

CLIAwaived™ Inc. Rapid Drug Test Cup

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE

CLIA CATEGORIZATION: WAIVED

INTENDED USE

The CLIAwaived™ Inc. "RDTC" Cup is a one-step immunoassay for the qualitative detection of multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

| Test | Calibrator | Cut-off (ng/ml) |
|------|--------------------------------|-----------------|
| AMP | d-Amphetamine | 1000 |
| BAR | Secobarbital | 300 |
| BZO | Oxazepam | 300 |
| COC | Benzoylcegonine | 300 |
| MDMA | 3,4-methylenedioxyamphetamine | 500 |
| MET | d-Methamphetamine | 1000 |
| MTD | dl-Methadone | 300 |
| OPI | Morphine | 2000 |
| OXY | Oxycodone | 100 |
| PCP | Phencyclidine | 25 |
| THC | 11-nor- Δ^9 -THC-9-COOH | 50 |
| TCA | Nortriptyline | 1000 |

The configurations of the CLIAwaived™ Inc. RDTC Cup consist of any combination of the drugs listed above with or without specimen validity test. The specimen validity test provides information regarding the integrity of urine sample in the drugs of abuse test by the semi-quantitative determination of creatinine, nitrite, pH, bleach/oxidant, and specific gravity in human urine. The CLIAwaived™ Inc. RDTC Cup is used to obtain a visual, qualitative result and is intended for professional use only. A certificate of waiver is needed for your laboratory in order to run this test. Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test or the test is considered high complexity and is no longer CLIA waived.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmation methods.

SUMMARY AND EXPLANATION

Amphetamine/Methamphetamine and metabolites are potent central nervous system stimulants. Acute higher doses induce euphoria, alertness, and sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, methamphetamine is also excreted to some extent unchanged. Thus the presence of the parent compound and metabolite in the urine indicates the use of methamphetamine.

Barbiturates are classified as central nervous system depressants. These products produce a state of intoxication that is similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination and impaired judgment. Depending on the dose, frequency, and duration of use, tolerance, physical dependence and psychological dependence on barbiturates can occur. Barbiturates are taken orally, or by intravenous and intramuscular injections. They are excreted in urine as parent compound, as well as metabolites.

Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites. Most benzodiazepines are excreted in the urine as conjugates and metabolites.

Cocaine is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in the urine primarily as benzoylecgonine in a short period of time. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hours), and can be generally detected for 24 to 60 hours after cocaine use or exposure.

3,4-methylenedioxyamphetamine (MDMA) is classified as both a stimulant and a hallucinogen, and is commonly known as Ecstasy. Like methamphetamine, adverse effects of 3,4-methylenedioxyamphetamine use include jaw clenching, teeth grinding, dilated pupils, perspiring, anxiety, blurred vision, vomiting, and increased blood pressure and heart rate. Overdose of 3,4-methylenedioxyamphetamine may cause heart failure or extreme heat stroke. 3,4-methylenedioxyamphetamine is taken orally in tablets or capsules and excreted in urine as parent compound, as well as metabolites.

Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver and has a biological half-life of 15-60 hours.

Opiates, such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. Opiates are prescribed primarily as analgesics. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma. Heroin is quickly metabolized to 6-acetylmorphine (6-AM), morphine, and morphine glucuronide. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the urine can indicate heroin, morphine, and/or codeine use.

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. It produces potent euphoria, analgesic and sedative effects, and has a dependence liability similar to morphine. Oxycodone is most often administered orally and is metabolized by demethylation to noroxycodone and oxymorphone followed by glucuronidation. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

Phencyclidine, commonly known as "angel dust" and "crystal cyclone", is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. The drug is abused by oral or nasal ingestion, smoking, or intravenous injection. It produces hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It is well absorbed following all routes of administration. Unchanged PCP is excreted in urine in moderate amounts (10% of the dose).

Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. When marijuana is ingested, the drug is metabolized by the liver; the primary metabolite of marijuana excreted in the urine is 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid. Therefore, the presences of detected cannabinoids, including the primary carboxyl metabolite, in the urine indicate marijuana/cannabis use.

Tricyclic antidepressants (TCAs) have been prescribed for depression and compulsive disorders. Because of the possibility of causing serious cardiac complications, TCAs can be lethal if misused at high doses. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

For all drugs, the length of time following drug use of which a positive result may occur is dependent upon several factors, including the frequency, amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

TEST PRINCIPLE

The CLIAwaived™ Inc. RDTC Cup is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample migrates upward and rehydrates the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein band on the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region as the antibody complexes with the drug-protein. When drug is present in the urine, it will compete with drug-protein for the limited antibody sites.

The line on the test region will become less intense with increasing drug concentration. When a sufficient concentration of drug is present in the urine, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein on the test region. Therefore, the presence of the line on the test region indicates a **negative** result for the drug and the absence of a line on the test region indicates a **positive** result for the drug.

A visible line generated by a different antigen/antibody reaction is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the urine sample. This means that **negative** urine sample will produce both a test line and control line, and a **positive** urine sample will generate only a control line. The presence of control lines serve as built-in control, which demonstrates that the test was performed properly.

REAGENTS & MATERIALS SUPPLIED

- 25 individually wrapped test devices. Each device consists of different test strips in a plastic test strip holder. The test strip contains a colloidal gold pad coated with antibody and rabbit antibody. It also contains a membrane coated with drug- protein conjugate in the test band and goat anti-rabbit antibody in the control band.
- 25 Cups for sample collection
- One (1) Instruction Sheet
- 25 Security Seals (if applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- External positive and negative controls

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Urine specimens and used devices may be potentially infectious. Proper handling and disposal methods should be established.
- Test device should remain sealed until ready for use.
- Do not use the test kit after the expiration date.
- Color blindness may affect interpretation of results.
- Do not store and/or expose reagent kits at temperature greater than 30°C. Do not freeze.

STORAGE

The CLIAwaived™ Inc. RDTC Cup should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and/or expose reagent kits at temperatures greater than 30°C.

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the container provided. Alternately, a clean, dry plastic or glass container may be used for specimen collection. If the specimen will not be tested immediately after collection, the specimen may be refrigerated at 2-8°C up to 2 days or frozen at -20°C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

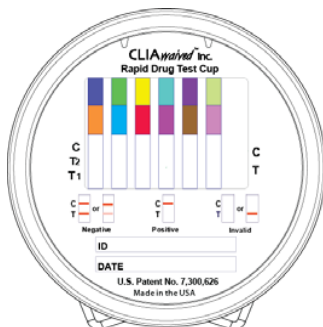
ASSAY PROCEDURE FOR DRUG TEST ONLY

Preparation

1. If a specimen, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2. Do not open test device pouch until ready to perform the test.

Testing

1. Remove test device lid from the sealed pouch and write donor name or ID on the cap in the section provided.
2. Secure test device lid to the filled specimen cup. **IMPORTANT:** Cup lid must be secured tightly by twisting it a quarter turn **AFTER** lid is snug. Place cup on its side to activate testing.
3. Read results of test in 5 minutes. Do not interpret result after 10 minutes.



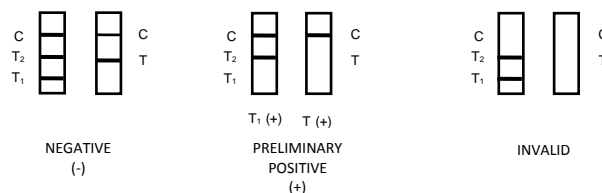
The CLIAwaived™ Inc. RDTC Cup without specimen validity test

INTERPRETATION OF RESULTS

Negative (-): Colored lines appear in both the Control Region (C) and the Test Region (T₁, T₂ for 2-drug strip and T for 1-drug strip). The line in the control region is the control line, which is used to indicate proper performance of the device. The line in the test region is the drug line. The test line may have varying intensity either weaker or stronger in color than that of the control line. A negative result for a drug indicates that the concentration for that drug in urine is below the cutoff level.

Positive (+): Colored line appears in the control region. No line appears at a specific drug test region. The complete absence of a test line indicates a preliminary positive result for that drug. A preliminary positive result for a drug indicates that the concentration of that drug in the urine is at or above the cutoff level.

Invalid: No colored line appears in the control region. If the control line does not form, the test result is invalid and should be repeated.



QUALITY CONTROL

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

To ensure proper kit performance, it is recommended that the CLIAwaived™ Inc. RDTC Cup be tested using external controls with each new lot or shipment of product, with each new operator (i.e. one who has not performed the test recently), when problems (storage, operator, instrument, or other) are suspected or identified, and as otherwise required by your laboratory's internal quality system procedures. Depending on storage conditions, operators may also test controls monthly as a check on continued storage conditions. Control specimens should be performed the same as patient specimens (refer to Directions for Use, Interpretation of Results). If unexpected results are seen when running the external positive or negative controls, review the Direction for Use, Interpretation of Results and Limitations sections and repeat the test with another cup. If the problem persists, discontinue use of the test kit immediately and call (1-888-882-7739). External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements accrediting organizations and/or local, state, and/or federal regulators.

LIMITATIONS OF PROCEDURE

1. The CLIAwaived™ Inc. RDTC Cup 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.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
6. This test does not distinguish between drugs of abuse and certain medication.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the CLIAwaived™ Inc. RDTC Cup was evaluated in comparison to commercially available drug screen tests. Sixty (60) negative urine samples collected from presumed non-user volunteers were tested using both CLIAwaived™ Inc. RDTC Cups and commercially available drug screen tests. Of these negative urine samples tested, all were found negative by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (TCA concentrations were determined by HPLC), were tested by the CLIAwaived™ Inc. RDTC Cup and commercial drug screen tests. The results of accuracy study are presented below:

| Drug Test | | GC/MS (<-50% C/O) | GC/MS (-50% C/O to C/O) | GC/MS (C/O to +50% C/O) | GC/MS (>+50% C/O) | % Agreement with GC/MS |
|-----------|-----|----------------------|-------------------------------|-------------------------------|----------------------|---------------------------|
| AMP | (+) | 0 | 0 | 10 | 55 | 98.5 |
| | (-) | 15 | 9 | 1 | 0 | 100 |
| BAR | (+) | 0 | 1 | 5 | 83 | 97.8 |
| | (-) | 15 | 7 | 2 | 0 | 95.7 |
| BZO | (+) | 0 | 2 | 13 | 37 | 100 |
| | (-) | 18 | 18 | 0 | 0 | 94.7 |
| COC | (+) | 0 | 0 | 8 | 71 | 98.8 |
| | (-) | 15 | 8 | 1 | 0 | 100 |
| MDMA | (+) | 0 | 1 | 6 | 37 | 100 |
| | (-) | 24 | 6 | 0 | 0 | 96.8 |
| MET | (+) | 0 | 0 | 5 | 58 | 98.4 |
| | (-) | 20 | 8 | 1 | 0 | 100 |
| MTD | (+) | 0 | 0 | 6 | 65 | 98.6 |
| | (-) | 15 | 5 | 1 | 0 | 100 |
| OPI | (+) | 0 | 2 | 9 | 45 | 100 |
| | (-) | 15 | 6 | 0 | 0 | 91.3 |
| OXY | (+) | 0 | 1 | 6 | 47 | 100 |
| | (-) | 15 | 7 | 0 | 0 | 91.3 |
| PCP | (+) | 0 | 0 | 4 | 56 | 96.8 |
| | (-) | 15 | 4 | 2 | 0 | 100 |
| THC | (+) | 0 | 1 | 24 | 32 | 100 |
| | (-) | 15 | 12 | 0 | 0 | 96.4 |
| TCA | (+) | 0 | 1 | 12 | 9 | 100 |
| | (-) | 23 | 11 | 0 | 0 | 97.1 |

B. Precision

A study was conducted at three physician offices and Ameditech in an effort to determine the precision of the CLIAwaived™ Inc. RDTC Cup across three (3) consecutive days. Testing was conducted on the methylenedioxymethamphetamine, amphetamine, barbiturates, benzodiazepines, cocaine, marijuana, methamphetamine, methadone, opiates, oxycodone, phencyclidine, and tricyclic antidepressants assays using three different lots of product to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded samples, containing drugs at specific concentrations around each assay cutoff was blinded and tested at each site. The correlation with expected results for the solutions targeted to +/- 50% of the cutoff was >99% across all lots, all sites and all operators.

C. Specificity

The specificity for the CLIAwaived™ Inc. RDTC Cup was determined by testing various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The following compounds produce positive results when tested at levels greater than the concentrations listed below.

| Compound | Conc. (ng/ml) | Compound | Conc. (ng/ml) |
|------------------------|---------------|-------------------|---------------|
| Amphetamine | | | |
| d-Amphetamine | 1,000 | d-Methamphetamine | 50,000 |
| dl-Amphetamine | 2,500 | (+/-)3,4-MDMA | 50,000 |
| (+/-)3,4-MDA | 1,250 | | |
| Barbiturates | | | |
| Secobarbital | 300 | Butobarbital | 400 |
| Allobarbital | 600 | Butalbital | 300 |
| Alphenal | 200 | Butethal | 450 |
| Amobarbital | 1500 | Pentobarbital | 400 |
| Aprobarbital | 300 | Phenobarbital | 450 |
| Barbital | 1500 | | |
| Benzodiazepines | | | |
| Oxazepam | 300 | Flunitrazepam | 300 |
| Alprazolam | 400 | Flurazepam | 300 |

| | | | |
|--------------------|------|-------------|-----|
| Bromazepam | 250 | Lorazepam | 500 |
| Chlordiazepoxide | 300 | Medazepam | 300 |
| Clobazam | 1000 | Nitrazepam | 250 |
| Clonazepam | 500 | Nordiazepam | 150 |
| Clorazepate | 150 | Prazepam | 500 |
| Desalkylflurazepam | 200 | Temazepam | 200 |
| Diazepam | 450 | Triazolam | 450 |
| Estazolam | 300 | | |

Cocaine

| | | | |
|-----------------|-----|---------|-----|
| Benzoylcegonine | 300 | Cocaine | 300 |
|-----------------|-----|---------|-----|

MDMA

| | | | |
|---------------|-----|--------------|-------|
| (+/-)3,4-MDMA | 500 | (+/-)3,4-MDA | 4,000 |
| (+/-)3,4-MDEA | 450 | | |

Methamphetamine

| | | | |
|-------------------|----------|-------------------|----------|
| d-Methamphetamine | 1000 | (+/-)3,4-MDMA | 3,000 |
| d-Amphetamine | 50,000 | l-Methamphetamine | 10,000 |
| l-Amphetamine | >100,000 | Ephedrine | >100,000 |
| (+/-)3,4-MDEA | 50,000 | Mephentermine | 75,000 |
| (+/-)3,4-MDA | 100,000 | | |

Methadone

| | | | |
|-----------------|-----|----------|-------|
| (+/-) Methadone | 300 | Methadol | 1,500 |
|-----------------|-----|----------|-------|

Opiates

| | | | |
|--------------------------|-------|------------------------|-------|
| Morphine | 2,000 | Hydrocodone | 4,000 |
| Codeine | 2,000 | Hydromorphone | 5,000 |
| Ethylmorphine | 1,000 | Morphine-3-glucuronide | 2,500 |
| Heroin(diacetylmorphine) | 5,000 | Nalorphine | 5,000 |

Oxycodone

| | | | |
|---------------|--------|------------|----------|
| Oxycodone | 100 | Morphine | >100,000 |
| Hydrocodone | 5,000 | Codeine | 50,000 |
| Hydromorphone | 50,000 | Nalorphine | 5,000 |

PCP

| | | | |
|---------------|----|---------------|-------|
| Phencyclidine | 25 | Tenocyclidine | 2,000 |
|---------------|----|---------------|-------|

THC

| | | | |
|-------------------------|-------|-------------------------|----------|
| 11-nor-Δ9-THC-9-COOH | 50 | Δ9-tetrahydrocannabinol | 5,000 |
| 11-hydroxy-Δ9-THC | 1,000 | Cannabinol | 10,000 |
| Δ8-tetrahydrocannabinol | 5,000 | Cannabidiol | >100,000 |

Tricyclic Antidepressant

| | | | |
|---------------|-------|-------------|-------|
| Nortriptyline | 1,000 | Promazine | 1,500 |
| Nordoxepin | 2,000 | Desipramine | 400 |
| Trimipramine | 2,000 | Doxepin | 3,000 |
| Amitriptyline | 1,500 | Maprotiline | 2,000 |

D. Interference

Two pools of drug-free urine were spiked with drug standards to 50% below and 50% above cutoff concentrations. The drug concentrations were confirmed by GC/MS. The following compounds were evaluated for potential positive and/or negative interference using the CLIAwaived™ Inc. RDTC Cup. All compounds were dissolved in the spiked sample solutions and tested with the CLIAwaived™ Inc. RDTC Cup. An unaltered sample was used as a control.

No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 µg/ml.

| | | |
|------------------------|--------------------------|--------------------------------|
| Acetaminophen | Diphenhydramine | (+/-)Norephedrine |
| Acetone | Dopamine | Oxalic Acid |
| Albumin | (+/-)Epinephrine | Penicillin-G |
| Ampicillin | Erythromycin | Pheniramine |
| Ascorbic Acid | Ethanol | Phenothiazine |
| Aspartame | Furosemide | l-Phenylephrine |
| Aspirin | Glucose | β-Phenylethylamine |
| Atropine | Guaiaacol Glyceryl Ether | Procaine |
| Benzocaine | Hemoglobin | Quinidine |
| Bilirubin | Ibuprofen | Ranitidine |
| Caffeine | (+/-)Isoproterenol | Riboflavin |
| Chloroquine | Ketamine | Sodium Chloride |
| (+)-Chlorpheniramine | Levorphanol | Sulindac |
| (+/-)-Chlorpheniramine | Lidocaine | Theophylline |
| Creatine | Myoglobin | Tyramine |
| Dexbrompheniramine | (+)-Naproxen | 4-Dimethylaminoantipyrine |
| Dextromethorphan | Niacinamide | (1R,2S)-(-)-N-Methyl-Ephedrine |
| | Nicotine | |

E. Effect of Specimen pH

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to pH 4-9 and tested using the CLIAwaived™ Inc. RDTC Cup. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

F. Effect of Specimen Specific Gravity

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to specific gravity 1.003-1.04 and tested using the CLIAwaived™ Inc. RDTC Cup. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

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