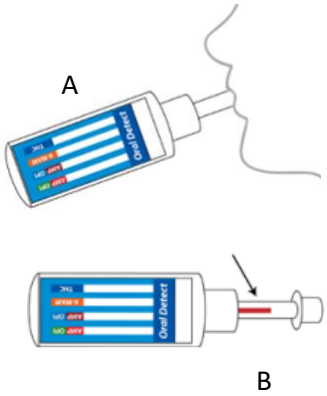
Oral Detect Quick User Guide

1



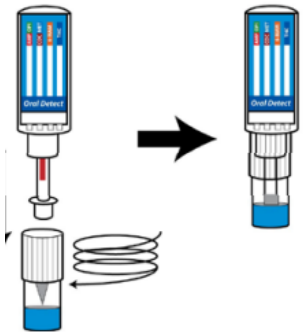
To begin collection, place the sponge end of the device into the donor's mouth. Have the donor **gently** sweep the sponge inside of their mouth, across their inner cheeks, gums and tongue.

Hold horizontally with collection sponge under the tongue. Collection should occur for at least 1 - 2 mins.

Do not bite, chew or suck on the sponge.

Collection is complete when the volume sufficiency indicator turns red as shown in figure B above.

2



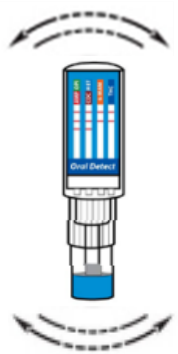
While holding the cap in one hand and main body of the device firmly in the other hand, thread the sponge into the cap of the device.

Keep the device upright while doing this step (strips at the top, cap at the bottom).

Continue to turn the sponge into the cap until all the thread has been used up.

The device and contents are now sealed

3



Gently shake the device 5 times right to left, until each strip starts to wet in the viewing window.

*If any drug strip is not activated, repeat shaking until the strip becomes wet and activated in the viewing window.

Note: The movement is a gentle left to right motion. Not a vigorous up/down movement.

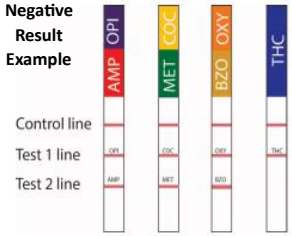
4

Stand the device Vertical. Read the results as per below.

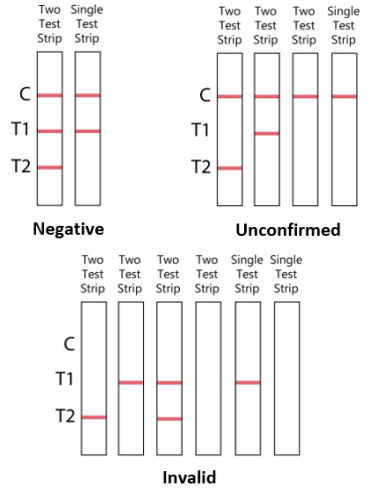
Negative results can be read as soon as the test line and control line appear on any strip **(often within 2 minutes).**

ANY shade of colour in the test region is considered negative regardless of how faint the line is.

Unconfirmed test results should be read at



INTERPRETATION OF RESULTS



UNCONFIRMED: A coloured band appears in the control region (C) but not at the test region. A positive result indicates that the drug concentration exceeds the detectable level.

NEGATIVE: Two coloured bands appear on the strip. One band appears in the control region (C) and another band appears in the test region (T). Negative results can be read as soon as test and control line appear on any strip (often within 2 minutes). A negative result indicates that the drug concentration is absent, or present but below the detectable level.

INVALID: No line appears at the control region. An invalid result means that the collection should be performed again and to ensure that enough saliva was collected.

NOTE:

1. The intensity of colour in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore**, any shade of colour in the test region (T), even if faint, should be considered negative.** Please note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

3. **The THC and BZO strip do not wick as quickly as the other strips. These strips are designed to wick slowly, which allows the sample and the antibody to incubate.**

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UNDERSTANDING THE TEST RESULTS

1. An unconfirmed test result does not always mean a person took illicit substances and a negative test result does not always mean a person did not take illicit substances It indicates that the individual does not have a detectable amount of the drug in their system as per AU/NZ 4760:2019 Standard.
2. An unconfirmed result sample must be tested by the laboratory to determine if a drug of abuse is present. Please refer to the Confirmation Testing section of this labeling.
3. ***What Is A False Positive Test***? The definition of a false positive test would be an instance where the Oral Detect device is positive even though target drugs are not in the sample. The most common causes of a false positive test are cross-reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.
4. ***What Is A False Negative Test***? The definition of a false negative test is that the initial target drugs are present but is not detected by Oral Detect. If the sample is diluted, or the sample is contaminated this may cause a false negative result. Please refer to the Specimen Collection and Procedure Sections of the insert for instructions to minimise or prevent sample dilution or contamination (such as from food or drinks in the mouth).

- Oral Detect should be only used for the qualitative detection of drugs of abuse in oral fluid.

LIMITATIONS

- This assay provides a presumptive analytical test result only. A more specific laboratory confirmation must be used to obtain a confirmed analytical result. Careful consideration and judgement should be applied to any test result, particularly when unconfirmed results are indicated.
- There is a possibility that technical or procedural errors, as well as other substances and factors, may interfere with the test and cause false results.
- An unconfirmed result indicates the presence of a drug/metabolite only and does not indicate or measure intoxication.
- A negative result does not at any time rule out the presence of drugs/metabolites in saliva, as they may be present below the minimum detection level of the test.
- This test does not distinguish between drugs of abuse and certain medications.

QUALITY CONTROL

- Oral Detect provides a built-in control band for each test strip to indicate that the test has performed correctly. The control band should always appear regardless of the presence of drugs it confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.
- The unconfirmed positive sample should be mailed to the laboratory the same day.

PERFORMANCE CHARACTERISTICS

B. Sensitivity

A pool of oral fluid control was spiked with drugs to target concentrations that were ±50% and 3X of the cut-off and tested with the Oral Detect Oral Fluid Drug Test. The results are summarized below where "N" is the number of samples evaluated.

Drug Conc. (Cutoff range)	N	AMP		BZO		COC		MET		OPI		OXY		THC	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
3X Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

C. Specificity

The following table lists the concentrations of compounds in (ng/mL) above which the Oral Detect Oral Fluid Drug Test identified unconfirmed results at 10 minutes.

Amphetamine related compounds	**Concentration (ng/mL)**	**Marijuana related compounds**	**Concentration (ng/mL)**
d-Amphetamine	50	Δ9-Tetrahydrocannabinol	15
(+/-)- Octopamine	5,000	Cannabinol	7,000
Benzodiazepine related compounds	**Concentration (ng/mL)**	(±)-11-Hydroxy-Δ9-THC	1,500
Oxazepam	10	11- nor -Δ9-THC-9 COOH	12.5
Temazepam	35	(-) Δ8 -THC	100
Desalkylflurazepam	400	(±) Δ8 -THC	40
Estazolam	60	**Methamphetamine related compounds**	**Concentration (ng/mL)**
Flunitrazepam	300	d-Methamphetamine	50
Lormetazepam	400	(1R,2S) - (-)-Ephedrine	200
Midazolam	500	Procaine Hydrochloride	500
Norchlordiazepoxide	50	MDMA	20
Nordiazepam Medazepam	40	(R) - (-)-Phenylephrine	100
Triazolam	500	(1R,2S) - (-)-N-Methylephedrine	350
Alprazolam	30	Adrenaline	5,000
Bromazepam	15	(±)-Methamphetamine Hydrochloride	10
α-Hydroxyalprazolam	100	Procaine Hydrochloride	50
Clobazam	20	3,4-Methylenedioxyethylamphetamine（3,4-MDEA）	500
Cocaine related compounds	**Concentration (ng/mL)**	**Opiate related compounds**	**Concentration (ng/mL)**
Cocaine	50	Morphine	50
Benzoylecgonine	50	Thebaine	6,250
Cocaethylene	25	Codeine	25
Oxycodone related compounds	**Concentration (ng/mL)**	Hydromorphone	25
Oxycodone	40	Hydrocodone	60
Levorphanol tartrate	10,000	6-monoacetylmorphine	60
Naloxone	2,000	6-Acetylcodeine	60
Naltrexone	2,000	Heroin	37.5
hydromorphone	2,000	Dihydrocodeine	50
Hydrocodone	1,000		

A. Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug- free oral fluid or drugs positive oral fluids. The following compounds show no cross-reactivity when tested with the Oral Detect Oral Fluid Drug Test at a concentration of 10 g/mL

Acetaminophen	Dextromethorphan	Kanamycin	Promethazine
Acetone	Diclofenac	Ketoprofen	Quinacrine
Acetophenetidin	Dicyclomine	Labetalol	Quinidine
Albumin	Diflunisal	Lidocaine	Ranitidine
Amoxapine	Digoxin	Lindane	Riboflavin
Amoxicillin	4-Dimethylaminoantipyrine	Loperamide	Sodium chloride
Ampicillin	Diphenhydramine	Meperidine	Sulfamethazine
Ascorbic acid	5,5-Diphenylhydantoin	Methoxyphenamine	Sulindac
Aspartame	Disopyramide	Metoprolol	Tetracycline
Aspirin	Dopamine	Nalidixic acid	Tetrahydrozoline
Atropine	Doxylamine	(+)-Naproxen	Theophylline
Benzocaine	Erythromycin	Niacinamide	Thiamine
Benzoic acid	Ethanol (Ethyl alcohol)	Nimesulide	Thioridazine
Bilirubin	Etodolac	Norephedrine	Tolbutamide
(+/-) Brompheniramine	Famprofazone	Norethindrone	Trazodone
Buspirone	Fenoprofen	Noscapine	Triamterene
Caffeine	Fluoxetine Hydrochloride	Orphenadrine	Trifluoperazine
Chloramphenicol	Furosemide	Oxalic acid	Trimethoprim
Chloroquine	Gentisic acid	Oxolinic acid	Trimipramine
(+/-)-Chlorpheniramine	D (+) Glucose	Oxymetazoline	Tryptamine
S- (+)-Chlorpheniramine maleate salt	Guaiacol Glyceryl Ether	Papaverine	Tyramine
Chlorpromazine	Hemoglobin	Pemoline	Uric acid
Chlorprothixene	Hydralazine	Penicillin-G	venlafaxine
Cimetidine	Hydrochlorothiazide	Perphenazine	Verapamil
Clomipramine	Hydroxyzine	Phenelzine	Zomepirac
Clonidine	Imipramine	Pheniramine	
Creatine	Isoproterenol hydrochloride	Phenothiazine	
Cyclobenzaprine	Isoxsuprine	β-Phenylethylamine	

LITERATURE REFERENCES

1. Moolchan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine", Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the FOFT-TIAFT meeting October 1998.
2. Jenkins, A.J., Oyler, J.M. and Cone, E.J. Comparison of Heroin and Cocaine Concentrations in Saliva with Concentrations in Blood and Plasma. J. Anal. Toxicology. 19: 359-374 (1995).
3. Kidwell, D.A., Holland, J.C., Athanaselis, S. Testing for Drugs of Abuse in Saliva and Sweat. J. Chrom. B. 713: 111-135 (1998).
4. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 10th ed.
5. Hawks RL, Chiang CN, eds. Oral Fluid Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute of Drug Abuse; 1986.

GLOSSARY OF SYMBOLS

REF	Catalog number	2°C 8°C	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	2	Do not reuse
CE	CE Mark under Directive IVDD 98/79/EC	EC REP	Authorized representative

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