# Intect® 7

**Version 2**

## Urine Adulteration Test Strip

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

***Patents Pending**

## Catalog No. AD007

### INTENDED USE

The Intect® 7 urine adulteration test strip is for the visual qualitative determination of creatinine, nitrite, glutaraldehyde, pH, specific gravity, bleach and pyridinium chlorochromate in urine to assess the integrity of urine specimens prior to Drugs-of-Abuse (DAU) testing. The Intect® 7 test strips provide only primary screen for urine adulteration. Positive results should be run by a confirmatory method.

**The Intect® 7 urine adulteration test strip is intended for professional forensic/toxicology use only. It is not intended for use in the diagnosis of disease or illness. This test is a screening test device for the visual qualitative determination of creatinine, nitrite, glutaraldehyde, pH, specific gravity, bleach and pyridinium chlorochromate in urine, it does not indicate the level or concentrations of compounds present in the sample.**

### 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 ensure that the samples are intact and consistent with normal human urine.

Intect® 7 urine adulteration test strips are plastic strips affixed with seven reagent pads. The pads are chemically treated with specific reagents to provide qualitative results 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 diluted or substituted with water or other liquids as indicated by the creatinine and specific gravity tests.
- Whether the sample contains commercially available adulterants including nitrite[3] ("KLEAR"), glutaraldehyde[4], bleach, pyridinium chlorochromate ("Insta Clean ADD-IT-IVE", "LUCKY LAB",) and other oxidizing agents ("STEALTH", "Urine Luck")[5].
- Whether the sample is contaminated with common household items[6,7] such vinegar, Drano, Hydrogen Peroxide and Bleach as indicated by the pH, Bleach and Pyridinium Chlorochromate tests.

The Intect® 7 test strips are ready-to-use and disposable. No equipment is required. 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 enough strips from the vial for immediate testing and recap the container 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, each test of the Intect® 7 urine adulteration test strip is based on a specific chemical reaction with normal urine constituents and common urine adulterants to assess the integrity of the urine specimen. Results are obtained by visually comparing the color of each of the test pads with the corresponding color chart label on the container. Each test pad on the Intect® 7 urine adulteration test strip is labeled in sequential order for easy visual reading.

**Pad #1, Creatinine**: In this assay, creatinine reacts with a creatinine indicator in an alkaline medium to form a purple-brown color complex. The color intensity of the test 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 utilizes the principle of multiple indicators that give a broad range of colors ranging from orange (low pH) to yellow and green (pH 4 to 9) and brown (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. When the released protons react with the indicator reagent, a colored reaction is produced. The color ranges from green to light green, olive green to red depending on the specific gravity of the sample.

**Pad #6, Bleach:** In this reaction, a color indicator reacts with bleach to form a blue complex.

**Pad #7, Pyridinium Chlorochromate:** In this assay, a color indicator reacts with pyridinium chlorochromate to form a blue, brown or black 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:** 0.15% indicator reagent and 99.85% 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® 7 test strips are for forensic/toxicology use only.
- Handle urine sample as if potentially infectious.
- Avoid contact of test strip with skin or mucous membrane.
- Remove only enough strips from the vial for immediate testing and recap tightly.

## STORAGE

- Store at room temperature between 15°–30°C (or 59°–86°F).
- All test strips should be stored in the original container. Do not remove desiccant from container.
- Do not touch the reagent pads.
- 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. The pH and Nitrite concentration of the urine may change due to ammonia build up from bacteria present in the urine. If testing cannot be performed within 1 hour of urine collection, refrigerate urine sample immediately. 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.
- An aliquot of urine sample may be separated into a container for testing.

## TEST PROCEDURE

1. Remove enough test strips from the vial for immediate testing and recap tightly.
2. Dip the numbered reagent pads in urine sample and remove immediately.
3. Blot the test strip gently on its side to remove excess urine. **Note: It is important to blot the test strip for consistent result.**
4. Read and compare the reagent pads with the corresponding color blocks on the color chart in one (1) minute. **Do not interpret test results after 2 minutes.**

Alternate Test Procedure (Recommended when using control solutions):

1. Using a dropper, add one (1) drop of specimen onto each of the test pad.
2. Blot the test strip gently on its side to remove excess urine as above.
3. Read and compare the reagent pads with the corresponding color blocks on the color chart in one (1) minute. **Do not interpret test results after 2 minutes.**

## INTERPRETATION OF RESULTS

Qualitative results are obtained by visually comparing the color of each numbered pad with the corresponding color blocks 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. For best results, "IntectCheck" controls are available for purchase from the manufacturer. The use of other commercially produced urine controls is not recommended since these do not contain analytes specific to Intect® 7, thus false positive results or atypical color appears on the reagent pads.

## EXPECTED RESULTS AND LIMITATIONS

Some compounds or physical properties, which may affect the test results, are listed below. Medications that discolor the urine may also cause abnormal results due to masking 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 constant[8]. The DOT guidelines[2] state that urine specimens with creatinine levels of less than 20 mg/dl are indications of dilution. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution, sample with creatinine level lower than 20 mg/dl should be considered diluted.

**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. Nitrite levels >50 mg/dl are abnormal and considered adulterated by DOT guidelines.

**Pad #3, Glutaraldehyde:** Glutaraldehyde is not a normal component of urine and its detection is an indication that the urine may have been adulterated since many commercially available urine adulterants contain glutaraldehyde. However, in ketoacidosis, starvation or other metabolic abnormalities, ketone bodies may appear in urine and interact with the glutaraldehyde pad to produce atypical colors.

**Pad #4, pH:** Normal urine pH ranges from 4.5 to 8.0. Values below pH 3.0 or above pH 11.0 are abnormal and indicative of adulteration.

**Pad #5, Specific Gravity:** The specific gravity of normal urine may range from 1.001 to 1.035, it is usually between 1.016 and 1.022 in adults with normal fluid intake[8]. However, high protein concentration in the urine may elevate the specific gravity value. DOT guidelines state that specific gravity should be evaluated in conjunction with clinical observation and creatinine levels. If a urine specimen exhibits abnormal clinical signs, or the creatinine concentration is < 5 mg/dl, then abnormal specific gravity (1.003 or less, or 1.020 or greater) is indicative of substitution. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is diluted or substituted.

**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, blackish blue, or light turquoise gray colors may also indicate the presence of other oxidative adulterants. "Stealth" produces a dark blue color. Nitrite concentrations greater than 12.5 mg/dl in the sample will produce very light bluish colors with both the bleach and pyridinium chlorochromate test pads.

**Pad #7, Pyridinium Chlorochromate:** The presence of pyridinium chlorochromate in the urine is indicative of adulteration as it is not a normal constituent of urine. The formation of a blue or light turquoise gray color may also indicate the presence of other oxidative adulterants such as "Urine Luck ver. 6.3."

## BIBLIOGRAPHY OF SUGGESTED READING


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**MANUFACTURED BY:**
Branan Medical Corporation, Irvine, CA 92618, USA
1-866-468-3287 (1-866-INTECT7) / 1-949-598-7166
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