

Information for:

MDMA One Step Ecstasy Rapid Test

(Urine)



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1 BACKGROUND

Methylenedioxymethamphetamine (Ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.¹ Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who have taken a reasonable dose of the drug, is to produce a clenching of the jaws.

The *HYSEN* MDMA One Step Ecstasy 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 Ecstasy s in urine. The MDMA One Step Ecstasy Test(Urine) yields a positive result when Methylenedioxymethamphetamine in urine exceeds 500 ng/mL

1.1 Test Principle

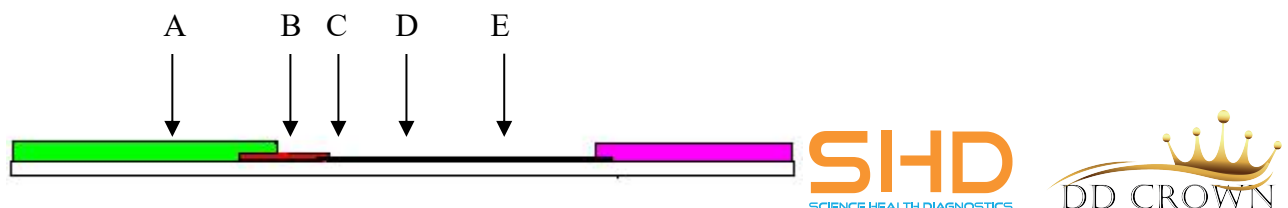
The *HYSEN* MDMA One Step Ecstasy Test(Urine) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Methylenedioxy-methamphetamine, if present in the urine specimen below 500 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 Methylenedioxymethamphetamine 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 Methylenedioxymethamphetamine level exceeds 500 ng/mL because it will saturate all the binding sites of anti-Methylenedioxymethamphetamine 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

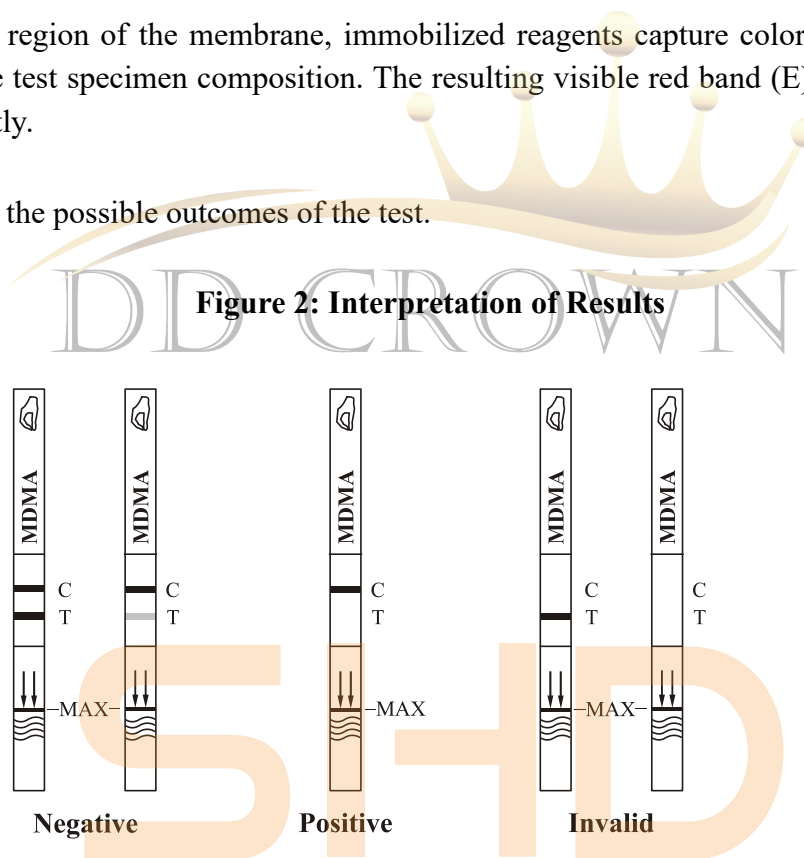
Figure 1: Test Principle



As shown in Figure 1 above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). MDMA present in the specimen below cut-off, will not saturate the binding sites of the gold-conjugated anti-MDMA antibodies and not form a colored antibody-antigen complex(C). The gold-conjugated antibodies will then be captured by immobilized MDMA 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 MDMA 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.



1.3 Storage

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

1.4 Stability

The *HYSEN* MDMA One Step Ecstasy 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) MDMA antibody |
| C) MDMA 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

- Precoat the colloidal gold-conjugated antibody on the label pad.
- Use sprayer to dispense MDMA antigen conjugate and goat antibody to the membrane.
- Assemble the membrane, label pad, absorbant pad, sample pad, and top and bottom analyte specific adhesive label on the plastic backing.
- Cut the plastic backing into s of selected size.
- Pack the product and a desiccant packet into a pouch and seal the pouch.
- 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

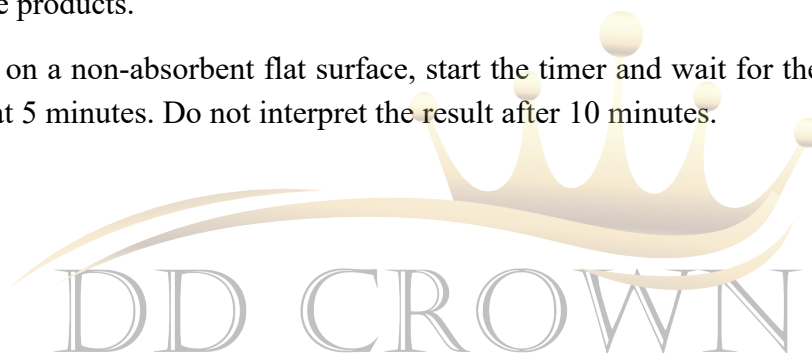
controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

1.8.3 PROCEDURE FOR EXTERNAL QUALITY CONTROL

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

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 products.

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 240 urine specimens. 88 positive urine specimens and 152 negative urine specimens were confirmed by GC/MS. These specimens were randomized and tested using the *HYSEN* MDMA One Step Ecstasy 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	
MDMA One Step Test	+	88	3
	-	0	149

Positive agreement with GC/MS: $88/(88+0) > 99\%$

Negative agreement with GC/MS: $149/(149+3) = 98\%$

Total agreement with GC/MS: $(88+149)/(88+0+3+149) = 99\%$

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2.2 Analytical Sensitivity

A drug-free urine pool was spiked with Ecstasy at the following concentrations: 0 ng/mL, 250 ng/mL, 375 ng/mL, 500 ng/mL, 625 ng/mL, 750 ng/mL and 1,000 ng/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:

MDMA Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
250	-50%	30	30	0
375	-25%	30	25	3
500	Cut-off	30	17	13
625	+25%	30	5	25
750	+50%	30	0	30
1,000	+100%	30	0	30

Strip:

MDMA Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
250	-50%	30	30	0
375	-25%	30	26	4
500	Cut-off	30	17	13
625	+25%	30	4	26
750	+50%	30	0	30
1,000	+100%	30	0	30

Conclusion: As indicated in table above: all specimens with MDMA concentration equal to or lower than 250ng/mL show negative results, all specimens with MDMA concentration of 500ng/mL are identified as “+/-”, and all specimens with MDMA concentration equal to or higher than 750ng/mL showed positive results. Therefore, the cut-off concentration of the *HYSEN* MDMA One Step Ecstasy Test(Urine) is determined to be 500ng/mL MDMA.

2.3 Analytical Specificity

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

Table 3: Analytical Specificity

Device:

Compound	Concentration (ng/mL)
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)	300

Strip:

Compound	Concentration (ng/mL)
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)	300

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

4-Acetamidophenol	Dextromethorphan	Meprobamate	Procaine
Acetophenetidin	Diclofenac	Methamphetamine	Promazine
N-Acetylprocainamide	Diazepam	Methadone	Promethazine
Acetylsalicylic acid	Diffunisal	Methoxyphenamine	D,L-Propranolol
Aminopyrine	Digoxin	Methylphenidate	D-Propoxyphene
Amitriptyline	Dicylomine	Morphine-	D-Pseudoephedrine
Amobarbital	Diphenhydramine	3-β-D-glucuronide	Quinacrine
Amoxicillin	5,5 - Diphenylhydantoin	Morphine sulfate	Quinidine
Ampicillin	Doxylamine	Nalidixic acid	Quinine
L-Ascorbic acid	Ecgonine hydrochloride	Naloxone	Ranitidine
D-Amphetamine	Ecgonine methylester	Naltrexone	Salicylic acid
D,L-Amphetamine sulfate	(-) -ψ-Ephedrine	Naproxen	Secobarbital
L-Amphetamine	[1R,2S](-) Ephedrine	Niacinamide	Serotonin
Apomorphine	L - Epinephrine	Nifedipine	(5-Hydroxytyramine)
Aspartame	Erythromycin	Nimesulidate	Sulfamethazine
Atropine	β-Estradiol	Norcodein	Sulindac
Benzilic acid	Estrone-3-sulfate	Norethindrone	Sustiva
Benzoic acid	Ethyl-p-aminobenzoate	D-Norpropoxyphene	Temazepam
Benzoylcegonine	Fenoprofen	Noscapine	Tetracycline
Benzphetamine	Furosemide	D,L-Octopamine	Tetrahydrocortisone,
Bilirubin	Gentisic acid	Oxalic acid	3- Acetate
(±) - Brompheniramine	Hemoglobin	Oxazepam	Tetrahydrocortisone
Buspiron	Hydralazine	Oxolinic acid	3-(β-D glucuronide)
Caffeine	Hydrochlorothiazide	Oxycodone	Tetrahydrozoline
Cannabidiol	Hydrocodone	Oxymetazoline	Thebaine
Cannabinol	Hydrocortisone	Papaverine	Theophylline
Chloralhydrate	O-Hydroxyhippuric acid	Penicillin-G	Thiamine
Chloramphenicol	p-Hydroxyamphetamine	Pentazocine	Trans-2-
Chlordiazepoxide	p-Hydroxy-	hydrochloride	phenylcyclopropylamine
Chlorothiazide	methamphetamine	Pentobarbital	Thioridazine
(±) - Chlorpheniramine	3-Hydroxytyramine	Perphenazine	Tolbutamide
Chlorpromazine	Imipramine	Phencyclidine	Trazodone
Chlorquine	Iproniazid	Phenelzine	D,L-Tyrosine
Cholesterol	(±) - Isoproterenol	Phenobarbital	Triamterene
Clomipramine	Isoxsuprine	Phentermine	Trifluoperazine
Clonidine	Ketamine	Trans-2-phenyl	Trimethoprim
Cocaethylene	Ketoprofen	cyclopropylamine	Trimipramine
Cocaine hydrochloride	Labetalol	hydrochloride	Tryptamine
Codeine	Levorphanol	L-Phenylephrine	D,L-Tryptophan
Cortisone	Loperamide	β-Phenylethylamine	Tyramine
(-) Cotinine	Maprotiline	Phenylpropanolamine	Uric acid
Creatinine	Meperidine	Prednisolone	Verapamil
Deoxycorticosterone	Mephentermine	Prednisone	Zomepirac

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 Ecstasy, Ecstasy spiked at levels $\pm 25\%$ of the assay cut-off and Ecstasy spiked at levels $\pm 50\%$ of the 500ng/mL assay cut-off were provided to each site. The results are presented in Table 5.

Table 5: Precision Results

Device:

Ecstasy Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	14	1	14	0	14	1
625	15	5	9	4	12	6	9
750	15	0	15	0	15	0	15

Strip:

Ecstasy Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	15	0	15	0
625	15	6	9	4	11	7	8
750	15	0	15	0	15	0	15

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2.6 Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 0ng/mL, 250ng/mL, 750ng/mL and 1,000ng/mL of Ecstasy. The *HYSEN* MDMA One Step Ecstasy 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		MDMA250ng/mL		MDMA750ng/mL		MDMA1000ng/mL	
			neg	pos	neg	pos	neg	pos	neg	pos
1	1.012	2	2	0	2	0	0	2	0	2
2	1.012	2	2	0	2	0	0	2	0	2
3	1.001	2	2	0	2	0	0	2	0	2
4	1.004	2	2	0	2	0	0	2	0	2
5	1.008	2	2	0	2	0	0	2	0	2
6	1.018	2	2	0	2	0	0	2	0	2
7	1.016	2	2	0	2	0	0	2	0	2
8	1.019	2	2	0	2	0	0	2	0	2
9	1.019	2	2	0	2	0	0	2	0	2
10	1.014	2	2	0	2	0	0	2	0	2
11	1.032	2	2	0	2	0	0	2	0	2
12	1.026	2	2	0	2	0	0	2	0	2
13	1.028	2	2	0	2	0	0	2	0	2
14	1.034	2	2	0	2	0	0	2	0	2
15	1.027	2	2	0	2	0	0	2	0	2

Strip:

Urine ID	Urine Specific Gravity	N*	Neat urine		MDMA250ng/mL		MDMA750ng/mL		MDMA1000ng/mL	
			neg	pos	neg	pos	neg	pos	neg	pos
1	1.012	2	2	0	2	0	0	2	0	2
2	1.012	2	2	0	2	0	0	2	0	2
3	1.001	2	2	0	2	0	0	2	0	2
4	1.004	2	2	0	2	0	0	2	0	2
5	1.008	2	2	0	2	0	0	2	0	2
6	1.018	2	2	0	2	0	0	2	0	2
7	1.016	2	2	0	2	0	0	2	0	2
8	1.019	2	2	0	2	0	0	2	0	2
9	1.019	2	2	0	2	0	0	2	0	2
10	1.014	2	2	0	2	0	0	2	0	2
11	1.032	2	2	0	2	0	0	2	0	2
12	1.026	2	2	0	2	0	0	2	0	2
13	1.028	2	2	0	2	0	0	2	0	2
14	1.034	2	2	0	2	0	0	2	0	2
15	1.027	2	2	0	2	0	0	2	0	2

Conclusion: Urinary specific gravity ranging from 1.001 – 1.034 did not interfere with the performance of *HYSEN* MDMA One Step Cotinine Test(Urine).

2.7 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 Ecstasy to 0ng/mL, 250 ng/mL, 750ng/mL and 1000ng/mL. The spiked, pH-adjusted urine was tested with the *HYSEN* MDMA One Step Ecstasy 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	MDMA 250ng/mL	MDMA 750ng/mL	MDMA 1000ng/mL
5	-	-	+	+
	-	-	+	+
6	-	-	+	+
	-	-	+	+
7	-	-	+	+
	-	-	+	+
8	-	-	+	+
	-	-	+	+
9	-	-	+	+
	-	-	+	+

Strip:

pH	Negative urine	MDMA 250ng/mL	MDMA 750ng/mL	MDMA 1000ng/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 *HYSEN* MDMA One Step Cotinine Test(Urine).

2.8 Real Time Stability

Real Time Stability of the *HYSEN* MDMA One Step Ecstasy Test(Urine) was evaluated using samples from three different lots. These samples were placed in an incubator with the temperature calibrated at 2-8°C and 30 ±3°C 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 MDMA concentration of 0, 250 ng/mL and 750ng/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					
		202008016		202008017		202008018	
		2-8°C	30°C	2-8°C	30°C	2-8°C	30°C
0	0ng/mL MDMA	10-	10-	10-	10-	10-	10-
	250ng/mL MDMA	10-	10-	10-	10-	10-	10-
	750ng/mL MDMA	10+	10+	10+	10+	10+	10+
3	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
6	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
9	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
12	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
15	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
18							
21							
24							
27							

Strip:

Month	Specimen	Lot					
		202008019		202008020		202008021	
		2-8°C	30°C	2-8°C	30°C	2-8°C	30°C
0	0ng/mL MDMA	10-	10-	10-	10-	10-	10-
	250ng/mL MDMA	10-	10-	10-	10-	10-	10-
	750ng/mL MDMA	10+	10+	10+	10+	10+	10+
3	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
6	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
9	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
12	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
15	0ng/mL MDMA	3-	3-	3-	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+	3+	3+	3+
18							
21							
24							
27							

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 real time stability study for the *HYSEN* MDMA One Step Ecstasy Test Device (Urine) is going on and will be finished in other 12 months.

2.9 Accelerated Stability

Accelerated Stability of the *HYSEN* MDMA One Step Ecstasy Test(Urine) was evaluated using samples from three different lots. These were placed in an incubator with the temperature calibrated at 45 °C 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. Tests were assayed using urine specimens with MDMA concentration of 0 and 125 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		
		202008016	202008017	202008018
0	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
7	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
14	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
21	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
28	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
35	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
42	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
56	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
70	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+

SCIENCE HEALTH DIAGNOSTICS

Strip:

Day	Specimen	Lot		
		202008019	202008020	202008021
0	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
7	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
14	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
21	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
28	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
35	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
42	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
56	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+
70	0ng/mL MDMA	3-	3-	3-
	250ng/mL MDMA	3-	3-	3-
	750ng/mL MDMA	3+	3+	3+

Note:

3- indicates 3 replicates negative test results.

3+ indicates 3 replicates positive test results.

SCIENCE HEALTH DIAGNOSTICS

Conclusion: The *HYSEN* MDMA One Step Ecstasy Test(Urine) is stable at 45 °C 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

1. Winger G. A Handbook of Drug and Alcohol Abuse. Third Edition, Oxford Press. 1992; 146
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, Chiang CN. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

