

Technical File

MET (Methamphetamine) Rapid Test (Urine)

DME-101/102/114/107

Document No.: SRG0017

HANGZHOU ALLTEST BIOTECH CO., LTD

Address: # 550, Yinhai Street, Hangzhou Economic & Technological Development Area,

Hangzhou-310018, P.R. China

Table of Contentes

1. PRODUCT DESCRIPTION	3
1.1 Product Name	3
1.2 Intended Use	3
1.3 Summary	3
1.4 Principles	3
1.5 Performance and Specification	4
1.5.1 Precautions	4
1.5.2 Storage and Stability	4
1.5.3 Specimen Collection and Preparation.	5
1.5.3.1 Urine Assay	5
Specimen Storage	5
1.5.4 Standard Testing Procedure	5
1.5.4.1 MET Rapid Test (Urine) Dipstick	5
1.5.4.2 MET Rapid Test (Urine) Cassette	5
1.5.4.3 MET Rapid Test (Urine) Panel:	6
1.5.4.4 MET Rapid Test (Urine) cup:	6
1.5.5 Interpretation of Results	7
1.5.6 Quality Control	7
1.5.7 Limitations	7
1.6 Product Detail	8
1.6.1 All Materials	8
1.7 User	错误！未定义书签。
1.8 Classification of Product	错误！未定义书签。
1.9 Product Certification Conformity Assessment Route	错误！未定义书签。
2. LIST OF APPLICABLE HARMONISED STANDARDS	错误！未定义书签。
3. ESSENTIAL REQUIREMENT CHECKLIST	错误！未定义书签。
4. TECHNICAL REPORT	10
4.1 Technical Report for MET Rapid Test Dipstick/Cassette/Panel/Cup (1000ng/ml)	10
4.1.1 Specimen Correlation	10
4.1.2 Analytical Sensitivity	11
4.1.3 Interfering Substances	12
4.1.4 Cross Reactivity	14
4.1.5 Between Day Reproducibility	16
4.1.6 Between Lot Reproducibility	20
4.1.7 Accelerated Stability	25
4.1.8 Precision	31
4.1.9 Effect of Urinary Specific Gravity	32
4.1.10 Effect of Urinary pH	35
4.1.11 Open Pouch Stability	36
4.2 Technical Report for MET Rapid Test Dipstick/Cassette/Panel/Cup (500ng/ml)	39

4.2.1 Specimen Correlation	39
4.2.2 Analytical Sensitivity	41
4.2.3 Interfering Substances	42
4.2.4 Cross Reactivity	44
4.2.5 Between Day Reproducibility	46
4.2.6 Between Lot Reproducibility	50
4.2.7 Accelerated Stability	54
4.2.8 Precision	61
4.2.9 Effect of Urinary Specific Gravity	62
4.2.10 Effect of Urinary pH	64
4.2.11 Open Pouch Stability	66
4.3 Technical Report for MET Rapid Test Dipstick/Cassette/Panel/Cup (300ng/ml)	69
4.3.1 Specimen Correlation	69
4.3.2 Analytical Sensitivity	70
4.3.3 Interfering Substances	71
4.3.4 Cross Reactivity	74
4.3.5 Between Day Reproducibility	75
4.3.6 Between Lot Reproducibility	79
4.3.7 Accelerated Stability	84
4.3.8 Precision	90
4.3.9 Effect of Urinary Specific Gravity	92
4.3.10 Effect of Urinary pH	94
4.3.11 Open Pouch Stability	95
Document History Summary	99

1. PRODUCT DESCRIPTION

1.1 Product Name

MET (Methamphetamine) Rapid Test

1.2 Intended Use

The MET Rapid Test is a rapid chromatographic immunoassay for the detection of Methamphetamine in human urine. This test will detect other compounds, please refer to Analytical Specificity table in package insert.

This assay provides only a qualitative, preliminary, analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

1.3 Summary

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.

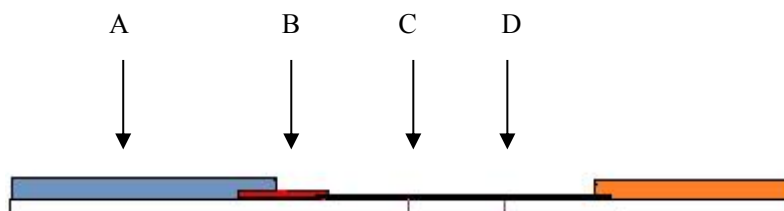
The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of 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 MET Rapid Test 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.

1.4 Principles

The MET Rapid Test is an immunoassay based on the principle of competitive binding. Drugs that 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 cut-off, will not saturate the binding sites of the antibody coated particles in the test device. 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 is at or above cut-off 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 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.



As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). Methamphetamine present in the specimen binds to the conjugate, forming a colored antibody-antigen complex. Methamphetamine antigen immobilized in the test zone of the membrane captures the test region (C). The formation of a visible color line in the test region indicates a negative result (C). The absence of a color line in the test zones suggests a positive result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (D) confirms control line.

1.5 Performance and Specification

The MET Rapid Test is a Rapid chromatographic immunoassay for the detection of Methamphetamine in human urine at different cut-off concentrations as validated in the studies done in further sections (1000ng/ml, 500ng/ml and 300ng/ml). The test utilizes a combination of MET antigen to selectively detect levels of MET in urine. At the level of claimed sensitivity, The MET Rapid Test Dipstick/Cassette/Panel/Cup shows no cross-reactivity interference from the drugs of Acetophenetidin, Amobarbital, Atropine, Codeine and so on.

For different cut-off levels, the catalog nos. have a at the end of the official catalog no. for cut-off level 1000ng/ml, b for cut-off level 500ng/ml and c for cut-off level 300ng/ml.

1.5.1 Precautions

- For professional in vitro diagnostic use. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

1.5.2 Storage and Stability

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

1.5.3 Specimen Collection and Preparation.

1.5.3.1 Urine Assay

A urine specimen must be collected in a clean and dry container. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

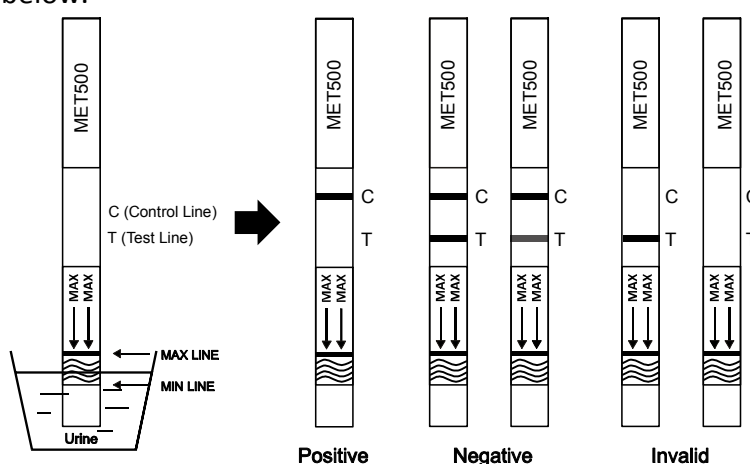
Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing. Specimens should not be frozen and thawed repeatedly.

1.5.4 Standard Testing Procedure

1.5.4.1 MET Rapid Test (Urine) Dipstick

Bring the pouch to room temperature (15-30 °C) before opening it. Remove the test Dipstick from the sealed pouch and use it within one hour.

With arrows pointing towards the urine specimen, immerse the test Dipstick vertically in the urine specimen in such a way that urine does not cross MAX line on the test Dipstick for 10-15 seconds. See the illustration below.

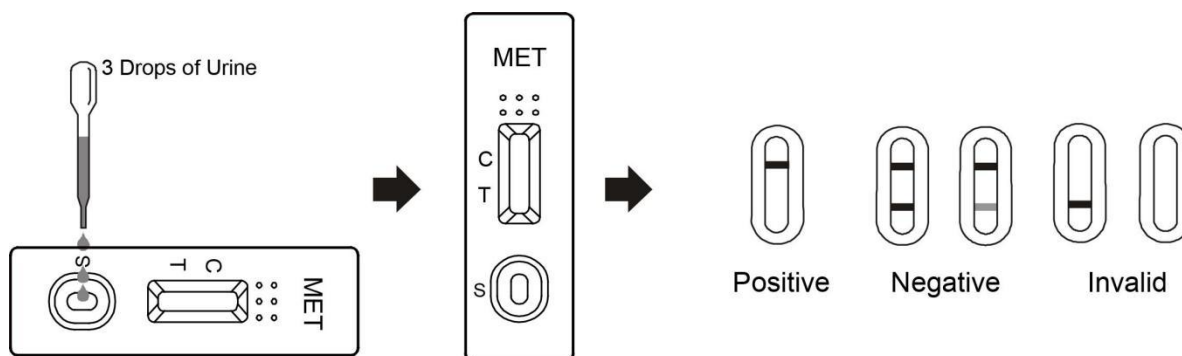


Bring the pouch to room temperature before opening it. Remove the test card from the sealed pouch and use it within one hour.

1.5.4.2 MET Rapid Test (Urine) Cassette

Allow the Cassette, urine specimen and/or controls to reach room temperature (15-30 °C) prior to testing.

Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µl) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well.



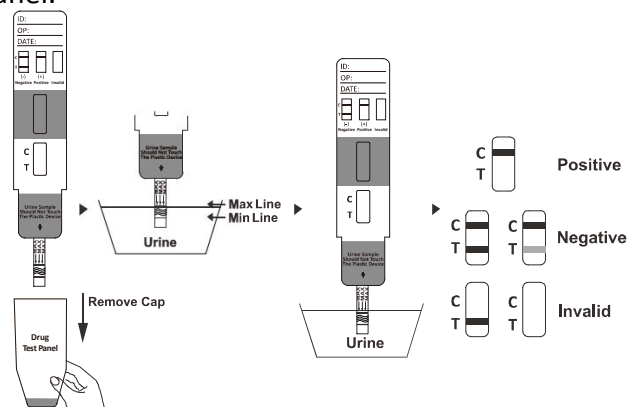
Wait for the color line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

1.5.4.3 MET Rapid Test (Urine) Panel:

Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.

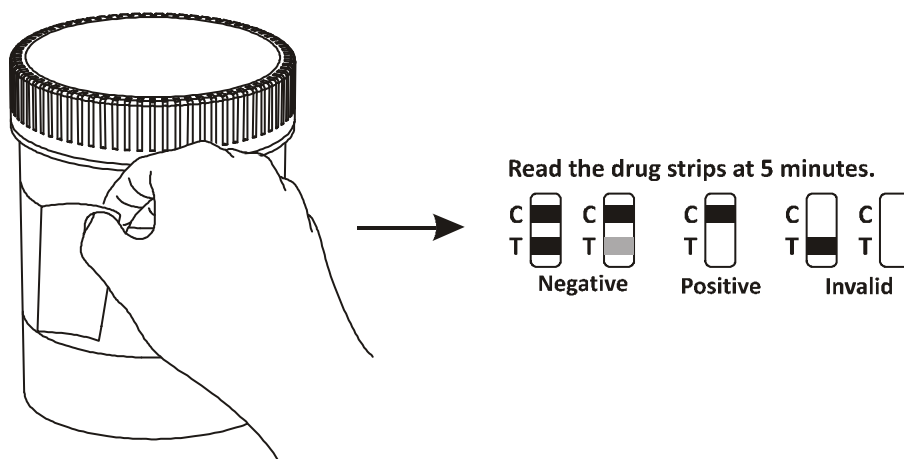
Remove the cap.

With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.



1.5.4.4 MET Rapid Test (Urine) cup:

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it within one hour.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 32-38°C (90-100°F).
5. Technician dates and initials the security seal and attaches the security seal over the cup cap.
6. Technician peels off the label on the multi-drug test card to view results.
7. The drug strip result should be read at 5 minutes. Do not interpret the result after 10 minutes.



1.5.5 Interpretation of Results

NEGATIVE: * Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of Methamphetamine present in the specimen. Therefore, any shade of color in the test line region (T) should be considered negative.

POSITIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test immediately and contact your local distributor.

1.5.6 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.

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

1.5.7 Limitations

The MET Rapid Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.

A positive result indicates presence of the drug or its metabolites but does not indicate level of

intoxication, administration route or concentration in urine.

A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

Test does not distinguish between drugs of abuse and certain medications.

1.6 Product Detail

1.6.1 All Materials

◆ Materials

- **Absorbent Pad:** Filter paper AN3

Thickness: 0.587mm

Water absorption: 991.2g/m²

Composition: 100% Cotton fiber

- **Label Pad:** 6613 Polyester film

Weight: 99.86g/m²

Thickness: 16.7mils

Composition: Polyester film

- **Sample Pad:** Fiberglass

Weight: 50.12g/ m²

Thickness: 12.53mils

Composition:

- **Nitrocellulose Membrane:** Sartorius CN140

Thickness of membrane layer (μ m): 120-160

Capillary wicking rate along the roll (mm/5min): >52

- **Backing Card:** Polystyrene (PS)

Thickness of card: 0.455mm

Composition: Polystyrene

◆ Major antibody

- **Control Zone:** Goat anti-Rabbit IgG (440ng/test) and Rabbit IgG (400ng/test)

- **Test Zone:** MET-BSA (150ng/test)

- **Conjugate pad:** MET monoclonal antibody (700ng/test)

◆ Major buffer

Phosphate Buffer

1.7 Production process

- ◆ Nitrocellulose membrane which has applied to an adhesive-backed is coated with a Goat Anti – Rabbit IgG Polyclonal Antibody solution in the Control Reaction Zone, and coated with MET-BSA solution in the Test Reaction Zone. The coated membrane is dried overnight.
- ◆ A buffered solution of MET monoclonal antibody – Colloidal Gold Conjugate is sprayed on polyester and then dried overnight.
- ◆ Treatment the fiberglass with a Tris-buffer solution dried them in an oven house for one night. Humidity is an important factor to influence the performance of the product, please keep dried when storage.
- ◆ Assemble the semi-product with absorbent pad, dried NC membrane, conjugate pad and sample

pad, cut them with the cutting machine.

- ◆ Put the test dipstick into moisture-proof foil and sealed in moisture-proof foil pouches along with a desiccant packet and a disposable plastic pipette Dipstick
- ◆ Put the test Dipstick into a suitable cassette and sealed in moisture-proof foil pouches along with a desiccant packet and a disposable plastic pipette.
- ◆ Put the test Dipstick into a suitable Panel and sealed in moisture-proof foil pouches along with a desiccant packet.
- ◆ Put the test Dipstick into a suitable Cup and sealed in moisture-proof foil pouches along with a desiccant packet.

2. TECHNICAL REPORT

2.1 Technical Report for MET Rapid Test Dipstick/Cassette/Panel/Cup (1000ng/ml)

2.1.1 Specimen Correlation

The specimen correlation used a specimen number (n) equal to 250 urine specimens. Including 81 positive urine specimens and 169 negative urine specimens were confirmed by GC/MS. These specimens were randomized and tested using the MET Rapid Test Dipstick/Cassette/Panel/Cup. Specimens were rated as either positive or negative at 5minutes. The test results are shown in Table below

Table: Specimen Correlation

Dipstick: MET14030001-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	76	5	81
	Negative	3	166	169
Total Result		79	171	250

Relative Sensitivity = $76/79=96.2\%$

Relative Specificity = $166/171=97.1\%$

Total Agreement = $242/250=96.8\%$

Cassette: MET14030004-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	76	5	81
	Negative	3	166	169
Total Result		79	171	250

Relative Sensitivity = $76/79=96.2\%$

Relative Specificity = $166/171=97.1\%$

Total Agreement = $242/250=96.8\%$

Panel: MET14030001p-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	76	5	81
	Negative	3	166	169
Total Result		79	171	250

Relative Sensitivity = $76/79=96.2\%$

Relative Specificity = $166/171=97.1\%$

Total Agreement = 242/250=96.8%

Cup: MET14030004c-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	76	5	81
	Negative	3	166	169
Total Result		79	171	250

Relative Sensitivity = 76/79=96.2%

Relative Specificity = 166/171=97.1%

Total Agreement = 242/250=96.8%

Conclusion: From the data above, the relative sensitivity for all MET Rapid Test Cassette/Dipstick/Panel/Cup and GC/MS was 96.2%, and the relative specificity was 97.1%, and total agreement was 96.8%.

2.1.2 Analytical Sensitivity

The analytical sensitivity was determined by spiking negative urine specimens with intact MET standard at 0, 500, 750, 1000, 1250, 1500, 3000ng/ml. The MET standards were randomized and coded. The results were confirmed by GC/MS. A total of 10 replicates for each standard were tested according to the package insert. The specimens were tested with visual interpretations occurring at 5minutes after specimen application. Results are presented in Table below:

Table: Analytical Sensitivity Summary

Dipstick:

MET 1,000 Standard	MET14030001-T	MET14030002-T	MET14030003-T
Free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
500ng/ml	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
750ng/ml	-,-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,-,+
1,000ng/ml	-,-,-,-,-,-,-,+,+,+	-,-,-,-,-,-,-,+,+,+	-,-,-,-,-,-,-,+,+,+
1,250ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
1,500ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
3,000ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+

Cassette:

MET 1,000 Standard	MET14030004-T	MET14030005-T	MET14030006-T
Free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
500ng/ml	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
750ng/ml	-,-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,-,+
1,000ng/ml	-,-,-,-,-,-,-,+,+,+	-,-,-,-,-,-,-,+,+,+	-,-,-,-,-,-,-,+,+,+
1,250ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
1,500ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
3,000ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+

Panel:

MET 1,000 Standard	MET14030001p-T	MET14030002p-T	MET14030003p-T
Free urine	- - - - -	- - - - -	- - - - -
500ng/ml	- - - - -	- - - - -	- - - - -
750ng/ml	- - - - - +	- - - - - +	- - - - - +
1,000ng/ml	- - - - - + + + +	- - - - - + + + +	- - - - - + + + +
1,250ng/ml	+ + + + + -	+ + + + + -	+ + + + + -
1,500ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +
3,000ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +

Cup:

MET 1,000 Standard	MET14030004c-T	MET14030005c-T	MET14030006c-T
Free urine	- - - - -	- - - - -	- - - - -
500ng/ml	- - - - -	- - - - -	- - - - -
750ng/ml	- - - - - +	- - - - - +	- - - - - +
1,000ng/ml	- - - - - + + + +	- - - - - + + + +	- - - - - + + + +
1,250ng/ml	+ + + + + -	+ + + + + -	+ + + + + -
1,500ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +
3,000ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +

Conclusion: The results showed the cut-off concentration of MET Rapid Test Dipstick/Cassette/Panel/Cup is determined to be 1000ng/ml.

4.1.3 Interfering Substances

The related compounds of MET will be spiked in drug-free urine, diluted sequentially to different concentrations and tested until the lowest concentration that has a negative result. The following compounds have negative result at their respective concentrations. And the cutoff concentrations were showed in the tables with “*”. Since Sensitivity and Specificity of Dipsticks and Panels have been demonstrated to be same and Panel is a Dipstick embedded in a panel card, testing with Dipsticks reflects the results with panel also. The specimens were tested in 5 replicates with visual interpretations occurring at 5 minutes after specimen application. Results are presented in below tables.

Table: Interfering Substances**Dipstick:**

Analytes	Conc. (ng/ml)	MET14030001-T		MET14030002-T		MET14030003-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	12,500	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	37,500	0	5	0	5	0	5
D-Methamphetamine	500	5	0	5	0	5	0
	*1,000	2	3	3	2	2	3
	1,500	0	5	0	5	0	5
L-Methamphetamine	10,000	5	0	5	0	5	0

MET RAPID TEST (URINE)

ne	*20,000	2	3	3	2	2	3
	30,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
Mephentermine	25,000	5	0	5	0	5	0
	*50,000	2	3	3	2	2	3
	75,000	0	5	0	5	0	5

Cassette:

Analytes	Conc. (ng/ml)	MET14030004-T		MET14030005-T		MET14030006-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	12,500	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	37,500	0	5	0	5	0	5
D-Methamphetamine	500	5	0	5	0	5	0
	*1,000	2	3	3	2	2	3
	1,500	0	5	0	5	0	5
L-Methamphetamine	10,000	5	0	5	0	5	0
	*20,000	2	3	3	2	2	3
	30,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
Mephentermine	25,000	5	0	5	0	5	0
	*50,000	2	3	3	2	2	3
	75,000	0	5	0	5	0	5

Panel:

Analytes	Conc. (ng/ml)	MET14030001p-T		MET14030002p-T		MET14030003p-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	12,500	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	37,500	0	5	0	5	0	5
D-Methamphetamine	500	5	0	5	0	5	0
	*1,000	2	3	3	2	2	3

MET RAPID TEST (URINE)

	1,500	0	5	0	5	0	5
L-Methamphetamine	10,000	5	0	5	0	5	0
	*20,000	2	3	3	2	2	3
	30,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
Mephentermine	25,000	5	0	5	0	5	0
	*50,000	2	3	3	2	2	3
	75,000	0	5	0	5	0	5

Cup:

Analytes	Conc. (ng/ml)	MET14030004c-T		MET14030005c-T		MET14030006c-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p-Hydroxymethamphetamine	12,500	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	37,500	0	5	0	5	0	5
D-Methamphetamine	500	5	0	5	0	5	0
	*1,000	2	3	3	2	2	3
	1,500	0	5	0	5	0	5
L-Methamphetamine	10,000	5	0	5	0	5	0
	*20,000	2	3	3	2	2	3
	30,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
Mephentermine	25,000	5	0	5	0	5	0
	*50,000	2	3	3	2	2	3
	75,000	0	5	0	5	0	5

Conclusion: The cutoff concentrations of MET related compounds were showed in the tables with “*”.

2.1.4 Cross Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine positive urine. And the compounds concentration is 100 µg/ml, respectively. The specimens were tested in triplicate in 3 lots of test Dipstick/Cassette/Panel/Cup. Visual interpretations occurred at 5 minutes after specimen application. Results are presented in Table below.

Table: Cross Reactivity

4-Acetamidophenol	Erythromycin	Papaverine
Acetophenetidin	β-Estradiol	Penicillin-G
N-Acetylprocainamide	Estrone-3-sulfate	Pentobarbital
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Perphenazine
Aminopyrine	Fenfluramine	Phencyclidine
Amitriptyline	Fenoprofen	Phenelzine
Amobarbital	Furosemide	Phenobarbital
Amoxicillin	Gentisic acid	Phentermine
Ampicillin	Hemoglobin	L-Phenylephrine
Ascorbic acid	Hydralazine	β-Phenylethylamine
D-Amphetamine	Hydrochlorothiazide	Phenylpropanolamine
D,L-Amphetamine	Hydrocodone	Prednisolone
L-Amphetamine	Hydrocortisone	Prednisone
Apomorphine	p-Hydroxyamphetamine	Procaine
Aspartame	O-Hydroxyhippuric acid	Promazine
Atropine	3-Hydroxytyramine	Promethazine
Benzilic acid	Ibuprofen	D,L-Propanolol
Benzoic acid	Imipramine	D-Propoxyphene
Benzoyllecgonine	Iproniazid	D-Pseudoephedrine
Benzphetamine	(-) Isoproterenol	Quinacrine
Bilirubin	Isoxsuprine	Quinidine
Brompheniramine	Ketamine	Quinine
Caffeine	Ketoprofen	Ranitidine
Cannabidiol	Labetalol	Salicylic acid
Chloralhydrate	Levorphanol	Methamphetamine
Chloramphenicol	Loperamide	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Maprotiline	
Chlorothiazide	Meperidine	Sulfamethazine
(±) Chlorpheniramine	Meprobamate	Sulindac
Chlorpromazine	Methadone	Temazepam
Chlorquine	Methoxyphenamine	Tetracycline
Cholesterol	(+)	Tetrahydrocortisone, 3 Acetate
Clomipramine	3,4-Methylenedioxy-amphetamine	
Clonidine	3,4-Methylenedioxyethyl-amphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Cocaethylene		
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-β-D-glucuronide	Thiamine
Cortisone		Thioridazine
(-) Cotinine	Nalidixic acid	D, L-Tyrosine

Creatinine	Naloxone	Tolbutamine
Deoxycorticosterone	Naltrexone	Trans-2-phenylcyclopropylamine
Dextromethorphan	Naproxen	
Diazepam	Niacinamide	Triamterene
Diclofenac	Nifedipine	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tryptophan
Ecgonine hydrochloride	Oxalic acid	Tyramine
Ecgonine methylester	Oxazepam	Uric acid
(1R,2S)-(-)-Ephedrine	Oxolinic acid	Verapamil
L-Epinephrine	Oxycodone	Zomepirac
(-) Y Ephedrine	Oxymetazoline	

Conclusion: The compounds listed in above table show no cross-reactivity when tested at a concentration of 100µg/ml in 5 minutes.

2.1.5 Between Day Reproducibility

MET concentration at 0, 500, 1500ng/ml urine specimens were run individually on ten separate days using the same lots of reagents. Results were read visually at 5 and 10minutes after specimen application. Results are presented in Table below.

Table: Between Day Results

Dipstick:

Lot1#: MET14030001-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030002-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

MET RAPID TEST (URINE)

3	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030003-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Cassette

Lot1#: MET14030004-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030005-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

MET RAPID TEST (URINE)

6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030006-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Panel:

Lot1#: MET14030001p-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030002p-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

MET RAPID TEST (URINE)

9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030003p-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Cup:

Lot1#: MET14030004c-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030005c-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030006c-T

Day	Free Drug Urine						500 ng/ml						1500 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Conclusion: Test results were consistent over the ten days period.

2.1.6 Between Lot Reproducibility

MET concentration at 0, 500, 1500ng/ml urine specimens were run in replicates of ten in three separate lots of products. Results were read visually at 5 and 10 minutes after specimen application. The test results are shown in Table below

Table: Between Lot Results

Dipstick:

Lot1#: MET14030001-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030002-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+

MET RAPID TEST (URINE)

3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030003-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Cassette:

Lot1#: MET14030004-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

MET RAPID TEST (URINE)

Lot2#: MET14030005-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030006-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Panel:

Lot1#: MET14030001p-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+

MET RAPID TEST (URINE)

6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030002p-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030003p-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Cup:

Lot1#: MET14030004c-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min

MET RAPID TEST (URINE)

1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030005c-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030006c-T						
Specimens	0ng/ml MET		500ng/ml MET		1500ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+

10	-	-	-	-	+	+
----	---	---	---	---	---	---

Conclusion: Test results were consistent among the three lots of test Dipstick/Cassette/Panel/Cup.

2.1.7 Accelerated Stability

Accelerated Stability of The AllTest MET Rapid Test Dipstick/Cassette/Panel/Cup was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45 °C and 55 °C, and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 7, 14, 21, 28, 35, 42, 56, 77, 84 days. Test Cassettes were assayed using MET concentration at 0, 500, 1500ng/ml urine specimens. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Table Timeline for Accelerated Stability Study

Day Temp.	0 day	7 days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45 °C	√	√	√	√	√	√	√	√	√	√
55 °C	√	√	√	√	√	√	√	×	×	×

Table: Accelerated Stability Summary

Dipstick:

Accelerated Stability Study Results at 45 °C															
Day	Specimen	Batch No.													
		Lot 1					Lot 2					Lot 3			
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+

MET RAPID TEST (URINE)

35	Negative	-	-	-	-	-	-	-	-	-	-				
	-50%cutoff	-	-	-	-	-	-	-	-	-	-				
	+50%cutoff	+	+	+	+	+	+	+	+	+	+				
42	Negative	-	-	-	-	-	-	-	-	-	-				
	-50%cutoff	-	-	-	-	-	-	-	-	-	-				
	+50%cutoff	+	+	+	+	+	+	+	+	+	+				
56	Negative	-	-	-	-	-	-	-	-	-	-				
	-50%cutoff	-	-	-	-	-	-	-	-	-	-				
	+50%cutoff	+	+	+	+	+	+	+	+	+	+				
77	Negative	-	-	-	-	-	-	-	-	-	-				
	-50%cutoff	-	-	-	-	-	-	-	-	-	-				
	+50%cutoff	+	+	+	+	+	+	+	+	+	+				
84	Negative	-	-	-	-	-	-	-	-	-	-				
	-50%cutoff	-	-	-	-	-	-	-	-	-	-				
	+50%cutoff	+	+	+	+	+	+	+	+	+	+				
Accelerated Stability Study Results at 55°C															
Day	Specimen	Batch No.													
		Lot 1				Lot 2				Lot 3					
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Cassette:

Accelerated Stability Study Results at 45°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Panel:

Accelerated Stability Study Results at 45°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Cup:

Accelerated Stability Study Results at 45°C
--

MET RAPID TEST (URINE)

Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Conclusion: MET Rapid Test Dipstick/Cassette/Panel/Cup is stable at 45 °C for 84 days or 55 °C for 42 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.

2.1.8 Precision

A study was conducted at three hospitals 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 no Methamphetamine, 25% Methamphetamine above and below the cut-off, and 50% Methamphetamine above and below the 1000ng/ml cut-off was provided to each site. The following results were tabulated:

Results:

Dipstick: MET14030001-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1250	10	1	9	2	8	1	9
1500	10	0	10	0	10	0	10

Cassette:MET14030004-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1250	10	1	9	2	8	1	9
1500	10	0	10	0	10	0	10

Dipstick: MET14030001-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1250	10	1	9	2	8	1	9
1500	10	0	10	0	10	0	10

Cup:MET14030004c-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1250	10	1	9	2	8	1	9
1500	10	0	10	0	10	0	10

Conclusion: Specimens determined to be negative, -50% cutoff, -25% cutoff, +25% cutoff and +50% cutoff values demonstrate high precision.

2.1.9 Effect of Urinary Specific Gravity

The urine specific gravity was measured with Clinical Refractometer. Five urine samples with the

specific gravity at each following range were used for the study: (1) Specific gravity >1.025. (2) Specific gravity 1.015 – 1.025. (3) Specific gravity < 1.015. Each urine sample was aliquoted to three parts: (1) Neat urine; (2) Urine samples were spiked with Methamphetamine to 500ng/ml; (3) Urine samples were spiked with Methamphetamine to 1500ng/ml. The Cassette, Dipstick, Panel and Cup were tested in duplicates with above urine samples. Read the result at 5 minutes after sample application.

Results:

Dipstick: MET14030001-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 500ng/ml		Methamphetamine 1500ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Cassette: MET14030004-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 500ng/ml		Methamphetamine 1500ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+

MET RAPID TEST (URINE)

14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Panel: MET14030001p-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 500ng/ml		Methamphetamine 1500ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Cup: MET14030004c-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 500ng/ml		Methamphetamine 1500ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Conclusion: The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

2.1.10 Effect of Urinary pH

Approximately 150ml of negative urine pool were allocated into 5 test tubes. The pH of the urine was adjusted within the range of 5 to 9 in 1 pH unit increments using NaOH or HCl. Each pH-adjusted urine was split into three glass containers (10ml/container): Methamphetamine was added to two aliquots to bring the final sample concentration of 500ng/ml and 1500ng/ml respectively. Each pH-adjusted urine was tested in duplicate and read 5 and 10 minutes after sample application.

Results:

Dipstick: MET14030001-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Cassette: MET14030004-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Panel: MET14030001p-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+

8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Cup: MET14030004c-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Conclusion: The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

2.1.11 Open Pouch Stability

Drug standards including negative urine, the MET -50% cutoff, MET + 50% cutoff and MET 300% cutoff were run in triplicate using the MET rapid tests which were opened pouch after 10 minutes, 20 minutes, 30 minutes, 1 hour, 1.5 hours and 2 hours at room temperature. One lot of Dipstick/Cassette/Panel/Cup (Lot 1 for each) was used. All results were read as positive or negative at 5 and 10 minutes after sample application. Read the results by Alltest gold color card at 5 minutes after sample application, T line ≤ 3.5 regard as positive, T line ≥ 4 regard as negative.

Dipstick:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+

MET RAPID TEST (URINE)

30 minutes	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+

Cassette:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
	1	-	-	-	-	+	+	+	+

MET RAPID TEST (URINE)

1.5 hours	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Panel:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Cup:

Time after opened pouch	N	Negative urine		MET –50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Conclusion: The products were stable at 1 hour after the pouch was opened.

2.2 Technical Report for MET Rapid Test Dipstick/Cassette/Panel/Cup (500ng/ml)

2.2.1 Specimen Correlation

The specimen correlation used a specimen number (n) equal to 250 urine specimens. Including 85 positive urine specimens and 165 negative urine specimens were confirmed by GC/MS. These specimens were randomized and tested using the MET Rapid Test Dipstick/Cassette/Panel/Cup. The test was performed as per package insert. Specimens were rated as either positive or negative at

5minutes. The test results are shown in Table below

Table: Specimen Correlation

Dipstick: MET14030007-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	83	5	88
	Negative	2	160	162
Total Result		85	165	250

Relative Sensitivity = $83/85=97.6\%$

Relative Specificity = $160/165=97.0\%$

Total Agreement = $243/250=97.2\%$

Cassette: MET14030010-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	83	5	88
	Negative	2	160	162
Total Result		85	165	250

Relative Sensitivity = $83/85=97.6\%$

Relative Specificity = $160/165=97.0\%$

Total Agreement = $243/250=97.2\%$

Panel: MET14030007p-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	83	5	88
	Negative	2	160	162
Total Result		85	165	250

Relative Sensitivity = $83/85=97.6\%$

Relative Specificity = $160/165=97.0\%$

Total Agreement = $243/250=97.2\%$

Cup: MET14030010c-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	83	5	88
	Negative	2	160	162
Total Result		85	165	250

Relative Sensitivity = $83/85=97.6\%$

Relative Specificity = 160/165=97.0%

Total Agreement = 243/250=97.2%

Conclusion: From the data above, the relative sensitivity of MET 500ng/ml Cut-off product was 97.6%, and the relative specificity was 97.0%, and total agreement was 97.2%.

2.2.2 Analytical Sensitivity

The analytical sensitivity was determined by spiking negative urine specimens with intact MET standard at 0, 250, 375, 500, 625, 750, 1500ng/ml. The MET standards were randomized and coded. The results were confirmed by GC/MS. A total of 10 replicates for each standard were tested according to the package insert. The specimens were tested with visual interpretations occurring at 5minutes after specimen application. Results are presented in Table below:

Table: Analytical Sensitivity Summary

Dipstick:

MET 500 Standard	MET14030007-T	MET14030008-T	MET14030009-T
Free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
250ng/ml	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
375ng/ml	-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,+
500ng/ml	-,-,-,-,-,+,-,+,-,+	-,-,-,-,-,+,-,+,-,+	-,-,-,-,-,+,-,+,-,+
625ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
750ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
1,500ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+

Cassette:

MET 500 Standard	MET14030010-T	MET14030011-T	MET14030012-T
Free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
250ng/ml	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
375ng/ml	-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,+
500ng/ml	-,-,-,-,-,+,-,+,-,+	-,-,-,-,-,+,-,+,-,+	-,-,-,-,-,+,-,+,-,+
625ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
750ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
1,500ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+

Panel:

MET 500 Standard	MET14030007p-T	MET14030008p-T	MET14030009p-T
Free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
250ng/ml	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
375ng/ml	-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,+
500ng/ml	-,-,-,-,-,+,-,+,-,+	-,-,-,-,-,+,-,+,-,+	-,-,-,-,-,+,-,+,-,+
625ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
750ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
1,500ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+

Cup:

MET 500 Standard	MET14030010c-T	MET14030011c-T	MET14030012c-T
------------------	----------------	----------------	----------------

MET RAPID TEST (URINE)

Free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
250ng/ml	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
375ng/ml	-,-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,-,+	-,-,-,-,-,-,-,-,-,+
500ng/ml	-,-,-,-,-,-,-,+,-,-	-,-,-,-,-,-,-,+,-,-	-,-,-,-,-,-,-,+,-,-
625ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
750ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
1,500ng/ml	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+

Conclusion: The results showed the cut-off concentration of MET Rapid Test Dipstick/Cassette/Panel/Cup is determined to be 500ng/ml.

2.2.3 Interfering Substances

The related compounds of MET will be spiked in drug-free urine, diluted sequentially to different concentrations and tested until the lowest concentration that has a negative result. The following compounds have negative result at their respective concentrations. And the cutoff concentrations were showed in the tables with “*”.

Table: Interfering Substances

Dipstick:

Analytes	Conc. (ng/ml)	MET14030007-T		MET14030008-T		MET14030009-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
D-Methamphetamine	250	5	0	5	0	5	0
	*500	2	3	3	2	2	3
	750	0	5	0	5	0	5
L-Methamphetamine	5,000	5	0	5	0	5	0
	*10,000	2	3	3	2	2	3
	15,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	3,125	5	0	5	0	5	0
	*6,250	2	3	3	2	2	3
	9,375	0	5	0	5	0	5
Mephentermine	6,250	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	18,750	0	5	0	5	0	5

Cassette:

Analytes	Conc. (ng/ml)	MET140300010-T		MET140300011-T		MET140300012-T	
		Negative	Positive	Negative	Positive	Negative	Positive

MET RAPID TEST (URINE)

p -Hydroxymethamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
D-Methamphetamine	250	5	0	5	0	5	0
	*500	2	3	3	2	2	3
	750	0	5	0	5	0	5
L-Methamphetamine	5,000	5	0	5	0	5	0
	*10,000	2	3	3	2	2	3
	15,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	3,125	5	0	5	0	5	0
	*6,250	2	3	3	2	2	3
	9,375	0	5	0	5	0	5
Mephentermine	6,250	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	18,750	0	5	0	5	0	5

Panel:

Analytes	Conc. (ng/ml)	MET14030007p-T		MET14030008p-T		MET14030009p-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
D-Methamphetamine	250	5	0	5	0	5	0
	*500	2	3	3	2	2	3
	750	0	5	0	5	0	5
L-Methamphetamine	5,000	5	0	5	0	5	0
	*10,000	2	3	3	2	2	3
	15,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	3,125	5	0	5	0	5	0
	*6,250	2	3	3	2	2	3
	9,375	0	5	0	5	0	5
Mephentermine	6,250	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	18,750	0	5	0	5	0	5

Cup:

Analytes	Conc. (ng/ml)	MET140300010c-T		MET140300011c-T		MET140300012c-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	6,250	5	0	5	0	5	0
	*12,500	2	3	3	2	2	3
	18,750	0	5	0	5	0	5
D-Methamphetamine	250	5	0	5	0	5	0
	*500	2	3	3	2	2	3
	750	0	5	0	5	0	5
L-Methamphetamine	5,000	5	0	5	0	5	0
	*10,000	2	3	3	2	2	3
	15,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	3,125	5	0	5	0	5	0
	*6,250	2	3	3	2	2	3
	9,375	0	5	0	5	0	5
Mephentermine	6,250	5	0	5	0	5	0
	*25,000	2	3	3	2	2	3
	18,750	0	5	0	5	0	5

Conclusion: The cutoff concentrations of MET related compounds were showed in the tables with “*”.

2.2.4 Cross Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine positive urine. And the compounds concentration is 100 µg/ml, respectively. The specimens were tested in triplicate in 3 lots of test Dipstick/Cassette/Panel/Cup. Since Sensitivity and Specificity of Dipsticks and Panels have been demonstrated to be same and Panel is a Dipstick embedded in a panel card, testing with Dipsticks reflects the results with panel also. Visual interpretations occurred at 5 minutes after specimen application. Results are presented in Table below.

Table: Cross Reactivity

4-Acetamidophenol	Erythromycin	Papaverine
Acetophenetidin	β-Estradiol	Penicillin-G
N-Acetylprocainamide	Estrone-3-sulfate	Pentobarbital
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Perphenazine
Aminopyrine	Fenfluramine	Phencyclidine
Amitriptyline	Fenoprofen	Phenelzine
Amobarbital	Furosemide	Phenobarbital
Amoxicillin	Gentisic acid	Phentermine
Ampicillin	Hemoglobin	L-Phenylephrine
Ascorbic acid	Hydralazine	β-Phenylethylamine
D-Amphetamine	Hydrochlorothiazide	Phenylpropanolamine

MET RAPID TEST (URINE)

D,L-Amphetamine	Hydrocodone	Prednisolone
L-Amphetamine	Hydrocortisone	Prednisone
Apomorphine	p-Hydroxyamphetamine	Procaine
Aspartame	O-Hydroxyhippuric acid	Promazine
Atropine	3-Hydroxytyramine	Promethazine
Benzilic acid	Ibuprofen	D,L-Propanolol
Benzoic acid	Imipramine	D-Propoxyphene
Benzoyllecgonine	Iproniazid	D-Pseudoephedrine
Benzphetamine	(-) Isoproterenol	Quinacrine
Bilirubin	Isoxsuprine	Quinidine
Brompheniramine	Ketamine	Quinine
Caffeine	Ketoprofen	Ranitidine
Cannabidiol	Labetalol	Salicylic acid
Chloralhydrate	Levorphanol	Methamphetamine
Chloramphenicol	Loperamide	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Maprotiline	
Chlorothiazide	Meperidine	Sulfamethazine
(±) Chlorpheniramine	Meprobamate	Sulindac
Chlorpromazine	Methadone	Temazepam
Chlorquine	Methoxyphenamine	Tetracycline
Cholesterol	(+)	Tetrahydrocortisone, 3 Acetate
Clomipramine	3,4-Methylenedioxy-amphetamine	
Clonidine	3,4-Methylenedioxyethyl-amphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Cocaethylene		
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-β-D-glucuronide	Thiamine
Cortisone		Thioridazine
(-) Cotinine	Nalidixic acid	D, L-Tyrosine
Creatinine	Naloxone	Tolbutamine
Deoxycorticosterone	Naltrexone	Trans-2-phenylcyclopropylamine
Dextromethorphan	Naproxen	
Diazepam	Niacinamide	Triamterene
Diclofenac	Nifedipine	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tryptophan
Ecgonine hydrochloride	Oxalic acid	Tyramine
Ecgonine methylester	Oxazepam	Uric acid
(1R,2S)-(-)-Ephedrine	Oxolinic acid	Verapamil
L-Epinephrine	Oxycodone	Zomepirac
(-) Y Ephedrine	Oxymetazoline	

Conclusion: The compounds listed in above table show no cross-reactivity when tested at a concentration of 100µg/ml in 5 minutes.

2.2.5 Between Day Reproducibility

MET concentration at 0, 250, 750ng/ml urine specimens were run individually on ten separate days using the same lots of reagents. Results were read visually at 5 and 10minutes after specimen application. Results are presented in Table below.

Table: Between Day Results

Dipstick:

Lot1#: MET14030007-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030008-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030009-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

MET RAPID TEST (URINE)

5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Cassette;

Lot1#: MET14030010-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030011-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030012-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

MET RAPID TEST (URINE)

8	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Panel:

Lot1#: MET14030007p-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030008p-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030009p-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Cup:

Lot1#: MET14030010c-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030011c-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030012c-T

Day	Free Drug Urine						250 ng/ml						750 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Conclusion: Test results were consistent over the ten days period.

2.2.6 Between Lot Reproducibility

MET concentration at 0, 250, 750ng/ml urine specimens were run in replicates of ten in three separate lots of products. Results were read visually at 5 and 10 minutes after specimen application. The test results are shown in Table below

Table: Between Lot Results

Dipstick:

Lot1#: MET14030007-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030008-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030009-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+

MET RAPID TEST (URINE)

2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Cassette:

Lot1#: MET14030010-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030011-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+

MET RAPID TEST (URINE)

10	-	-	-	-	+	+
Lot3#: MET14030012-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Panel:

Lot1#: MET14030007p-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030008p-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+

MET RAPID TEST (URINE)

5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030009p-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Cup:

Lot1#: MET14030010c-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030011c-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	

	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030012c-T						
Specimens	0ng/ml MET		250ng/ml MET		750ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Conclusion: Test results were consistent among the three lots of test Dipstick/Cassette/Panel/Cup.

2.2.7 Accelerated Stability

Accelerated Stability of The AllTest MET Rapid Test Dipstick/Cassette/Panel/Cup was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45 °C and 55 °C, and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 7, 14, 21, 28, 35, 42, 56, 77, 84 days. Test Cassettes were assayed using MET concentration at 0, 250, 750ng/ml urine specimens. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Table Timeline for Accelerated Stability Study

MET RAPID TEST (URINE)

Day Temp.	0 day	7 days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45°C	√	√	√	√	√	√	√	√	√	√
55°C	√	√	√	√	√	√	√	×	×	×

Table: Accelerated Stability Summary

Dipstick:

Accelerated Stability Study Results at 45°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Cassette:

Accelerated Stability Study Results at 45°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C											
Day	Specimen	Batch No.									
		Lot 1					Lot 2				
0	Negative	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	+50%cutoff	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+

Panel:

Accelerated Stability Study Results at 45°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C															
Day	Specimen	Batch No.													
		Lot 1					Lot 2					Lot 3			
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Cup:

Accelerated Stability Study Results at 45°C															
Day	Specimen	Batch No.													
		Lot 1					Lot 2					Lot 3			
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	+50%cutoff	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C											
Day	Specimen	Batch No.									
		Lot 1					Lot 2				
0	Negative	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+

35	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+

Conclusion: MET Rapid Test Dipstick/Cassette/Panel/Cup is stable at 45°C for 84 days or 55°C for 42 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.

2.2.8 Precision

A study was conducted at three hospitals 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 no Methamphetamine, 25% Methamphetamine above and below the cut-off, and 50% Methamphetamine above and below the 500ng/mL cut-off was provided to each site. The following results were tabulated:

Results:

Dipstick: MET14030007-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0ng/ml	10	10	0	10	0	10	0
250ng/ml	10	10	0	10	0	10	0
375ng/ml	10	9	1	9	1	9	1
625ng/ml	10	1	9	1	9	1	9
750ng/ml	10	0	10	0	10	0	10

Cassette: MET14030010-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0ng/ml	10	10	0	10	0	10	0
250ng/ml	10	10	0	10	0	10	0
375ng/ml	10	9	1	9	1	9	1
625ng/ml	10	1	9	1	9	1	9
750ng/ml	10	0	10	0	10	0	10

Panel: MET14030007p-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0ng/ml	10	10	0	10	0	10	0
250ng/ml	10	10	0	10	0	10	0
375ng/ml	10	9	1	9	1	9	1
625ng/ml	10	1	9	1	9	1	9
750ng/ml	10	0	10	0	10	0	10

Cup: MET14030010c-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0ng/ml	10	10	0	10	0	10	0
250ng/ml	10	10	0	10	0	10	0
375ng/ml	10	9	1	9	1	9	1
625ng/ml	10	1	9	1	9	1	9
750ng/ml	10	0	10	0	10	0	10

Conclusion: Specimens determined to be negative, -50% cutoff, -25% cutoff, +25% cutoff and +50% cutoff values demonstrate high precision.

2.2.9 Effect of Urinary Specific Gravity

The urine specific gravity was measured with Clinical Refractometer. Five urine samples with the specific gravity at each following range were used for the study: (1) Specific gravity >1.025. (2) Specific gravity 1.015 – 1.025. (3) Specific gravity < 1.015. Each urine sample was aliquoted to three parts: (1) Neat urine; (2) Urine samples were spiked with Methamphetamine to 250ng/ml; (3) Urine samples were spiked with Methamphetamine to 750ng/ml. The Cassette, Dipstick, Panel and Cup were tested in duplicates with above urine samples. Read the result at 5 minutes after sample application.

Results:**Dipstick: MET14030007-T**

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 250ng/ml		Methamphetamine 750ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+

MET RAPID TEST (URINE)

4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Cassette: MET14030010-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 250ng/ml		Methamphetamine 750ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Panel: MET14030007p-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 250ng/ml		Methamphetamine 750ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+

9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Cup: MET14030010c-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 250ng/ml		Methamphetamine 750ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Conclusion: The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

2.2.10 Effect of Urinary pH

Approximately 150ml of negative urine pool were allocated into 5 test tubes. The pH of the urine was adjusted within the range of 5 to 9 in 1 pH unit increments using NaOH or HCl. Each pH-adjusted urine was split into three glass containers (10ml/container): Methamphetamine was added to two aliquots to bring the final sample concentration of 250ng/ml and 750ng/ml respectively. Each pH-adjusted urine was tested in duplicate and read 5 and 10 minutes after sample application.

Results:

Dipstick: MET14030007-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+

MET RAPID TEST (URINE)

7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Cassette: MET2011090010-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Panel: MET14030007p-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Cup: MET2011090010c-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+

9	-	-	-	-	+	+
9	-	-	-	-	+	+

Conclusion: The results demonstrate that varying ranges of pH from 5-9 do not interfere with the performance of the MET test.

2.2.11 Open Pouch Stability

Drug standards including negative urine, the MET -50% cutoff, MET + 50% cutoff and MET 300% cutoff were run in triplicate using the MET rapid tests which were opened pouch after 10 minutes, 20 minutes, 30 minutes, 1 hour, 1.5 hours and 2 hours at room temperature. One lot of Dipstick/Cassette/Panel/Cup (Lot 1 for each) was used. All results were read as positive or negative at 5 and 10 minutes after sample application. Read the results by Alltest gold color card at 5 minutes after sample application, T line ≤ 3.5 regard as positive, T line ≥ 4 regard as negative.

Dipstick:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+

MET RAPID TEST (URINE)

2 hours	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+

Cassette:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Panel:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+

MET RAPID TEST (URINE)

10 minutes	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Cup:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
	1	-	-	-	-	+	+	+	+

MET RAPID TEST (URINE)

30 minutes	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Conclusion: The products were stable at 1 hour after the pouch was opened.

2.3 Technical Report for MET Rapid Test Dipstick/Cassette/Panel/Cup (300ng/ml)

2.3.1 Specimen Correlation

The specimen correlation used a specimen number (n) equal to 250 urine specimens. Including 90 positive urine specimens and 160 negative urine specimens were confirmed by GC/MS. These specimens were randomized and tested using the MET Rapid Test Dipstick/Cassette/Panel/Cup. The test was performed as per package insert. Specimens were rated as either positive or negative at 5 minutes. The test results are shown in Table below

Table: Specimen Correlation

Dipstick: MET14030013-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	88	4	92
	Negative	2	156	158
Total Result		90	160	250

Relative Sensitivity = $88/90=97.8\%$

Relative Specificity = $156/160=97.5\%$

Total Agreement = $244/250=97.6\%$

Cassette: MET14030016-T

Method	GC/MS	Total Result
--------	-------	--------------

MET RAPID TEST (URINE)

MET Rapid Test	Results	Positive	Negative	
	Positive	88	4	92
	Negative	2	156	158
Total Result		90	160	250

Relative Sensitivity = $88/90=97.8\%$

Relative Specificity = $156/160=97.5\%$

Total Agreement = $244/250=97.6\%$

Panel: MET14030013p-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	88	4	92
	Negative	2	156	158
Total Result		90	160	250

Relative Sensitivity = $88/90=97.8\%$

Relative Specificity = $156/160=97.5\%$

Total Agreement = $244/250=97.6\%$

Cup: MET14030016c-T

Method		GC/MS		Total Result
MET Rapid Test	Results	Positive	Negative	
	Positive	88	4	92
	Negative	2	156	158
Total Result		90	160	250

Relative Sensitivity = $88/90=97.8\%$

Relative Specificity = $156/160=97.5\%$

Total Agreement = $244/250=97.6\%$

Conclusion: From the data above, The relative sensitivity of MET 300ng/ml Cut-off product was 97.8%, and the relative specificity was 97.5%, and total agreement was 97.6%.

2.3.2 Analytical Sensitivity

The analytical sensitivity was determined by spiking negative urine specimens with intact MET standard at 0, 150, 225, 300, 375, 450, 900ng/ml. The MET standards were randomized and coded. The results were confirmed by GC/MS. A total of 10 replicates for each standard were tested according to the package insert. The specimens were tested with visual interpretations occurring at 5minutes after specimen application. Results are presented in Table below:

Table: Analytical Sensitivity Summary

Dipstick:

MET 300 Standard	MET14030013-T	MET14030014-T	MET14030015-T
------------------	---------------	---------------	---------------

MET RAPID TEST (URINE)

Free urine	- - - - -	- - - - -	- - - - -
150ng/ml	- - - - -	- - - - -	- - - - -
225ng/ml	- - - - - +	- - - - - +	- - - - - +
300ng/ml	- - - - - + + + + +	- - - - - + + + + +	- - - - - + + + + +
375ng/ml	+ + + + + + + + -	+ + + + + + + + -	+ + + + + + + + -
450ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +
900ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +

Cassette:

MET 300 Standard	MET14030016-T	MET14030017-T	MET14030018-T
Free urine	- - - - -	- - - - -	- - - - -
150ng/ml	- - - - -	- - - - -	- - - - -
225ng/ml	- - - - - +	- - - - - +	- - - - - +
300ng/ml	- - - - - + + + + +	- - - - - + + + + +	- - - - - + + + + +
375ng/ml	+ + + + + + + + -	+ + + + + + + + -	+ + + + + + + + -
450ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +
900ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +

Panel:

MET 300 Standard	MET14030013p-T	MET14030014p-T	MET14030015p-T
Free urine	- - - - -	- - - - -	- - - - -
150ng/ml	- - - - -	- - - - -	- - - - -
225ng/ml	- - - - - +	- - - - - +	- - - - - +
300ng/ml	- - - - - + + + + +	- - - - - + + + + +	- - - - - + + + + +
375ng/ml	+ + + + + + + + -	+ + + + + + + + -	+ + + + + + + + -
450ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +
900ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +

Cup:

MET 300 Standard	MET14030016c-T	MET14030017c-T	MET14030018c-T
Free urine	- - - - -	- - - - -	- - - - -
150ng/ml	- - - - -	- - - - -	- - - - -
225ng/ml	- - - - - +	- - - - - +	- - - - - +
300ng/ml	- - - - - + + + + +	- - - - - + + + + +	- - - - - + + + + +
375ng/ml	+ + + + + + + + -	+ + + + + + + + -	+ + + + + + + + -
450ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +
900ng/ml	+ + + + + + + + +	+ + + + + + + + +	+ + + + + + + + +

Conclusion: The results showed the cut-off concentration of MET Rapid Test Dipstick/Cassette/Panel/Cup is determined to be 300ng/ml.

2.3.3 Interfering Substances

The related compounds of MET will be spiked in drug-free urine, diluted sequentially to different concentrations and tested until the lowest concentration that has a negative result. The following

compounds have negative result at their respective concentrations. And the cutoff concentrations were showed in the tables with “*”. The specimens were tested in 5 replicates with visual interpretations occurring at 5 minutes after specimen application. Results are presented in below tables.

Table: Interfering Substances

Dipstick:

Analytes	Conc. (ng/ml)	MET140300013-T		MET140300014-T		MET140300015-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	3,750	5	0	5	0	5	0
	*7,500	2	3	3	2	2	3
	11,250	0	5	0	5	0	5
D-Methamphetamine	150	5	0	5	0	5	0
	*300	2	3	3	2	2	3
	450	0	5	0	5	0	5
L-Methamphetamine	3,000	5	0	5	0	5	0
	*6,000	2	3	3	2	2	3
	9,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	1,875	5	0	5	0	5	0
	*3,750	2	3	3	2	2	3
	5,625	0	5	0	5	0	5
Mephentermine	7,500	5	0	5	0	5	0
	*15,000	2	3	3	2	2	3
	22,500	0	5	0	5	0	5

Cassette:

Analytes	Conc. (ng/ml)	MET140300016-T		MET140300017-T		MET140300018-T	
		Negative	Positive	Negative	Positive	Negative	Positive
p -Hydroxymethamphetamine	3,750	5	0	5	0	5	0
	*7,500	2	3	3	2	2	3
	11,250	0	5	0	5	0	5
D-Methamphetamine	150	5	0	5	0	5	0
	*300	2	3	3	2	2	3
	450	0	5	0	5	0	5
L-Methamphetamine	3,000	5	0	5	0	5	0
	*6,000	2	3	3	2	2	3
	9,000	0	5	0	5	0	5

MET RAPID TEST (URINE)

(±)-3,4-Methylenedioxy-methamphetamine	1,875	5	0	5	0	5	0
	*3,750	2	3	3	2	2	3
	5,625	0	5	0	5	0	5
Mephentermine	7,500	5	0	5	0	5	0
	*15,000	2	3	3	2	2	3
	22,500	0	5	0	5	0	5

Panel:

Analytes	Conc. (ng/ml)	MET140300013p-T		MET140300014p-T		MET140300015p-T	
		Negative	Positive	Negative	Positive	Negative	Positive
ρ -Hydroxymethamphetamine	3,750	5	0	5	0	5	0
	*7,500	2	3	3	2	2	3
	11,250	0	5	0	5	0	5
D-Methamphetamine	150	5	0	5	0	5	0
	*300	2	3	3	2	2	3
	450	0	5	0	5	0	5
L-Methamphetamine	3,000	5	0	5	0	5	0
	*6,000	2	3	3	2	2	3
	9,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	1,875	5	0	5	0	5	0
	*3,750	2	3	3	2	2	3
	5,625	0	5	0	5	0	5
Mephentermine	7,500	5	0	5	0	5	0
	*15,000	2	3	3	2	2	3
	22,500	0	5	0	5	0	5

Cup:

Analytes	Conc. (ng/ml)	MET14030016c-T		MET14030017c-T		MET14030018c-T	
		Negative	Positive	Negative	Positive	Negative	Positive
ρ -Hydroxymethamphetamine	3,750	5	0	5	0	5	0
	*7,500	2	3	3	2	2	3
	11,250	0	5	0	5	0	5
D-Methamphetamine	150	5	0	5	0	5	0
	*300	2	3	3	2	2	3
	450	0	5	0	5	0	5
L-Methamphetamine	3,000	5	0	5	0	5	0

ne	*6,000	2	3	3	2	2	3
	9,000	0	5	0	5	0	5
(±)-3,4-Methylenedioxy-methamphetamine	1,875	5	0	5	0	5	0
	*3,750	2	3	3	2	2	3
	5,625	0	5	0	5	0	5
Mephentermine	7,500	5	0	5	0	5	0
	*15,000	2	3	3	2	2	3
	22,500	0	5	0	5	0	5

Conclusion: The cutoff concentrations of MET related compounds were showed in the tables with “*”.

2.3.4 Cross Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine positive urine. And the compounds concentration is 100 µg/ml, respectively. The specimens were tested in triplicate in 3 lots of test Dipstick/Cassette/Panel/Cup. Since Sensitivity and Specificity of Dipsticks and Panels have been demonstrated to be same and Panel is a Dipstick embedded in a panel card, testing with Dipsticks reflects the results with panel also. Visual interpretations occurred at 5 minutes after specimen application. Results are presented in Table below.

Table: Cross Reactivity

4-Acetamidophenol	Erythromycin	Papaverine
Acetophenetidin	β-Estradiol	Penicillin-G
N-Acetylprocainamide	Estrone-3-sulfate	Pentobarbital
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Perphenazine
Aminopyrine	Fenfluramine	Phencyclidine
Amitriptyline	Fenoprofen	Phenelzine
Amobarbital	Furosemide	Phenobarbital
Amoxicillin	Gentisic acid	Phentermine
Ampicillin	Hemoglobin	L-Phenylephrine
Ascorbic acid	Hydralazine	β-Phenylethylamine
D-Amphetamine	Hydrochlorothiazide	Phenylpropanolamine
D,L-Amphetamine	Hydrocodone	Prednisolone
L-Amphetamine	Hydrocortisone	Prednisone
Apomorphine	p-Hydroxyamphetamine	Procaine
Aspartame	O-Hydroxyhippuric acid	Promazine
Atropine	3-Hydroxytyramine	Promethazine
Benzilic acid	Ibuprofen	D,L-Propanolol
Benzoic acid	Imipramine	D-Propoxyphene
Benzoyllecgonine	Ipreniazid	D-Pseudoephedrine
Benzphetamine	(-) Isoproterenol	Quinacrine
Bilirubin	Isoxsuprine	Quinidine
Brompheniramine	Ketamine	Quinine

Caffeine	Ketoprofen	Ranitidine
Cannabidiol	Labetalol	Salicylic acid
Chloralhydrate	Levorphanol	Methamphetamine
Chloramphenicol	Loperamide	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Maprotiline	
Chlorothiazide	Meperidine	Sulfamethazine
(±) Chlorpheniramine	Meprobamate	Sulindac
Chlorpromazine	Methadone	Temazepam
Chlorquine	Methoxyphenamine	Tetracycline
Cholesterol	(+)	Tetrahydrocortisone, 3 Acetate
Clomipramine	3,4-Methylenedioxy-amphetamine	
Clonidine	3,4-Methylenedioxyethyl-amphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Cocaethylene		
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-β-D-glucuronide	Thiamine
Cortisone		Thioridazine
(-) Cotinine	Nalidixic acid	D, L-Tyrosine
Creatinine	Naloxone	Tolbutamine
Deoxycorticosterone	Naltrexone	Trans-2-
Dextromethorphan	Naproxen	phenylcyclopropylamine
Diazepam	Niacinamide	Triamterene
Diclofenac	Nifedipine	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tryptophan
Ecgonine hydrochloride	Oxalic acid	Tyramine
Ecgonine methylester	Oxazepam	Uric acid
(1R,2S)-(-)-Ephedrine	Oxolinic acid	Verapamil
L-Epinephrine	Oxycodone	Zomepirac
(-) Y Ephedrine	Oxymetazoline	

Conclusion: The compounds listed in above table show no cross-reactivity when tested at a concentration of 100µg/ml in 5 minutes.

2.3.5 Between Day Reproducibility

MET concentration at 0, 150, 450ng/ml urine specimens were run individually on ten separate days using the same lots of reagents. Results were read visually at 5 and 10minutes after specimen application. Results are presented in Table below.

Table: Between Day Results

Dipstick:

Lot1#: MET14030013-T

MET RAPID TEST (URINE)

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030014-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030015-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Cassette:

Lot1#: MET14030016-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

MET RAPID TEST (URINE)

2	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030017-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030018-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Panel:

Lot1#: MET14030013p-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

MET RAPID TEST (URINE)

5	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030014p-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030015p-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Cup:

Lot1#: MET14030016c-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

8	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot2#: MET14030017c-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Lot3#: MET14030018c-T

Day	Free Drug Urine						150 ng/ml						450 ng/ml					
	5 min			10 min			5 min			10 min			5 min			10 min		
1	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
2	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
3	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
7	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
8	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+

Conclusion: Test results were consistent over the ten days period.

2.3.6 Between Lot Reproducibility

MET concentration at 0, 150, 450ng/ml urine specimens were run in replicates of ten in three separate lots of products. Results were read visually at 5 and 10 minutes after specimen application. The test results are shown in Table below

Table: Between Lot Results

Dipstick:

Lot1#: MET14030013-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+

MET RAPID TEST (URINE)

3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030014-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030015-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Cassette:

MET RAPID TEST (URINE)

Lot1#: MET14030016-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030017-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030018-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+

MET RAPID TEST (URINE)

7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Panel:

Lot1#: MET14030013p-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030014p-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot3#: MET14030015p-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+

MET RAPID TEST (URINE)

2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Cup:

Lot1#: MET14030016c-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+
Lot2#: MET14030017c-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+

10	-	-	-	-	+	+
Lot3#: MET14030018c-T						
Specimens	0ng/ml MET		150ng/ml MET		450ng/ml MET	
	5min	10min	5min	10min	5min	10min
1	-	-	-	-	+	+
2	-	-	-	-	+	+
3	-	-	-	-	+	+
4	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
10	-	-	-	-	+	+

Conclusion: Test results were consistent among the three lots of test Dipstick/Cassette/Panel/Cup.

2.3.7 Accelerated Stability

Accelerated Stability of The AllTest MET Rapid Test Dipstick/Cassette/Panel/Cup was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45 °C and 55 °C, and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 7, 14, 21, 28, 35, 42, 56, 77, 84 days. Test Cassettes were assayed using MET concentration at 0, 150,450ng/ml urine specimens. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Table Timeline for Accelerated Stability Study

Day Temp.	0 day	7 days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45°C	√	√	√	√	√	√	√	√	√	√
55°C	√	√	√	√	√	√	√	×	×	×

Table: Accelerated Stability Summary

Dipstick:

Accelerated Stability Study Results at 45°C															
Day	Specimen	Batch No.													
		Lot 1					Lot 2					Lot 3			
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

MET RAPID TEST (URINE)

14	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+

Cassette:

Accelerated Stability Study Results at 45°C															
Day	Specimen	Batch No.													
		Lot 1					Lot 2					Lot 3			
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+

MET RAPID TEST (URINE)

56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C															
Day	Specimen	Batch No.													
		Lot 1					Lot 2					Lot 3			
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Panel:

Accelerated Stability Study Results at 45°C															
Day	Specimen	Batch No.													
		Lot 1					Lot 2					Lot 3			
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	+50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C																
Day	Specimen	Batch No.														
		Lot 1					Lot 2					Lot 3				
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

MET RAPID TEST (URINE)

	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+

Cup:

Accelerated Stability Study Results at 45°C															
Day	Specimen	Batch No.													
		Lot 1				Lot 2				Lot 3					
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
Accelerated Stability Study Results at 55°C											
Day	Specimen	Batch No.									
		Lot 1					Lot 2				
0	Negative	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+

Conclusion: MET Rapid Test Dipstick/Cassette/Panel/Cup is stable at 45°C for 84 days or 55°C for 42 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.

2.3.8 Precision

A study was conducted at three hospitals 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 no Methamphetamine, 25% Methamphetamine above and below the cut-off,

and 50% Methamphetamine above and below the 300ng/mL cut-off was provided to each site. The following results were tabulated:

Results:

Dipstick: MET14030013-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

Cassette: MET14030016-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

Panel: MET14030013p-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

Cup: MET14030016c-T

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

Conclusion: Specimens determined to be negative, -50% cutoff, -25% cutoff, +25% cutoff and +50% cutoff values demonstrate high precision.

2.3.9 Effect of Urinary Specific Gravity

The urine specific gravity was measured with Clinical Refractometer. Five urine samples with the specific gravity at each following range were used for the study: (1) Specific gravity >1.025. (2) Specific gravity 1.015 – 1.025. (3) Specific gravity < 1.015. Each urine sample was aliquoted to three parts: (1) Neat urine; (2) Urine samples were spiked with Methamphetamine to 150ng/ml; (3) Urine samples were spiked with Methamphetamine to 450ng/ml. The Cassette, Dipstick, Panel and Cup were tested in duplicates with above urine samples. Read the result at 5 minutes after sample application.

Results:

Dipstick: MET14030013-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 150ng/ml		Methamphetamine 450ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Cassette: MET14030016-T

MET RAPID TEST (URINE)

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 150ng/ml		Methamphetamine 450ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Panel: MET14030013p-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 150ng/ml		Methamphetamine 450ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+
3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Cup: MET14030016c-T

Urine ID	Urine Specific Gravity	N*	Negative		Methamphetamine 150ng/ml		Methamphetamine 450ng/ml	
1	1.010	2	-	-	-	-	+	+
2	1.011	2	-	-	-	-	+	+

3	1.007	2	-	-	-	-	+	+
4	1.005	2	-	-	-	-	+	+
5	1.012	2	-	-	-	-	+	+
6	1.014	2	-	-	-	-	+	+
7	1.015	2	-	-	-	-	+	+
8	1.018	2	-	-	-	-	+	+
9	1.017	2	-	-	-	-	+	+
10	1.025	2	-	-	-	-	+	+
11	1.036	2	-	-	-	-	+	+
12	1.045	2	-	-	-	-	+	+
13	1.036	2	-	-	-	-	+	+
14	1.041	2	-	-	-	-	+	+
15	1.043	2	-	-	-	-	+	+

Conclusion: The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

2.3.10 Effect of Urinary pH

Approximately 150 ml of negative urine pool were allocated into 5 test tubes. The pH of the urine was adjusted within the range of 5 to 9 in 1 pH unit increments using NaOH or HCl. Each pH-adjusted urine was split into three glass containers (10ml/container): Methamphetamine was added to two aliquots to bring the final sample concentration of 150ng/ml and 450ng/ml respectively. Each pH-adjusted urine was tested in duplicate and read 5 and 10 minutes after sample application.

Results:

Dipstick: MET14030013-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Cassette: MET14030016-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+

MET RAPID TEST (URINE)

7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Panel: MET14030013p-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Cup: MET14030016c-T

pH	Negative urine		-50% cutoff		+50% cutoff	
	5min	10min	5min	10min	5min	10min
5	-	-	-	-	+	+
5	-	-	-	-	+	+
6	-	-	-	-	+	+
6	-	-	-	-	+	+
7	-	-	-	-	+	+
7	-	-	-	-	+	+
8	-	-	-	-	+	+
8	-	-	-	-	+	+
9	-	-	-	-	+	+
9	-	-	-	-	+	+

Conclusion: The results demonstrate that varying ranges of pH from 5-9 do not interfere with the performance of the MET test.

2. 3.11 Open Pouch Stability

Drug standards including negative urine, the MET -50% cutoff, MET + 50% cutoff and MET 300% cutoff were run in triplicate using the MET rapid tests which were opened pouch after 10 minutes, 20 minutes, 30 minutes, 1 hour, 1.5 hours and 2 hours at room temperature. One lot of Dipstick/Cassette/Panel/Cup (Lot 1 for each) was used. All results were read as positive or negative at 5 and 10 minutes after sample application. Read the results by Alltest gold color card at 5 minutes after sample application, T line ≤ 3.5 regard as positive, T line ≥ 4 regard as negative.

Dipstick:

MET RAPID TEST (URINE)

Time after opened pouch	N	Negative urine		MET –50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+

Cassette:

Time after opened pouch	N	Negative urine		MET –50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
	1	-	-	-	-	+	+	+	+

MET RAPID TEST (URINE)

20 minutes	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Panel:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+

MET RAPID TEST (URINE)

1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Cup:

Time after opened pouch	N	Negative urine		MET -50% cutoff		MET + 50% cutoff		MET 300% cutoff	
		5min	10min	5min	10min	5min	10min	5min	10min
10 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
20 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
30 minutes	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1 hour	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	+	+	+	+
	4	-	-	-	-	+	+	+	+
	5	-	-	-	-	+	+	+	+
1.5 hours	1	-	-	-	-	+	+	+	+
	2	-	-	-	-	+	+	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+

MET RAPID TEST (URINE)

	5	-	-	-	-	-	-	+	+
2 hours	1	-	-	-	-	-	-	+	+
	2	-	-	-	-	-	-	+	+
	3	-	-	-	-	-	-	+	+
	4	-	-	-	-	-	-	+	+
	5	-	-	-	-	+	+	+	+

Conclusion: The products were stable at 1 hour after the pouch was opened.

Document History Summary

Version No.	Date	Description	Remark
03	2016.12.06	Add open pouch stability study	N/A
04	2017.03.31	Add the experiment data of cup	N/A