CLIA WAIVED

Fastect® II Drug Screen Dipstick Test
Package Insert

This is a CLIA-Waived Test. A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read this entire Instruction Sheet carefully before use. If a laboratory modifies the following test instructions including QC, the test will be considered high complexity and no longer considered CLIA Waived.

Intended Use
The Fastect® II Drug Screen Dipstick Test is a screening device for the detection of drugs and drug metabolites in human urine. The Fastect® II Dipstick Test is only the first step in a two-step process for detecting drugs of abuse in urine. The first step is screening the urine. The second step is confirming the results.

The Fastect® II Drug Screen Dipstick Test may include 1 drug test or up to 4 individual drug tests. The device detects the following drugs or drug metabolites in human urine at or above the detection level listed.

Abbreviation	Drug or Drug Metabolite	Detection Level
AMP	Amphetamine	1000 ng/ml †
BAR	Secobarbital	300 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoylecgonine	300 ng/ml †
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MET	Methamphetamine	500 ng/ml
MTD	Methadone	300 ng/ml
OPI	Morphine	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml †
TCA	Nortriptyline	1000 ng/ml
THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml †

† SAMHSA mandated cut-off concentration

The Fastect® II Drug Screen Dipstick Test provides visual qualitative results and is for *in vitro* diagnostic use only. It is not for over-the-counter sale to non-professionals.

The Fastect® II Drug Screen Dipstick Test provides only a preliminary screening test result. For a quantitative analytical result or to confirm positive results obtained by Fastect® II, a more specific method must be used. The Substance Abuse Mental Health Sources Administration (SAMHSA) has established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method.

Summary and Explanation
AMP: Amphetamine is a man-made drug used to control weight, treat narcolepsy and ADHD. Amphetamine can be snorted, taken orally, smoked, or injected. When used, amphetamines will stimulate the central nervous system. Short-term amphetamine use includes increased heart rate and blood pressure, reduced appetite, and feelings of increased energy and power. Long-term use of amphetamine can lead to violent and aggressive behavior, weight loss, insomnia and restlessness. The detection time for amphetamine in urine is 3-5 days after use.

BAR: Barbiturates are a class of central nervous system depressants. There are three types of Barbiturates: short acting, short-to-intermediate acting and long acting. Phenobarbital is an example of long acting barbiturate while Pentobarbital and Secobarbital are examples of short acting barbiturates. The short acting barbiturates are used as anesthetics or sedatives in conjunction with other inhalants. The short-to-intermediate acting barbiturates are used as sleeping pills. Short-to-intermediate acting barbiturates are the most commonly abused barbiturates; these include amobarbital, butabarbital and secobarbital. Long acting barbiturates are used for treatment of epilepsy, ulcers and high blood pressure. Barbiturate abuse can lead to impaired motor coordination, mental disorder, respiratory collapse, coma and even death. Barbiturates can be detected in urine for 4 to 6 days after use.

BZO: Benzodiazepines are a class of drugs most commonly prescribed and used for panic disorder and other anxiety disorders. Benzodiazepines are also used for age-related sleep problems. Use of Benzodiazepines can result in drowsiness and confusion. The effects of benzodiazepines can be increased when combined with other central nervous system depressants, such as alcohol and pain relievers. Physical dependency of benzodiazepines can develop if high

doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by injection. The drug is metabolized in the liver and excreted in the urine as the parent compound or as oxazepam (in the case of chlorodiazepoxide and diazepam). Oxazepam is detectable in the urine for up to 7 days.

COC: Street names for cocaine are coke, blow, snow, and nose candy. Cocaine is derived from the leaves of the coca plant. The white powder form of cocaine can be snorted, or dissolved in water and injected, while "Crack" cocaine, a white chunky material is usually smoked. Cocaine use creates a sense of increased energy and confidence; these effects are accompanied by increased heart rate, pupil dilation, fever, tremors, and sweating. Cocaine is highly addictive and can cause lung complications, cardiac arrest or seizures. Cocaine is mainly excreted in urine as benzoylecgonine and can generally be detected for 24–60 hours after use.

MDMA: 3,4-methylenedioxymethamphetamine (MDMA) is a synthetic drug. MDMA has been available as a street drug since the 1980s, however, since the 1990s its use has increased, particularly among teenagers and young adults. The drug has street names that include "Ecstasy, XTC, Clarity, Essence and Adam". The common method of use is oral ingestion, although the powder form can be snorted or smoked. MDMA has properties of both stimulants and hallucinogens. The effects of the drug last up to 6 hours after oral ingestion. MDMA effects include elevated blood pressure, increased heart rate, hypothermia, dehydration, anxiety, paranoia and insomnia. The detection period of MDMA in urine is 1-3 days for single use and up to 5 days for heavy use.

MET: Street names for methamphetamine are speed, glass, ice, and crystal meth. Methamphetamine is usually a white powder that can be inhaled, injected or smoked. When used, methamphetamine causes increased heart rate and blood pressure. Higher doses of methamphetamine lead to a sense of increased energy and power. Methamphetamine can also cause respiratory problems, irregular heartbeat and anorexia. Methamphetamine can be detected in the urine within 4-6 hours after use and for 3-5 days, depending on urine pH level.

MTD: Methadone is a synthetic analgesic drug that is originally used for the treatment of narcotic addiction. Methadone use induces psychological effects such as analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver. The major route of methadone excretion is in the urine. The effects of methadone last up to 24 hours after use and can be detected in the urine up to 14 days. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the user's age, weight, activity and diet.

OPI: Opiates are a group of drugs that include morphine, heroin and codeine. Heroin, morphine and codeine come from a resin taken from the seed pod of the opium poppy. With the exception of heroin, health care professionals use opiates as pain relievers. Inside the body, heroin is quickly converted to morphine. Thus, morphine and morphine metabolites may both be found in the urine of a person who has taken only heroin. The body also converts codeine to morphine. The presence of morphine (or morphine metabolite) in the urine indicates heroin, morphine and/or codeine use. Generally, opiates can be detected in the urine within 2 to 6 hours after use and remains detectable up to 3 days.

OXY: Oxycodone is a synthetic drug. Oxycodone is taken orally for the relief of moderate to severe pain. Long-term use of Oxycodone can lead to physical dependence. Withdrawal symptoms include restlessness, insomnia, vomiting, and muscle and bone pain. The major route of oxycodone excretion is in the urine. The effects of oxycodone last up to 4 hours after use. Oxycodone can be detected in the urine for 2-4 days after use.

PCP: PCP (phencyclidine) was developed in the 1950s as an anesthetic. Use of PCP was ended when patients had psychotic reactions to the drug. PCP is now made illegally and can be found on the street under names such as Angel Dust, Hog and Rocket Fuel. PCP can be eaten, snorted, injected or smoked. Effects of PCP include sense of well-being, blurred vision, numbness, confusion or anxiety. PCP may be detected in the urine for up to 10 days.

TCA: Tricyclic antidepressants (TCAs) are a type of prescription drugs used for the treatment of depressive disorders. Tricyclic Antidepressants consist of two main chemical classes. The tertiary amines boost serotonin levels and are usually prescribed for insomnia, irritability and overstimulation; these include amitryptiline, imipramine, trimipramine and doxepin. The secondary amines, which include nortryptiline, desipramine and protryptiline, enhance norepinephrine levels and are prescribed for fatigue, withdrawal and inertness. TCA abuse can result in respiratory depression, convulsions, blood pressure deviation, severe cardiac conditions, and coma. TCAs are taken orally or sometimes by injection. TCAs are excreted in the urine mostly in the form of metabolites and can be detected for up to ten days after use.

THC: Tetrahydrocannabinol (THC) is the substance detected in urine from marijuana use. Street names for marijuana are grass, pot, weed and dope. Marijuana is the green leafy material or brown black lump that can be smoked or eaten. Use of marijuana may cause respiratory problems, anxiety, and impaired memory and learning. Long-term marijuana use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, insomnia, anorexia, and nausea. The detection time of THC in urine is 3-5 days for occasional users and up to 14 days for chronic users.

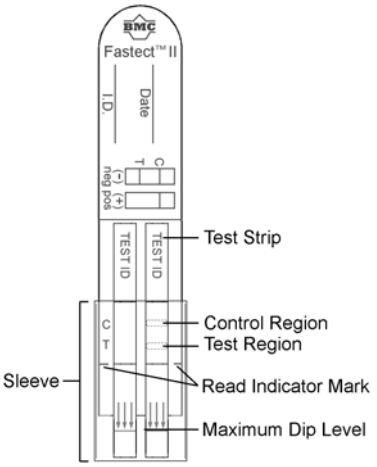
Test Principle
The test device consists of one, two, three or up to four individual test strips placed into separate chambers of a plastic holder. On each test strip, a drug conjugate is pre-coated onto specific region known as the test region (T). A colored antibody-colloidal gold conjugate is coated onto a pad and placed at one end of the strip. During testing, the Fastect® II device is dipped into a urine sample. This allows the urine to come into contact with the sample pads, which allows the urine to move across the strip. If any drug is present in the urine, it competes with the drug conjugate for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibody binding sites and the colored colloidal gold conjugate cannot bind to the drug conjugate on the strip.

The absence of a color line at a specific test region indicates a positive result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible line at the test region. The presence of a color line at the test region indicates a negative result for that particular test.

A control line with a different antigen/antibody reaction is added to the membrane strip at the control region (C) to indicate that the test performed properly. This control line should always appear regardless of the presence of drug or metabolite. The appearance of the control line during testing indicates that the test has completed and the test is valid.

Reagents
Protein conjugate for amphetamine, barbiturate, benzodiazepine, benzoylecgonine, methamphetamine, MDMA, methadone, morphine, oxycodone, phencyclidine, nortriptyline or THC is coated onto the test region of the membrane.

The colored conjugate pad for each test strip contains monoclonal antibodies for amphetamine, barbiturate, benzodiazepine, benzoylecgonine, methamphetamine, MDMA, methadone, morphine, oxycodone, phencyclidine, nortriptyline or THC.



Materials Provided
Each Fastect® II Drug Screen Dipstick Test Kit contains:
1. 1 Package Insert (directions for use).
2. 50 Dipstick Tests. Each test is packaged in a pouch with a desiccant.

Warnings and Precautions
- For in vitro diagnostic use only (not for internal use).
- Keep the Fastect® II Drug Screen Dipstick Test in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Do not use the Fastect® II Drug Screen Dipstick Test after the expiration date printed on the pouch.
- Be careful with urine because it may contain infectious diseases. Always wear gloves and wash hands with soap and water after handling urine.
- To ensure that the test device will work properly and results are accurate, the testing instructions must be followed.
- Dispose of the Fastect® II Drug Screen Dipstick Test and used contents according to local, state and federal requirements.
- Do not use this test if you are color-blind.

Product Storage
The Fastect® II Drug Screen Dipstick Test kit should be stored at room temperature 59˚F to 86˚F (15˚C to 30˚C) until the expiration date on the pouch. Do not open the pouch until ready to perform the test.

Specimen Collection and Handling
The Fastect® II Drug Screen Dipstick Test is formulated for use with urine specimens. Use only freshly voided, untreated urine. Do not centrifuge or add preservatives to urine. Urine samples should be collected and tested as soon as possible. Urine samples that have been collected should be refrigerated if testing cannot be performed within the 8-hour workday. Urine samples can be refrigerated up to 3 days and frozen up to 6 months and still obtain accurate test results. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

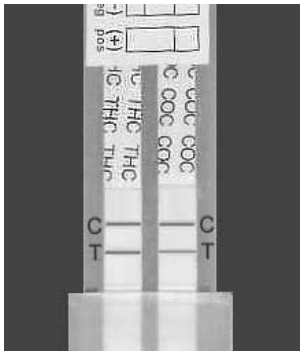
Note: All materials coming in contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid contact and follow good laboratory practice.

Test Procedure
IMPORTANT: If testing refrigerated or frozen urine sample, the sample should be brought to room temperature (15–30°C) before testing. Do not open pouch until ready to perform the test.

1. Open the pouch and remove the device from the pouch.
2. Write the urine sample ID number on the device.
3. Push the sleeve all the way up.
4. Dip the device into the urine sample for at least 10 seconds and remove. Do not dip above the tip of the arrows.
5. Push the sleeve down to the Read Indicator Mark. Place the device on a flat surface.
6. Read test result after 5 minutes. Do not read results after 1 hour.
7. Look at each test strip separately.

Interpretation of Results

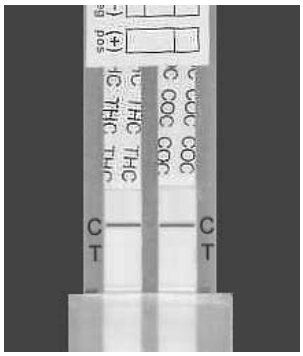
Negative:



Negative: The result is negative when there are two red lines, one in the control region (C) and one in the test region (T).
The picture to the left indicates that both the THC and COC tests are negative.

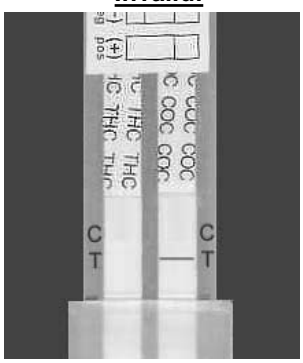
Note: Any test line, even a very faint test line, is considered a negative result.

Preliminary Positive:



Positive: The result is preliminary positive when there is a red line in the control region (C) and no line in the test region (T).
The picture to the left indicates that both the THC and COC tests are preliminary positive since there are no red lines at the test region (T).

Invalid:



Invalid: The result is invalid when no line appears at the control region (C). The test is invalid even if there is a line in the test region (T). Do not use this result. Repeat the test using a new device. Contact CLIAwaived.com if you have any question.

The picture to the left indicates that both the THC and COC tests are invalid.

Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test lines at the test regions should be considered negative. The Fastect® II Drug Screen Dipstick Test provides qualitative results for the presence of drug(s) at specified detection concentration(s). It is recommended that samples with questionable test lines and preliminary positive results be confirmed with a more specific method (Gas Chromatography/Mass Spectrometry).

Quality Control
An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer's recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality control samples, follow the same testing procedure as for testing urine samples.

Contact the Customer Service Department at CLIAwaived.com at 1-888-882-7739 or email to info@cliawaived.com for the appropriate external controls. Do nt use commercially available urine controls since these products may not be compatible with the Fastect® II Dipstick Test.

Limitations of the Test

- Use the test with human urine only.
- The test is for one time use only; it is not reusable.
- This test is a screening device; it does not detect the actual concentration of a drug.
- Contaminated or tainted urine sample may give false results.
- Certain foods or medications may cause the test to give false results. See Specificity section for the list of substances that will produce either positive results, or that do not interfere with test performance.
- The colors of human urine usually range from amber yellow to very light yellow. Dark urine or urine with a brown or abnormal color should not be tested using this test. Dark urines should be sent to a laboratory for testing.
- Send preliminary positive or uncertain results to a laboratory to confirm results.
- If it is suspected that the sample may have been mislabeled a new specimen should be collected.
- If it is suspected that the sample may have been tampered, the test should be repeated, and a new specimen should be collected.

Expected Results

The Fastect® II Drug Screen Dipstick Test should give a negative result when testing the urine of a normal healthy person. The Fastect® II device will give a preliminary positive result when the drug or drug metabolite is present in the urine at or above the detection level. The Fastect® II Drug Screen Dipstick Test is only the first step in a two-step process for detecting drugs of abuse in urine. Any urine specimen that produced a questionable or preliminary positive result should be sent to a laboratory for confirmation testing with a more specific method.

Performance Characteristics

Accuracy and Precision

To demonstrate that Fastect® II device is a simple test and can by used by untrained users to obtain accurate test results, site studies were conducted at three (3) non-laboratory sites. The participants (untrained users) at these sites are non-laboratory professionals with no training or previous experience with drugs-of-abuse tests or the Fastect® II device. The participants are a demographically diverse population that includes a range of ages, educational and regional background and are representative of the users of a CLIA Waived test.

For each specific drug test contained in the Fastect® II device, drug-free normal urine was spiked with drug standards to various concentrations (-50%, -20%, +20% and +50%). Each of the concentration was divided into 20 aliquots and each aliquot was blind-labeled with a unique code. A total of 20 tests per concentration were performed at each of the three sites to validate the test performance around the cut-off concentration. The results are summarized below:

			PRODUCT A								PRODUCT B								PRODUCT C							
Site	Conc.	# of sample per conc. per test	THC		COC		MET		OPI		AMP		BZO		BAR		OXY		PCP		MTD		TCA		MDMA	
			-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
1	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	18	2	20	0	19	1	20	0	20	0	20	0	20	0	19	1	20	0	19	1	20	0	20	0
	+20%	20	0	20	1	19	0	20	0	20	1	19	0	20	1	19	0	20	1	19	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
2	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	20	0	19	1	20	0	19	1	20	0	19	1	20	0	20	0	19	1	20	0	19	1	19	1
	+20%	20	1	19	0	20	0	20	0	20	0	20	0	20	0	20	0	20	1	19	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
3	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	18	2	20	0	20	0	20	0	20	0	20	0	19	1	20	0	18	2	20	0	20	0	19	1
	+20%	20	1	19	0	20	0	20	1	19	0	20	1	19	0	20	0	20	1	19	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
	Total (-) per test		118		120		119		120		121		120		120		119		120		119		119		118	
	Total (+) per test		122		120		121		120		119		120		120		121		120		121		121		122	

Of the total 240 blind-labeled samples tested per site for products A, B and C, the study participants at site 1 obtained 96% agreement with the expected negative results and 97% agreement with the expected positive results.

The study participants at site 2 obtained 95% agreement with the expected negative results and 98% agreement with the expected positive results. Similarly the study participants at site 3 obtained 95% agreement with the expected negative results and 97% agreement with the expected positive results.

A study administrator (laboratory professional) was assigned to each of the three sites. The study administrator re-reads each test that each participant has completed (within 1 hour) and recorded his/her own test results independently of the study participants. The results are summarized below:

			PRODUCT A								PRODUCT B								PRODUCT C							
Std. Adm	Conc.	# of sample per conc. per test	THC		COC		MET		OPI		AMP		BZO		BAR		OXY		PCP		MTD		TCA		MDMA	
			-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
1	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	20	0	20	0	20	0	20	0	20	0	20	0	19	1	20	0	19	1	20	0	20	0	20	0
	+20%	20	1	19	0	20	0	20	0	20	0	20	1	19	1	19	0	20	1	19	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
2	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	19	1	20	0	20	0	19	1	20	0	20	0	20	0	20	0	20	0	19	1	20	0	20	0
	+20%	20	1	19	1	19	0	20	0	20	0	20	0	20	0	20	1	19	0	20	0	20	1	19	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
3	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	+20%	20	1	19	1	19	0	20	0	20	0	20	1	19	0	20	0	20	1	19	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
	Total (-) per test		122		122		120		119		120		122		120		121		121		119		121		120	
	Total (+) per test		118		118		120		121		120		118		120		119		119		121		119		120	

The confidence interval between untrained users and professionals has been assessed using the equation for calculating Odds Ratio (Odds Ratio = Odds of Positive $_{Consumers}$ / Odds of Positive $_{Professionals}$). The Odds Ratio for Fastect® II Product A, B and C at the weak negative (-20%) and weak positive (+20%) levels has been calculated and are listed below.

Note: Consumer results are results from the study participants and professional results are results from the study administrators.

PRODUCT A

Weak Negatives (-20%)

	(-)	(+)	Total
Consumer	53	7	60
Professional	58	2	60

$$\frac{\text{Odds of Positive}_{\text{consumer}}}{\text{Odds of Positive}_{\text{professional}}} = 3.830 \text{ for weak negatives}$$

Weak Positives (+20%)

	(-)	(+)	Total
Consumer	4	56	60
Professional	5	55	60

$$\frac{\text{Odds of Positive}_{\text{consumer}}}{\text{Odds of Positive}_{\text{professional}}} = 1.273 \text{ for weak positives}$$

PRODUCT B

Weak Negatives (-20%)

	(-)	(+)	Total
Consumer	57	3	60
Professional	59	1	60

$$\frac{\text{Odds of Positive}_{\text{consumer}}}{\text{Odds of Positive}_{\text{professional}}} = 3.105 \text{ for weak negatives}$$

Weak Positives (+20%)

	(-)	(+)	Total
Consumer	3	57	60
Professional	4	56	60

$$\frac{\text{Odds of Positive}_{\text{consumer}}}{\text{Odds of Positive}_{\text{professional}}} = 1.357 \text{ for weak positives}$$

PRODUCT C

Weak Negatives (-20%)

	(-)	(+)	Total
Consumer	53	7	60
Professional	58	2	60

$$\frac{\text{Odds of Positive}_{\text{consumer}}}{\text{Odds of Positive}_{\text{professional}}} = 3.830 \text{ for weak negatives}$$

Weak Positives (+20%)

	(-)	(+)	Total
Consumer	3	57	60
Professional	3	57	60

$$\frac{\text{Odds of Positive}_{\text{consumer}}}{\text{Odds of Positive}_{\text{professional}}} = 1.000 \text{ for weak positives}$$

To obtain a 95% Confidence Interval between consumer and professional, the Odds Ratio should be in the range of 0.25 to 4 for the weak negative (-20%) and weak positive (+20%) levels. The results indicate that there is at least 95% Confidence Interval between consumer and professional for the Fastect® II Product A, B and C because the Odd Ratio for the weak negative and weak positive levels ranges from 1.000 to 3.830.

Specificity

The Fastect® II Drug Screen Dipstick Test performance at cutoff level was previously analyzed and found not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030

The specificity study for the drug test was evaluated by adding structurally related compounds to normal human urine. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

AMP

Compound	ng/ml	Compound	ng/ml
d-Amphetamine	1,000	l-Amphetamine	10,000
(+/-) 3,4-MDA	5,000		

BAR

Compound	ng/ml	Compound	ng/ml
Secobarbital	300	Pentobarbital	400
Alphenal	400	Phenobarbital	400
Aprobarbital	400	Allobarbital	1,500
Barbital	400	Amobarbital	1,500
Butabarbital	400	Butalbital	3,000
Butethal	400		

BZO

Compound	ng/ml	Compound	ng/ml
Clorazepam	100	Bromazepam	800
Nordiazepam	100	Flunitrazepam	1,000
Alprazolam	150	Lormetazepam	1,000
Diazepam	150	Nitrozepam	1,000
Temazepam	150	Prazepam	1,000
Clobazam	200	Lorazepam	1,500
Estazolam	300	Triazolan	1,500
Flurazepam	300	Medazepam	2,000
Oxazepam	300	Delorazepam	6,000
Chlordiazepoxide	300	Clonazepam	25,000

COC

Compound	ng/ml	Compound	ng/ml
Benzoylecgonine	300	Ecgonine	>100,000
Cocaine	300	Ecgonine Methyl Ester	>100,000

MDMA

Compound	ng/ml	Compound	ng/ml
(+/-) 3,4-MDEA	250	(+/-) 3,4-MDA	2,000

MET

Compound	ng/ml	Compound	ng/ml
d-Methamphetamine	500	Chloroquine	50,000
(+/-)3,4-MDA	1,000	(+/-)-Ephedrine	50,000
l-Methamphetamine	25,000	β-Phenylethylamine	50,000
Procaine	10,000	Ranitidine	50,000
d-Amphetamine	50,000		

MTD

Compound	ng/ml	Compound	ng/ml
Methadol	1,000	2-ethylidene1,5-dimethyl-3,3-diphenylpyrolidine	50,000

OPI

Compound	ng/ml	Compound	ng/ml
Codeine	300	Hydromorphone	400
Ethyl morphine	300		

OXY

Compound	ng/ml	Compound	ng/ml
Oxycodone	100	Hydromorphone	2,250
Heroin	500	Morphine	5,000
Hydrocodone	600	Codeine	10,000

PCP

Compound	ng/ml
Tenocyclidine	2,000

TCA

Compound	ng/ml	Compound	ng/ml
Protryptiline	350	Cyclobenzaprine	1,500
Desipramine	750	Trimipramine	1,500
Imipramine	750	Clomipramine	7,500
Amitryptiline	1,000	Promazine	10,000
Doxepin	1,000	Perphenazine	50,000
Nordoxepin	1,000	Chlorpromazine	100,000
Nortryptiline	1,000		

THC

Compound	ng/ml	Compound	ng/ml
11-nor-Δ-8-THC-9-COOH	50	Δ-9-tetrahydrocannabinol	10,500
11-hydroxy-Δ9-THC	2,500	Cannabinol	10,000
Δ-8-tetrahydrocannabinol	7,000	Cannabidiol	100,000

Interference

The following compounds were found not to cross-react with the Fastect® II Drug Screen Dipstick Test when tested at concentrations of 100 μg/ml (100,000 ng/ml):

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol)
Acetone
Acetylsalicylic acid (Aspirin)
Albumin
Aminopyrine
Amitriptyline (except TCA assay)
Amobarbital (except BAR assay)
Amoxapine
Amoxicillin
d-Amphetamine (except AMP, MET assays)
d,l-Amphetamine (except AMP, MET assays)
l-Amphetamine (except AMP, MET assays)
Ampicillin
Apomorphine
l-Ascorbic Acid (Vitamin C)
Ibuprofen
Imipramine (except TCA assay)
(-) Isoproterenol
(+/-) Isoproterenol
Lidocaine
Lorazepam (except BZO assay)
Meperidine
Methadone
(+/-) Methadone
Methamphetamine (except MET assay)
(+) Methamphetamine (except MET assay)
(+/-) Methamphetamine (except MET assay)
Methaqualone
Methoxyphenamine
N-Methyl-Ephedrine
(1R,2S) N-Methyl-Ephedrine

Aspartame
Aspartamine
Atropine (except OPI assay)
Benzilic acid
Benzocaine (Ethyl p-Aminobenzoate)
Benzoic acid
Benzoylecgonine (except COC assay)
Benzphetamine
Bilirubin
(+) Brompheniramine
Butalbital (except BAR assay)
Caffeine
Cannabinol (except THC assay)
Chloralhydrate
Chlordiazepam-HCl-Di(H2O)
Chlordiazepoxide (except BZO assay)
Chloroquine (except MET assay)
(+) Chlorpheniramine
(+/-) Chlorpheniramine
l-Chlorpheniramine
Chlorpromazine (except TCA assay)
Cholesterol
Clobazam (except BZO assay)
Clomipramine (except TCA assay)
Clonazepam (except BZO assay)
Cocaine (except COC assay)
Cortisone
(-) Cotinine
Creatine
Creatinine
Cyclobenzaprine (except TCA assay)
Delorazepam
Deoxycorticosterone
Desipramine (except TCA assay)
Desmethyldiazepam
Dexbrompheniramine
Dextromethorphan
Diazepam (except BZO assay)
4-Dimethylaminoantipyrine
Diphenhydramine
Dopamine (3-Hydroxytyramine)
Doxylamine
Ecgonine (except COC assay)
Ecgonine Methyl Ester (except COC assay)
(-) Ephedrine
(-) Epinephrine
(+) Epinephrine
(+/-) Ephedrine (except MET assay)
Erythromycin
Estazolam (except BZO assay)
β-Estradiol
Estrone-3-Sulfate
Ethanol
Ethyl Morphine (except OPI assay)
Ethyl-p-aminobenzoate
2-Ethylidene-1.5-Dimethyl-1-3.3-Diphenyl (except MTD assay)
Flunitrazepam (except BZO assay)
Flurazepam (except BZO assay)
Furosemide
Gentisic acid
Glucose
Glutethimide
2-Methylamine-Propiophenone
(+/-) 3,4- Methylenedioxymethamphetamine (except MET, MDMA assays)
(+/-) 3,4-Methylenedioxyamphetamine (except MET, MDMA assays)
Methylphenidate
Morphine (except OPI, OXY assays)
Nalidixic acid
Naloxone
(+) Naproxen
Niacinamide
Nitrazepam (except BZO assay)
Nordiazepam (except BZO assay)
(+/-) Norephedrine
(+/-) Norephedrine-(+) Phenylpropanolamine
Norethindrone
D-Norpropoxyphene
Nortriptyline (except TCA assay)
Oxalic Acid
Oxazepam (except BZO assay)
Oxolinic acid
Oxycodone (except OXY assay)
Papaverine
Penicillin-G (Benzylpenicillin)
Penicillin-G Phentermine
Pentazocaine
Pentobarbital (except BAR assay)
Perphenazine
Phencyclidine
Pheniramine
Phenobarbital (except BAR assay)
Phenothiazine (Thiodiphenylamine)
Phentermine
Phenylephrine
β-Phenylethylamine (except MET assay)
Prednisolone
Prazepam (Ethanol) (except BZO assay)
Procaine
Promethazine
d-Propoxyphene
Protriptyline (except TCA assay)
d-Pseudoephedrine
Pyrolidine
Quinidine
Quinine
Ranitidine (except MET assay)
Riboflavin
Salicylic acid
Secobarbital (except BAR assay)
Serotonin
Sodium Chloride
Sulfamethazine
Sulindac
Temazepam (except BZO assay)
Tetracycline
Δ8-THC (except THC assay)
Δ9-THC (except THC assay)
11-Nor-Δ8-THC-9-Carboxylic Acid (except THC assay)
Tetrahydrocortisone
Thiamine
Thimethobenzamide
Thioridazine

Guaiacol Glyceryl Ether
Hemoglobin
Hippuric acid
Hydrochlorothizide
Hydrocodone (except OXY assay)
Hydrocortisone
Hydromorphone (except OPI, OXY assay)
3-Hydroxyptyramine
11-Hydroxy-Δ-9-THC (except THC assay)
11-Hydroxy-Δ-9-THC-9-Carboxylic Acid (except THC assay)
p-Hydrozymethamphetamine
Triazolam (except BZO assay)
Trifluoperazine
Trimethobenzamide
Trimipramine Maleate
Tryptamine
d,l-Tryptophan
Tyramine
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

Bibliography of Suggested Reading

1. Wong, R., The Current Status of Drug Testing in the US Workforce, Am. Clin. Lab., 2002; 21(1): 21-23
2. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.
3. Urine testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
4. Wong, R., The Effect of Adulterants on Urine Screen for Drugs of Abuse: Detection by an On-site Dipstick Device, Am. Clin. Lab., 2002; 21(3); 14-18
5. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.
6. McBay, A.J. Clin. Chem. 33, 33B-40B, 1987.
7. Gilman, A.G., and Goodman, L.S. The Pharmacological Basis of Therapeutics, Eds. MacMillan Publishing, New York, NY, 1980.
8. Ringsrud, K.M and Linne, J.J., Urinalysis and Body Fluids, A color Text and Atlas, Mosby-Year Book, Inc., 1995.
9. U.S Department of Transportation, Drug Testing Procedures Handbook

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