Information for:

MET One Step Methamphetamine Rapid Test

(Urine)

CONFIDENTIAL

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1 BACKGROUND

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours, and the drug has a half-life of 9-24 hours in the body. In urines of normal pH approximately 43% of a dose is eliminated as unchanged methamphetamine in a 24hour period, with about 4-7% eliminated as amphetamine. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The *HYSEN* MET One Step Methamphetamine 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 Methamphetamine in urine. The *HYSEN* MET One Step Methamphetamine Test(Urine) yields a positive result when the Methamphetamine in urine exceeds 1000 ng/mL.

1.1 Test Principle

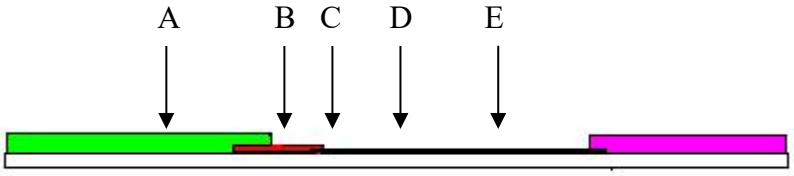
The *HYSEN* MET One Step Methamphetamine Test(Urine) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Methamphetamine, if present in the urine specimen below 1000 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 Methamphetamine 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 Methamphetamine level exceeds 1000 ng/mL because it will saturate all the binding sites of anti-Methamphetamine 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

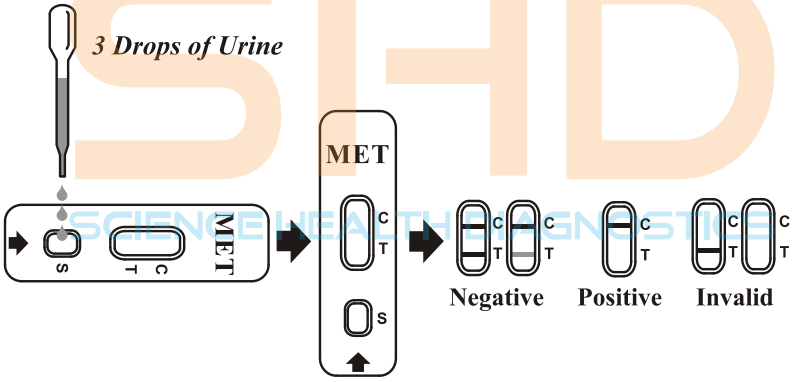


As shown in Figure 1 above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). MET present in the specimen below cut-off, will not saturate the binding sites of the gold-conjugated anti-MET antibodies and not form a colored antibody-antigen complex(C).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

C) MET conjugate

D) Membrane

E) Adhesive plastic backing

F) Label pad

G) Absorbant pad

H) Sample pad

I) Dropper

J)

K) Pouch

L) Desiccant (in pouch)

1.7 Manufacturing Procedure

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

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

c) Assemble the membrane, label pad, absorbent pad and sample pad on the plastic backing.

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

e) Lay the strip into the plastic , pack the product, dropper 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 red line appearing in the control line region (C) is considered an internal positive 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, 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 strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip.
2. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not read results after 10 minutes.

2 PERFORMANCE CHARACTERISTICS

2.1 Specimen Correlation

The specimen correlation study was performed on 300 urine specimens. 140 positive urine specimens and 160 negative urine specimens were confirmed by GC/MS. These specimens were randomized and tested using the *HYSEN* MET One Step Methamphetamine 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	
		+	-
MET One Step Test	+	139	7
	-	1	153

Positive agreement with GC/MS: 139/(139+1) = 99%

Negative agreement with GC/MS: 153/(153+7) = 96%

Total agreement with GC/MS: (139+153)/(139+7+153+1) = 97%

2.2 Analytical Sensitivity

A drug-free urine pool was spiked with Methamphetamine at the following concentrations: 0ng/mL, 250ng/mL, 375ng/mL, 500ng/mL, 625ng/mL, 750ng/mL and 1000ng/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:

MET Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
500	-50%	30	30	0
750	-25%	30	27	3
1000	Cut-off	30	13	17
1,250	+25%	30	7	23
1,500	+50%	30	0	30
2,000	+100%	30	0	30

Strip:

MET Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
500	-50%	30	30	0
750	-25%	30	30	0
1000	Cut-off	30	18	12
1,250	+25%	30	1	29
1,500	+50%	30	0	30
2,000	+100%	30	0	30

Conclusion: As indicated in table above: all specimens with MET concentration equal to or lower than 250ng/mL show negative results, all specimens with MET concentration of 1000ng/mL are identified as "+/-", and all specimens with MET concentration equal to or higher than 1500ng/mL showed positive results. Therefore, the cut-off concentration of the *HYSEN* MET One Step Methamphetamine Test(Urine) is determined to be 1000ng/mL MET.

2.3 Analytical Specificity

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

Table 3: Analytical Specificity

Device:

Compound	Concentration (ng/mL)
ρ-Hydroxymethamphetamine	15,000
D-Methamphetamine	1,000
L-Methamphetamine	4,000
(±)-3,4-Methylenedioxymethamphetamine	1,000
Mephentermine	25,000
D-Amphetamine	50,000
D,L-Amphetamine	75,000
Chloroquine	12,500
(1R,2S)-(-)-Ephedrine	50,000
L-Phenylephrine	100,000
β-Phenylethylamine	75,000

Strip:

Compound	Concentration (ng/mL)
ρ-Hydroxymethamphetamine	15,000
D-Methamphetamine	1,000
L-Methamphetamine	4,000
(±)-3,4-Methylenedioxymethamphetamine	1,000
Mephentermine	25,000
D-Amphetamine	50,000
D,L-Amphetamine	75,000
Chloroquine	12,500
(1R,2S)-(-)-Ephedrine	50,000
L-Phenylephrine	100,000
β-Phenylethylamine	75,000

2.4 Cross-Reactivity

Urine specimens were spiked with the following compounds at a concentration of 100 µ g/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	Diazepam	Meperidine	Promazine
Acetophenetidin	Diclofenac	Meprobamate	Promethazine
N-Acetylprocainamide	Diflunisal	Methadone	D,L-Propanolol
Acetylsalicylic acid	Digoxin	Methoxyphenamine	D-Propoxyphene
Aminopyrine	Diphenhydramine	(+) 3,4-Methylenedioxy-	D-Pseudoephedrine
Amitryptyline	Doxylamine	amphetamine	Quinacrine
Amobarbital	Ecgonine hydrochloride	3,4-Methylenedioxyethyl-	Quinidine
Amoxicillin	Ecgonine methylester	amphetamine	Quinine
Ampicillin	L-Epinephrine	Methylphenidate	Ranitidine
L-Ascorbic acid	(-)Y Ephedrine	Morphine-3-β-D-	Salicylic acid
L-Amphetamine	Erythromycin	glucuronide	Secobarbital
Apomorphine	β-Estradiol	Nalidixic acid	Serotonin
Aspartame	Estrone-3-sulfate	Naloxone	(5-Hydroxytyramine)
Atropine	Ethyl-p-aminobenzoate	Naltrexone	Sulfamethazine
Benzilic acid	Fenfluramine	Naproxen	Sulindac
Benzoic acid	Fenoprofen	Niacinamide	Temazepam
Benzoylecgonine	Furosemide	Nifedipine	Tetracycline
Benzphetamine	Gentisic acid	Norethindrone	Tetrahydrocortisone,
Bilirubin	Hemoglobin	D-Norpropoxyphene	3-Acetate
(±)-Brompheniramine	Hydralazine	Noscapine	Tetrahydrocortisone 3-
Caffeine	Hydrochlorothiazide	D,L-Octopamine	(β-D glucuronide)
Cannabidiol	Hydrocodone	Oxalic acid	Tetrahydrozoline
Chloralhydrate	Hydrocortisone	Oxazepam	Thiamine
Chloramphenicol	p-Hydroxyamphetamine	Oxolinic acid	Thioridazine
Chlordiazepoxide	O-Hydroxyhippuric acid	Oxycodone	D, L-Tyrosine
Chlorothiazide	Hydrocortisone	Oxymetazoline	Tolbutamine
(±)-Chlorpheniramine	3-Hydroxytyramine	Papaverine	Trans-2- phenyl
Chlorpromazine	Ibuprofen	Penicillin-G	cyclopropylamine
Cholesterol	Imipramine	Pentobarbital	Triamterene
Clomipramine	Iproniazid	Perphenazine	Trifluoperazine
Clonidine	(±)-Isoproterenol	Phencyclidine	Trimethoprim
Cocaethylene	Isoxsuprine	Phenelzine	Trimipramine
Cocaine	Ketamine	Phenobarbital	Tryptamine
Codeine	Ketoprofen	Phentermine	D, L-Tryptophan
Cortisone	Labetalol	Phenylpropanolamine	Tyramine
(-) Cotinine	Levorphanol	Prednisolone	Uric acid
Creatinine	Loperamide	Prednisone	Verapamil
Deoxycorticosterone	Maprotiline	Procaine	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 Methamphetamine, Methamphetamine spiked at levels +/- 25% of the assay cut-off and Methamphetamine spiked at levels +/-50% of the 1000 ng/mL assay cut-off were provided to each site. The results are presented in Table 5.

Table 5: Precision Results

Device：

Methamphetamine Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	13	2
750	15	11	4	10	5	10	5
1,250	15	8	7	4	11	6	9
1,500	15	1	14	1	14	0	15

Strip：

Methamphetamine Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	13	2
750	15	11	4	10	5	10	5
1,250	15	8	7	4	11	6	9
1,500	15	1	14	1	14	0	15

2.6 Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 0, 500ng/mL, 1500ng/mL and 2000ng/mL of Methamphetamine. The *HYSEN* MET One Step Methamphetamine 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		MET 500ng/mL		MET 1500ng/mL		MET 2000ng/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		MET 500ng/mL		MET 1500ng/mL		MET 2000ng/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 *HYSEN* MET One Step Methamphetamine 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 Methamphetamine to 0ng/mL, 500ng/mL, 1500ng/mL and 2000ng/mL. The spiked, pH-adjusted urine was tested with the *HYSEN* MET One Step Methamphetamine 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	MET 500ng/mL	MET 1500ng/mL	MET2000ng/mL
5	-	-	+	+
	-	-	+	+
6	-	-	+	+
	-	-	+	+
7	-	-	+	+
	-	-	+	+
8	-	-	+	+
	-	-	+	+
9	-	-	+	+
	-	-	+	+

Strip：

pH	Negative urine	MET 500ng/mL	MET 1500ng/mL	MET2000ng/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 MET One Step Methamphetamine Test(Urine).

2.8 Real Time Stability

Real Time Stability of the *HYSEN* MET One Step Methamphetamine 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 MET concentration of 0, 500 and 2000ng/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					
		202008001		202008002		202008003	
		2-8℃	30℃	2-8℃	30℃	2-8℃	30℃
0	0ng/mL MET	10-	10-	10-	10-	10-	10-
	500ng/mL MET	10-	10-	10-	10-	10-	10-
	2000ng/mL MET	10+	10+	10+	10+	10+	10+
3	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
6	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
9	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
12	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
15	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
18	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						
21	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						
24	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						
27	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						

Strip:

Month	Specimen	Lot					
		202008004		202008005		202008006	
		2-8℃	30℃	2-8℃	30℃	2-8℃	30℃
0	0ng/mL MET	10-	10-	10-	10-	10-	10-
	500ng/mL MET	10-	10-	10-	10-	10-	10-
	2000ng/mL MET	10+	10+	10+	10+	10+	10+
3	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
6	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
9	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
12	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
15	0ng/mL MET	3-	3-	3-	3-	3-	3-
	500ng/mL MET	3-	3-	3-	3-	3-	3-
	2000ng/mL MET	3+	3+	3+	3+	3+	3+
18	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						
21	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						
24	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						
27	0ng/mL MET						
	500ng/mL MET						
	2000ng/mL MET						

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 study is going on and will be finished in other 12 months.

2.9 Accelerated Stability

Accelerated Stability of the *HYSEN* MET One Step Methamphetamine 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 73days. Test s were assayed using urine specimens with MET concentration of 0, 500ng/mL and 2000 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		
		202008001	202008002	202008003
0	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
7	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
14	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
21	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
28	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
35	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
42	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
56	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
73	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+

Strip:

Day	Specimen	Lot		
		202008004	202008005	202008006
0	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
7	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
14	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
21	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
28	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
35	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
42	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
56	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+
73	0ng/mL MET	3-	3-	3-
	500ng/mL MET	3-	3-	3-
	2000ng/mL MET	3+	3+	3+

Note:
3- indicates 3 replicates negative test results.
3+ indicates 3 replicates positive test results.

Conclusion: The *HYSEN* MET One Step Methamphetamine Test(Urine) is stable at 45℃ for 73 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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