

CDIA™ Drug Tests Dip card (Saliva)

CDIA™ Drug Tests Dip card (Saliva) is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human saliva at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	50
Barbiturate (BAR)	Barbiturate	50
Benzodiazepine (BZO)	Oxazepam	50
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoyllecgonine	20
Cotinine (COT)	Cotinine	40
Ecstasy (MDMA)	3,4-Methylenedioxyamphetamine	60
Ketamine (KET)	Ketamine	100
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	12
Methadone (MTD)	Methadone	35
Methadone Metabolites (EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Methamphetamine (MET)	D-Methamphetamine	50
6-MAM	6-Monoacetylmorphine	
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	50
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	Propoxyphene	50
Tramadol (TRA)	Tramadol	
Tricyclic Antidepressants (TCA)	Nortriptyline	40
Alcohol (ALC)	Alcohol	>0.02% B.A.C

General Description

CDIA™ Drug Tests Dip card (Saliva) is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening specific drugs and their metabolites without the need of instrumentation. The method employs a unique mixture of antibodies to selectively detect the elevated levels of specific drugs and their metabolites in saliva.

Amphetamine (AMP): Amphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and overall feeling of well-being. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Large doses and extended usage can result in higher tolerance levels and physiological dependency leading to substance abuse. The effect of amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the saliva in unchanged form, with the remainder as hydroxylated and deaminated derivatives. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of amphetamine in saliva..

Barbiturates (BAR): Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of barbiturate could develop tolerance and physiological dependency and lead to its abuse. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of barbiturates in saliva.

Benzodiazepines (BZO): Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (saliva) and the liver where it is conjugated to glucuronic acid. Large doses of benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of benzodiazepines are excreted unaltered in the saliva, most of benzodiazepines in saliva is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in

saliva for up to one week, which makes oxazepam a useful marker of benzodiazepines abuse. The test utilizes a monoclonal antibody to selectively detect elevated levels of benzodiazepines in saliva.

Buprenorphine (BUP): Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain buprenorphine HCl alone or in combination with naloxone HCl. Therapeutically, buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free buprenorphine and norbuprenorphine in saliva may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations. The plasma half life of buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in saliva is thought to be approximately 3 days. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of buprenorphine in saliva.

Cocaine (COC): Cocaine is an alkaloid present in Coca leaves (Erythroxine coca). Its pharmacological properties, such as stimulating and euphoric effects, have been known for centuries. Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In large dose, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Cocaine is excreted in the saliva primarily as benzoylecgonine, which can generally be detected for 24-48 hours after cocaine exposure. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of cocaine in saliva.

Cotinine (COT): Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. In a 24-hour saliva, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. The CDIA™ Cotinine Test Cassette (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of cotinine in saliva.

Ecstasy (MDMA): MDMA belongs to a family of man-made drugs. Its relatives include MDA and MDEA. They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood altering chemicals, such as cartoning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2-3 hours. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of MDMA in saliva.

Ketamine (KET): Ketamine is a drug used in human and veterinary medicine. Ketamine has a wide range of effects in humans, including analgesia, anesthesia, hallucinations and elevated blood pressure. Ketamine is primarily used for the induction and maintenance of general anesthesia, usually in combination with a sedative. The common way to abuse ketamine is smoking, inhalants, intravenous injection or drink. Ketamine is metabolized mostly into metabolites and only 5% of the prototype. The drug is metabolized quickly in the body, and usually can be detected within 2-3 hours after smoking. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of KET in saliva.

Marijuana (THC): THC (Δ^9 -tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). THC is central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short-term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increases heart rate. Large doses of marijuana could develop tolerances and physiological dependency and lead its abuse. The main metabolite excreted in the saliva is 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid, which is found in the saliva within hours of exposure and remains detectable for 3-10 days after smoking. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of marijuana in saliva.

Methadone (MTD): Detoxification using methadone can either be done relatively rapidly in less than a month or gradually over as long as six months. While a single dose has a rapid effect, maximum effect can take five days of use. The effects last about six hours after a single dose and a day and a half after long-term use in people with normal liver function. Methadone is usually taken by mouth and rarely by injection into a muscle or vein. Side effects are similar to those of other opioids. Commonly these include dizziness, sleepiness, vomiting, and sweating. Serious risks include opioid abuse and a decreased effort to breathe. Abnormal heart rhythms may also occur including prolonged QT. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can

be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of methadone in saliva.

Methadone Metabolites (EDDP): Methadone, a Schedule II controlled substance, is often used in the treatment of opiate addiction and pain management; it also has a high potential for abuse. Methadone is metabolized primarily into two pharmacologically inactive metabolites, EDDP and EMDP. EDDP represents a better saliva marker for monitoring methadone maintenance than testing for un-metabolized methadone alone. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of EDDP in saliva.

Methamphetamine (MET, mAMP): Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of methamphetamine are greater. Methamphetamine can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Methamphetamine is excreted in the saliva as amphetamine and oxidized and deaminated derivatives. However, 10 to 20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the saliva indicates methamphetamine use. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of methamphetamine in saliva.

6-MAM: 6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-AM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). The production of black tar heroin results in significant amounts of 6-MAM in the final product. 6-MAM is approximately 30 percent more active than diacetylmorphine itself. This is why despite lower heroin content, black tar heroin may be more potent than some other forms of heroin. The CDIA™ 6-MAM Test Cassette (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of 6-MAM in saliva.

Opiates (OPI): Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (saliva) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in saliva as result of heroin, morphine, codeine or poppy seed

intake. The CDIA™ Opiate Test Cassette (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of opiates in saliva..

Oxycodone (OXY): Oxycodone is an analgesic, which works by depressing the central nervous system. Oxycodone is abused for its opiate-like effects. In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) use. For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The drug is most often administered orally. Like other opiates, oxycodone can also depress the respiratory system resulting in suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of oxycodone abuse include extreme loss of appetite and weight, cramps, nausea, vomiting, excessive scratching and complaint of itching, excessive sweating, constipation, pin-point pupils and watery eyes, reduced vision, drowsiness, euphoria, trance-like states, excessive thirst, tremors, twitching, irritability, hallucinations and lethargy. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of oxycodone in saliva.

Phencyclidine (PCP): Phencyclidine, commonly known as PCP or “angel dust” is used primarily as recreational drug due to its hallucinogenic effects. It is generally self-administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. The effects of PCP are very much dose related. Small amounts of phencyclidine are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heart rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of phencyclidine can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of phencyclidine could develop tolerances and physiological dependency and lead to its abuse. PCP can be found in saliva within 4 to 6 hours after use and will remain in saliva for 7 to 14 days. Phencyclidine is excreted in the saliva as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of phencyclidine in saliva.

Propoxyphene (PPX): Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of propoxyphene in saliva.

Tramadol (TRA): Tramadol is a centrally acting opioid analgesic, used in treating moderate to severe pain. Tramadol possesses weak agonist actions at the μ -opioid receptor, releases serotonin, and inhibits the reuptake of norepinephrine. Tramadol undergoes hepatic metabolism, being O- and N- demethylated to five different metabolites. Of these, O-desmethyltramadol is the most significant. Approximately 30% of the dose is excreted in the saliva as unchanged drug, whereas 60% of the dose is excreted as metabolites, the remainder is excreted either as unidentified or an unextractable metabolites. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of tramadol in saliva.

Tricyclic Antidepressants (TCA): Tricyclic Antidepressants are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscularly injection (IM). The symptoms of TCAs overdoses include agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to several days. The commonly used TCAs are excreted with a very low percentage of unchanged drugs in the saliva. Therefore, detection of the metabolites of TCAs in human saliva has been used for screening the abuse of TCAs. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of TCAs in saliva.

Alcohol (ALC): Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02 g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. The CDIA™ Drug Tests Dip card (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Alcohol in saliva.

Principle of the Test

CDIA™ Drug Tests Dip card (Saliva) is a competitive binding immunoassay in which drugs and drug metabolites in a saliva sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of saliva specimen is applied to the sample pad of the test device, the saliva specimen migrates through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the saliva specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

Materials Provides

1. Drug Test Tube
2. Product insert
3. Procedure Card
4. Saliva Collector
5. Color chart for alcohol test (optional)
6. One instruction.

Materials Required but Not Provided

1. External controls
2. Timer

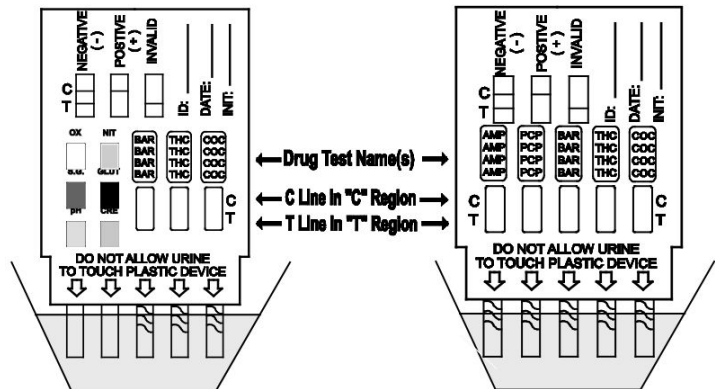
Specimen Collection and Preparation

The saliva specimen should be collected using the collector provided with the kit. No other collection devices should be used with this assay. Saliva collected at any time of the day may be used.

Assay Operation

Allow the test device, specimen and/or control to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection of saliva specimen.

1. Open the sealed pouch, then remove the saliva collector from the sealed plastic bag.
2. Insert the sponge into the mouth, actively swab the inside of the mouth and tongue to collect saliva for approximately 3 minutes until the sponge becomes soft and fully saturated. The sponge will be free from hard spots when fully saturated.
3. Remove the test tube from the pouch, put the tube on a flat surface. Remove the collector from the mouth and put the saturated saliva collector into the strainer of the tube (on the central of the bottom).
4. Keep the tube upright, push the Cap into the tube vertically and start the timer.
5. Read the test results in 5 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes.



Results

Negative: Two lines appear. One colored line should be in the control region (C) and another apparent colored line should be in the test line region (T).



Positive: One colored line appears in the control line region (C). No line appears in the test line region (T).



Invalid: Line C has no color, which indicates the strips are invalid. In this case, please read the instructions again, and redo the assay with new cassette device.



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.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

Limitation

1. The CDIA™ Drug Tests Dip card (Saliva) 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) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.
4. There is a possibility that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.

Storage

The CDIA™ Drug Tests Dip card (saliva) can be stored at room temperature or refrigerated (2-30°C). It is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Notice for Operations

1. Please do the assay following the instruction, don not touch the membrane of the strip.
2. This Tests Dip card is used for only once; please do not use it repeatedly.