

Druglizer

DRUGLIZER LE5: CARTRIDGE & ORAL FLUID COLLECTOR

Part of the Druglizer LE5 Drug Testing System – for rapid screening of drugs of abuse.

INTENDED USE

Druglizer LE5 Drug Testing System is for the rapid oral fluid screening of drugs of abuse. The system incorporates a Druglizer Cartridge, a Druglizer Oral Fluid Collector and a LE5 Drug Tester. The system is intended to be used by a trained professional to provide a first line screen. An 'on' or 'off' response will require confirmation by a laboratory based reference assay like Gas chromatography – Mass Spectrometry or Liquid Chromatography – Mass Spectrometry.

Druglizer LE5 Drug Testing System is available in a number of drug formats which include screening for Marijuana, Methamphetamine, Amphetamine, Opiates, Cocaine, Benzodiazepine, and Oxycodone.

TEST PRINCIPLE

The Druglizer LE5 Drug Testing System is based on a competitive lateral flow immunoassay technique where drug molecules that may be present in the oral fluid sample compete with the same drug attached to the nitrocellulose wicking membrane, for limited binding sites on tagged drug specific antibodies. For THC a sandwich assay is used. The antibodies are tagged with gold colloids to produce a conjugate with a red colour.

During testing, an oral fluid sample is absorbed onto the oral fluid collector pad. Chemicals react with the saliva to remove sample interferences a portion of this sample wicks onto the conjugate pad where drugs in the sample react with tagged antibody specific for the drug. The sample continues to wick by capillary forces along the nitrocellulose membrane, onto which is attached the same drug of interest. If no drug is present in the oral fluid sample the tagged antibody can bind to the drug bound to the nitrocellulose and a red line is produced.

If drug is present in the oral fluid sample at concentrations greater than the cut-off concentration the tagged antibody sites will be saturated with drug and will not be able to bind to the nitrocellulose bound drug, hence no line is produced.

As the drug concentration in the sample increases the colour intensity of the test line decreases. The test strip is not intended to be viewed visually rather it is intended to be interrogated by a meter. The meter measures the colour intensity of the membrane at the test line. The cut-off for a particular drug is based on this colour intensity. The opposite is true for THC as the greater the concentration, the stronger the red colour.

MATERIALS PROVIDED

- 25 Druglizer Cartridges – contains 3 lateral flow membranes mounted within a plastic cartridge.
- 25 Oral Fluid Collectors;

The LE5 Drug Tester is purchased separately. No timing devices are required.

WARNINGS AND PRECAUTIONS

- For professional use.
- If storing pouches in a fridge, allow the pouch environment to reach room temperature (+15 to +30°C) before use.
- Do not open pouch until just prior to use.
- Do not utilise a pouch if it is damaged or has been tampered with.
- Do not use contents after expiration date.
- Pouch contents are for single use only.
- Take precautions with oral fluid.
- Dispose of in as part of your non-recyclable waste and as per local waste requirements.
- **DO NOT insert the Oral Fluid Collector into the Cartridge until the Collector indicator changes to an even blue colour that is a consistent from edge to edge. Failure to follow this warning may result in an "Invalid" test.**

PRODUCT STORAGE

Store the pouch at room temperature from between +5° and +38°C. Do not freeze.

INTERPRETATION OF RESULTS

- **INVALID (grey)** – likely due to insufficient or premature saliva sampling.
- **NEGATIVE (green)** – drug concentration is zero or below the detectable level of the test.
- **UNCONFIRMED (red)** – concentration of drug is above detectable level of the test.
- Interpret only with an active Druglizer LE5 Drug Tester.

LIMITATIONS OF PROCEDURE

- Only human oral fluid should be used.
- Results on the LE5 Drug Tester are preliminary qualitative analytical test results. An 'on' or 'off' response will require confirmation by a laboratory based reference assay.
- The presumptive presence of drugs is not a measure of intoxication.
- A negative result may not necessarily indicate a drug free sample. Drugs may be present below the stated cut off.
- Foods/medicines or preclinical errors may result in false results.

DIRECTIONS FOR USE

Prior to use, the test device and cartridge should reach room temperature (+15 to +30°C). See overleaf for full instructions of use.

PERFORMANCE CHARACTERISTICS

Independent Laboratory Testing

Test strips were evaluated against the AS/NZ 4760:2019 standard at an independent laboratory and are compliant.

Testing used fresh saliva with no drugs provided a 'Negative' saliva, and with fresh saliva spiked to give drug concentrations at +50% of the cut-off, 'Positive' saliva.

The drug concentrations were verified using LC-MS/MS.

Ten independent tests were made at each drug concentration.

The drug calibrators used were Methamphetamine, Cocaine, Amphetamine, Oxycodone, Δ-9-THC and Morphine.

DRUG	CUT-OFF ng/ml	% ACCURACY NEG saliva (n=10)	% ACCURACY +ive saliva (n=10)
Methamphetamine	50 ng/ml	100	90
Cocaine	50 ng/ml	90	100
Amphetamine	50 ng/ml	100	80
Δ9-THC	15 ng/ml	100	100
Opiates	50 ng/ml	100	90
Oxycodone	40 ng/ml	100	100

SPECIFICITY

Druglizer LE5 results listed in the following table are based on our manufacturers statements provided. The specificity was evaluated by testing various drugs, their metabolites and other drugs present in oral fluid. All compounds are prepared in an artificial saliva. Positive results are obtained at concentrations greater than that listed.

DRUG TEST	TEST COMPOUNDS	CONCENTRATION (ng/ml)
Amphetamine (AMP50)	D-Amphetamine	50
	L-Amphetamine	4,000
	β-Phenylethylamine	25,000
	Tryptamine	12,500
	p-Hydroxyamphetamine	100
	(+)-3,4Methylenedioxyamphetamine (MDA)	100
Cocaine (COC50)	Methoxyphenamine	12,500
	Benzoylcegonine	50
	Cocaine	50
	Cocaeethylene	50
	Ecgonine	3,000
Marijuana (THC15)	Ecognine methyl ester	25,000
	Δ9-Tetrahydrocannabinol	15
	Δ8-Tetrahydrocannabinol	35
	11-nor-Δ9-THC-9 COOH	>1000
Methamphetamine (MET50)	11-hydroxy-Δ9-THC	5
	d-Methamphetamine	50
	Fenfluramine	60,000
	p-Hydroxymethamphetamine	400
	L-Phenylephrine	6,250
	MDEA	50

	MDMA	50
	Procaine	2,000
	Methoxyphenamine	25,000
	Mephentermine	1,500
	Ephedrine	400
	Benzphetamine	25,000
Opiates (OPI50)	Morphine	50
	Codeine	30
	Diacetylmorphine (Heroin)	75
	Ethylmorphine	30
	Hydrocodone	125
	Hydromorphone	125
	6-Monoacetylmorphine (6-MAM)	25
	Morphine-3-β-D-Glucuronide	75
	Nalorphine	12,500
	Oxycodone	31,250
	Oxymorphone	31,250
	Thebaine	2,500
	Levorphanol	500
	Norcodeine	9,000
	Normorphine	31,250
	Pholcodine	500
	Methadone	1,000
	Dolantin	1,000
Benzodiazepine (BZO10)	Clobazam	10
	Clonazepam	25
	Delorazepam	50
	Alprazolam	10
	Hydroxyalprazolam	100
	Bromazepam	50
	Chlordiazepoxide	50
	Clorazepate	25
	Diazepam	100
	Estazolam	400
	Desalkylflurazepam	10
	Flunitrazepam	10
	Lorazepam	200
	Nordiazepam	50
	Midazolam	400
	Norchlordiazepoxide	10
	Oxazepam	10
Temazepam	10	
	Tranxene	25
	Triazolam	200
Oxycodone (OXY40)	Oxycodone	40
	Oxymorphone	80
	Lorazepam	10,000
	Hydrocodone	1,500
	Hydromorphone	10,000
	Naloxone	5,000
	Naltrexone	5,000

BIBLIOGRAPHY

1. Oral Fluid Testing for Drugs of Abuse. Bosker W.M. Huestis M.A – *Clin.Chem* 55:11 1910-1931 2009.
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3. Current knowledge on cannabinoids in oral fluid. Lee D, Huestis M.A – *Drug Test Analysis* 2014, 6, 88-111.
4. Methamphetamine: An update on epidemiology, pharmacology, clinical phenomenology and treatment literature. Courtney K.E Ray L.A – *Drug Alcohol Depend.* 2014, Oct 1; 143: 11-21.

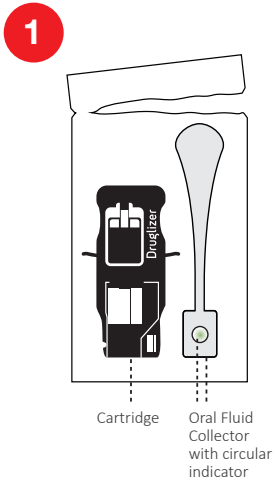
Alcolizer Pty Ltd | www.alcolizer.com
36 Mumford Place, Balclatta WA 6021, Australia.

Reference: 00755-00

Druglizer

LE5 drug tester

Druglizer Cartridge & Oral Fluid Testing



It is recommended the subject **not consume food, beverages or smoke at least 15 minutes prior to oral fluid (saliva) collection.**



It is important the subject declare any medication that might affect the test results. This includes prescribed, non-prescribed and illicit substances. The presence of any medication may result in false results and this information is vital for laboratory confirmation.

Inspect the pouch and collector packet for damage or evidence of tampering. Do not use a pouch or collector if it is damaged or has been tampered with. Do not open the pouch containing the test cartridge until just prior to use.

Tear open the pouch containing a Druglizer Cartridge and Druglizer Oral Fluid Collector.



Turn the Druglizer LE5 Drug Reader Module into the Druglizer LE5 Drug Tester on. The "Insert Cartridge" message will display.

Take the Druglizer Cartridge and insert it into the top of the Druglizer LE5 Drug Reader Module.

The flat area should face back while the area with the collector recess should face towards the front. When inserted the screen will display "Collect Saliva Sample" and start a 60 second countdown.



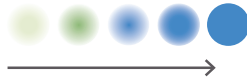
Instruct subject to insert "collector" inside of mouth and wipe inside of each cheek four times.

Instruct subject to place "collector" on top of tongue, close mouth and tilt head towards chest.

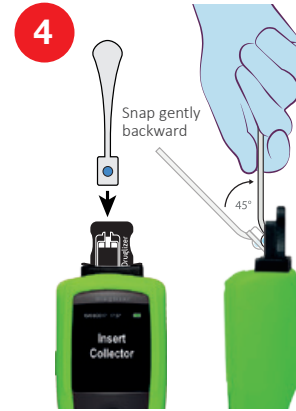
Instruct subject to stay in this position for 60 seconds (to be timed for best results) and push the saliva into the sponge of the "collector" to flood the sponge with saliva. Instruct subject to not suck or chew on the sponge.

When removing collector from mouth take care not to drag across teeth or gums to prevent loss of saliva.

IMPORTANT: Druglizer LE5 Drug Tester training **MUST** be undertaken in order to ascertain correct saliva collection. Collect saliva until the Collector indicator changes to a **BLUE** that is consistent from edge to edge:



Failure to follow this instruction may result in an 'Invalid' test.

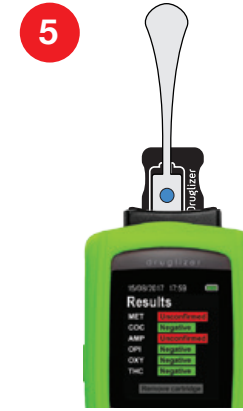


Position the Collector vertically with the pad facing downward.

Insert into the Druglizer Cartridge recess and snap (gently backward) into place.

The Druglizer LE5 Drug Tester will automatically detect the wetted collector and begin analysing after approximately 10 seconds.

Position the Druglizer LE5 Drug Tester horizontally – preferably on a flat surface. Orientation alerts will help you from moving or tilting the device while it is analysing a test sample.



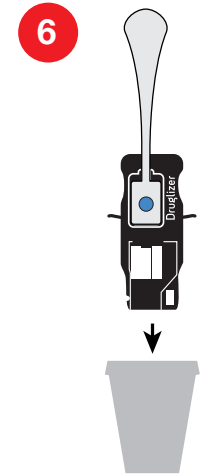
Allow up to 2 minutes for the device to provide results for all drug groups. They are updated as they are calculated and may display:

Negative (green)

Unconfirmed (red)

Invalid (grey)

Results can be accessed from the Druglizer LE5 Drug Tester at a later time.



After each test, pull out both the cartridge and collector and dispose of with other waste as per local waste disposal requirements.

The Druglizer LE5 Drug Tester will automatically reset and be ready to insert a new Druglizer Cartridge by displaying "Insert Cartridge".

Alcolizer
technology

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- Do not use contents beyond the expiry date printed on the pouch.
- Ensure the collector pad is not chewed during collection.