CLIAwaived™ Inc. Single Drug Dipstick Test

Step-by-Step Testing Instructions

The *CLIAwaived Inc*. Single Drug Dipstick Test (SDDT) is a preliminary screening test that detects drugs-of-abuse in urine at specified detection levels. For a quantitative result or to confirm preliminary positive results, a more specific method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

This is a CLIA-Waived Test. A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read this entire Instruction Sheet carefully before use. If a laboratory modifies the following test instructions including QC, the test will be considered high complexity and no longer considered CLIA Waived. This Instruction Sheet provides a brief summary of the testing procedure. For more information see the Product Insert that is provided with the product.

Warnings and Precautions

- For *in vitro* diagnostic use only (not for internal use).
- Store the SDDT Test at room temperature 59°F to 86°F (15°C to 30°C).
- Keep the SDDT Test in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Do not use the SDDT Test after the expiration date printed on the pouch.
- Be careful with urine because it may contain infectious diseases. Always wear gloves and wash hands with soap and water after handling urine.
- To ensure that the test will work properly the testing instructions must be followed. Failure to do so may result in inaccurate screening results.
- Do not use this test if you are color-blind.

Limitations of the Test

- Use the test with human urine only.
- The test is for one time use only; it is not reusable.
- This test is a screening device; it does not detect the actual concentration of a drug.
- Contaminated or tainted urine sample may give false results.
- Certain foods or medications may cause the test to give false results.
- Send preliminary positive or uncertain results to a laboratory to confirm results.
- The colors of human urine usually range from amber yellow to very light yellow. Dark urine or urine with a brown or abnormal color should not be tested using this test. Dark urines should be sent to a laboratory for testing.

Expected Results

The SDDT Test should give a negative result when testing the urine of a normal healthy person. The SDDT Test Single Dip Card will give a preliminary positive result when the drug or drug metabolite is present in the urine at or above the detection level. The SDDT Test is only the first step in a two-step process for detecting drugs of abuse in urine. Any urine specimen that produced a questionable or preliminary positive result should be sent to a laboratory for confirmation testing with a more specific method.

Detection Levels

The *CLIAwaived Inc.* Single Drug Dipstick Test may not detect drug amounts lower than the detection levels.

Drug Test	Detection Level
THC	50 ng/mL
Cocaine	300 ng/mL
Opiates	300 ng/mL
Methamphetamine	500 ng/mL
Amphetamine	1000 ng/mL
Barbiturates	300 ng/mL
Benzodiazepine	300 ng/mL
Oxycodone	100 ng/mL
PCP	25 ng/mL
MDMA	500 ng/mL
TCA	1000 ng/mL
Methadone	300 ng/mL
Buprenorphine	10 ng/mL

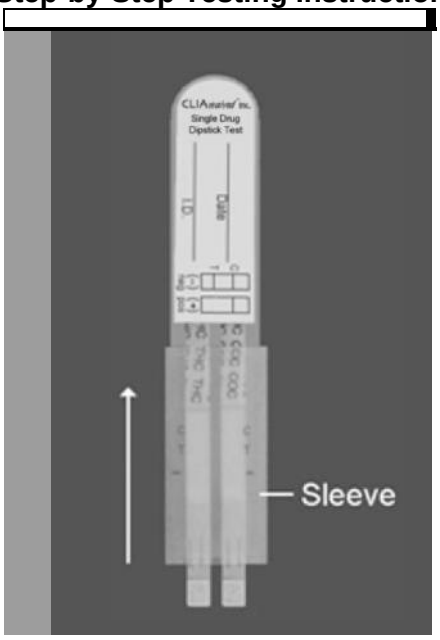
Quality Control

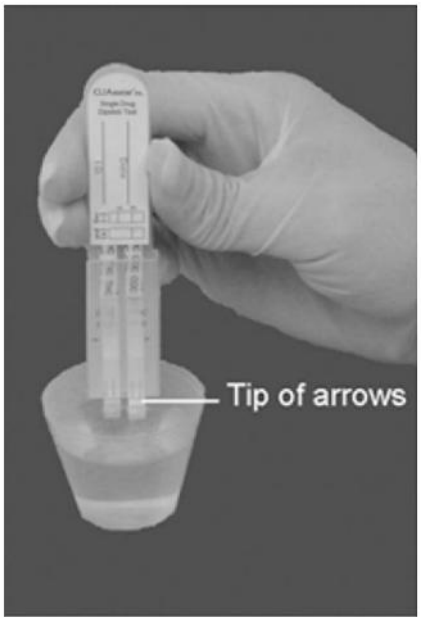
An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer's recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

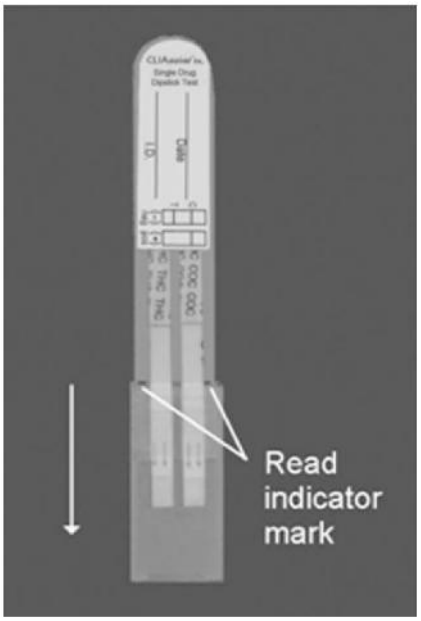
The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality control samples, follow the same testing procedure as for testing urine samples.

Contact the Customer Service Department at *CLIAwaived Inc.* at 1-888-882-7739 or email to info@cliawaived.com for the appropriate external controls. Do not use commercially available urine controls since these products may not be compatible with the SDDT Test.

Step-by-Step Testing Instructions

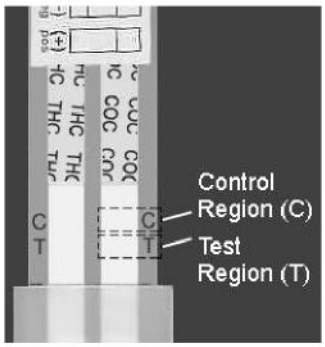
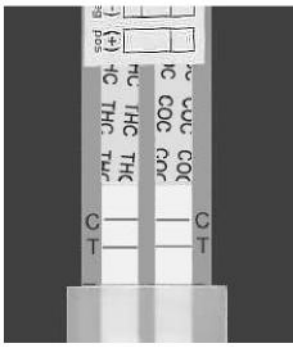
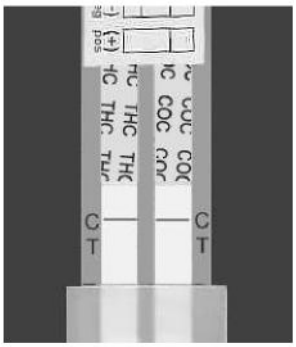
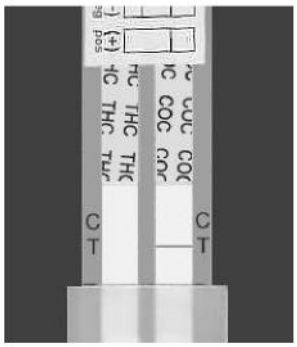






1. Open the pouch and remove the device from the pouch. 2. Write the urine sample ID number on the device. 3. Push the sleeve all the way up.	4. Dip the device into the urine sample for 10 seconds. Do not dip above the tip of the arrows.	5. Push the sleeve down to the Read Indicator Mark. Place the device on a flat surface.

Interpretation of Results

			
6. Read test results at 5 - 30 minutes*. *Read TCA and MTD results at 5-8 minutes. Do not interpret BUP results after 15 minutes. 7. The device may have two sides. Read test results on one side then turn the device over and read the test results on the other side.	*Look at each test strip separately* Negative (–) The result is negative when there are two red lines, one in the control region (C) and one in the test region (T). The picture above indicates that both the THC and COC tests are negative. *Note: Any test line, even a faint test line, is considered a negative result.*	*Look at each test strip separately* Preliminary Positive (+) The result is preliminary positive when there is a red line in the control region (C) and no line in the test region (T). The picture above indicates that both the THC and COC tests are preliminary positive since there are no red lines at the test region (T).	*Look at each test strip separately* Invalid The result is invalid when no line appears at the control region (C). The test is invalid even if there is a line in the test region (T). Do not use this result. Repeat the test using a new device. Contact *CLIAwaived Inc.* if you have any question. The picture above indicates that both the THC and COC tests are invalid.

CLIA*waived* Inc. Single Drug Dipstick Test

Rx Only

THC/COC/OPI/MET/AMP/PCP/BZO/BAR/MDMA/OXY/TCA/MTD/BUP

1-Panel: CLIA-SDDT-10, CLIA-SDDT-11, CLIA-SDDT-13, CLIA-SDDT-14, CLIA-SDDT-16, CLIA-SDDT-17, CLIA-SDDT-18, CLIA-SDDT-19, CLIA-SDDT-20, CLIA-SDDT-21, CLIA-SDDT-22, CLIA-SDDT-23, CLIA-SDDT-25

4-Panel: CLIA-SDDT-QF08, CLIA-SDDT-QF09, CLIA-SDDT-QF10, CLIA-SDDT-QF12

This package insert covers any single or combination test of THC, cocaine, opiates, methamphetamine, amphetamine, phencyclidine, benzodiazepines, barbiturates, MDMA, oxycodone tricyclic antidepressants, methadone, or buprenorphine in the *CLIAwaived Inc.* devices.

Intended Use

The *CLIAwaived Inc.* Single Drug Dipstick Test (SDDT) is an *in vitro* screen test for the rapid detection of a maximum of 4 drugs and drug metabolites (in any combination of the 13 listed below) in human urine at or above the following cutoff concentrations:

THC	11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/mL
COC	Benzoylecgonine	300 ng/mL
OPI	Morphine	300 ng/mL
MET	Methamphetamine	500 ng/mL
AMP	Amphetamine	1000 ng/mL
PCP	Phencyclidine	25 ng/mL
BZO	Oxazepam	300 ng/mL
BAR	Secobarbital	300 ng/mL
MDMA	3,4-methylenedioxymethamphetamine	500 ng/mL
OXY	Oxycodone	100 ng/mL
TCA	Nortriptyline	1000 ng/mL
MTD	Methadone	300 ng/mL
BUP	Buprenorphine	10 ng/mL

The SDDT Test provides visual qualitative results and is intended for *in vitro* diagnostic use in both laboratory and non-laboratory (CLIA Waived) settings. It is not intended for over-the-counter sale to nonprofessionals.

The SDDT Test provides only a preliminary screening test result. For a quantitative result or to confirm positive results obtained by the SDDT Test, a more specific alternative method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.[1]

Summary and Explanation

THC: THC use may impair short-term memory and inhibit learning capacity. It may also alter mood and sensory perceptions, cause loss of coordination, induce anxiety, paranoia, hallucinations, depression, confusion, and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur. Long term THC use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, insomnia, anorexia, and nausea.

COC: Cocaine derived from the leaves of the coca plant, is a potent central nervous system stimulant, and has been used as a local anesthetic. Cocaine use induces euphoria, confidence, and a sense of increased energy; these psychological effects are accompanied by increased heart rate, pupil dilation, fever, tremors, and sweating. Cocaine is generally smoked or administered intravenously or orally. Cocaine base can be smoked in the form commonly known as “crack”, which is likely to lead to dependence since the effect is more rapid and heightened. Cocaine is primarily excreted as benzoylecgonine and can generally be detected for 24–60 hours after cocaine use or exposure.[2]

OPI: Heroin, morphine and codeine are opiates that are derived from the resin of the opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide may both be found in the urine of a person who has taken only heroin. The body also converts codeine to morphine. Thus, the presence of morphine (or morphine metabolite) in the urine indicates heroin, morphine and/or codeine use. Generally, morphine and other opiates can be detected in the urine within 2 to 6 hours after use and remains detectable up to 3 days.[2,3] However, the length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of usage, metabolic rate, excretion rate, drug half-life, and the drug user’s age, weight, activity and diet.

MET: Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Methamphetamine use in acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. Methamphetamine is excreted in the urine as amphetamine and oxidized as deaminated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine can be detected in the urine within 4-6 hours after use and for 3-5 days, depending on urine pH level.[2,3]

AMP: Amphetamine is chemically related to the human body’s natural catecholamines, epinephrine, and norepinephrine. It has therapeutic applications and is a potent sympathomimetic agent. Amphetamine use in acute higher doses leads to enhanced stimulation of the central nervous system and induces euphoria, alertness, reduced appetite, and a sense of increased energy and power. Generally about 30% of amphetamine is excreted unchanged in 24-hour urine.

PCP: Phencyclidine is an arychlohexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, Angel Dust, Crystal Cyclone, Love Boat, Hog, or Killer Weed. PCP can produce lethargy, disorientation, and loss of coordination, visual distortion, euphoria, ataxia, and even coma. PCP can be taken orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys. The half-life of phencyclidine is about 3 days.

BZO: Benzodiazepines are anxiolytic drugs that are most widely prescribed and used as anti-anxiety agents. They are also used as hypnotics, muscle relaxants and anticonvulsants. Some metabolites of benzodiazepines also exhibit pharmacological activities. Use of benzodiazepines can result in drowsiness and confusion; it also potentiates alcohol and other central nervous system depressants. Psychological and physical dependence on benzodiazepines can develop if higher doses of the drug are given over a prolonged period.[1,2] Benzodiazepines are taken orally or by injection. The drug is metabolized in the liver and excreted in the urine as the parent compound or as oxazepam (in the case of chlorodiazepoxide and diazepam). Oxazepam is detectable in the urine for up to 7 days. [2,3]

BAR: Barbiturates are a class of central nervous system depressants. Phenobarbital has been used as a daytime sedative and extensively as an anticonvulsant. Phenobarbital is an example of long acting barbiturate derivative while pentobarbital and secobarbital are examples of short acting barbiturate sedatives. Barbiturate abuse can lead not only to impaired motor coordination and mental disorder, but also to respiratory collapse, coma and even death. Short acting barbiturates will generally be excreted in urine as metabolites, while long acting barbiturates will primarily appear unchanged. Barbiturates normally remain detectable in urine for 4 to 6 days after use (up to 30 days for phenobarbital).[2,3]

MDMA: 3,4-methylenedioxymethamphetamine (MDMA) is a synthetic drug that is chemically related to the amphetamine family of compounds. MDMA has been available as a street drug since the 1980s; however, since the 1990s its use has increased, particularly among teenagers and young adults. The drug has street names that include "Ecstasy, XTC, Clarity, Essence and Adam". MDMA is typically available in tablet form containing appropriately 60-150 milligrams of MDMA. The common method of use is oral ingestion, although the powder form can be snorted and occasionally smoked. MDMA has properties of both stimulants and hallucinogens. The effects of the drug last up to 6 hours after oral ingestion. The adverse effects include elevated blood pressure, increased heart rate, hyperthermia, dehydration, anxiety, paranoia and insomnia. The detection period of MDMA in urine is 1-3 days for single use and up to 5 days for heavy use.[1]

TCA: Tricyclic antidepressants (TCAs) are a type of prescription drugs used for the treatment of depressive disorders. Tricyclic Antidepressants consist of two main chemical classes. The tertiary amines boost serotonin levels and are usually prescribed for insomnia, irritability and overstimulation; these include amitryptiline, imipramine, trimipramine and doxepin. The secondary amines, which include nortryptinlline, desipramine and protryptiline, enhance norepinephrine levels and are prescribed for fatigue; withdrawal and inertness.[4-5]TCA abuse can result in respiratory depression, convulsions, blood pressure deviation, severe cardiac conditions, and coma. TCAs are taken orally or sometimes by injection. TCAs are excreted in the urine mostly in the form of metabolites for up to 10 days.

MTD: Methadone is a synthetic analgesic drug that is originally used for the treatment of narcotic addiction. Methadone use induced psychological effects such as 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. The major route of methadone excretion is in the urine. The effects of methadone last up to 24 hours after use and can be detected in the urine up to 14 days. [2,3] The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the user’s age, weight, activity and diet.

BUP: Buprenorphine is a synthetic derivative of thebaine with partial agonist and antagonist actions[6]. It is 25 to 40 times more potent than morphine as an analgesic. It has been used for the treatment of opiate addiction as an alternative to methadone. Buprenorphine has a half-life of 2-4 hours in plasma and complete elimination of a single dose can take up to 6 days.

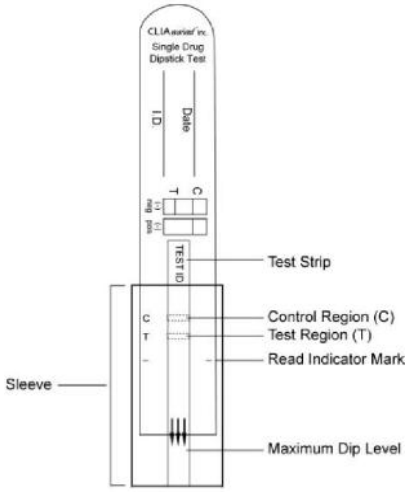
OXY: Oxycodone is a synthetic analgesic drug administered orally for the relief of pain. The major route of oxycodone excretion is in the urine. The effects of oxycodone last up to 4 hours after use. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of usage, metabolic rate, excretion rate, drug half-life, and the drug user’s age, weight, activity, and diet.[2,3]

Test Principle

Urine based screening tests for drugs of abuse are available from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for screening urine for drugs of abuse. The *CLIA waived Inc* line of drug screen cards is based on the principle of the highly specific immunochemical reactions between antigens and antibodies, which are used for the analysis of specific substances in urine.[1] The SDDT Test is based on a competitive immunoassay procedure in which immobilized drug conjugates compete with the drug(s) present in urine for limited antibody binding sites. The test device consists of individual test strips assembled into separate chambers of a plastic insert. On each membrane strip, a drug conjugate is pre-coated at a specific region known as the test region (T). A colored antibody-colloidal gold conjugate is coated onto a pad and placed at one end of the membrane strip. In the test procedure, the SDDT Test is dipped into a urine sample. This allows the urine into contact with the sample pads of the SDDT Test. The urine then migrates across the

membrane by capillary action. If any drug is present in the urine, it competes with the drug conjugate, which is immobilized on the membrane for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibody binding sites and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. The absence of a color band at a specific test region indicates a positive result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible band at the specific test region of the membrane. The presence of a color band at a specific test region indicates a negative result for that particular test.

A control band with a different antigen/antibody reaction is added to the immuno-chromatographic membrane strip at the control region (C) to indicate that the test performed properly. This control band should always appear regardless of the presence of drug or metabolite.



Reagents

Protein conjugate for benzoylecgonine, morphine, methamphetamine, THC, amphetamine, phencyclidine, benzodiazepine, barbiturate, methadone, nortriptyline, MDMA, oxycodone, or buprenorphine is coated onto the test region of the membrane.

The colored conjugate pad for each strip contains antibodies for benzoylecgonine, morphine, methamphetamine, THC, amphetamine, phencyclidine, benzodiazepine, barbiturate, methadone, tricyclic antidepressant, MDMA, oxycodone, or buprenorphine.

Materials Provided

Each SDDT Test Kit contains:

1. 1 Package Insert (directions for use).
2. 25 Dip Card Tests. Each device is packaged in a pouch with a desiccant.

Warnings and Precautions

- For *in vitro* diagnostics use only.
- For professional use only.
- The test device should remain in its original sealed pouch until ready for use. Discard the test device if package is ripped or torn.
- Handle all urine specimens as if potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.

Product Storage

The SDDT Test kit should be stored at room temperature (15°–30°C) until the expiration date on the pouch. Do not open pouch until ready to perform the assay.

Specimen Collection and Handling

The SDDT Test is formulated for use with urine specimens. Use only freshly voided, untreated urine.[4] Do not centrifuge or add preservatives to urine. Urine samples should be collected so that testing may be performed as soon as possible, preferably during the same day. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

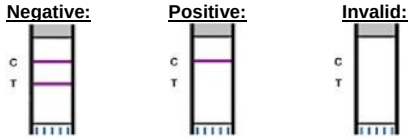
Note: All materials coming in contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid contact and follow good laboratory practice.

Test Procedure

IMPORTANT: Donor sample (urine specimen) should be brought to room temperature (15–30°C) prior to testing. Do not open pouch until ready to perform the assay.

1. Remove the test device from the sealed pouch.
2. Push the sleeve all the way up.
3. Dip the sample pad of the test device into the sample for at least 10 seconds. **Dip up to, but not beyond the tips of the arrows.**
4. Slide the sleeve down to the read indicator mark and lay the device on a level surface.
5. Once the control band (C) appears (in **5 minutes** or less) results are ready to interpret. Read results at 5 minutes.

Interpretation of Results



**Note: The above results are for illustration purposes only; see the explanations below for interpretation of results.*

Negative: The presence of a colored band at the control region (C) and a colored band at a specific test region (T) regardless of the intensity indicate that the result is negative for that particular test.

Positive: The presence of a colored band at the control region (C) and the absence of a colored band at the test region (T) indicate a positive result for that particular test.

Invalid: No band appears at the control region (C). The test is inconclusive even if there is a band in the test region (T). If the test device does not produce a band at the control region, check testing procedures, samples, and/or control materials, and repeat the test using a new device.

Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test bands at the test regions should be considered negative. The SDDT Test provides qualitative results for the presence of drug(s) at specified cut-off concentration(s). It is recommended that samples with a questionable test band and positive result be confirmed with a more specific quantitative method (Gas Chromatography/Mass Spectrometry).

Quality Control: Non-Waived Test Sites

Internal control: The SDDT Test has built-in internal procedural controls. The appearance of the control band (C) is considered an internal negative procedural control. This band should always appear if adequate sample volume is used and the testing procedure is followed. Additionally, the background color should become clear and provide distinct test result. If the control band (C) does not appear then the test is invalid. The test should be repeated using a new device.

External control: It is recommended that negative and positive urine controls be used to initially test each new lot of product to ensure proper kit performance. The same assay procedure should be followed with external control materials as with a urine specimen. When external controls do not produce the expected results, do not run test specimens. Follow the proper federal, state and local guidelines when running external controls.

Quality control testing at regular intervals is a good laboratory practice and may be required by federal, state or local guidelines. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

Quality Control: CLIA Waived Test Sites

An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer's recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality control samples, follow the same testing procedure as for testing urine samples.

Contact the Customer Service Department at CLIAwaived Inc. at 1-888-882-7739 or email to info@cliawaived.com for the appropriate external controls. Do not use commercially available urine controls since these products may not be compatible with the SDDT Test.

Limitations of Procedure

- The assay is designed for use with human urine only.
- Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances in certain food and medication may interfere with the test and cause false results. See Specificity section for the list of substances that will produce either positive results, or that do not interfere with test performance.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain food and/or medication.
- If it is suspected that the sample may have been mislabeled a new specimen should be collected.
- If it is suspected that the sample may have been tampered, a new specimen should be collected.

Performance Characteristics

Precision

For each specific drug test, drug-free normal urine was spiked with drug standards to various concentrations (-50%, -25%, +25% and +50%). For each concentration, a minimum of 25 tests were performed to validate the test performance around the cut-off concentration. The results for each drug test in the SDDT Test are summarized below:

Drug Test	Total # of Test / Conc.	Concentration							
		-50%		-25%		+25%		+50%	
		-	+	-	+	-	+	-	+
THC50	30	30	0	26	4	0	30	0	30
COC300	30	30	0	24	6	0	30	0	30
MOP300	30	30	0	25	5	4	26	0	30
MET500	30	30	0	25	5	2	28	0	30
AMP1000	30	30	0	24	6	1	29	0	30
PCP25	30	30	0	25	5	1	29	0	30
BZO300	30	30	0	26	4	0	30	0	30
BAR300	30	30	0	25	5	0	30	0	30
MDMA500	30	30	0	28	2	4	26	0	30
TCA1000	30	30	0	24	6	0	30	0	30
MTD300	30	30	0	26	4	3	27	0	30
BUP10	25	25	0	25	0	0	25	0	25
OXY100	30	30	0	27	3	2	28	0	30

Accuracy

The accuracy of SDDT Test was evaluated in comparison to the results from GC/MS analysis or other commercially available confirmatory methods. Minimum of thirty-six (36) negative urine samples were collected from volunteer donors and tested with each drug test strip. Of the 36 negative urine samples tested, all were found negative by both methods (100% agreement).

Additionally, for each drug test, a minimum of 40 clinical urine samples previously analyzed by GC/MS method with known concentration(s) of drug(s) values were blind labeled and evaluated. The results are summarized below:

Drug Test		GC/MS Neg.	GC/MS < -50%	GC/MS - 50% to < C/O	GC/MS ≥ C/O to +50%	GC/MS > +50%	% Agreement w/ GC/MS	
							Neg (-)	Pos(+)
THC50	Pos. (+)	0	0	1	6	33	97.6%	97.5%
	Neg. (-)	36	0	4	1	0		
COC300	Pos. (+)	0	0	2	6	34	95.3%	100.0%
	Neg. (-)	36	0	5	0	0		
MOP300	Pos. (+)	0	0	2	5	36	95.0%	100.0%
	Neg. (-)	36	0	2	0	0		
MET500	Pos. (+)	0	0	2	5	34	95.0%	97.5%
	Neg. (-)	36	0	2	1	0		
AMP1000	Pos. (+)	0	0	3	4	34	93.3%	95.0%
	Neg. (-)	36	0	6	2	0		
PCP25	Pos. (+)	0	0	1	4	36	97.5%	100.0%
	Neg. (-)	36	0	3	0	0		
BZO300	Pos. (+)	0	0	1	5	34	97.5%	97.5%
	Neg. (-)	36	0	3	1	0		
BAR300	Pos. (+)	0	0	2	5	34	95.3%	97.5%
	Neg. (-)	36	0	5	1	0		
MDMA500	Pos. (+)	0	0	1	3	36	97.5%	97.5%
	Neg. (-)	36	0	3	1	0		
TCA 1000	Pos. (+)	0	0	3	29	11	92.9%	97.6%
	Neg. (-)	36	0	3	1	0		
MTD 300	Pos. (+)	0	0	2	6	34	95.2%	100.0%
	Neg. (-)	36	0	4	0	0		
BUP 10	Pos. (+)	0	0	3	6	33	94.1%	100.0%
	Neg. (-)	40	3	5	0	0		
OXY 100	Pos. (+)	0	0	2	4	35	95.1%	97.5%
	Neg. (-)	36	0	3	1	0		

CLIA Waiver Performance

Accuracy and Precision

To demonstrate that the SDDT Test is a simple test and can be used by untrained users to obtain accurate test results, site studies were conducted at three (3) non-laboratory sites. The participants (untrained users) at these sites are non-laboratory professionals with no training or previous experience with drugs-of-abuse tests or the SDDT Test device. The participants are a demographically diverse population that includes a range of ages, educational and regional background and are representative of the users of a CLIA Waived test.

For each specific drug test contained in the SDDT Test, drug-free normal urine was spiked with drug standards to various concentrations (-50%, -20%, +20% and +50%). Each of the concentration was divided into 20 aliquots and each aliquot was blind-labeled with a unique code. A total of 20 tests per concentration were performed at each of the three sites to validate the test performance around the cut-off concentration. The results are summarized below:

Site	Conc.	# of sample per conc. per test	*CLIAwaived Inc.* Device							
			THC50		COC300		MET500		MOP300	
			-	+	-	+	-	+	-	+
1	-50%	20	20	0	20	0	20	0	20	0
	-20%	20	18	2	20	0	19	1	20	0
	+20%	20	0	20	1	19	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20
2	-50%	20	20	0	20	0	20	0	20	0
	-20%	20	20	0	19	1	20	0	19	1
	+20%	20	1	19	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20
3	-50%	20	20	0	20	0	20	0	20	0
	-20%	20	18	2	20	0	20	0	20	0
	+20%	20	1	19	0	20	0	20	1	19
	+50%	20	0	20	0	20	0	20	0	20
Total (-) per test			118		120		119		120	
Total (+) per test			122		120		121		120	

Site	Conc.	# of sample per conc. per test	*CLIAwaived Inc.* Device							
			AMP1000		BZO300		BAR300		OXY100	
			-	+	-	+	-	+	-	+
1	-50%	20	20	0	20	0	20	0	20	0
	-20%	20	20	0	20	0	20	0	19	1
	+20%	20	1	19	0	20	1	19	0	20
	+50%	20	0	20	0	20	0	20	0	20
2	-50%	20	20	0	20	0	20	0	20	0
	-20%	20	20	0	19	1	20	0	20	0
	+20%	20	0	20	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20
3	-50%	20	20	0	20	0	20	0	20	0
	-20%	20	20	0	20	0	19	1	20	0
	+20%	20	0	20	1	19	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20
Total (-) per test			121		120		120		119	
Total (+) per test			119		120		120		121	

Site	Conc.	# of sample per conc. per test	*CLIAwaived Inc.* Device									
			PCP25		MDMA500		MTD300		TCA1000		BUP10	
			-	+	-	+	-	+	-	+	-	+
1	-50%	20	20	0	20	0	20	0	20	0	20	0
	-20%	20	20	0	20	0	19	1	20	0	20	0
	+20%	20	1	19	0	20	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20
2	-50%	20	20	0	20	0	20	0	20	0	20	0
	-20%	20	19	1	19	1	20	0	19	1	20	0
	+20%	20	1	19	0	20	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20
3	-50%	20	20	0	20	0	20	0	20	0	20	0
	-20%	20	18	2	19	1	20	0	20	0	20	0
	+20%	20	1	19	0	20	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20
Total (-) per test			120		118		119		119		120	
Total (+) per test			120		122		121		121		120	

The percent of correct results of all drug tests for the strong negative (-50%) and strong positive (+50%) was 100% (95% CI: 93% to 100%). The percent of correct results for the weak negative (-20%) was from 93.3% (95% CI: 84% to 98%) for the THC and PCP tests to 100% (95% CI: 93% to 100%) for the AMP and BUP tests. The percent of correct results for the weak positive (+20%) was from 95% (95% CI: 86% to 99%) for the PCP test to 100% (95% CI: 93% to 100%) for the AMP, OXY, MTD, TCA, MDMA and BUP tests.

The data demonstrated that there was no statistically significant difference in the percent of correct results among the three sites for strong negative, weak negative, weak positive, and strong positive concentrations for all the above-mentioned drugs.

Specificity

The effects of pH and specific gravity of the specimen on the performance of the drugs-of-abuse tests at cutoff levels were tested. Results obtained were acceptable and not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030.

The specificity study for the drug test was evaluated by adding structurally related compounds to normal human urine. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

THC 50 ng/ml

Compound	ng/ml	Compound	ng/ml
Cannabidiol	100,000	11-Hydroxy-Δ9-THC	2,500
Cannabinol	100,000	Δ-8-Tetrahydrocannabinol	7,000
11-nor-Δ-8-THC-9-COOH	50	Δ-9-Tetrahydrocannabinol	10,500
11-nor-Δ-9-THC-9-COOH	50		

COC 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Benzoylecgonine	300	Ecgonine	100,000

OPI 300 ng/ml

Compound	ng/ml	Compound	ng/ml
6-Acetylmorphine	500	Hydrocodone	1,000
Codeine	300	Hydromorphone	400
Dihydrocodeine	500	Morphine	300
Ethyl morphine	300	Morphine-3-β-D-Glucuronide	500
Heroin	100	Nalorphine	5,000

MET 500 ng/ml

Compound	ng/ml	Compound	ng/ml
Ephedrine	10,000	l-Methamphetamine	25,000
p-Hydroxymethamphetamine	1,750	Procaine	50,000
d,l-3,4-MDMA	1000	Trimethobenzamide	75,000
d-Methamphetamine	500		

AMP 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
d-Amphetamine	1,000	Phentermine	3,000
l-Amphetamine	25,000	β-Phenylethylamine	100,000
d,l-3,4-MDA	5,000		

PCP 25 ng/ml

Compound	ng/ml
Phencyclidine	25

BZO 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Alprazolam	150	Lorazepam	1,500
Bromazepam	800	Lormetazepam	1,000
Chlordiazepoxide	2,000	Medazepam	2,000
Clobazam	200	Nitrazepam	1,000
Clonazepam	4,000	Nordiazepam	100
Delorazepam	6,000	Oxazepam	300
Diazepam	150	Prazepam	1,000
Estazolam	300	Temazepam	150
Flunitrazepam	1,000	Triazolam	1,500
Flurazepam	300		

BAR 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Allobarbital	1,500	Butalbital	300
Alphenal	400	Butethal	400
Amobarbital	1,500	Pentobarbital	400
Aprobarbital	400	Phenobarbital	400
Barbital	400	Secobarbital	300
Butabarbital	400		

MDMA 500 ng/ml

Compound	ng/ml	Compound	ng/ml
d,l-3,4-MDA	2,000	d,l-3,4-MDMA	500
d,l-3,4-MDEA	250	d-Methamphetamine	50,000

OXY 100 ng/ml

Compound	ng/ml	Compound	ng/ml
Codeine	10,000	Oxycodone	100
Hydrocodone	600	Hydromorphone	25,000

MTD 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Doxylamine	50,000	Methadone	300
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrolidine	50,000	Pheniramine	75,000

TCA 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
Amitryptiline	1,000	Nordoxepin	1,000
Clomipramine	7,500	Nortriptyline	1,000
Cyclobenzaprine	1,500	Perphenazine	50,000
Desipramine	750	Promazine	10,00
Doxepin	1,000	Protryptiline	350
Imipramine	750	Trimipramine	1,500

BUP 10 ng/ml

Compound	ng/ml	Compound	ng/ml
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine Glucuronide	5	Norbuprenorphine	50

Interference

The following compounds were found not to cross-react with the SDDT Test when tested at concentrations of 100 µg/ml (100,000 ng/ml):

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol)
Acetone
6-Acetylmorphine *(except MOP assay)*
Acetylsalicylic acid (Aspirin)
Albumin
Allobarbital *(except BAR assay)*
Alphenal *(except BAR assay)*
Alprazolam *(except BZO assay)*
Amitriptyline *(except TCA assay)*
Amobarbital *(except BAR assay)*
Amoxapine
Amoxicillin
Aprobarbital *(except BAR assay)*
d-Amphetamine *(except AMP assay)*
l-Amphetamine *(except AMP assay)*
Ampicillin
Apomorphine
l-Ascorbic Acid (Vitamin C)
Aspartame
Atropine
Barbital *(except BAR assay)*
Benzilic acid
Benzocaine (Ethyl p-Aminobenzoate)
Benzoic acid
Benzoylecgonine *(except COC assay)*
Benzphetamine
Bilirubin
Bromazepam *(except BZO assay)*
d-Brompheniramine
Buprenorphine *(except BUP assay)*
Buprenorphine Glucuronide *(except BUP assay)*
Butabarbital *(except BAR assay)*
Butalbital *(except BAR assay)*
Butethal *(except BAR assay)*
Caffeine
Cannabidiol *(except THC assay)*
Cannabinol *(except THC assay)*
Clonazepam *(except BZO assay)*
Chlordiazepoxide *(except BZO assay)*
Chloroquine
d-Chlorpheniramine
d,l-Chlorpheniramine
Chlorpromazine
Cholesterol
Clobazam *(except BZO assay)*
Clomipramine *(except TCA assay)*
Cocaine
Codeine *(except MOP & OXY assays)*
Cortisone
l-Cotinine
Creatine
Creatinine
Cyclobenzaprine *(except TCA assay)*
Delorazepam *(except BZO assay)*
Deoxycorticosterone
Desipramine *(except TCA assay)*
Dextromethorphan
Diazepam *(except BZO assay)*
Dihydrocodeine *(except MOP assay)*
4-Dimethylaminoantipyrine
Diphenhydramine
Dopamine (3-Hydroxytyramine)
Doxepin *(except TCA assay)*
Doxylamine *(except MTD assay)*
Ecgonine *(except COC assay)*
Ecgonine Methyl Ester
d,l-Ephedrine *(except MET assay)*
l-Epinephrine
Erythromycin
Estazolam *(except BZO assay)*
β-Estradiol
Estrone-3-Sulfate
Ethanol
Ethyl Morphine *(except MOP assay)*
Ethyl-p-aminobenzoate
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrolidone *(except MTD assay)*
Flunitrazepam *(except BZO assay)*
Flurazepam *(except BZO assay)*
Furosemide
Gentisic acid
Glucose
Glutethimide
Guaiacol Glyceryl Ether
Hemoglobin
Heroin *(except MOP assay)*
Hippuric acid
Hydrochlorothizide
Hydrocodone *(except MOP & OXY assays)*
Hydrocortisone
Hydromorphone *(except MOP & OXY assays)*
p-Hydroxymethamphetamine *(except MET assay)*
11-Hydroxy-Δ-9-THC *(except THC assay)*
Ibuprofen
Imipramine *(except TCA assay)*
l-Isoproterenol
d,l-Isoproterenol
Ketamine HCl
Lidocaine
Lorazepam *(except BZO assay)*
Lormetazepam *(except BZO assay)*
Medazepam *(except BZO assay)*
Meperidine
Methadone *(except MTD assay)*
d-Methamphetamine *(except MET& MDMA assays)*
l-Methamphetamine *(except MET assay)*
Methaqualone
Methoxyphenamine
(1R,2S) N-Methyl-Ephedrine
2-Methylamine-Propiophenone
d,l-3,4-Methylenedioxyamphetamine *(except AMP & MDMA assays)*
d,l-3,4-Methylenedioxyethylamphetamine *(except MDMA assay)*
d,l-3,4-Methylenedioxymethamphetamine *(except MET& MDMA assays)*
Methylphenidate
Morphine *(except MOP assay)*
Morphine-3-β-D-Glucuronide *(except MOP assay)*
Nalidixic acid
Nalorphine *(except for MOP assay)*
Naloxone
d-Naproxen
Niacinamide
Nicotine
Nitrazepam *(except BZO assay)*
Norbuprenorphine *(except BUP assay)*
Norbuprenorphine Glucuronide *(except BUP assay)*
Nordiazepam *(except BZO assay)*
Nordoxepin *(except TCA assay)*
d,l-Norephedrine
Norethindrone
d-Norpropoxyphene
Nortriptyline *(except TCA assay)*
Oxalic Acid
Oxazepam *(except BZO assay)*
Oxolinic acid
Oxycodone *(except OXY assay)*
Papaverine
Penicillin-G (Benzylpenicillin)
Pentazocaine
Pentobarbital *(except BAR assay)*
Perphenazine *(except TCA assay)*
Phencyclidine *(except PCP assay)*
Pheniramine *(except MTD assay)*
Phenobarbital *(except BAR assay)*
Phenothiazine (Thiodiphenylamine)
Phentermine *(except AMP assay)*
Phenylephrine
β-Phenylethylamine *(except AMP assay)*
Prednisolone
Prazepam *(except BZO assay)*
Procaine *(except MET assay)*
Promazine *(except TCA assay)*
Promethazine
d-Propoxyphene
Protryptiline *(except TCA assay)*
d-Pseudoephedrine
Pyrrolidine
Quinidine
Quinine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital *(except BAR assay)*
Serotonin
Sodium Chloride
Sulfamethazine
Sulindac
Temazepam *(except BZO assay)*
Tetracycline
Δ8-THC *(except THC assay)*
Δ9-THC *(except THC assay)*
11-nor-Δ8-THC-9-Carboxylic Acid *(except THC assay)*
11-nor-Δ-9-THC-9-Carboxylic Acid *(except THC assay)*
Thiamine
Thioridazine
Triazolam *(except BZO assay)*
Trifluoperazine
Trimethobenzamide *(except MET500 assay)*
Trimipramine Maleate *(except TCA assay)*
Tryptamine
d,l-Tryptophan
Tyramine
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

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P/N: PI-X07-CLIA-SDDT Rev 1. 09/2018

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Made in the U.S.A. CE

GLOSSARY OF SYMBOLS

	Description	ISO 15223-1* Reference #	ISO 7000* Reference #
	Temperature limit	5.3.7	0632
	Consult instructions for use	5.4.3	1641
	Keep away from sunlight	5.3.2	0624
	Keep dry	5.3.4	0626
	Do not reuse	5.4.2	1051
	*In vitro* diagnostic medical device	5.5.1	Not applicable
	Batch code	5.1.5	2492
	Catalogue number	5.1.6	2493
	Use by date	5.1.4	2607
	Manufacturer	5.1.1	3082
	Contains sufficient for 25 tests	5.5.5	0518
R_x Only	For Prescription Use Only	Not applicable	Not applicable

*ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

ISO 7000: Graphical symbols for use on equipment – Registered symbols