



**AccuBioTech Co.,Ltd**  
*Accurate, Reliable, Cost Effective*

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**Performance Evaluation Report of**  
**ACCU-TELL<sup>®</sup>**  
**Multi Line Drug Cassette (Urine)**  
**(AMP-BAR-BZO-COC-MET-MDMA-MOP-MTD-PCP-TCA-**  
**TML-THC)**  
**No. PER-Multi12-BT01/01**

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## 1. Back ground

### 1.1. Product Name

Accu-Tell® Multi Line Drug Cassette (Urine)

The combinations: AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50

### 1.2. Intended Use

Accu-Tell® Multi Line Drug Cassette (Urine) is a rapid chromatographic immunoassay for the detection of drugs and drug metabolites in urine at the following cut-off concentrations in urine:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 500)	d-Amphetamine	500
Barbiturates (BAR 200)	Secobarbital	200
Benzodiazepines (BZO 300)	Oxazepam	300
Cocaine (COC 150)	Benzoyllecgonine	150
Marijuana (THC 50)	11-nor- $\Delta^9$ -THC-9 COOH	50
Methadone (MTD 300)	Methadone	300
Methamphetamine (MET 500)	d-Methamphetamine	500
Methylenedioxymethamphetamine (MDMA 500)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP 300)	Morphine	300
Phencyclidine (PCP 25)	Phencyclidine	25
Tricyclic Antidepressants (TCA 1000)	Nortriptyline	1,000
Tramadol (TML 100)		100

This assay provides only a 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

Accu-Tell® Multi Line Drug Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

#### 1.3.1 Amphetamine

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

#### 1.3.2 Barbiturates



Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.

**The approximate detection time limits for barbiturates are:**

Short acting (e.g. Secobarbital )	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days

### 1.3.3 Benzodiazepines

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, and loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3- 7 days.

### 1.3.4 Cocaine

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine. 3,4 Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.<sup>4</sup>

### 1.3.5 Marijuana

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

### 1.3.6 Methadone

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral

methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.<sup>7</sup>

### **1.3.7 Methamphetamine**

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.

### **1.3.8 Methylenedioxymethamphetamine**

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.<sup>5</sup> Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin.

MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

### **1.3.9 Morphine (MOP)/OPI**

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

### **1.3.10 Phencyclidine**

Phencyclidine, also known as PCP or AngelDust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.<sup>6</sup> PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

### **1.3.11 Tricyclic Antidepressants**

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

### **1.3.12 Tramadol (TML)**

Tramadol (TML) is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O-demethylation, glucuronidation or sulfation in the liver.

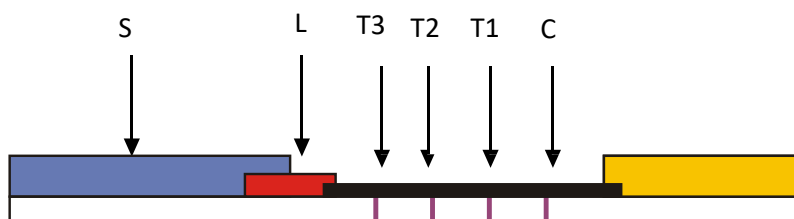
## **1.4. Principle**

Accu-Tell® Multi Line Drug Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

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 will generate a line in the test line region because of the absence of drug competition. 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 (S) migrates via capillary action along the membrane to react with the colored conjugate (L). Antidepressants antigen immobilized in the test zone of the membrane captures the test region (T1, T2, T3). The formation of a visible color line in the test region indicates a negative result (T1, T2, T3). 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 (C) confirms control line.

### 1.5. Performance and Specification

Accu-Tell® Multi Line Drug Cassette (Urine) is a rapid chromatographic immunoassay for the detection of drugs and drug metabolites in urine. The test utilizes a combination of Antidepressants antigen to selectively detect levels of Antidepressants in urine. At the level of claimed sensitivity, Accu-Tell® Multi Line Drug Cassette (Urine) shows no cross-reactivity interference from the drugs of Acetophenetidin, Bilirubin, Isoxsuprine, and so on.

### 1.6. 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.

### 1.7. Specimen Collection and Preparation

According to the Package Insert

### 1.8. Manufacturing Procedure

- 8.1. Coat the gold conjugated Monoclonal drug antibody and Rabbit IgG on the label pad.
- 8.2. Use the sprayer to dispense drug antigen and Goat anti rabbit IgG onto the membrane.
- 8.3. Assemble the membrane, label pad, absorbant pad and sample pad on the plastic backing.
- 8.4. Use the cutter to cut the plastic backing into strips of selected size.
- 8.5. For cassette, lay the strip into the plastic cassette, pack the cassette and a desiccant packet into a pouch and seal the pouch.
- 8.6. Test the cassette according to the QC procedure and release the finished product.

## 2. Sample correlation

### 2.1 Specimen Correlation

#### Material

Accu-Tell® Multi Line Drug Cassette (Urine):

LOT: DOA12030201-T Lot# TML11120004-T





The combinations: ( AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50 )

**Method:**

Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing which were confirmed by GC/MS. These specimens were randomized and tested using the Accu-Tell® Multi Line Drug Cassette (Urine). Specimens were rated as either positive or negative at 5minutes. The test results are shown in table below.

**Results:**

Lot# **DOA12030201-T**

Method		GC/MS		% Agreement with GC/MS	Overall agreement
Accu-Tell® Multi Line Drug Cassette (Urine)		Positive	Negative		
Benzodiazepines (BZO 300ng/mL)	Positive	118	4	97.5%	97.2%
	Negative	3	125	96.9%	
Tricyclic Antidepressants (TCA 1000ng/mL)	Positive	109	11	94.0%	92.8%
	Negative	7	123	91.8%	
Barbiturates (BAR200ng/mL)	Positive	117	2	98.3%	98.4%
	Negative	2	129	98.5%	

Method		GC/MS		% Agreement with GC/MS	Overall agreement
Accu-Tell® Multi Line Drug Cassette (Urine)		Positive	Negative		
Amphetamine (AMP 500ng/mL)	Positive	101	11	99.0%	95.2%
	Negative	1	137	92.6%	
Morphine (MOP 300ng/mL)	Positive	103	11	95.4%	93.6%
	Negative	5	119	91.5%	
Phencyclidine (PCP 25ng/mL)	Positive	108	4	95.6%	96.4%
	Negative	5	133	97.1%	
Methamphetamine (MET 500ng/mL)	Positive	103	7	97.2%	96.0%
	Negative	3	137	95.1%	
Cocaine (COC 150ng/mL)	Positive	105	0	99.1%	99.6%
	Negative	1	144	>99.9%	
Marijuana (THC50ng/mL)	Positive	115	3	>99.9%	98.8%
	Negative	0	132	97.8%	
Methylenedioxymethamphetamine	Positive	125	5	96.9%	96.4%
	Negative	4	116	95.9%	
Methadone (MTD 300ng/mL)	Positive	107	5	96.4%	96.4%
	Negative	4	134	96.4%	
<b>Lot# TML11120004-T</b>					
Tramadol (TML)	Positive	98	2	99.0%	98.8%
	Negative	1	149	98.7%	

**Conclusion:** From the data above, Clinical samples for each drug were run using the Accu-Tell® Multi Line Drug Cassette (Urine) (AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50) at a professional point of care site. It obtained high agreement of positive agreement, negative agreement and overall agreement rates with GC/MS data.

**2.2 Analytical Sensitivity**

**Material**





Accu-Tell® Multi Line Drug Cassette (Urine):

**LOT 1: DOA12030201-T**

**LOT2: DOA12030202-T**

**LOT 3: DOA12030203-T**

**LOT 4: TML11120001-T**

**LOT5: TML11120002-T**

**LOT 6: TML11120003-T**

**The combinations:** (AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50)

**Method:**

The analytical Sensitivity was determined by spiking negative urine specimens with intact drugs standard at drug free urine, -50% Cut-off, -25% Cut-off, Cut-off, +25% Cut-off, +50% Cut-off, +300% Cut-off. The standards were randomized and coded. The results were confirmed by GC/MS. A total of 10 replicates for each standard were tested. The specimens were tested with visual interpretations occurring at 5minutes after specimen application. Results are presented in table below:

**Table: Analytical Sensitivity Summary**

Drugs Standard	DOA12030201-T						DOA12030202-T						DOA12030203-T					
	T1:BZO		T2:TCA		T3:BAR		T1:BZO		T2:TCA		T3:BAR		T1:BZO		T2:TCA		T3:BAR	
	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.
Drugs free urine	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	8	2	9	1	9	1	9	1	9	1	9	1	9	1	9	1	9	1
Cut-off	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
+25% Cut-off	1	9	1	9	1	9	2	8	1	9	1	9	1	9	1	9	1	9
+50% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+300% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
Drugs Standard	T4: AMP		T5: MOP		T6: PCP		T4: AMP		T5: MOP		T6: PCP		T4: AMP		T5: MOP		T6: PCP	
	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.
Drugs free	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	8	2	9	1	9	1	9	1	9	1	9	1	9	1	9	1	9	1
Cut-off	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
+25% Cut-off	1	9	1	9	1	9	2	8	1	9	1	9	1	9	1	9	1	9
+50% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+300% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
Drugs Standard	T7: MET		T8: COC		T9: THC		T7: MET		T8: COC		T9: THC		T7: MET		T8: COC		T9: THC	
	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.
Drugs free	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	8	2	9	1	9	1	9	1	9	1	9	1	9	1	9	1	9	1
Cut-off	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
+25% Cut-off	1	9	1	9	1	9	2	8	1	9	1	9	1	9	1	9	1	9
+50% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+300% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10



Drugs free	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	9	1	9	1	9	1	9	1	9	1	9	1	9	1	9	1	9	1
Cut-off	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
+25% Cut-off	1	9	1	9	1	9	1	9	1	9	1	9	1	9	1	9	1	9
+50% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+300% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
Drugs Standard	T10: MDMA		T11: MTD		T10: MDMA		T11: MTD		T10: MDMA		T11: MTD							
	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.						
Drugs free	10	0	10	0	10	0	10	0	10	0	10	0						
-50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0						
-25% Cut-off	9	1	9	1	9	1	9	1	9	1	9	1						
Cut-off	5	5	5	5	5	5	5	5	5	5	5	5						
+25% Cut-off	1	9	1	9	1	9	1	9	1	9	1	9						
+50% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10						
+300% Cut-off	0	10	0	10	0	10	0	10	0	10	0	10						
Drugs Standard	T12: TML11120004-T		T12:TML11120005-T		T12:TML11120006-T													
	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.												
Drugs free	10	0	10	0	10	0												
-50% Cut-off	10	0	10	0	10	0												
-25% Cut-off	9	1	9	1	9	1												
Cut-off	5	5	5	5	5	5												
+25% Cut-off	1	9	1	9	1	9												
+50% Cut-off	0	10	0	10	0	10												
+300% Cut-off	0	10	0	10	0	10												

**Conclusion:** The results indicated the cut-off concentration of Accu-Tell® Multi Line Drug Cassette (Urine) is determined to be 300ng/mL (BZO), 1000ng/mL (TCA) ,200ng/mL (BAR), 500ng/mL (AMP), 300ng/mL (MOP) an,25ng/mL (PCP), 500ng/mL (MET), 150ng/mL (COC) ,50ng/mL (THC), 500ng/mL (MDMA) ,300ng/mL (MTD) and 100 ng/mL (TML).

### 2.3 Analytical Specificity



**Material**

Accu-Tell® Multi Line Drug Cassette (Urine):

**LOT 1: DOA12030201-T**

**LOT2: DOA12030202-T**

**LOT 3: DOA12030203-T**

**LOT 4: TML11120001-T**

**LOT5: TML11120002-T**

**LOT 6: TML11120003-T**

**The combinations:** ( AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50 )

**Method:**

The related compounds of Accu-Tell® Multi Line Drug Cassette (Urine) 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 table below.

**Result:**

**Table: Interfering Substances**

Product	Analytes	Conc. (ng/mL)	DOA12030201-T					DOA12030202-T					DOA12030203-T				
<b>BZO</b>	Alprazolam	50	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*100	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		150	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	a-hydroxyalprazolam	750	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*1,500	-	-	+	+	+	-	-	+	+	+	-	-	-	+	+
		2,250	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Bromazepam	390	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*780	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
		1,170	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Chlordiazepoxide	390	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*780	-	-	-	+	+	-	-	+	+	+	-	-	+	+	+
		1,170	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Clobazam	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*200	-	-	-	+	+	-	-	+	+	+	-	-	+	+	+
		300	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Clonazepam	195	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*390	-	-	-	+	+	-	-	+	+	+	-	-	+	+	+
		585	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Clorazepate dipotassium	195	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*390	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		585	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Delorazepam	390	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*780	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		1,170	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Desalkylflurazepam	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*200	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		300	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Flunitrazepam	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*200	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		300	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1,550	-	-	-	-	-	-	-	-	-	-	-	-	-	-	



	(±) Lorazepam	*3,100	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	
		4,650	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	S-Lorazepam glucuronide	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*200	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
	Midazolam	300	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		3,125	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*6,250	-	-	-	+	+	-	-	+	+	+	-	-	+	+	+	+
	Nitrazepam	9,375	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*200	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
	Norchloridiazepoxide	300	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		50	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*100	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
	Nordiazepam	150	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		390	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*780	-	-	-	+	+	-	-	+	+	+	-	-	+	+	+	+
	Oxazepam	1,170	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		150	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*300	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
	Temazepam	450	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		50	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*100	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
	Diazepam	150	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		750	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*1,500	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
	Estazolam	2,250	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		3,125	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*6,250	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+	+
Triazolam	9,375	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	1,550	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	*3,100	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+	+	
TCA	Nortriptyline	4,650	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*1,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+	+
	Nordoxepine	1,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		200	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*400	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
	Trimipramine	800	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*3,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+	+
	Amitriptyline	4,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		750	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*1,500	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
	Promazine	3,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*3,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+	+
	Desipramine	4,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*200	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
			400	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+



Cyclobenzaprine	75	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*1,500	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	3,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Imipramine	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*400	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
	80	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Clomipramine	25,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*50,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	75,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Doxepine	75	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*1,500	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
	3,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Maprotiline	75	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*1,500	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	3,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Promethazine	12,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*25,000	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
	50,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Perphenazine	12,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*25,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	50,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Amobarbital	1,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*2,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	3000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5,5-Diphenylhydantoin	2,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*4,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	6,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Allobarbitol	15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*300	-	+	+	+	+	-	-	-	+	+	-	-	+	+	+
	45	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Barbital	2,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*4,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	6,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Talbutal	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*2	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	3	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyclopentobarbital	8,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*17,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	25,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pentobarbital	2,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*4,000	-	-	+	+	+	-	-	-	+	+	-	-	-	+	+
	6,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Alphenol	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*200	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	30	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Aprobarbital	15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*300	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	45	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*100	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+



	Butabarbital	15	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	Butalbital	2,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*4,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	
		6,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	Butethal	15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*300	-	-	+	+	+	-	-	-	+	+	-	-	+	+	
		45	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	Phenobarbital	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*200	-	-	+	+	+	-	-	-	+	+	-	-	+	+	
		30	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	Secobarbital	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*200	-	-	+	+	+	-	-	-	+	+	-	-	+	+	
		30	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
<b>Product</b>	<b>Analytes</b>	<b>Conc. (ng/mL)</b>	<b>DOA12030201-T</b>					<b>DOA12030202-T</b>					<b>DOA12030203-T</b>				
<b>AMP</b>	D,L-Amphetamine sulfate	50	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*100	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
		200	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	L-Amphetamine	6,250	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*12,500	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		25,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	3,4-Methylenedioxy amphetamine	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*200	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
		400	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Phentermine	200	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*400	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
		800	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Maprotiline	12,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*25,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
		50,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Methoxyphenamine	1,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*3,000	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		6,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
D-Amphetamine	250	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	*500	-	-	-	+	+	-	-	+	+	+	-	-	+	+	+	
	1,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Codeine	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	*200	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+	
	300	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	Levorphanol	750	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*1,500	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
		2,250	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
3-β-D-Glucuronide	400	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	*800	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	
	1200	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Ethylmorphine	3,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	*6,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	
	9,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		25,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	



<b>MOP</b>	Hydrocodone	*50,000	-	-	-	-	+	-	-	-	-	+	-	-	+	+	+	
		75,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Hydromorphone	1,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*3,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
		4,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	6-Monoacetylmorphine	200	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*400	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
		600	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Norcodeine	3,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*6,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
		9,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Normorphone	25,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*50,000	-	-	+	+	+	-	+	+	+	+	-	+	+	+	+	+
		75,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Oxycodone	15,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*30,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
		45,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Oxymorphone	25,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*50,000	-	-	-	-	+	-	-	-	-	+	-	-	-	-	-	+
		75,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Procaine	7,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*15,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
		22,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	Thebaine	3,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
*6,000		-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+	
9,000		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Morphine	150	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	*300	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+	
	450	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
<b>PCP</b>	Phencyclidine	12.5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*25	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+	
		37.5	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	4-Hydroxyphencyclidine	3,125	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*6,250	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
	9,375	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
<b>Product</b>	<b>Analytes</b>	<b>Conc. (ng/mL)</b>	DOA12030201-T					DOA12030202-T					DOA12030203-T					
<b>MET</b>	p-Hydroxymethamphetamine	6,250	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*12,500	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	
		18,750	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	D-Methamphetamine	250	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*500	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+	+
		750	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	L-Methamphetamine	4,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		*9,000	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+
		13,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
(±)-3,	1,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	*3,000	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+	+	





	(,4-Methylenedioxy-	4,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	Mephentermine	6,250	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
		*25,000	-	-	-	+	+	-	-	+	+	+	-	-	-	+	+		
		18,750	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
COC	Benzoylecgonine	75	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
		*150	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+		
		225	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	Cocaine HCl	50	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*100	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+		
	Cocaethylene	150	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		3,125	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*6,250	-	-	-	-	+	-	-	-	+	+	-	-	+	+	+		
	Ecgonine	9,375	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		7,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*15,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+		
	THC	Cannabinol	22,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
10,000			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
*20,000			-	-	+	+	+	-	-	-	+	+	-	-	+	+	+		
11-nor- $\Delta^8$ -THC-9 COOH		30,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*30	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+		
11-nor- $\Delta^9$ -THC-9 COOH		45	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		25	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
$\Delta^8$ -THC		*50	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+		
		75	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		7,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
$\Delta^9$ -THC		*15,000	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+		
		22,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		7,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Product		Analytes	Conc. (ng/mL)	DOA12030201-T					DOA12030202-T					DOA12030203-T					
			( $\pm$ )	250	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
			3,4-Methylenedioxyamphetamine HCl	*500	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
MDMA		(±)	750	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	1,500		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	3,4-Methylenedioxyamphetamine HCl		3,000	-	-	-	-	+	-	-	+	+	+	-	-	+	+	+	
	4,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	4-Methylenedioxyethylamphetamine	150	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		300	-	-	+	+	+	-	+	+	+	+	-	-	+	+	+		
450		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
MTD	Methadone	150	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
		*300	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+		
		450	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	Doxylamine	50,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		*100,000	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+		
150,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
TML	Analytes	Conc. (ng/ml)	TML11120004-T					TML11120005-T					TML11120006-T						



n-Desmethyl-cis-tramadol	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*200	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	300	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cis-tramadol	75	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*150	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
	225	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Procyclidine	50,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*100,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	150,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
o-Desmethyl-cis-tramadol	3,500	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*7,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	10,500	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Phencyclidine	50,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*100,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	150,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
d,l-O-Desmethyl venlafaxine	25,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*50,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	75,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

**Conclusion:** The cutoff concentrations of Accu-Tell® Multi Line Drug Cassette (Urine) related compounds were showed in the tables with “\*”.

## 2.4 Cross Reactivity

### Material

Accu-Tell® Multi Line Drug Cassette (Urine)

### Method:

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

### Result

**Table: Cross Reactivity**

Acetophenetidin	Cortisone	Ketamine	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methylphenidate	Sulfamethazine
l-Ascorbic acid	Digoxin	Nalidixic acid	Sulindac
Apomorphine	Diphenhydramine	Naproxen	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Niacinamide	Tetrahydrocortisone,
Atropine	β-Estradiol	Nifedipine	3-acetate
Benzilic acid	Estrone-3-sulfate	Norethindrone	Tetrahydrocortisone
Benzoic acid	Erythromycin	Noscapine	Tetrahydrozoline
Bilirubin	Fenoprofen	d,l-Octopamine	Thiamine
d,l-Brompheniramine	Furosemide	Oxalic acid	Thioridazine



Caffeine	Gentisic acid	Oxolinic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxymetazoline	Tolbutamide
Chloral hydrate	Hydralazine	Papaverine	Triamterene
Chloramphenicol	Hydrochlorothiazide	Penicillin-G	Trifluoperazine
Chlorothiazide	Hydrocortisone	Perphenazine	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Phenelzine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Prednisone	Uric acid
Cholesterol	d,l-Isoproterenol	d,l-Propranolol	Verapamil
Clonidine	Isoxsuprine		Zomepirac

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

## 2.5 Between Day Reproducibility

### Material

Accu-Tell® Multi Line Drug Cassette (Urine):

**LOT 1: DOA12030201-T**

**LOT2: DOA12030202-T**

**LOT 3: DOA12030203-T**

**LOT 4: TML11120001-T**

**LOT5: TML11120002-T**

**LOT 6: TML11120003-T**

**The combinations:** (AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50)

### Method:

Drugs concentration at Drug free urine, -50% Cut-off, +50% Cut-off urine specimens were run individually on ten separate days using the same lot of reagents. The specimens were tested in triplicate in 3 lots of test cassettes. Results were read visually at 5 and 10minutes after specimen application. Results are presented in table below.

### Result:

**Table: Between Day Results**

Day			1	2	3	4	5	6	7	8	9	10	
DOA12030201-T	Drug free urine	T1: BZO	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
		T2: TCA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T3: BAR	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	-50% Cut-off	T1: BZO	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T2: TCA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T3: BAR	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	+50% Cut-off	T1: BZO	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+





		<b>T3: BAR</b>	10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+		
<b>Da</b>				<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>		
DOA12030201-T	Drug free urine	<b>T4: AMP500</b>	5min	---	---	---	---	---	---	---	---	---	---		
			10min	---	---	---	---	---	---	---	---	---	---		
		<b>T5: MOP</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
		<b>T6: PCP</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
	-50% Cut-off	<b>T4: AMP500</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
		<b>T5: MOP</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
		<b>T6: PCP</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
	+50% Cut-off	<b>T4: AMP500</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
		<b>T5: MOP</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
		<b>T6: PCP</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
	DOA12030202-T	Drug free urine	<b>T4: AMP500</b>	5min	---	---	---	---	---	---	---	---	---	---	
				10min	---	---	---	---	---	---	---	---	---	---	
			<b>T5: MOP</b>	5min	---	---	---	---	---	---	---	---	---	---	---
				10min	---	---	---	---	---	---	---	---	---	---	---
			<b>T6: PCP</b>	5min	---	---	---	---	---	---	---	---	---	---	---
				10min	---	---	---	---	---	---	---	---	---	---	---
-50% Cut-off		<b>T4: AMP500</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
		<b>T5: MOP</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
		<b>T6: PCP</b>	5min	---	---	---	---	---	---	---	---	---	---	---	
			10min	---	---	---	---	---	---	---	---	---	---	---	
+50% Cut-off		<b>T4: AMP500</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	



DOA12030203-T	Drug free urine	<b>T5: MOP</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+		
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+		
		<b>T6: PCP</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
		-50% Cut-off	<b>T4: AMP500</b>	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
				10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	<b>T5: MOP</b>		5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
	<b>T6: PCP</b>		5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	<b>T4: AMP500</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
		<b>T5: MOP</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
		<b>T6: PCP</b>	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
	<b>Product</b>				<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>		
	DOA12030201-T	Drug free urine	<b>T7: MET</b>	5min	-	-	-	-	-	-	-	-	-	-	-	
				10min	-	-	-	-	-	-	-	-	-	-	-	
			<b>T8: COC</b>	5min	-	-	-	-	-	-	-	-	-	-	-	-
				10min	-	-	-	-	-	-	-	-	-	-	-	-
			<b>T9: THC</b>	5min	-	-	-	-	-	-	-	-	-	-	-	-
				10min	-	-	-	-	-	-	-	-	-	-	-	-
		-50% Cut-off	<b>T7: MET</b>	5min	-	-	-	-	-	-	-	-	-	-	-	-
10min				-	-	-	-	-	-	-	-	-	-	-	-	
<b>T8: COC</b>			5min	-	-	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	-	-	
<b>T9: THC</b>			5min	-	-	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	-	-	
+50% Cut-off	5min	<b>T7: MET</b>	+	+	+	+	+	+	+	+	+	+	+			



		10min		+	+	+	+	+	+	+	+	+	+
		5min	<b>T8: COC</b>	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+
		5min	<b>T9: THC</b>	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+
DOA12030202-T	Drug free urine	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
	-50% Cut-off	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
+50% Cut-off	5min	<b>T7: MET</b>	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	
	5min	<b>T8: COC</b>	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	
	5min	<b>T9: THC</b>	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	
DOA12030203-T	Drug free urine	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
	-50% Cut-off	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-
+50% Cut-off	5min	<b>T7: MET</b>	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	
	5min	<b>T8: COC</b>	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	





		5min	T9: THC	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+

Day				1	2	3	4	5	6	7	8	9	10	
DOA12030201-T	Drug free urine	T10: MDMA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T11: MTD	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	-50% Cut-off	T10: MDMA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T11: MTD	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	+50% Cut-off	T10: MDMA	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
		T11: MTD	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
DOA12030202-T	Drug free urine	T10: MDMA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T11: MTD	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	-50% Cut-off	T10: MDMA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T11: MTD	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	+50% Cut-off	T10: MDMA	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
		T11: MTD	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
			10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
DOA12030203-T	Drug free urine	T10: MDMA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T11: MTD	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	-50% Cut-off	T10: MDMA	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T11: MTD	5min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
			10min	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		T10: MDMA	5min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+



	+50% Cut-off	T11: MTD	10min	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	
<b>TML11120004</b> <b>-T</b>	Drug free urine	5min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
		10min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	-50% Cut-off	5min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
		10min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-
	+50% Cut-off	5min	T12: TML	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
		10min	T12: TML	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
<b>TML11120005</b> <b>-T</b>	Drug free urine	5min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
		10min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	5min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
		10min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	5min	T12: TML	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
		10min	T12: TML	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
<b>TML11120006</b> <b>-T</b>	Drug free urine	5min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
		10min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	5min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
		10min	T12: TML	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	5min	T12: TML	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+
		10min	T12: TML	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+	+,+,+

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

## 2.6 Between Lot Reproducibility (lot to lot variability)

### Material

Accu-Tell® Multi Line Drug Cassette (Urine):

**LOT 1: DOA12030201-T**

**LOT2: DOA12030202-T**

**LOT 3: DOA12030203-T**

**LOT 4: TML11120001-T**

**LOT5: TML11120002-T**

**LOT 6: TML11120003-T**

**The combinations:** (AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50)

### Method:

Drug concentration at Drug free urine, -50% Cut-off, +50% Cut-off 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.

### Result:

**Table: Between Lot Results**

Product				1	2	3	4	5	6	7	8	9	10
Drug free	<b>T1: BZO</b>	5min		-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-



DOA12030201-T	urine	<b>T2: TCA</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T3: BAR</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
	-50% Cut-off	<b>T1: BZO</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
		<b>T2: TCA</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
		<b>T3: BAR</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
	+50% Cut-off	<b>T1: BZO</b>	5min	+	+	+	+	+	+	+	+	+	+	
			10min	+	+	+	+	+	+	+	+	+	+	
<b>T2: TCA</b>		5min	+	+	+	+	+	+	+	+	+	+		
		10min	+	+	+	+	+	+	+	+	+	+		
<b>T3: BAR</b>		5min	+	+	+	+	+	+	+	+	+	+		
		10min	+	+	+	+	+	+	+	+	+	+		
DOA12030202-T	Drug free urine	<b>T1: BZO</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
		<b>T2: TCA</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
	<b>T3: BAR</b>	5min	-	-	-	-	-	-	-	-	-			
		10min	-	-	-	-	-	-	-	-	-			
	-50% Cut-off	<b>T1: BZO</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
		<b>T2: TCA</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
		<b>T3: BAR</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
+50% Cut-off	<b>T1: BZO</b>	5min	+	+	+	+	+	+	+	+	+			
		10min	+	+	+	+	+	+	+	+	+			
	<b>T2: TCA</b>	5min	+	+	+	+	+	+	+	+	+			
		10min	+	+	+	+	+	+	+	+	+			
	<b>T3: BAR</b>	5min	+	+	+	+	+	+	+	+	+			
		10min	+	+	+	+	+	+	+	+	+			
DOA12030203-T	Drug free urine	<b>T1: BZO</b>	5min	-	-	-	-	-	-	-	-			
			10min	-	-	-	-	-	-	-	-			
		<b>T2: TCA</b>	5min	-	-	-	-	-	-	-	-			
			10min	-	-	-	-	-	-	-	-			
			5min	-	-	-	-	-	-	-				



	-50% Cut-off	<b>T3: BAR</b>	10min	-	-	-	-	-	-	-	-	-	-	
		<b>T1: BZO</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T2: TCA</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T3: BAR</b>	5min	-	-	-	-	-	-	-	-	-	-	-
	10min		-	-	-	-	-	-	-	-	-	-	-	
	+50% Cut-off	<b>T1: BZO</b>	5min	+	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+	+
		<b>T2: TCA</b>	5min	+	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+	+
		<b>T3: BAR</b>	5min	+	+	+	+	+	+	+	+	+	+	+
10min			+	+	+	+	+	+	+	+	+	+	+	
<b>Product</b>				<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	
DOA12030201-T	Drug free urine	<b>T4: AMP500</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
		<b>T5: MOP</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
		<b>T6: PCP</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
	-50% Cut-off	<b>T4: AMP500</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
		<b>T5: MOP</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
		<b>T6: PCP</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
	+50% Cut-off	<b>T4: AMP500</b>	5min	+	+	+	+	+	+	+	+	+	+	
			10min	+	+	+	+	+	+	+	+	+	+	
		<b>T5: MOP</b>	5min	+	+	+	+	+	+	+	+	+	+	
			10min	+	+	+	+	+	+	+	+	+	+	
		<b>T6: PCP</b>	5min	+	+	+	+	+	+	+	+	+	+	
			10min	+	+	+	+	+	+	+	+	+	+	
DOA12030202-T	Drug free urine	<b>T4: AMP500</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
		<b>T5: MOP</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
		<b>T6: PCP</b>	5min	-	-	-	-	-	-	-	-	-		
			10min	-	-	-	-	-	-	-	-	-		
	-50%		5min	-	-	-	-	-	-	-	-	-		



	Cut-off	<b>T4: AMP500</b>	10min	-	-	-	-	-	-	-	-	-	-
			5min	-	-	-	-	-	-	-	-	-	-
		<b>T5: MOP</b>	10min	-	-	-	-	-	-	-	-	-	-
			5min	-	-	-	-	-	-	-	-	-	-
		<b>T6: PCP</b>	10min	-	-	-	-	-	-	-	-	-	-
			5min	-	-	-	-	-	-	-	-	-	-
	+50% Cut-off	<b>T4: AMP500</b>	5min	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+
		<b>T5: MOP</b>	5min	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+
		<b>T6: PCP</b>	5min	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+
DOA12030203-T	Drug free urine	<b>T4: AMP500</b>	5min	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	
		<b>T5: MOP</b>	5min	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	
		<b>T6: PCP</b>	5min	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	
	-50% Cut-off	<b>T4: AMP500</b>	5min	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	
		<b>T5: MOP</b>	5min	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	
		<b>T6: PCP</b>	5min	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	
	+50% Cut-off	<b>T4: AMP500</b>	5min	+	+	+	+	+	+	+	+	+	
			10min	+	+	+	+	+	+	+	+	+	
		<b>T5: MOP</b>	5min	+	+	+	+	+	+	+	+	+	
			10min	+	+	+	+	+	+	+	+	+	
		<b>T6: PCP</b>	5min	+	+	+	+	+	+	+	+	+	
			10min	+	+	+	+	+	+	+	+	+	
<b>Product</b>				<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>
DOA12030201-T	Drug free urine	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-
				10min	-	-	-	-	-	-	-	-	-
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	
				10min	-	-	-	-	-	-	-	-	
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	
				10min	-	-	-	-	-	-	-	-	
			5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	
			5min	-	-	-	-	-	-	-	-	-	



	-50% Cut-off	10min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-	
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-	-
		10min		-	-	-	-	-	-	-	-	-	-	-
	+50% Cut-off	5min	<b>T7: MET</b>	+	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+	+
		5min	<b>T8: COC</b>	+	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+	+
		5min	<b>T9: THC</b>	+	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+	+
	DOA12030202-T	Drug free urine	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-
10min				-	-	-	-	-	-	-	-	-	-	
5min			<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-	
10min				-	-	-	-	-	-	-	-	-	-	
5min			<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-	
10min				-	-	-	-	-	-	-	-	-	-	
-50% Cut- off		5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
+50% Cut-off	5min	<b>T7: MET</b>	+	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	+	
	5min	<b>T8: COC</b>	+	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	+	
	5min	<b>T9: THC</b>	+	+	+	+	+	+	+	+	+	+	+	
	10min		+	+	+	+	+	+	+	+	+	+	+	
DOA12030203-T	Drug free urine	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
	-50% Cut- off	5min	<b>T7: MET</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
		5min	<b>T8: COC</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	
		5min	<b>T9: THC</b>	-	-	-	-	-	-	-	-	-	-	
		10min		-	-	-	-	-	-	-	-	-	-	



	+50% Cut-off	5min	<b>T7: MET</b>	+	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+	+
	+50% Cut-off	5min	<b>T8: COC</b>	+	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+	
	+50% Cut-off	5min	<b>T9: THC</b>	+	+	+	+	+	+	+	+	+	+	+
		10min		+	+	+	+	+	+	+	+	+	+	
<b>Product</b>				<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	
DOA12030201-T	Drug free urine	<b>T10: MDMA</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T11: MTD</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
	-50% Cut- off	<b>T10: MDMA</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T11: MTD</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
	+50% Cut- off	<b>T10: MDMA</b>	5min	+	+	+	+	+	+	+	+	+	+	+
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T11: MTD</b>	5min	+	+	+	+	+	+	+	+	+	+	+
			10min	-	-	-	-	-	-	-	-	-	-	-
DOA12030202-T	Drug free urine	<b>T10: MDMA</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T11: MTD</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
	-50% Cut- off	<b>T10: MDMA</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
		<b>T11: MTD</b>	5min	-	-	-	-	-	-	-	-	-	-	-
			10min	-	-	-	-	-	-	-	-	-	-	-
	+50% Cut- off	<b>T10: MDMA</b>	5min	+	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+	+
		<b>T11: MTD</b>	5min	+	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+	+
DOA12030203-T	Drug free urine	<b>T10: MDMA</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	+	+	+	+	+	+	+	+	+	+	
		<b>T11: MTD</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
	-50% Cut- off	<b>T10: MDMA</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	
		<b>T11: MTD</b>	5min	-	-	-	-	-	-	-	-	-	-	
			10min	-	-	-	-	-	-	-	-	-	-	





	+50% Cut-off	<b>T10: MDMA</b>	5min	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+
		<b>T11: MTD</b>	5min	+	+	+	+	+	+	+	+	+	+
			10min	+	+	+	+	+	+	+	+	+	+
<b>TML</b>													
<b>TML11120004-T</b>	Drug free urine	5min	-	-	-	-	-	-	-	-	-	-	-
		10min	-	-	-	-	-	-	-	-	-	-	-
	-50% Cut-off	5min	-	-	-	-	-	-	-	-	-	-	-
		10min	-	-	-	-	-	-	-	-	-	-	-
	+50% Cut-off	5min	+	+	+	+	+	+	+	+	+	+	+
		10min	+	+	+	+	+	+	+	+	+	+	+
<b>TML11120005-T</b>	Drug free urine	5min	-	-	-	-	-	-	-	-	-	-	-
		10min	-	-	-	-	-	-	-	-	-	-	-
	-50% Cut-off	5min	-	-	-	-	-	-	-	-	-	-	-
		10min	-	-	-	-	-	-	-	-	-	-	-
	+50% Cut-off	5min	+	+	+	+	+	+	+	+	+	+	+
		10min	+	+	+	+	+	+	+	+	+	+	+
<b>TML11120006-T</b>	Drug free urine	5min	-	-	-	-	-	-	-	-	-	-	-
		10min	-	-	-	-	-	-	-	-	-	-	-
	-50% Cut-off	5min	-	-	-	-	-	-	-	-	-	-	-
		10min	-	-	-	-	-	-	-	-	-	-	-
	+50% Cut-off	5min	+	+	+	+	+	+	+	+	+	+	+
		10min	+	+	+	+	+	+	+	+	+	+	+

**Conclusion:** Test results were consistent among the three lots of test cassettes.

## 2.7 Accelerated Stability

### Material

Accu-Tell® Multi Line Drug Cassette (Urine):

**LOT 1: DOA12030201-T**

**LOT2: DOA12030202-T**

**LOT 3: DOA12030203-T**

**LOT 4: TML11120001-T**

**LOT5: TML11120002-T**

**LOT 6: TML11120003-T**

**The combinations:** (AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50)

### Method:

Accelerated Stability of Accu-Tell® Multi Line Drug Cassette (Urine) 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. Tests were assayed using drug concentration at Drug free urine, -50% Cut-off, +50% Cut-off 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 tables below.

### Result:



**Table: Timeline for Accelerate 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	√	√	√	√	√	√	√	X	X	X

**Table: Accelerated Stability Summary**

1. Accelerated Stability Study Results at 45°C					
Day	Product	Specimen	Batch No.		
			DOA12030201-T	DOA12030202-T	DOA12030203-T
0	T1: BZO	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T2: TCA	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T3: BAR	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T4: AMP500	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T5: MOP	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T6: PCP	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T7: MET	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T8: COC	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T9: THC	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T10: MDMA	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
	T11: MTD	Drug free urine	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		-50% Cut-off	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -	-, -, -, -, -, -, -, -, -, -
		+50% Cut-off	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +	+, +, +, +, +, +, +, +, +
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>			
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>	



7	T12: TML	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-										
		-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-										
		+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+										
T1: BZO	T2: TCA	T3: BAR	T4: AMP500	T5: MOP	T6: PCP	T7: MET	T8: COC	T9: THC	T10: MDMA	T11: MTD	T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
												-50% Cut-off	-,-,-	-,-,-	-,-,-
												+50% Cut-off	+,+,+	+,+,+	+,+,+
14	T1: BZO	T2: TCA	T3: BAR	Drug free urine	-,-,-	-,-,-	-,-,-								
				-50% Cut-off	-,-,-	-,-,-	-,-,-								
				+50% Cut-off	+,+,+	+,+,+	+,+,+								
		<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>											
				<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>									
		T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-									
			-50% Cut-off	-,-,-	-,-,-	-,-,-									
			+50% Cut-off	+,+,+	+,+,+	+,+,+									



T4: AMP500	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T9: THC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T10: MDMA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T11: MTD	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T1: BZO	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T2: TCA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T3: BAR	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T4: AMP500	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+

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T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T9: THC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T10: MDMA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T11: MTD	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T1: BZO	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T2: TCA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T3: BAR	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T4: AMP500	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T9: THC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T10: MDMA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T11: MTD	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+

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	Product	Specimen	Batch No.		
			TML11120004-T	TML11120005-T	TML11120006-T
T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T1: BZO	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T2: TCA	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T3: BAR	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T4: AMP500	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T9: THC	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T10: MDMA	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T11: MTD	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
	<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
			<b>TML1</b>	<b>TML1</b>	<b>TML1</b>
T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T1: BZO	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
T2: TCA	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
	+50% Cut-off	+,+,+	+,+,+	+,+,+	
		Drug free urine	-,-,-	-,-,-	-,-,-

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T3: BAR	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T4: AMP500	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T5: MOP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T6: PCP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T7: MET	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T8: COC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T9: THC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T10: MDMA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T11: MTD	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T1: BZO	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T2: TCA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T3: BAR	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T4: AMP500	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T5: MOP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T6: PCP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-

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T7: MET	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T8: COC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T9: THC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T10: MDMA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T11: MTD	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T1: BZO	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T2: TCA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T3: BAR	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T4: AMP500	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T5: MOP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T6: PCP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T7: MET	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T8: COC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T9: THC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T10: MDMA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
	Drug free urine	-,-,-	-,-,-	-,-,-

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	T11: MTD	-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
			<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
	T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
84	T1: BZO	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T2: TCA	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T3: BAR	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T4: AMP500	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T9: THC	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T10: MDMA	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	T11: MTD	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
			<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
	T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+

2. Accelerated Stability Study Results at 55 °C

Day	Product	Specimen	Batch No.		
			DOA12030201-T	DOA12030202-T	DOA12030203-T
		Drug free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-



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T1: BZO	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T2: TCA	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T3: BAR	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T4: AMP500	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T5: MOP	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T6: PCP	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T7: MET	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T8: COC	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T9: THC	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T10: MDMA	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T11: MTD	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	-50% Cut-off	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
	+50% Cut-off	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+
	Drug free urine	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-
T1: BZO	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T2: TCA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T3: BAR	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T4: AMP500	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-

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T5: MOP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T6: PCP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T7: MET	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T8: COC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T9: THC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T10: MDMA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T11: MTD	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T1: BZO	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T2: TCA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T3: BAR	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T4: AMP500	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T5: MOP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T6: PCP	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T7: MET	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T8: COC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-

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T9: THC	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T10: MDMA	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
T11: MTD	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
	Drug free urine	-,-,-	-,-,-	-,-,-
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T1: BZO	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T2: TCA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T3: BAR	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T4: AMP500	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T9: THC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T10: MDMA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T11: MTD	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-



28	T1: BZO	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T2: TCA	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T3: BAR	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T4: AMP500	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T5: MOP	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T6: PCP	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T7: MET	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T8: COC	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T9: THC	+50% Cut-off	+,+,+	+,+,+	+,+,+
		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
	T10: MDMA	+50% Cut-off	+,+,+	+,+,+	+,+,+
Drug free urine		-,-,-	-,-,-	-,-,-	
-50% Cut-off		-,-,-	-,-,-	-,-,-	
T11: MTD	+50% Cut-off	+,+,+	+,+,+	+,+,+	
	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>			
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>	
T12: TML	+50% Cut-off	+,+,+	+,+,+	+,+,+	
	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
T1: BZO	+50% Cut-off	+,+,+	+,+,+	+,+,+	
	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
T2: TCA	+50% Cut-off	+,+,+	+,+,+	+,+,+	
	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
T3: BAR	+50% Cut-off	+,+,+	+,+,+	+,+,+	
	Drug free urine	-,-,-	-,-,-	-,-,-	
	-50% Cut-off	-,-,-	-,-,-	-,-,-	
T4: AMP500	+50% Cut-off	+,+,+	+,+,+	+,+,+	
	Drug free urine	-,-,-	-,-,-	-,-,-	



	+50% Cut-off	+,+,+	+,+,+	+,+,+
T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T9: THC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T10: MDMA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T11: MTD	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
<b>Product</b>	<b>Specimen</b>	<b>Batch No.</b>		
		<b>TML11120004-T</b>	<b>TML11120005-T</b>	<b>TML11120006-T</b>
T12: TML	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T1: BZO	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T2: TCA	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T3: BAR	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T4: AMP500	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T5: MOP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T6: PCP	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T7: MET	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-
	+50% Cut-off	+,+,+	+,+,+	+,+,+
T8: COC	Drug free urine	-,-,-	-,-,-	-,-,-
	-50% Cut-off	-,-,-	-,-,-	-,-,-



		+50% Cut-off	+,+,+	+,+,+	+,+,+
T9: THC		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
T10: MDMA		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
T11: MTD		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
Product	Specimen	Batch No.			
		TML1	TML1	TML1	
T12: TML		Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+

**Note:**

“-” indicates negative test results.

“+” indicates positive test results.

**Conclusion:** Accu-Tell® Multi Line Drug Cassette (Urine) is stable at 45°C for 84 days and 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 data of manufacture.

**2.8 Precision**

**Material**

Accu-Tell® Multi Line Drug Cassette (Urine):

LOT 1: DOA12030201-T

LOT 2: DOA12030202-T

LOT 3: DOA12030203-T

LOT 4: TML11120001-T

LOT 5: TML11120002-T

LOT 6: TML11120003-T

**The combinations:** (AMP500-BAR200-BZO300-COC150-MET500-MDMA500-MOP300-MTD300-PCP25-TCA1000-TML100-THC50)

**Method:**

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 cassette of coded specimens, containing drug free urine, -50% cut-off, -25% cut-off, +25% cut-off and +50% cut-off was provided to each site.

Product	Drug Concentration	n per Site	Site A		Site B		Site C	
			DOA12030201-T		DOA12030202-T		DOA12030203-T	
			-	+	-	+	-	+





1: BZO	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	9	1	9	1	8	2
	+25% cut-off	10	1	9	1	9	1	9
	+50% cut-off	10	0	10	0	10	0	10
T2: TCA	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	9	1	9	1	9	1
	+25% cut-off	10	1	9	1	9	1	9
	+50% cut-off	10	0	10	0	10	0	10
T3: BAR	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	8	2	8	2	8	2
	+25% cut-off	10	2	8	1	9	2	8
	+50% cut-off	10	0	10	0	10	0	10

Product	Drug Concentration	n per Site	Site A		Site B		Site C	
			DOA12030201-T		DOA12030202-T		DOA12030203-T	
			-	+	-	+	-	+
T4: AMP	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	9	1	9	1	9	1
	+25% cut-off	10	1	9	2	8	1	9
	+50% cut-off	10	0	10	0	10	0	10
T5: MOP	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	9	1	9	1	9	1
	+25% cut-off	10	1	9	1	9	1	9
	+50% cut-off	10	0	10	0	10	0	10
T6:PCR	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	9	1	9	1	9	1
	+25% cut-off	10	1	9	2	8	1	9
	+50% cut-off	10	0	10	0	10	0	10
T7: AMP	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	9	1	8	2	8	2
	+25% cut-off	10	1	9	1	9	1	9
	+50% cut-off	10	0	10	0	10	0	10
T8: MOP	Drug free urine	10	10	0	10	0	10	0
	-50% cut-off	10	10	0	10	0	10	0
	-25% cut-off	10	8	2	8	2	8	2
	+25% cut-off	10	1	9	1	9	1	9
	+50% cut-off	10	0	10	0	10	0	10



T9: PCR	Drug free urine	10	10	0	10	0	10	0	
	-50% cut-off	10	10	0	10	0	10	0	
	-25% cut-off	10	9	1	9	1	9	1	
	+25% cut-off	10	1	9	1	9	1	9	
	+50% cut-off	10	0	10	0	10	0	10	
T10: MDMA	Drug free urine	10	10	0	10	0	10	0	
	-50% cut-off	10	10	0	10	0	10	0	
	-25% cut-off	10	9	1	8	2	9	1	
	+25% cut-off	10	1	9	1	9	1	9	
	+50% cut-off	10	0	10	0	10	0	10	
T11: MTD	Drug free urine	10	10	0	10	0	10	0	
	-50% cut-off	10	10	0	10	0	10	0	
	-25% cut-off	10	9	1	9	1	9	1	
	+25% cut-off	10	1	9	1	9	1	9	
	+50% cut-off	10	0	10	0	10	10	10	
TML1112000 4-T	T12: TML	Drug free urine	10	10	0	10	0	10	0
		-50% cut-off	10	10	0	10	0	10	0
		-25% cut-off	10	9	1	9	1	8	2
		+25% cut-off	10	1	9	1	9	1	9
		+50% cut-off	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 for Accu-Tell® Multi Line Drug Cassette (Urine).

## 2.9 Effect of Urinary Specific Gravity

### Material:

Accu-Tell® Multi Line Drug Cassette (Urine):

LOT: DOA12030201-T

LOT: TML11120004-T

### Method:

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 Multi-Line Rapid Test to -50% Cut-off; (3) Urine samples were spiked with Multi-Line Rapid Test to +50% Cut-off. The Cassette were tested in duplicates with above urine samples. Read the result at 5 minutes after sample application.

### Result:

**Table: Effect of Urinary Specific Gravity**

Product: DOA12030201-T	Urine ID	Urine Specific Gravity	N*	Drug free urine		-50% Cut-off		+50% Cut-off	
	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+



<b>T1: BZO</b>	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T2: TCA</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T3: BAR</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T4: AMP500</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+



	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T5: MOP</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T6: PCP</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T7: MET500</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T8: COC150</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+



	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T9: THC50</b>	1	1.004	2	-	-	-	-	+	+
	2	1.012	2	-	-	-	-	+	+
	3	1.013	2	-	-	-	-	+	+
	4	1.009	2	-	-	-	-	+	+
	5	1.013	2	-	-	-	-	+	+
	6	1.017	2	-	-	-	-	+	+
	7	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	9	1.017	2	-	-	-	-	+	+
	10	1.024	2	-	-	-	-	+	+
	11	1.037	2	-	-	-	-	+	+
	12	1.047	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.041	2	-	-	-	-	+	+
	15	1.044	2	-	-	-	-	+	+
<b>T10: MDMA</b>	1	1.012	2	-	-	-	-	+	+
	2	1.005	2	-	-	-	-	+	+
	3	1.011	2	-	-	-	-	+	+
	4	1.007	2	-	-	-	-	+	+
	5	1.008	2	-	-	-	-	+	+
	6	1.013	2	-	-	-	-	+	+
	7	1.027	2	-	-	-	-	+	+
	8	1.023	2	-	-	-	-	+	+
	9	1.015	2	-	-	-	-	+	+
	10	1.023	2	-	-	-	-	+	+
	11	1.036	2	-	-	-	-	+	+
	12	1.042	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.019	2	-	-	-	-	+	+
	15	1.017	2	-	-	-	-	+	+
<b>T11: MTD</b>	1	1.012	2	-	-	-	-	+	+
	2	1.005	2	-	-	-	-	+	+
	3	1.011	2	-	-	-	-	+	+
	4	1.007	2	-	-	-	-	+	+
	5	1.008	2	-	-	-	-	+	+
	6	1.013	2	-	-	-	-	+	+
	7	1.027	2	-	-	-	-	+	+
	8	1.023	2	-	-	-	-	+	+
	9	1.015	2	-	-	-	-	+	+



	10	1.023	2	-	-	-	-	+	+
	11	1.036	2	-	-	-	-	+	+
	12	1.042	2	-	-	-	-	+	+
	13	1.036	2	-	-	-	-	+	+
	14	1.019	2	-	-	-	-	+	+
	15	1.017	2	-	-	-	-	+	+
<b>Product: TML11120004-T</b>	<b>Urine ID</b>	<b>Urine Specific Gravity</b>	<b>N*</b>	<b>Drug free urine</b>		<b>-50% Cut-off</b>		<b>+50% Cut-off</b>	
<b>T12: TML</b>	16	1.005	2	-	-	-	-	+	+
	32	1.011	2	-	-	-	-	+	+
	31	1.012	2	-	-	-	-	+	+
	67	1.010	2	-	-	-	-	+	+
	52	1.013	2	-	-	-	-	+	+
	33	1.017	2	-	-	-	-	+	+
	6	1.021	2	-	-	-	-	+	+
	8	1.024	2	-	-	-	-	+	+
	55	1.018	2	-	-	-	-	+	+
	12	1.024	2	-	-	-	-	+	+
	13	1.030	2	-	-	-	-	+	+
	4	1.028	2	-	-	-	-	+	+
	7	1.039	2	-	-	-	-	+	+
29	1.040	2	-	-	-	-	+	+	
21	1.042	2	-	-	-	-	+	+	

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

## 2.10 Effect of Urinary pH

### Material:

Accu-Tell® Multi Line Drug Cassette (Urine):

LOT: DOA12030201-T

LOT: TML11120004-T

### Method:

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 (10 ml/container): Drugs was added to two aliquots to bring the final sample concentration of -50% cut-off and +50% cut-off respectively. Each pH-adjusted urine was tested in duplicate and read 5 and 10 minutes after sample application.

### Result:

**Table: Effect of Urinary pH**

<b>Product: DOA12030201-T</b>	<b>pH</b>	<b>Negative urine</b>		<b>-50% cutoff</b>		<b>+50% cutoff</b>	
		<b>5min</b>	<b>10min</b>	<b>5min</b>	<b>10min</b>	<b>5min</b>	<b>10min</b>
<b>T1: BZO</b>	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+



	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
	9	-	-	-	-	+	+
T2: TCA	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
9	-	-	-	-	+	+	
T3: BAR	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
9	-	-	-	-	+	+	
T4: AMP500	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
9	-	-	-	-	+	+	
T5: MOP	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
9	-	-	-	-	+	+	
T6: PCP	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+



	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
	9	-	-	-	-	+	+
T7: MET500	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
	9	-	-	-	-	+	+
T8: COC150	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
	9	-	-	-	-	+	+
T9: THC50	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
	9	-	-	-	-	+	+
T10: MDMA	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+
	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
	9	-	-	-	-	+	+
T11: MTD	5	-	-	-	-	+	+
	5	-	-	-	-	+	+
	6	-	-	-	-	+	+
	6	-	-	-	-	+	+
	7	-	-	-	-	+	+
	7	-	-	-	-	+	+





	8	-	-	-	-	+	+
	8	-	-	-	-	+	+
	9	-	-	-	-	+	+
	9	-	-	-	-	+	+
<b>Product:</b> TML11120004-T	<b>pH</b>	<b>Negative urine</b>		<b>-50% cutoff</b>		<b>+50% cutoff</b>	
		<b>5min</b>	<b>10min</b>	<b>5min</b>	<b>10min</b>	<b>5min</b>	<b>10min</b>
T12: TML	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

### 3. Bibliography

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