

Information for:

THC One Step Marijuana Rapid Test

(Urine)



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Table of Contents

1	BACKGROUND.....	3
1.1	Test Principle	3
1.2	Illustrations	4
1.3	Storage.....	4
1.4	Stability	5
1.5	Description of Test Methods.....	5
1.5.1	General remarks	5
1.5.2	Receiving inspection and control of raw materials.....	5
1.6	Composition of Product	5
1.7	Manufacturing Procedure	5
1.8	Quality Control	6
1.8.1	Internal Quality Control	6
1.8.2	External Quality Control	6
1.8.3	Procedure for External Quality Control	6
2	PERFORMANCE CHARACTERISTICS	7
2.1	Specimen Correlation	7
2.2	Analytical Sensitivity.....	8
2.3	Analytical Specificity	9
2.4	Cross Reactivity	10
2.5	Precision	11
2.6	Effect of Urinary Specific Gravity	12
2.7	Effect of Urinary pH	13
2.8	Real Time Stability	14
2.9	Accelerated Stability	17
3	BIBLIOGRAPHY	20
	Figure 1: Test Principle	4
	Figure 2: Interpretation of Results.....	4
	Table 1: Specimen Correlation	7
	Table 2: Analytical Sensitivity Summary.....	8
	Table 3: Analytical Specificity.....	9
	Table 4: Non Cross-Reacting Compounds	10
	Table 5: Precision Results	11
	Table 6: Results of Urinary Specific Gravity Effect	12
	Table 7: Results of Urinary pH Effect	13
	Table 8: Real Time Stability Summary	15
	Table 9: Accelerated Stability Summary	18

1 BACKGROUND

THC (Δ^9 -tetrahydrocannabinol) is the primary active ingredient in cannabinoids (Marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking Marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -THC-COOH).

The *HYSEN* THC One Step Marijuana 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 Marijuana in urine. The THC One Step Marijuana Test(Urine) yields a positive result when the concentration of Marijuana in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).¹

1.1 Test Principle

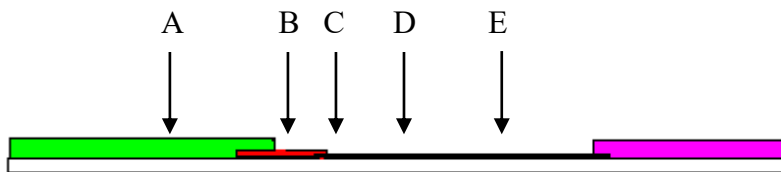
The THC One Step Marijuana Test(Urine) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Marijuana, if present in the urine specimen below 50 ng/mL, will not saturate the binding sites of the antibody coated particles in the test. The antibody coated particles will then be captured by immobilized Marijuana 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 Marijuana level is above 50 ng/mL because it will saturate all the binding sites of anti-Marijuana antibodies.

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

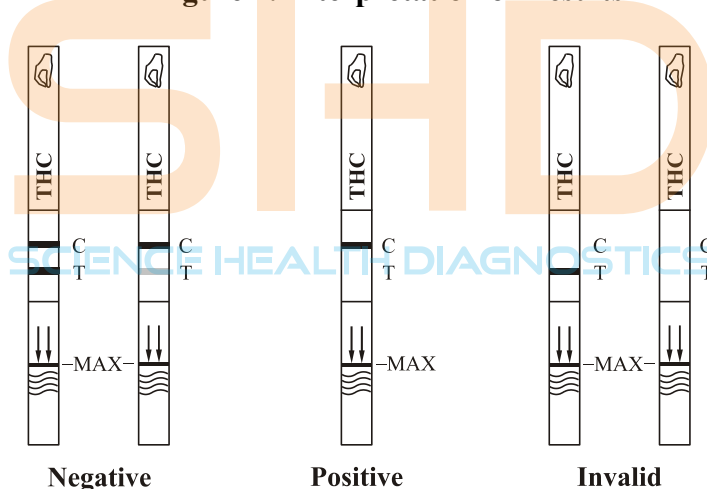


As shown in Figure 1 above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). THC present in the specimen below cut-off, will not saturate the binding sites of the gold-conjugated anti-THC antibodies and not form a colored antibody-antigen complex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

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. All specimens were confirmed by GC/MS. These specimens were randomized and tested using the *HYSEN* THC One Step Marijuana Test(Urine). Specimens were rated as either positive or negative at 5minutes. The test results are shown in Table 1.

Table 1: Specimen Correlation

When compared to GC/MS at 50 ng/mL, the following results were tabulated:

		GC/MS	
		+	-
THC One Step Test	+	118	22
	-	4	156

Positive agreement with GC/MS: $118/(118+4) = 97\%$

Negative agreement with GC/MS: $156/(156+22) = 88\%$

Total agreement with GC/MS: $(118+156)/(118+4+22+156) = 91\%$

When compared to GC/MS at 25 ng/mL, the following results were tabulated:

		GC/MS	
		+	-
THC One Step Test	+	135	5
	-	6	154

Positive agreement with GC/MS: $135/(135+6) = 96\%$

Negative agreement with GC/MS: $154/(154+5) = 97\%$

Total agreement with GC/MS: $(135+154)/(135+6+5+154) = 96\%$

2.2 Analytical Sensitivity

A drug-free urine pool was spiked with Marijuana at the following concentrations: 0 ng/mL, 25 ng/mL, 37.5 ng/mL, 50 ng/mL, 62.5 ng/mL, 75 ng/mL and 100 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

11-nor- Δ^9 -THC-9 COOH Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
37.5	-25%	30	12	18
50	Cut-off	30	12	18
62.5	+25%	30	1	29
75	+50%	30	1	29
100	+100%	30	0	30

Conclusion: As indicated in table above: all specimens with THC concentration equal to or lower than 25ng/mL show negative results, all specimens with THC concentration of 50ng/mL are identified as “+/-”, and all specimens with THC concentration equal to or higher than 75ng/mL showed positive results. Therefore, the cut-off concentration of the *HYSEN* THC One Step Marijuana Test(Urine) is determined to be 50ng/mL THC.

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2.3 Analytical Specificity

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

Table 3: Analytical Specificity

Compound	Concentration (ng/mL)
Cannabinol	20,000
11-nor- Δ^8 -THC-9 COOH	30
11-nor- Δ^9 -THC-9 COOH	50
Δ^8 -THC	15,000
Δ^9 -THC	15,000

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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	Deoxycorticosterone	(+) 3,4-Methylenedioxy-	Prednisolone
Acetophenetidin	Dextromethorphan	amphetamine	Prednisone
N-Acetylprocainamide	Diazepam	(+) 3,4-Methylenedioxy-	Procaine
Acetylsalicylic acid	Diclofenac	methamphetamine	Promazine
Aminopyrine	Diffunisal	Methylphenidate	Promethazine
Amitriptyline	Digoxin	Methypylon	D,L-Propanolol
Amobarbital	Diphenhydramine	Morphine-3-	D-Propoxyphene
Amoxicillin	Doxylamine	β-D-glucuronide	D-Pseudoephedrine
Ampicillin	Ecgonine hydrochloride	Nalidixic acid	Quinidine
L-Ascorbic acid	Ecgonine methylester	Nalorphine	Quinine
D,L-Amphetamine	(-)-ψ-Ephedrine	Naloxone	Ranitidine
L-Amphetamine	Erythromycin	Naltrexone	Salicylic acid
Apomorphine	β-Estradiol	Naproxen	Secobarbital
Aspartame	Estrone-3-sulfate	Niacinamide	Serotonin (5-Hydroxytyramine)
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Sulfamethazine
Benzilic acid	Fenoprofen	Norcodein	Sulindac
Benzoic acid	Furosemide	Norethindrone	Temazepam
Benzoylcegonine	Gentisic acid	D-Norpropoxyphene	Tetracycline
Benzphetamine	Hemoglobin	Noscapine	Tetrahydrocortisone,
Bilirubin	Hydralazine	D,L-Octopamine	3-Acetate
(±)-Brompheniramine	Hydrochlorothiazide	Oxalic acid	Tetrahydrocortisone
Caffeine	Hydrocodone	Oxazepam	3-(β-D-glucuronide)
Cannabidiol	Hydrocortisone	Oxolinic acid	Tetrahydrozoline
Chloralhydrate	O-Hydroxyhippuric acid	Oxycodone	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxymetazoline	Thiamine
Chlordiazepoxide	Ibuprofen	p-Hydroxy-	Thioridazine
Chlorothiazide	Imipramine	methamphetamine	D, L-Thyroxine
(±) Chlorpheniramine	Iproniazid	Papaverine	Tolbutamine
Chlorpromazine	(±) - Isoproterenol	Penicillin-G	Triamterene
Chlorquine	Isoxsuprine	Pentazocine	Trifluoperazine
Cholesterol	Ketamine	Pentobarbital	Trimethoprim
Clomipramine	Ketoprofen	Perphenazine	Trimipramine
Clonidine	Labetalol	Phencyclidine	Tryptamine
Cocaine hydrochloride	Levorphanol	Phenelzine	D, L-Tryptophan
Codeine	Loperamide	Phenobarbital	Tyramine
Cortisone	Maprotiline	Phentermine	D, L-Tyrosine
(-) Cotinine	Meprobamate	L-Phenylephrine	Uric acid
Creatinine	Methadone	β-Phenylethylamine	Verapamil
	Methoxyphenamine	Phenylpropanolamine	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 three physicians' offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid, 25% 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid above and below the cut-off, and 50% 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid above and below the 50 ng/mL cut-off was provided to each site. The results are presented in Table 5

Table 5: Precision Results

Device:

11-nor- Δ^9 -THC-9 COOH Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	0
37.5	15	9	2	14	2	10	6
62.5	15	0	13	0	15	0	15
75	15	0	15	0	15	0	15

Strip:

11-nor- Δ^9 -THC-9 COOH Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	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 0 ng/mL, 25 ng/mL, 75 ng/mL and 100 ng/mL of Marijuana. The THC One Step Marijuana 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		THC25ng/mL		THC75 ng/mL		THC100ng/mL	
			neg	pos	neg	pos	neg	pos	neg	pos
1	1.011	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	1.010	2	2	0	2	0	0	2	0	2
5	1.007	2	2	0	2	0	0	2	0	2
6	1.022	2	2	0	2	0	0	2	0	2
7	1.015	2	2	0	2	0	0	2	0	2
8	1.018	2	2	0	2	0	0	2	0	2
9	1.022	2	2	0	2	0	0	2	0	2
10	1.018	2	2	0	2	0	0	2	0	2
11	1.032	2	2	0	2	0	0	2	0	2
12	1.027	2	2	0	2	0	0	2	0	2
13	1.027	2	2	0	2	0	0	2	0	2
14	1.028	2	2	0	2	0	0	2	0	2
15	1.025	2	2	0	2	0	0	2	0	2

Strip:

Urine ID	Urine Specific Gravity	N*	Neat urine		THC25ng/mL		THC75 ng/mL		THC100ng/mL	
			neg	pos	neg	pos	neg	pos	neg	pos
1	1.011	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	1.010	2	2	0	2	0	0	2	0	2
5	1.007	2	2	0	2	0	0	2	0	2
6	1.022	2	2	0	2	0	0	2	0	2
7	1.015	2	2	0	2	0	0	2	0	2
8	1.018	2	2	0	2	0	0	2	0	2
9	1.022	2	2	0	2	0	0	2	0	2
10	1.018	2	2	0	2	0	0	2	0	2
11	1.032	2	2	0	2	0	0	2	0	2
12	1.027	2	2	0	2	0	0	2	0	2
13	1.027	2	2	0	2	0	0	2	0	2
14	1.028	2	2	0	2	0	0	2	0	2
15	1.025	2	2	0	2	0	0	2	0	2

Conclusion: Urinary specific gravity ranging from 1.007–1.032 did not interfere with the performance of *HYSEN* THC One Step Marijuana 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 Marijuana to 0ng/mL, 25 ng/mL, 75ng/mL and 100ng/mL. The spiked, pH-adjusted urine was tested with the *HYSEN* THC One Step Marijuana 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	THC 25ng/mL	THC 75ng/mL	THC 100ng/mL
5	-	-	+	+
	-	-	+	+
6	-	-	+	+
	-	-	+	+
7	-	-	+	+
	-	-	+	+
8	-	-	+	+
	-	-	+	+
9	-	-	+	+
	-	-	+	+

Strip:

pH	Negative urine	THC 25ng/mL	THC 75ng/mL	THC 100ng/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* THC One Step Marijuana Test(Urine).

2.8 Real Time Stability

Real Time Stability of the *HYSEN* THC One Step Marijuana 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 and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 0, 3, 6, 9, 11 months. Tests were assayed using urine specimens with THC concentration of 25 ng/mL and 75 ng/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					
		202007016		202007017		202007018	
		2-8°C	30°C	2-8°C	30°C	2-8°C	30°C
0	0ng/mL THC	10-	10-	10-	10-	10-	10-
	25ng/mL THC	10-	10-	10-	10-	10-	10-
	75ng/mL THC	10+	10+	10+	10+	10+	10+
3	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
6	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
9	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
12	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
15	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
18	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
21	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
24	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
27	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						

Strip:

Month	Specimen	Lot					
		202007022		202007023		202007024	
		2-8°C	30°C	2-8°C	30°C	2-8°C	30°C
0	0ng/mL THC	10-	10-	10-	10-	10-	10-
	25ng/mL THC	10-	10-	10-	10-	10-	10-
	75ng/mL THC	10+	10+	10+	10+	10+	10+
3	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
6	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
9	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
12	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
15	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
18	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
21	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
24	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
27	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						

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 *HYSEN* THC One Step Marijuana Test(Urine) is stable at the temperature of 2-30°C for 15 months and the study will be finished in other 12 months.

2.9 Accelerated Stability

Accelerated Stability of the *HYSEN* THC One Step Marijuana 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 70days. Test s were assayed using urine specimens with THC concentration of 0, 25 and 75 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					
		202007016		202007017		202007018	
		2-8°C	30°C	2-8°C	30°C	2-8°C	30°C
0	0ng/mL THC	10-	10-	10-	10-	10-	10-
	25ng/mL THC	10-	10-	10-	10-	10-	10-
	75ng/mL THC	10+	10+	10+	10+	10+	10+
7	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
14	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
21	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
28	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
35	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
42	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
56	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
70	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						

SCIENCE HEALTH DIAGNOSTICS

Strip:

Day	Specimen	Lot					
		202007022		202007023		202007024	
		2-8°C	30°C	2-8°C	30°C	2-8°C	30°C
0	0ng/mL THC	10-	10-	10-	10-	10-	10-
	25ng/mL THC	10-	10-	10-	10-	10-	10-
	75ng/mL THC	10+	10+	10+	10+	10+	10+
7	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
14	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
21	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
28	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
35	0ng/mL THC	3-	3-	3-	3-	3-	3-
	25ng/mL THC	3-	3-	3-	3-	3-	3-
	75ng/mL THC	3+	3+	3+	3+	3+	3+
42	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
56	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						
70	0ng/mL THC						
	25ng/mL THC						
	75ng/mL THC						

Note:

3- indicates 3 replicates negative test results.

3+ indicates 3 replicates positive test results.

Conclusion: The *HYSEN* THC One Step Marijuana 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

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