PRECISION SalivaScan™

For Forensic use only

INTENDED USE

The Oral Screen Saliva Drug Test is a rapid visual immunoassay for the qualitative detection of drugs of abuse in human oral fluid specimens. The test system consists of up to 16 membrane strips mounted in a plastic device. This test detects combinations of the following drugs at the concentrations listed below. Specific combinations will vary according to the test in question:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	40/50
Barbiturate(BAR)	Secobarbital	50
Benzodiazepine (BZO)	Oxazepam	10/50
Buprenorphine(BUP)	Buprenorphine	5
Cocaine (COC)	Cocaine	20/30/50
Cotinine(COT)	Cotinine	50
MEP	Mephedrone	100
MQL	Methaqualone	30
MDPV	3,4-Methylenedioxypyrovalerone	50
EDDP(EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Dip henylpyrrolidine	20
K2	JWH-018/JWH-073	30
Ketamine (KET)	Ketamine	50/100
Methadone (MTD)	Methadone	30/50
Fentanyl(FYL)	Fentanyl	10
Tricyclic Antidepressants(TCA)	Nortriptyline	100
Methamphetamine (MET)	D-Methamphetamine	50/40
Ecstasy (MDMA)	3,4-Methylenedioxymethampheta mine	50/40
6-MAM	6-Monoacetylmorphine	10
Opiates (OPI)	Morphine	25/40/50
Oxycodone(OXY)	Oxycodone	20/40
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene(PPX)	Propoxyphene	50
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	12
Marijuana (THC parent)	Δ^9-THC	30/50
Tramadol(TRA)	Tramadol	30
Alcohol（ALC）	Alcohol	0.02%

PRINCIPLE

The Oral Screen Saliva Drug Test is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

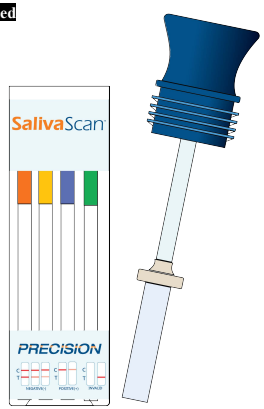
A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Saliva Alcohol Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

MATERIALS

Materials Provided

Individually packed screening devices
Oral fluid collection swabs
Package insert



Materials Required but Not provided

Timer
Positive and negative controls

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

STORAGE AND STABILITY

- The kit should be stored at 36-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The Oral Screen Saliva Drug Test is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.
- Perform testing immediately after specimen collection.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

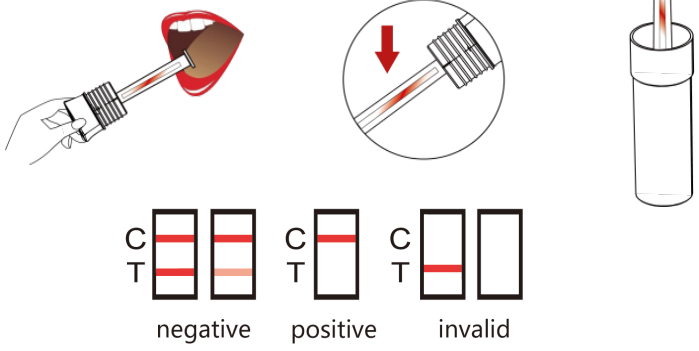
PROCEDURE

Bring tests, specimens, and/or controls to room temperature (60-86°F or 15-30°C) before use. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

- The oral fluid specimen should be collected using the collector provided with the kit. No other collection devices should be used with this assay.
- Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.
- Bring tests, specimens, and/or controls to room temperature (60-86°F or 15-30°C) before use.
- Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, and tongue) several times, and then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. Important: Do not bite, suck, or chew on the sponge.

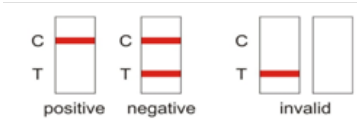
NOTE: After 7 minutes, proceed with the test below, even if color on the saturation indicator has not appeared in the indicator window.

- Remove the collection swab from the mouth and insert it, sponge first, into the screening device. Screw cap down tightly until fully locked.
- Test device upright on flat surface and keep upright while test is running. Wait for the colored bands to appear in test results area. Read results at 5 minutes. Do not interpret the result after 20 minutes. NOTE:
- Once the collection swab locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).



For ALC, read result at 3min

Other Drug Tests，read result at 5min



INTERPRETATION OF RESULTS

• INTERPRETATION OF DOA RESULTS:

(See previous illustration)

POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

INVALID: Control band fails to appear. Results from any test which has not produced a control band (C) at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) 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 band failure.

For Alcohol tests:

Positive: The One Step Saliva Alcohol Test will produce a color change in the presence of saliva alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The One Step Saliva Alcohol Test is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% relative blood alcohol.

Negative: When the One Step Saliva Alcohol Test shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the color pad has a blue color before applying saliva sample, do not use the test.

NOTE: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with saliva. The test is not reusable.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Oral Screen Saliva Drug Test is for professional in vitro diagnostic use, and should be only used for the qualitative detection of drugs of abuse in oral fluid.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. 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.
4. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
5. 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.
6. This test does not distinguish between drugs of abuse and certain medications.

Limitation of ALC test:

1. Failure to wait 10 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
2. The Saliva Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol Test. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.

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3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

PERFORMANCE CHARACTERISTICS

A. Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with The Oral Screen Saliva Drug Test. The results are summarized below.

Drug Conc. (Cut-off range)	n	AMP		BUP		BZO		COC	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	30	0	29	1
Cut-off	30	12	18	11	19	14	16	12	18
+25% Cut-off	30	2	28	8	22	4	26	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	COT		EDDP		KET		MET	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	27	3	30	0
Cut-off	30	11	19	13	17	9	21	13	17
+25% Cut-off	30	1	29	2	28	3	27	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MOR		MTD		OXY		PCP	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	30	0	28	2	28	2
Cut-off	30	10	20	10	20	10	20	11	19
+25% Cut-off	30	9	21	2	28	4	26	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC		THC parent		BAR		PPX	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	27	3	30	0
Cut-off	30	10	20	10	20	9	21	10	20
+25% Cut-off	30	5	25	4	26	3	27	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MDMA		6-MAM		MOR25		K2	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	30	0	26	4	26	4
Cut-off	30	14	16	15	15	13	17	10	20
+25% Cut-off	30	4	26	2	28	9	21	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MEP		MQL		MDPV		FYL	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	20	10	12	18	22	8	22	8
Cut-off	30	8	22	14	16	10	20	12	18
+25% Cut-off	30	4	26	9	21	4	26	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	TCA		TRA	
		-	+	-	+
0% Cut-off	30	30	0	30	0
-50% Cut-off	30	30	0	30	0
-25% Cut-off	30	25	5	10	20
Cut-off	30	11	19	21	9
+25% Cut-off	30	6	24	15	15
+50% Cut-off	30	0	30	0	30

B. Specificity

The following table lists the concentrations of compounds (in ng/ml) above which The Oral Screen Saliva Drug Test identified positive results at 10 minutes

Amphetamine 40-Related Compounds			**Ecstasy 40-Related Compounds**	
D-Amphetamine	40		3,4-Methylenedioxymethamphetamine(MDMA)	40
L-Amphetamine	3,000		3,4-Methylenedioxyamphetamine (MDA)	200
(+)-3,4-Methylenedioxyamphetamine (MDA)	120		3,4-Methylenedioxyethylamphetamine (MDEA)	50
Phentermine	30,000		Paramethoxyamphetamine (PMA)	1,200
PMA	100		Paramethoxymethamphetamine(PMMA)	120
Tyramine	2,500		**Ecstasy 50-Related Compounds**	
Amphetamine 50-Related Compounds			3,4-Methylenedioxymethamphetamine(MDMA)	50
D-Amphetamine	50		3,4-Methylenedioxyamphetamine (MDA)	250
L-Amphetamine	4,000		3,4-Methylenedioxyethylamphetamine (MDEA)	60
(+)-3,4-Methylenedioxyamphetamine (MDA)	150		Paramethoxyamphetamine (PMA)	1,600
Phentermine	40,000		Paramethoxymethamphetamine(PMMA)	160
PMA	125		**MDPV 50-Related Compounds**	
Tyramine	3,000		3,4-Methylenedioxypyrovalerone	50
Barbiturate 50-Related Compounds			Desmethyl Pyrovalerone HCI	3000
Barbiturate (BAR)	50		Pyrovalerone	>100,000
Allobarbital	200		**Methamphetamine 40-Related Compounds**	
Alphenal	100		D-Methamphetamine	40
Amobarbital	100		Fenfluramine	2,500
Aprobarbital	30		L-Methamphetamine	400
Butabarbital	15		L-Phenylephrine	2,000
Butalbital	400		MDEA	300
Butethal	30		3,4-Methylenedioxymethamphetamine (MDMA)	60
Cyclopentobarbital	60		Mephentermine	150
Pentobarbital	150		PMMA	40
Phenobarbital	300		Procaine	2,000
Buprenorphine5 -Related Compounds			**Methamphetamine 50-Related Compounds**	
Buprenorphine	5		D-Methamphetamine	50
Buprenorphine Glucuronide	10		Fenfluramine	3,000
Buprenorphine–3–β–D–Glucuronide	5		L-Methamphetamine	500
Norbuprenorphine	10		L-Phenylephrine	2,500
Norbuprenorphine–3–β–D–Glucuronide	200		MDEA	400
Benzodiazepine 10-Related Compounds			3,4-Methylenedioxymethamphetamine (MDMA)	75
Oxacepam	10		Mephentermine	200
Alprazolam	15		PMMA	50
Bromazepam	8		Procaine	2,500
Chlordiazepoxide	10		**MEP 100-Related Compounds**	
Clonazepam	40		Mephedrone	100
Clorazepate	20		**MQL -Related Compounds**	
Clbazam	6		Methaqualone	30
Diazepam	15		**Methadone 30 -Related Compounds**	
Estazolam	10		Methadone	30
Desalkyflurazepam	8		Alpha-Methadol	125
Flunitrazepam	10		Biperiden	80,000
Flurazepam	10		Doxylamine	12,500
Lorazepam	20		2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine (EDDP)	10,000
Medazepam	10		Phencyclidine	12,500
Nitrazepam	10		Pheniramine	25,000
Nordiazepam	6		**Methadone 50 -Related Compounds**	
Prazepam	20		Methadone	50
Temazepam	8		Alpha-Methadol	200
Triazola	15		Biperiden	100,000
Benzodiazepine 50-Related Compounds			Doxylamine	20,000
Oxacepam	50		2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine (EDDP)	15,000
Alprazolam	75		Phencyclidine	20,000
Bromazepam	40		Pheniramine	40,000
Chlordiazepoxide	50		**Opiates25 -Related Compounds**	
Clonazepam	200		Morphine	25
Clorazepate	100		Codeine	8
Clbazam	30		Diacetylmorphine (Heroin)	30
Diazepam	75		Ethylmorphine	15
Estazolam	50		Hydrocodone	25
Desalkyflurazepam	40		Hydromorphone	80
Flunitrazepam	50		6-Monoacetylmorphine (6-MAM)	15
Flurazepam	50		Morphine-3- β-d-glucuronide	40
Lorazepam	100		Nalorphine	8,000
Medazepam	50		Oxycodone	15,000
Nitrazepam	50		Oxymorphone	15,000
Nordiazepam	30		Thebaine	3,000
Prazepam	100		**Opiates 40-Related Compounds**	
Temazepam	40		Morphine	40
Triazola	75		Codeine	50
Cocaine 20-Related Compounds			Diacetylmorphine (Heroin)	50
Cocaine	20		Ethylmorphine	24
Benzoylecgonine	200		Hydrocodone	50
Ecgonine	100,000		Hydromorphone	100
Ecgonine methyl ester	10,000		6-Monoacetylmorphine (6-MAM)	25

Cocaine 30-Related Compounds	
Cocaine	30
Benzoylecgonine	300
Ecgonine	>100000
Ecgonine methyl ester	30,000
Cocaine 50-Related Compounds	
Cocaine	50
Benzoylecgonine	500
Ecgonine	>100,000
Ecgonine methyl ester	50,000
Cotinine 50-Related Compounds	
Cotinine	50
Buprenorphine	>100,000
EDDP 20 -Related Compounds	
EDDP	20
Meperidine	20,000
Methadone	20,000
Norfentanyl	20,000
Phencyclidine	20,000
Promazine	10,000
Promethazine	5,000
Prothipendyl	10,000
Fentanyl 10-Related Compounds	
Fentanyl	10
K2 30-Related Compounds	
JWH-018-5 pentanoic	30
JWH-073-4 Butanoic	30
JWH-250 5-Hydroxypentyl	>10,000
Ketamine 50-Related Compounds	
Ketamine(KET)	50
Norketamine	50
Dextromethorphan	>10000
D-Norpropoxyphene	>100000
Meperidine	>100000
D-Methamphetamine	>100000
3,4-Methylenedioxyethylamphetamine (MDEA)	>100000
Phencyclidine	250
Promethazine	>100000
Ketamine 100-Related Compounds	

Morphine-3- β-d-glucuronide	50
Nalorphine	10,000
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	5,000
Opiates 50 -Related Compounds	
Morphine	50
Codeine	15
Diacetylmorphine (Heroin)	60
Ethylmorphine	30
Hydrocodone	60
Hydromorphone	125
6-Monoacetylmorphine (6-MAM)	60
Morphine-3- β-d-glucuronide	60
Nalorphine	12,500
Oxycodone	31,250
Oxymorphone	31,250
Thebaine	6,250
Oxycodone 20-Related Compounds	
Oxycodone	20
Hydrocodone	500
Hydromorphone	3,000
Naloxone	3,000
Oxymorphone	20
Oxycodone 40-Related Compounds	
Oxycodone	40
Hydrocodone	1,000
Hydromorphone	6,250
Naloxone	6,250
Oxymorphone	40
Phencyclidine 10-Related Compounds	
Phencyclidine (PCP)	10
Hydrocodone	2,000
Hydromorphone	2,000
Morphine-3- β-d-glucuronide	20,000
Nalorphine	10,000
Propoxyphene 50-Related Compounds	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200

Ketamine(KET)	100
Norketamine	100
Dextromethorphan	>10000
D-Norpropoxyphene	>100000
Meperidine	>100000
D-Methamphetamine	>100000
3,4-Methylenedioxyethylamphetamine (MDEA)	>100000
Phencyclidine	400
Promethazine	>100000
6-MAM-Related Compounds	
6-Monoacetylmorphine	10
Acetylcodeine	>10,000
Buprenorphine	>10,000
Codeine	>10,000
Diacetylmorphine	1000
Dihydrocodeine	>10,000
Ethylmorphine	>10,000
Hydrocodone	>10,000
Hydromorphone	5,000
Morphine	10,000
Morphine-3-glucuronide	>10,000
Nalorphine	5,000
Thebaine	>20,000

Tricyclic Antidepressants 100-Related Compounds	
Nortriptyline	100
Marijuana 50 -Related Compounds	
Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	75
11-nor-Δ9 -THC-9 COOH	12
11-hydroxy-Δ9 -THC	300
Cannabinol	2,000
Cannabidiol	>10,000
Marijuana 30 -Related Compounds	
Δ9-Tetrahydrocannabinol	30
Δ8-Tetrahydrocannabinol	40
11-nor-Δ9-THC-9 COOH	8
11-hydroxy-Δ9 -THC	150
Cannabinol	1,000
Cannabidiol	>10,000
Marijuana 12 -Related Compounds	
11-nor-Δ9 -THC-9 COOH	12
Δ8-Tetrahydrocannabinol	2,000
Δ9-Tetrahydrocannabinol	4,000
11-hydroxy-Δ9 -THC	300
Tramadol 30 related compounds	
Tramadol	30

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on The Oral Screen Saliva Drug Test when tested at concentrations up to 100 ug/ml.

(-)-Ephedrine(Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine(Except MET)	Dextromethorphan	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	Phenothiazine
Acetaminophen(Except ACE)	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline(Except TCA)	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine(Except TCA)	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	
Chloroquine	Methadone(Except MTD)	

For ALC test:
The following substances may interfere with the Saliva Alcohol Test when using samples other than saliva. The named substances do not normally appear in sufficient quantity in saliva to interfere with the test.

A. Agents which enhance color development
- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	…	Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

Number: 1110015352

Version 3.0/Effective date: 2016-05-05

Manufacture for:
American Screening, LLC
9742 St. Vincent Ave Ste 100, Shreveport, LA 71106
Customer Service Phone: 866-526-2873

EC REP Ltd
5 Fitzwilliam Square East
Dublin 2, Ireland
Tel: +353 1 2 544 944
Info@ecrep.ie
www.ecrep.ie