Creatinine: Daily creatinine excretion, related to the muscle mass of the human body, is usually constant⁶. The DOT guideline¹ 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 distribution², sample with creatinine level of lower than 20 mg/dl should be considered adulterated.
- Pad #2 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. In the Intect[®]7 test strip, nitrite level above 7.5 mg/dl is considered abnormal.
- Pad #3 Glutaraldehyde: Glutaraldehyde is not a normal component of urine. Hence, the detection of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, in ketoacidosis, starvation or other metabolic abnormalities, ketone bodies may appear in urine, interact with the glutaraldehyde pad and provide a false result.
- Pad #4 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.

- Pad #5 Specific Gravity: Fresh urine samples should have a range of 1.002 to 1.030. A mean value of 1.017 has also been reported. However, high protein concentration in the urine may elevate the specific gravity value. DOT guideline¹ states that urine specimen with specific gravity level of less than 1.003 is indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.
- Pad #6 Bleach: The presence of bleach in the urine is indicative of adulteration since bleach is not a normal constituent of urine. The formation of brown or blackish blue pad color may also indicate the presence of other oxidative adulterants.
- Pad #7 Pyridinium Chlorochromate: The presence of pyridinium chlorochromate in the urine is indicative of adulteration since it is not a normal constituent of urine. The formation of blue pad color may also indicate the presence of other oxidative adulterants.

BIBLIOGRAPHY OF SUGGESTED READING

1. U.S. Department of Transportation, Drug Testing Procedures Handbook.
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5. Chu, S.Y. and Sparks ., *Clinical Chemistry*, 17, 1984.
6. Ringsrud, K.M. and Linne, J.J., *Urinalysis and Body Fluids A Color Text and Atlas*, Mosby-Year Book, Inc., 1995.