Information for:

COC One Step Cocaine Rapid Test

(Urine)

CONFIDENTIAL

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1 BACKGROUND

Cocaine, is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, Cocaine causes fever, unresponsiveness, and difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.[1,2] Benzoylecgonine, a major metabolite of Cocaine, has a longer biological half-life (5 - 8 hours) than Cocaine (0.5 - 1.5 hours), and can generally be detected for 24-48 hours after Cocaine exposure.[2]

The *FUNWORLD* COC One Step Cocaine Test(Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cocaine metabolite in urine. The COC One Step Cocaine Test(Urine) yields a positive result when the Cocaine metabolite in urine exceeds 300 ng/mL.

1.1 Test Principle

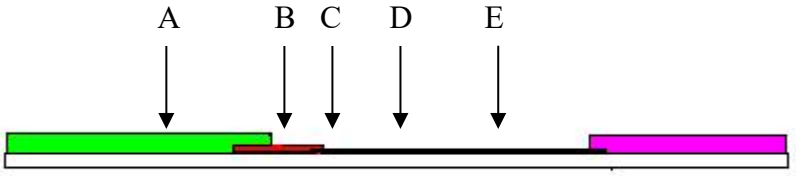
The *FUNWORLD* COC One Step Cocaine Test(Urine) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Benzoylecgonine, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized Benzoylecgonine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Benzoylecgonine level exceeds 300ng/mL because it will saturate all the binding sites of antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug in a concentration less than the cut-off will generate a colored line in the test line region. 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.

1.2 Illustrations

Figure 1: Test Principle



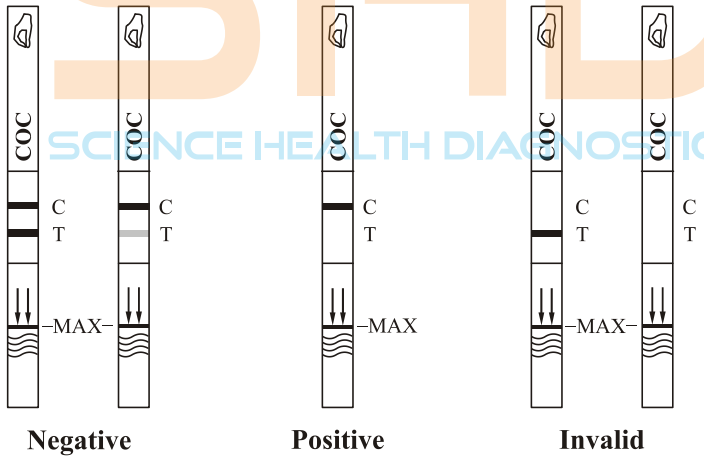
As shown in Figure 1 above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). COC present in the specimen below cut-off, will not saturate the binding sites of the gold-conjugated anti-COC antibodies and not form a colored antibody-antigen complex(C). The gold-conjugated antibodies will then be captured by immobilized COC conjugate and a visible red band will form indicating a negative result (D). The absence of line formation in the test line region indicates a positive reading and that the COC level of the test specimen is above the detection sensitivity of the test.

In the control line region of the membrane, immobilized reagents capture colored conjugate regardless of the presence of the test specimen composition. The resulting visible red band (E) confirms that the assay is functioning correctly.

Figure 2 illustrates the possible outcomes of the test.

Figure 2: Interpretation of Results

1.3 Storage



Store the test at 2-30°C. Freezing must be avoided.

1.4 Stability

The *FUNWORLD* COC One Step Cocaine Test(Urine) is stable for 24 months from the date of production when stored properly in unopened aluminum foil pouches with desiccant.

1.5 Description of Test Methods

1.5.1 GENERAL REMARKS

The Quality Control department performs testing according to written procedures. Testing equipment is checked prior to use and calibrated at scheduled intervals.

1.5.2 RECEIVING INSPECTION AND CONTROL OF RAW MATERIALS

A sample batch of each raw material (chemicals, packaging and labeling) is inspected/tested (where applicable) for suitability and functionality. Primary packaging is inspected for correct dimensions, cleanliness and suitability. Only QC approved raw material is employed for production.

1.6 Composition of Product

A) Goat antibody

B) COC antibody

C) COC conjugate

D) Membrane

E) Adhesive plastic backing

F) Label pad

G) Absorbant pad

H) Sample pad

I) Top and bottom analyte specific adhesive label

J) Desiccant (in pouch)

K) Pouch

1.7 Manufacturing Procedure

a) Precoat the colloidal gold-conjugated antibody on the label pad.

b) Use sprayer to dispense COC antigen conjugate and goat antibody to the membrane.

c) Assemble the membrane, label pad, absorbant pad, sample pad, and top and bottom analyte specific adhesive label on the plastic backing.

d) Cut the plastic backing into s of selected size.

e) Pack the product and a desiccant packet into a pouch and seal the pouch.

f) Test the product according to QC procedure and release the finished product.

1.8 Quality Control

1.8.1 Internal Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

1.8.2 External Quality Control

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

1.8.3 Procedure for External Quality Control

1. Device：Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 μL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).

   Strip： With arrows pointing toward the urine specimen, immerse the test vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test when immersing the product.

2. Place the test on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.

2 PERFORMANCE CHARACTERISTICS

2.1 Specimen Correlation

The specimen correlation study was performed on 300 urine specimens. 124 positive urine specimens and 176 negative urine specimens were confirmed by GC/MS. These specimens were randomized and tested using the *FUNWORLD* COC One Step Cocaine Test(Urine). Specimens were rated as either positive or negative at 5minutes. The test results are shown in Table 1.

Table 1: Specimen Correlation

		GC/MS	
		+	-
COC One Step Test	+	119	17
	-	5	159

Positive agreement with GC/MS: 119/(119+5) = 96%

Negative agreement with GC/MS: 159/(159+17) = 90%

Total agreement with GC/MS: (119+159)/(119+5+17+159) = 93%

2.2 Analytical Sensitivity

A drug-free urine pool was spiked with Cocaine at the following concentrations: 0ng/mL, 150ng/mL, 225ng/mL, 300ng/mL, 375ng/mL, 450ng/mL and600mg/ml. The result demonstrates > 99% accuracy at 50% above and 50% below the cut-off concentration. Results are presented in Table 2 below.

Table 2: Analytical Sensitivity Summary

Device:

COC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	30	0
300	Cut-off	30	4	26
375	+25%	30	0	30
450	+50%	30	0	30
600	+100%	30	0	30

Strip:

COC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	30	0
300	Cut-off	30	4	26
375	+25%	30	0	30
450	+50%	30	0	30
600	+100%	30	0	30

Conclusion: As indicated in table above: all specimens with COC concentration equal to or lower than 150ng/mL show negative results, all specimens with COC concentration of 300ng/mL are identified as "+/-", and all specimens with COC concentration equal to or higher than 450ng/mL showed positive results. Therefore, the cut-off concentration of the *FUNWORLD* COC One Step Test(Urine) is determined to be 300ng/mL COC.

2.3 Analytical Specificity

Table 3 lists the compounds that are positively detected in urine by the *FUNWORLD* COC One Step Cocaine Test(Urine) at 5 minutes and the concentrations at which they are detected.

Table 3: Analytical Specificity

Device：

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Benzoylecgonine	150	Ecgonine HCl	12,500
Cocaine HCl	400	Ecgonine methylester	50,000
Cocaethylene	6,250		

Strip：

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Benzoylecgonine	150	Ecgonine HCl	12,500
Cocaine HCl	400	Ecgonine methylester	50,000
Cocaethylene	6,250		

2.4 Cross-Reactivity

Urine specimens were spiked with the following compounds at a concentration of 100 µg/mL. The specimens were tested in triplicate with 3 lots of test s. Visual interpretations were made 5 minutes after specimen application. The results are presented in Table 4 below.

Table 4: Non Cross-Reacting Compounds

Acetominophen	Diazepam	Methadone	Prednisone
Acetophenetidin	Diclofenac	Methoxyphenamine	Procaine
N-Acetylprocainamide	Diflunisal	(±)-3,4-Methylenedioxy-	Promazine
Acetylsalicylic acid	Digoxin	amphetamine	Promethazine
Aminopyrine	Diphenhydramine	(±)-3,4-Methylenedioxy-	D,L-Propranolol
Amitryptyline	Doxylamine	methamphetamine	D-Propoxyphene
Amobarbital	Ecgonine methylester	Morphine-3-β-D	D-Pseudoephedrine
Amoxicillin	(-)-ψ-Ephedrine	glucuronide	Quinidine
Ampicillin	Erythromycin	Morphine Sulfate	Quinine
L-Ascorbic acid	β-Estradiol	Nalidixic acid	Ranitidine
D,L-Amphetamine sulfate	Estrone-3-sulfate	Naloxone	Salicylic acid
Apomorphine	Ethyl-p-aminobenzoate	Naltrexone	Secobarbital
Aspartame	Fenoprofen	Naproxen	Serotonin
Atropine	Furosemide	Niacinamide	Sulfamethazine
Benzilic acid	Gentisic acid	Nifedipine	Sulindac
Benzoic acid	Hemoglobin	Norcodein	Temazepam
Benzphetamine	Hydralazine	Norethindrone	Tetracycline
Bilirubin	Hydrochlorothiazide	D-Norpropoxyphene	Tetrahydrocortisone,
(±) -Brompheniramine	Hydrocodone	Noscapine	3-Acetate
Caffeine	Hydrocortisone	D,L-Octopamine	Tetrahydrocortisone
Cannabidiol	O-Hydroxyhippuric acid	Oxalic acid	3-(β-D glucuronide)
Cannabinol	p-Hydroxy-	Oxazepam	Tetrahydrozoline
Chloralhydrate	methamphetamine	Oxolinic acid	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxycodone	Thiamine
Chlordiazepoxide	Ibuprofen	Oxymetazoline	Thioridazine
Chlorothiazide	Imipramine	Papaverine	D,L-Tyrosine
(±) -Chlorpheniramine	Iproniazid	Penicillin-G	Tolbutamide
Chlorpromazine	(±) - Isoproterenol	Pentobarbital	Triamterene
Chlorquine	Isoxsuprine	Perphenazine	Trifluoperazine
Cholesterol	Ketamine	Phencyclidine	Trimethoprim
Clomipramine	Ketoprofen	Phenelzine	Trimipramine
Clonidine	Labetalol	Phenobarbital	Tryptamine
Codeine	Levorphanol	Phentermine	D,L-Tryptophan
Cortisone	Loperamide	L-Phenylephrine	Tyramine
(-) Cotinine	Maprotiline	β-Phenylethylamine	Uric acid
Creatinine	Meperidine	Phenylpropanolamine	Verapamil
Deoxycorticosterone	Meprobamate	Prednisolone	Zomepirac
Dextromethorphan			

Conclusion: The compounds listed in the table above show no cross-reactivity at 5 minutes when tested at concentrations of 100 µg/mL.

2.5 Precision

A study was conducted at 3 physicians' offices by untrained operators using 3 different lots of product to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded specimens containing no Cocaine, Cocaine spiked at levels +/- 25% of the assay cut-off and Cocaine spiked at levels +/-50% of the 300 ng/mL assay cut-off were provided to each site. The results are presented in Table 5.

Table 5: Precision Results

Device：

Cocaine Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14*	0	15	0	15	0
150	15	14	1	15	0	14	1
225	15	4	11	5	10	8	7
375	15	0	15	0	15	0	15
450	15	0	15	0	15	1	14
Non Valid	15	16/16		15/15		15/15	

Strip：

Cocaine Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14*	0	15	0	15	0
150	15	14	1	15	0	14	1
225	15	4	11	5	10	8	7
375	15	0	15	0	15	0	15
450	15	0	15	0	15	1	14
Non Valid	15	16/16		15/15		15/15	

*Note: Non-valid results were obtained in this treatment. Non-valid tests were provided as part of this study to ensure that readers would accurately identify non-valid test results.

2.6 Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 0 ng/mL, 150 ng/mL, and 450 ng/mL of Cocaine. The *FUNWORLD* COC One Step Cocaine Test(Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Table 6: Results of Urinary Specific Gravity Effect

Device:

Urine ID	Urine Specific Gravity	N*	Neat urine		COC 150ng/mL		COC 450ng/mL		COC 600ng/mL	
			neg	pos	neg	pos	neg	pos	neg	pos
1	1.009	2	2	0	2	0	0	2	0	2
2	1.010	2	2	0	2	0	0	2	0	2
3	1.012	2	2	0	2	0	0	2	0	2
4	1.014	2	2	0	2	0	0	2	0	2
5	1.015	2	2	0	2	0	0	2	0	2
6	1.016	2	2	0	2	0	0	2	0	2
7	1.017	2	2	0	2	0	0	2	0	2
8	1.020	2	2	0	2	0	0	2	0	2
9	1.021	2	2	0	2	0	0	2	0	2
10	1.024	2	2	0	2	0	0	2	0	2
11	1.025	2	2	0	2	0	0	2	0	2
12	1.026	2	2	0	2	0	0	2	0	2
13	1.027	2	2	0	2	0	0	2	0	2
14	1.029	2	2	0	2	0	0	2	0	2
15	1.030	2	2	0	2	0	0	2	0	2

Strip:

Urine ID	Urine Specific Gravity	N*	Neat urine		COC 150ng/mL		COC 450ng/mL		COC 600ng/mL	
			neg	pos	neg	pos	neg	pos	neg	pos
1	1.009	2	2	0	2	0	0	2	0	2
2	1.010	2	2	0	2	0	0	2	0	2
3	1.012	2	2	0	2	0	0	2	0	2
4	1.014	2	2	0	2	0	0	2	0	2
5	1.015	2	2	0	2	0	0	2	0	2
6	1.016	2	2	0	2	0	0	2	0	2
7	1.017	2	2	0	2	0	0	2	0	2
8	1.020	2	2	0	2	0	0	2	0	2
9	1.021	2	2	0	2	0	0	2	0	2
10	1.024	2	2	0	2	0	0	2	0	2
11	1.025	2	2	0	2	0	0	2	0	2
12	1.026	2	2	0	2	0	0	2	0	2
13	1.027	2	2	0	2	0	0	2	0	2
14	1.029	2	2	0	2	0	0	2	0	2
15	1.030	2	2	0	2	0	0	2	0	2

Conclusion: Urinary specific gravity ranging from 1.009 – 1.030 did not interfere with the performance of *FUNWORLD* COC One Step Cocaine Test(Urine).

2.6 Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Cocaine to 0ng/mL, 150 ng/mL, 450ng/mL and 600ng/mL. The spiked, pH-adjusted urine was tested with the *FUNWORLD* COC One Step Cocaine Test(Urine) in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Table 7: Results of Urinary pH Effect

Device:

pH	Negative urine	COC 150ng/mL	COC 450ng/mL	COC 600ng/mL
5	-	-	+	+
	-	-	+	+
6	-	-	+	+
	-	-	+	+
7	-	-	+	+
	-	-	+	+
8	-	-	+	+
	-	-	+	+
9	-	-	+	+
	-	-	+	+

Strip:

pH	Negative urine	COC 150ng/mL	COC 450ng/mL	COC 600ng/mL
5	-	-	+	+
	-	-	+	+
6	-	-	+	+
	-	-	+	+
7	-	-	+	+
	-	-	+	+
8	-	-	+	+
	-	-	+	+
9	-	-	+	+
	-	-	+	+

Conclusions: The pH of the samples, when tested from a range pH5.0 to pH9.0, did not interfere with the performance of the *FUNWORLD* COC One Step Cotinine Test(Urine).

2.7 Real Time Stability

Real Time Stability of the *FUNWORLD* COC One Step Cocaine Test(Urine) was evaluated using samples from three different lots. These samples were placed in an incubator with the temperature calibrated at 2-8℃ and 30±3℃ with relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 0, 3, 6, 9, 12, 15, 18, 21, 24 and 27 months. Test s were assayed using urine specimens with COC concentration of 0, 150 ng/mL and 450ng/mL. Run ten replicates per sample for day 0 and three replicates per sample for other time points. Read result at 5 and 10 minutes. The tests were performed according to the package insert. The results are presented in Table 8.

Table 8: Real Time Stability Summary

Device：

Month	Specimen	Lot					
		202008025		202008026		202008027	
		2-8℃	30℃	2-8℃	30℃	2-8℃	30℃
0	0ng/mL COC	10-	10-	10-	10-	10-	10-
	150ng/mL COC	10-	10-	10-	10-	10-	10-
	450ng/mL COC	10+	10+	10+	10+	10+	10+
3	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
6	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
9	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
12	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
15	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
18	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						
21	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						
24	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						
27	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						

Strip：

Month	Specimen	Lot					
		202008010		202008011		202008012	
		2-8℃	30℃	2-8℃	30℃	2-8℃	30℃
0	0ng/mL COC	10-	10-	10-	10-	10-	10-
	150ng/mL COC	10-	10-	10-	10-	10-	10-
	450ng/mL COC	10+	10+	10+	10+	10+	10+
3	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
6	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
9	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
12	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
15	0ng/mL COC	3-	3-	3-	3-	3-	3-
	150ng/mL COC	3-	3-	3-	3-	3-	3-
	450ng/mL COC	3+	3+	3+	3+	3+	3+
18	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						
21	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						
24	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						
27	0ng/mL COC						
	150ng/mL COC						
	450ng/mL COC						

Note:

10- indicates negative test results with 10 replicates

10+ indicates positive test results with 10 replicates

3- indicates negative test results with 3 replicates

3+ indicates positive test results with 3 replicates

Conclusion: The *FUNWORLD* COC One Step Cocaine Test(Urine) is stable at the temperature of 2-30℃ for 15 months and the study will be finished in other 12 months.

2.8 Accelerated Stability

Accelerated Stability of the *FUNWORLD* COC One Step Cocaine Test(Urine) was evaluated using samples from three different lots. These were placed in an incubator with the temperature calibrated at 45℃ and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56 and 70 days. Test s were assayed using urine specimens with COC concentration of 0 and 450 ng/mL. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert. Results are presented in Table 9.

Table 9: Accelerated Stability Summary

Device：

Day	Specimen	Lot		
		202008025	202008026	202008027
0	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
7	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
14	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
21	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
28	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
35	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
42	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
56	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
70	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+

Strip：

Day	Specimen	Lot		
		202008010	202008011	202008012
0	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
7	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
14	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
21	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
28	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
35	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
42	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
56	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+
70	0ng/mL COC	3-	3-	3-
	450ng/mL COC	3+	3+	3+

Note:

3- indicates 3 replicates negative test results.

3+ indicates 3 replicates positive test results.

Conclusion: The *FUNWORLD* COC One Step Cocaine Test(Urine) is stable at 45℃ for 70 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 24 months from the date of manufacture.

3 BIBLIOGRAPHY

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