

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE: * All test lines appear. One colored line should be in the control region (C), and other apparent colored line should be adjacent in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level or drug free.

***NOTE:** The shade of color in the test region (Drug/T) will vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control region (C). Any test line not appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A colored 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.

LIMITATIONS

- The **Alere iScreen® OFD Drug Test Device** 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) are preferred confirmatory methods.
- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- 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.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A PBS pool was spiked with drugs to target concentrations of $\pm 50\%$ cut-off and $\pm 25\%$ cut-off and tested with the **Alere iScreen® OFD Drug Test Device**. The results are summarized below.

Drug Conc. (Cut-off range)	AMP		COC		THC		mAMP		OPI		PCP		OXY	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	90	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	90	0
-25% Cut-off	26	4	30	0	24	6	28	2	26	4	30	0	90	0
Cut-off	19	11	20	10	15	15	23	7	20	10	22	8	53	37
+25% Cut-off	7	23	6	24	11	19	7	23	5	25	8	22	0	90
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	90

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the **Alere iScreen® OFD Drug Test Device** for AMP/mAMP/COC/OPI/THC/PCP/OXY identified positive results at a read time of 10 minutes.

COCAINE (COC)	
Benzoyllecgonine	20
Cocaine	20
Cocaeethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
AMPHETAMINE (AMP)	
d-Amphetamine	50
d,l-Amphetamine	125
β -Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
METHAMPHETAMINE (mAMP)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S) - (-) Ephedrine	400

MARIJUANA (THC)	
11-nor- Δ^9 -THC-9 COOH	12
Cannabinol	12,500
11-nor- Δ^8 -THC-9 COOH	2
Δ^8 -THC	6,000
Δ^9 -THC	10,000
OPIATES (OPI)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3- β -D-Glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
OXYCODONE (OXY)	
Hydrocodone	6,250
Levorphanol	12,500
Naloxone	12,500
Naltrexone	6,250
Oxycodone	20
Secobarbital	50,000
Oxymorphone	100
Hydromorphone	25,000

Cross-Reactivity

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 **Alere iScreen® OFD Drug Test Device** when tested with concentrations up to 100 μ g/mL.

Acetaminophen	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid
Aminopyrine	Amoxicillin
Ampicillin	l-Ascorbic acid
Apomorphine	Aspartame
Atropine	Benzilic acid
Benzoic acid	Benzphetamine
Bilirubin	d,l-Brompheniramine
Caffeine	Cannabidiol
Chloralhydrate	Chloramphenicol
Chlorothiazide	d,l-Chloropheniramine
Chlorpromazine	Chloroquine
Cholesterol	Clonidine
Cortisone	l-Cotinine
Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac
Diffunisal	Digoxin
Diphenhydramine	l- Ψ -Ephedrine
β -Estradiol	Estrone-3-sulfate
Ethyl-p-aminobenzoate	l-(-)-Epinephrine
Erythromycin	Fenoprofen
Furosemide	Gentisic acid
Hemoglobin	Hydralazine
Hydrochlorothiazide	Hydrocortisone
o-Hydroxyhippuric acid	p-Hydroxytyramine
Ibuprofen	lproniazid
d,l-Isoproterenol	Isosuprine
Ketamine	Ketoprofen

Labetalol	Loperamide
Meperidine	Meproamate
Methylphenidate	Nalidixic acid
Naproxen	Niacinamide
Nifedipine	Norethindrone
d-Norpropoxyphene	Noscapine
d,l-Octopamine	Oxalic acid
Oxolinic acid	Oxymetazoline
Papaverine	Penicillin-G
Pentazocine	Perphenazine
Phenelzine	Trans-2-phenylcyclopropylamine
Phenylpropanolamine	Prednisolone
Prednisone	d,l-Propranolol
d-Propoxyphene	d-Pseudoephedrine
Quinacrine	Quinine
Quindine	Ranitidine
Salicylic acid	Serotonin
Sulfamethazine	Sulindac
Tetracycline	Tetrahydrocortisone 3-Acetate
Thiamine	Thioridazine
d,l-Tyrosine	Tolbutamide
Triamterene	Trifluoperazine
Trimethoprim	d,l-Tryptophan
Tyramine	Uric acid
Verapamil	Zomepirac

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Manufactured for Alere Toxicology Services-Products Division
Portsmouth, VA 23704 USA
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Printed in China

DN: 1156023101
Eff. Date: 2011-11-21