The Split-Specimen Cup™ is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

- AMPHETAMINE (AMP) 1,000 ng/mL
- BARBITURATES (BAR) 300 mg/mL
- Benzodiazepines (BZD) 200 ng/mL
- Methadone (MOP 300) 300 ng/mL
- Methamphetamine (MAMP) 1,000 ng/mL
- Methylenedioxymethamphetamine (MDMA) 1,000 ng/mL
- Morphine (MOP 300) 300 ng/mL
- OPIATE (OPI 2000) 200 ng/mL
- Phencyclidine (PCP) 25 ng/mL
- THC (THC-COOH) 50 ng/mL
- TRICYP (TC) 50 ng/mL
- Trippy Acid (TCA) 25 ng/mL

The Split-Specimen Cup™ is a rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in urine at the cut-off concentrations listed above. It is designed for use in all laboratories, including point-of-care sites. This test is intended for in vitro diagnostic use only. The Split-Specimen Cup™ is not to be used in conjunction with any other test to establish a diagnosis or for the management of medical treatment.

The Split-Specimen Cup™ is a rapid urine screening test that can be performed without the use of an instrument. It is a qualitative test for the presence or absence of multiple drugs and drug metabolites in urine. The test is performed by adding the appropriate volume of urine to the test device, which contains a membrane strip, a control line, a test line, and a dye pad. The presence or absence of a drug is indicated by a line appearing in the test or control region of the membrane strip. A line appearing in the control region indicates that the test was performed correctly.

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THE SPLIT-SPECIMEN CUP™

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DIRECTIONS FOR USE

1. Allow the test card, urine specimen (if refrigerated), and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

2. Donor provides specimen and sees the cap tight.

3. Remove the seal from the test card. Be sure the urine sample is the correct one.

4. Place the card on a flat surface, insert key and push in.

5. If the card contains adulteration test strips, read the adulteration strips between 2-5 minutes. Compare the colors on the adulteration strips to the chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimen. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.

6. Read the drug strips at 5 minutes. The drug test results remain stable for up to sixty minutes.

7. If the cup contains adulteration test strip(s), read the adulteration strip(s) between 2-5 minutes. Compare the colors on the adulteration strips to the chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimen. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.

8. Read the drug strips at 5 minutes. The drug test results remain stable for up to sixty minutes. See the illustration below for detailed operation instructions. Please refer to the Procedure Card and Color Chart.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: Two lines appear: One should be in the test region (T) and another red or pink line should be in the test region (DrugT). This negative result indicates that the drug concentration is below the detection limits of the test.

NOTE: The shade of red in the test region (DrugT) will vary, but it should be considered significant whenever there is a even faint pink line.

POSITIVE: One red line appears in the control region (C). No lines appear in the test region (DrugT). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for an invalid result. If the problem persists, discontinue the use immediately and contact your manufacturer.

ADULTERATION INTERPRETATION

(Please refer to the color chart for color comparison)

The test strips aid in the detection of false negative results for drugs of abuse tests. The test is based on the chemical reaction to the naphthol on the pads with the specimen in the urine sample affecting color changes. Results are obtained by comparing the color on the test pads with a corresponding color chart.

Glutaraldehyde tests for the presence of glutaraldehyde. Adolescents such as UrnAid and Clear Choice contain glutaraldehyde and can cause false negative screening results by disrupting the test. Glutaraldehyde is not normally in urine and detection is generally an indicator of adulteration.

Color – A clear color may indicate that the sample has been diluted. Unaltered, normal urine should be pink to dark yellow or amber in color. However, a sample should be tested by color strips, but should be suspect for closer examination.

Temperature – The temperature of a urine specimen should be between 91 and 98 degrees when checked within 4 minutes of collection. Urine that is submited at body temperature will exceed 95 degrees Fahrenheit. A specimen that is allowed to equilibrate to room temperature (15-30°C) will have a temperature between 80-90°F. A temperature that is above 95°F warrants a retest.

ADULTERATION LIMITATIONS

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

If any controls are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify test performance.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

If any controls are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify test performance.

LIMITATIONS

1. The adulteration test included with this product are meant to aid in the determination of abnormal samples.

2. Normal urine should contain no nitrites.

3. Normal urine should contain no trace of oxidants.

4. Elevated levels of protein in urine may cause specific gravity values to be higher.

5. Normal creatinine levels are between 20 and 350 mg/dl. Under rare conditions, certain kidney diseases show elevated creatinine levels.

6. Normal urine should contain no trace of oxidants or PCC. A dark blue or green color may indicate their presence.

7. Normal urine should contain no trace of nitrites. However, nitrites in urine may indicate urinary tract infections or bacterial infections.

8. Elevated levels of protein in urine may cause specific gravity values to be higher.

9. Normal creatinine levels are between 20 and 350 mg/dl. Under rare conditions, certain kidney diseases show elevated creatinine levels.

SUMMARY

The Split-Specimen Cup TM provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Barbiturates (BAR)

Desmethyldiazepam, a-ximethylpentobarbital, Methaqualone, Phencyclidine, Pentobarbital, Secobarbital, Sibutramine, Tubocurarine, Thiothixene, Trimethadione, Valium

Barbiturates (BAR)

Secobarbital (Barbiturates) (mg/mL)

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Secobarbital (Barbiturates) (mg/mL)

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Secobarbital (Barbiturates) (mg/mL)
### COCAINE (COC)

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### MARIJUANA (THC)

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### TRICYCLIC ANTIDEPRESSANTS (TCA)

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### OPIATE (OP 200)

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### MORPHINE (MOP 305)

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</table>

### ANALYTIC SENSITIVITY

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by One Step Drug Screen Test Card at 5 minutes.
Doxylamine  50,000

**METHAMPHETAMINE**
- D-Methamphetamine  1,000
- 3,4-Methylenedioxymethamphetamine  1,000
- L-Methamphetamine  8,000
- (+)-3,4-Methylenedioxyamphetamine  2,000
- Mephentermine  50,000
- **METHYLENEDIOXYMETHAMPHETAMINE (MDMA)**
  - D,L-3,4-Methylenedioxymethamphetamine HCI (MDMA)  500
  - 3,4-Methylenedioxyamphetamine HCI (MDA)  3,000
  - 3,4-Methylenedioxyethylamphetamine (MDEA)  300
- **OPIATE 300 (MOP)**
  - Morphine  300
  - Codeine  300
  - Ethylmorphine  3,200
  - Hydrocodone  1,250
  - Codeine  300
  - Hydromorphone  100,000
  - Procaine  1,000
  - Thebaine  1,000
- **OPIATES 2000**
  - Morphine  2,000
  - Codeine  2,000
  - Ethylmorphine  5,000
  - Hydrocodone  12,500
  - Codeine  2,000
  - Hydromorphone  1,000
  - Procaine  15,000
  - Thebaine  6,250
- **PCP**
  - Phencyclidine  25
  - 4-Hydroxyphencyclidine  12,500
- **TCA**
  - Notocryptine  1,000
  - Nortryptamine  1,000
  - Tramadol  3,000
  - Amphetamine  1,500
  - Phenmetrazine  200
  - Imipramine  400
  - Clomipramine  12,500
  - Desipramine  500
  - Maprotiline  2,000
  - Promethazine  25,000

**Effect of Urinary Specific Gravity**
Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Split-Specimen Cup™ was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

**Effect of Urinary pH**
The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Split-Specimen Cup™. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

**Cross-Reactivity**
A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiates, Phencyclidine or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the Split-Specimen Cup™ at a concentration of 100 μg/mL.

**Non Cross-Reacting Compounds**
- Acetaminophen
- Acetophenetidin
- N-Acetylprocaine
- Acetylsalicylic acid
- Aminopyrine
- Aminopyrine
- Amphetamine
- Aspartame
- L-Ascorbic acid
- Apomorphine
- Aspirin
- L-β-Ephedrine
- Ethyl-p-aminobenzoate
- [1R,2S] (-) Ephedrine
- L(–)-Epinephrine
- Ecgonine methyl ester
- Erythromycin
- Fenoprofen
- Furosemide
- Hydralazine
- Glycopyrrolate
- D-L-Phenylephrine
- Hydroxyphosphonic acid
- Hydroxyamphetamine
- Hydroxyamphetamine
- Hydroxyamphetamine
- Ilethorphan
- Labetalol
- Lactobionate
- L-Phenylephrine
- Prednisolone
- Prednisone
- D,L-Propranolol
- D-Pseudoephedrine
- Quinacrine
- Quinidine
- Ranitidine
- Serotonin
- Sulfamethazine
- Sulindac
- Tetrahydrocortisone 3-acetate
- Tetrahydrozoline
- Tetracycline
- Thalidomide
- Trans-2-phenylcyclopropylamine hydrochloride
- Triamterene
- Trimipramine
- Tyramine
- Valine
- Zolmitriptan

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.

**BIBLIOGRAPHY**
7. Riewoldt RD.  Detection of Total Drugs and Chemicals in Mag. 3rd Ed. Biomedical Publ., Davis, CA 1982; 487.