Performance Evaluation of Multi-Drug Rapid Test for Rapid Detection of Multiple Drugs and Drug Metabolites in Human Blood Samples

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ABSTRACT

Objective: The Multi-Drug Rapid Test Cassette, developed by Hangzhou AllTest Biotech Co., Ltd, is a rapid chromatographic immunoassay designed for the qualitative detection of multiple drugs and drug metabolites in human whole blood, serum, or plasma. It aims to simultaneously detect various abused substances, including Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Cannabis (THC), Methadone (MTD), Methamphetamine (MET), 3,4-Methylenedioxymethamphetamine (MDMA), Morphine (MOP/OPI), Propoxyphene (PPX), Tricyclic antidepressants (TCA), Oxycodone (OXY), 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Cotinine (COT), Tramadol (TML), Fentanyl (FYL), 3,4-Methylenedioxy pyrovalerone (MDPV), Synthetic cannabinoids(K2), Phencyclidine(PCP), Ketamine(KET), Lysergic acid diethylamide(LSD), 3,4-Methylenedioxyamphetamine(MDA), Acetaminophen(ACE), Ketamine(CAT), 6-Monoacetylmorphine (6-MAM), Zolpidem (ZOL), AB-PINACA (ABP/K3). Therefore, the present research was done to evaluate the diagnostic performance of this test.

Material and Method: In this study, the accuracy, precision, and sensitivity of the drug testing methods were assessed. Approximately 100 specimens of each drug, obtained from previous drug screening tests, were tested. The results were compared to confirmatory analysis using GC/MS, and the accuracy of the testing was determined based on the comparative classification results. The evaluation of precision included measuring the consistency of measurements within a single run, between different runs, and among different operators, using the AllTest multi-drug detection tool across three different hospitals and three different batches. To evaluate the sensitivity of the detection method, various concentrations of drugs were added to a pool of whole blood, serum, or plasma without any drugs. The positive and negative results obtained from the testing were analyzed to assess the method's ability to detect drugs at different concentrations.

Results: In this study, we evaluated the performance of the Multi-Drug Rapid Test Cassette developed by Hangzhou AllTest Biotech Co., Ltd. The results demonstrated excellent performance of the test in terms of accuracy, sensitivity, and precision.

Conclusion: The Multi-Drug Rapid Test Cassette developed by Hangzhou AllTest Biotech Co., Ltd exhibited reliable detection of multiple drugs and drug metabolites, providing trustworthy results for drug abuse screening. These findings have significant implications for drug control and monitoring, as well as supporting the broad application of this test in clinical and legal settings.

Keywords: Drugs of abuse; Immunoassay test; Drug abuse detection; Blood; Cocaine; Fentanyl, Amphetamine; Opiates

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Received: Nov 24, 2023; **Accepted**: Nov 29, 2023; **Published**: Dec 04, 2023

Citation: Lei Z, Feng Y, Junzhe Z (2023) Performance Evaluation of Multi-Drug Rapid Test for Rapid Detection of Multiple Drugs and Drug Metabolites in Human Blood Samples. Global Health Science Journal 3:113. **DOI**: https://doi.org/10.61309/ghs.1000113

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INTRODUCTION

According to the latest data from the *World Drug Report 2023* by the United Nations Office on Drugs and Crime, the estimated number of global injectable drug users was approximately 13.2 million in 2021, which is 18% higher than previous estimates. On a global scale, the number of drug users exceeded 296 million in 2021, marking a 23% increase compared to a decade ago. Moreover, the number of people suffering from drug addiction has skyrocketed to 39.5 million, indicating a 45% increase over the past decade [1]. Given the widespread nature of this drug abuse phenomenon, screening for illegal drug use is necessary. The most sophisticated drug-testing approach is gas chromatography coupled with mass spectrometry (GC/MS), which is regarded as a "gold standard"; it is used in confirmatory testing. Typically, GC/MS is preceded by a rapid immunoassay method to eliminate the majority of the specimens/individuals with negative drug test results, thereby preventing an excessive burden on more complex and time-consuming confirmation processes [2].

There are several biological samples that can be used for testing. These include blood or serum, sweat, hair, oral fluid, nails, and urine. The most commonly used biological sample is urine, as it is non-invasive, and the concentration of a given xenobiotic is generally higher when compared to other samples. This usually results in a higher sensitivity. Additional considerations include how long a xenobiotic remains detectable in various matrices. This consideration becomes particularly significant when determining the appropriate testing approach based on the specific objectives and reasons for conducting the test [3]. In emergency situations, blood testing offers the advantage of providing a precise assessment of a specific level [4]. The detection window is usually one to two days [5].

Immunoassays remain the most common and easily accessible form of testing. More advanced methods, particularly in confirmatory testing, are available and include gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/mass spectrometry (LC/MS). These advanced methods tend to have higher specificity and sensitivity as compared to immunoassays, but are more expensive and require specialized equipment and training [6].

Due to the urgency of drug abuse detection, timely and accurate testing is crucial. Blood screening method reduce the possibility of sample tampering, making it a commonly used and feasible approach.

As a result, blood drug screening devices need to meet several criteria. They should be reliable and provide rapid results. Additionally, they should be cost-effective and user-friendly, allowing testing to be conducted by individuals with minimal training,

even outside of a laboratory setting. On-site drug screening devices are designed to fulfill these requirements.

Traditional drug testing methods have limitations as they typically focus on specific drugs, which may not provide a comprehensive assessment of drug abuse patterns. Therefore, the development of a tool capable of simultaneously detecting multiple drugs is essential to achieve a more comprehensive screening of drug abuse.

MATERIAL AND METHOD

Sample Materials

The samples used in this study include whole blood, serum, or plasma obtained through either a venipuncture or a fingerstick procedure.

To collect fingerstick whole blood specimens, the patient's hand should be washed with soap and warm water or cleaned with an alcohol swab. After drying, the hand is gently massaged without touching the puncture site. The skin is then punctured with a sterile lancet, and the first sign of blood is wiped away. The hand is gently rubbed to form a rounded drop of blood over the puncture site.

To add the fingerstick whole blood specimen to the test, a capillary tube is used. The end of the capillary tube is touched to the blood until filled to approximately 40μL, ensuring no air bubbles are present. The bulb is then placed onto the top end of the capillary tube, and the whole blood is dispensed into the specimen well of the test cassette by squeezing the bulb.

Testing should be done immediately after specimen collection, without leaving the specimens at room temperature for extended periods. Specimens for long-term storage should be kept below -20°C, while whole blood collected by venipuncture can be stored at 2-8°C if the test will be conducted within 2 days. Fingerstick whole blood specimens should be tested immediately. Prior to testing, specimens should be brought to room temperature. If frozen, specimens must be completely thawed and mixed well before testing. If specimens need to be shipped, they should be packed following local regulations for transporting etiologic agents.

Screen Test

The AllTest Multi-Drug Rapid Test Cassette is a rapid screening test that can detect specific drugs in whole blood, serum, or plasma without the need for an instrument. The cassette allows for the customization of drug combinations, ranging from 2 to 17 different drugs. Each drug is represented by a separate test line on the cassette. The specific drugs that can be detected include Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Cannabis (THC), Methadone (MTD), Methamphetamine (MET), 3,4-Methylenedioxymethamphetamine (MDMA), Morphine (MOP/OPI), Propoxyphene (PPX), Tricyclic antidepressants (TCA), Oxycodone (OXY), 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Cotinine (COT), Tramadol (TML), Fentanyl (FYL), 3,4-Methylenedioxy pyrovalerone (MDPV), Synthetic cannabinoids(K2), Phencyclidine(PCP), Ketamine(KET), Lysergic acid diethylamide(LSD), 3,4-Methylenedioxyamphetamine(MDA), Acetaminophen(ACE), Ketamine(CAT), 6-Monoacetylmorphine (6-MAM), Zolpidem (ZOL), AB-PINACA (ABP/K3).

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line system contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

During the test, a specimen of whole blood, serum, or plasma migrates upward through capillary action. If a drug is present in the specimen below its designated cut-off concentration, it will not saturate the binding sites of its specific antibody. In this case, the antibody will react with the drug-protein conjugate, resulting in a visible colored line in the test region. If the drug concentration exceeds the cut-off level, it will saturate all the binding sites of the antibody, preventing the formation of a colored line in the test region. A drug-positive specimen will not generate a colored line in the specific test region due to drug competition, while a drug-negative specimen will produce a line in the test region due to the absence of drug competition. To ensure proper procedure, a colored line will always appear at the control region, indicating that the correct volume of the specimen has been added and that membrane wicking has occurred. This serves as a procedural control.

Prior to conducting the test, ensure that the test kit, specimen, buffer, and controls have reached room temperature (15-30°C). Place the cassette on a clean and level surface. For serum or plasma specimens, transfer 1 drop of serum or plasma (approximately 40 µL) to the designated specimen area. Add 1 drop of buffer (approximately 40 µL) to the same area and start the timer.

For venipuncture whole blood specimens, transfer 2 drops of whole blood (approximately 80 µL) to the designated area. Add 1 drop of buffer (approximately 40 µL) and start the timer. When dealing with fingerstick whole blood specimens, there are two options. Firstly, fill a capillary tube with approximately 80 µL of blood and transfer it to the designated area. Add 1 drop of buffer (approximately 40 µL) and start the timer. Alternatively, allow 2 hanging drops of blood (approximately 80 µL) to fall into the specimen area. Add 1 drop of buffer (approximately 40 µL) and start the timer.

After adding the samples, it is necessary to wait until colored lines appear. The results should be precisely read at the 5-minute mark. It is crucial not to interpret the results after 20 minutes. It should be noted that this test provides preliminary data and is not suitable for monitoring drug levels. For accurate confirmation of results, confirmatory methods such as gas chromatography/mass spectrometry (GC/MS) should be utilized.

RESULT AND DISCUSSION

Accuracy

A side-by-side comparison was conducted using the Multi-Drug Rapid Test Cassette and commercially available drug rapid tests. Testing was performed on approximately hundred specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS (Table 1).

Method		GC/MS(Whole Blood/Serum/Plasma)		% agreement with GC/MS
Multi-Drug Rapid Test		Positive	Negative	
AMP 80	Positive	20	1	95.20%
	Negative	1	68	98.60%
AMP 50	Positive	20	1	95.20%
	Negative	1	68	98.60%
BAR 100	Positive	20	2	90.90%
	Negative	2	66	97.10%
BZO 100	Positive	19	2	90.50%
	Negative	2	67	97.10%
BUP 5	Positive	21	2	95.50%
	Negative	1	66	97.10%
BUP 10	Positive	20	2	90.90%
	Negative	2	66	97.10%
COC 50	Positive	25	1	96.20%
	Negative	1	63	98.40%
THC 50	Positive	24	1	92.30%
	Negative	2	63	98.40%
THC 35	Positive	24	1	92.30%
	Negative	2	63	98.40%
THC 12	Positive	24	1	92.30%
	Negative	2	63	98.40%
MTD 40	Positive	19	2	95.00%
	Negative	1	68	97.10%
MET 70	Positive	25	2	92.60%
	Negative	2	61	96.80%
MET 50	Positive	25	2	92.60%
	Negative	2	61	96.80%
MDMA 50	Positive	20	2	90.90%
	Negative	2	66	97.10%
MOP/OPI 40	Positive	23	2	92.00%
	Negative	2	63	96.90%
PPX 100	Positive	24	2	96.00%
	Negative	1	63	96.90%
TCA 300	Positive	23	2	92.00%
	Negative	2	63	96.90%
OXY 20	Positive	27	2	93.10%
	Negative	2	59	96.70%
COT 100	Positive	23	1	92.00%

	Negative	2	64	98.50%
COT 10	Positive	23	2	95.80%
	Negative	1	64	97.00%
EDDP 50	Positive	18	2	90.00%
	Negative	2	68	97.10%
TML 50	Positive	19	1	90.50%
	Negative	2	75	98.70%
MDPV 300	Positive	18	3	90.00%
	Negative	2	67	95.70%
FYL 15	Positive	24	1	92.30%
	Negative	2	63	98.40%
K2-100	Positive	21	2	91.30%
	Negative	2	65	97.00%
PCP 20	Positive	21	1	95.50%
	Negative	1	67	98.50%
KET 200	Positive	24	3	92.30%
	Negative	2	61	95.30%
LSD 20	Positive	20	1	95.20%
	Negative	1	69	98.60%
MDA 80	Positive	23	1	95.80%
	Negative	1	68	98.60%
ACE 1,000	Positive	29	1	93.50%
	Negative	2	68	98.60%
CAT 150	Positive	19	2	90.50%
	Negative	2	73	97.30%
6-MAM 30	Positive	24	1	96.00%
	Negative	1	65	98.50%
ZOL 150	Positive	20	2	90.90%
	Negative	2	66	97.10%
ABP/K3 10	Positive	23	2	92.00%
	Negative	2	68	97.10%

Table 1: Clinic Result of Whole Blood/Serum/Plasma.

Precision

This study was performed at three hospitals using three different batches of a product. The purpose of the study was to evaluate the precision of the measurements within a single run, between different runs, and between different operators.

To assess the precision, a card with coded specimens was prepared. These specimens contained drugs at concentrations that were either higher or lower than the predetermined cut-off level by up to 50%. The card was labeled and its contents were concealed to ensure unbiased testing. The card was then tested at each of the three hospital sites (Table 2).

AMP 50	**Site A**		**Site B**		**Site C**		**AMP 80**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
25	8	2	9	1	9	1	40	8	2	9	1	9	1
75	1	9	1	9	2	8	120	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
BAR 100	**Site A**		**Site B**		**Site C**		**BZO 100**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
50	8	2	9	1	9	1	50	8	2	9	1	9	1
150	1	9	1	9	2	8	150	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
BUP 5	**Site A**		**Site B**		**Site C**		**BUP 10**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
2.5	8	2	9	1	9	1	5	8	2	9	1	9	1
7.5	1	9	1	9	2	8	15	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
COC 50	**Site A**		**Site B**		**Site C**		**THC 50**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
25	8	2	9	1	9	1	25	8	2	9	1	9	1
75	1	9	1	9	2	8	75	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
THC 35	**Site A**		**Site B**		**Site C**		**THC 12**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
17.5	8	2	9	1	9	1	6	8	2	9	1	9	1
52.5	1	9	1	9	2	8	18	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
MTD 40	**Site A**		**Site B**		**Site C**		**MET 70**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
20	8	2	9	1	9	1	35	8	2	9	1	9	1
60	1	9	1	9	2	8	105	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	

MET 50	Site A		Site B		Site C		MDMA 50	Site A		Site B		Site C	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
25	8	2	9	1	9	1	25	8	2	9	1	9	1
75	1	9	1	9	2	8	75	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	

MOP/OPI 40	Site A		Site B		Site C		PPX 100	Site A		Site B		Site C	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
20	8	2	9	1	9	1	50	8	2	9	1	9	1
60	1	9	1	9	2	8	150	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	

TCA 300	Site A		Site B		Site C		OXY 20	Site A		Site B		Site C	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
150	8	2	9	1	9	1	10	8	2	9	1	9	1
450	1	9	1	9	2	8	30	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	

COT 10	Site A		Site B		Site C		COT 100	Site A		Site B		Site C	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
5	8	2	9	1	9	1	50	8	2	9	1	9	1
15	1	9	1	9	2	8	150	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	

EDDP 50	Site A		Site B		Site C		TML 50	Site A		Site B		Site C	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
25	8	2	9	1	9	1	25	10	0	10	0	10	0
75	1	9	1	9	2	8	75	0	10	0	10	0	10
Precision	**90%**		**93.30%**		**90%**		**Precision**	**100%**		**100%**		**100%**	

FYL 15	Site A		Site B		Site C		MDPV 300	Site A		Site B		Site C	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
7.5	8	2	9	1	9	1	150	8	2	9	1	9	1

22.5	1	9	1	9	2	8	450	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
K2-100	**Site A**		**Site B**		**Site C**		**PCP 20**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
50	8	2	9	1	9	1	10	8	2	9	1	9	1
150	1	9	1	9	2	8	30	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
KET 200	**Site A**		**Site B**		**Site C**		**LSD 20**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
100	9	1	9	1	9	1	10	8	2	9	1	9	1
300	1	9	1	9	1	9	30	1	9	1	9	2	8
Precision	**93.30%**		**93.30%**		**93.30%**		**Precision**	**90%**		**93.30%**		**90%**	
MDA 80	**Site A**		**Site B**		**Site C**		**ACE 1000**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
40	8	2	9	1	9	1	500	9	1	9	1	8	2
120	1	9	1	9	2	8	1500	1	9	1	9	1	9
Precision	**90%**		**93.30%**		**90%**		**Precision**	**93.30%**		**93.30%**		**90%**	
CAT 150	**Site A**		**Site B**		**Site C**		**6-MAM 30**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
75	8	2	9	1	9	1	15	8	2	9	1	9	1
225	1	9	1	9	2	8	45	1	9	1	9	2	8
Precision	**90%**		**93.30%**		**90%**		**Precision**	**90%**		**93.30%**		**90%**	
ZOL 150	**Site A**		**Site B**		**Site C**		**ABP/K3 10**	**Site A**		**Site B**		**Site C**	
	-	+	-	+	-	+		-	+	-	+	-	+
0	10	0	10	0	10	0	0	10	0	10	0	10	0
75	9	1	10	0	10	0	5	8	2	9	1	9	1
225	0	10	1	9	0	10	15	1	9	1	9	2	8
Precision	**96.70%**		**96.70%**		**100%**		**Precision**	**90%**		**93.30%**		**90%**	

Table 2: Test Results from Three Sites.

Sensitivity

A drug-free mixture of whole blood/serum/plasma was subjected to a drug-spiking experiment with drugs at concentrations of 0%, -50%, 100%, 150%, and 300%. Now, the sensitivity of the drug detection assay in this experiment needs to be calculated. The results are summarized below (Table 3).

Drug Concentration Cut-off Range	AMP 80		AMP 50		BAR 100		BZO 100		BUP 5		BUP 10		COC 50		THC 35		THC 12	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	15	15	16	14	15	15	14	16	13	17	13	17	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	MTD 40		MET 70		MET 50		MDMA 50		MOP/OPI 40		PPX 100		TCA 300		FYL 15	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	14	16	14	16	15	15	15	15	14	16	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	MDPV 300		OXY 20		COT 10		COT 100		EDDP 50		TML 50		K2 100		PCP 20		KET 200	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	15	15	15	15	14	16	15	15	15	15	15	15	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	LSD 20		MDA 80		THC 50		ACE 1000		CAT 150		6-MAM 30		ZOL 150		ABP/K3 10	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	29	1	30	0
Cut-off	15	15	15	15	16	14	14	16	15	15	15	15	14	16	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	1	29	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Table 3: Analytical Sensitivity.

DISCUSSION

Based on the data results presented above, the Multi-Drug Rapid Test Cassette demonstrates favorable performance in terms of accuracy, precision, and sensitivity. By providing reliable and precise results, this test cassette can aid healthcare professionals, forensic analysts, and drug screening agencies in making informed decisions, enabling timely interventions, and contributing to public health and safety.

The Multi-Drug Rapid Test Cassette (Whole Blood/Serum/Plasma) has certain limitations that should be acknowledged. Firstly, it provides only a qualitative, preliminary result, necessitating the use of a secondary analytical method to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) is the recommended confirmatory method [7].

Secondly, technical or procedural errors, as well as the presence of interfering substances in the whole blood, serum, or plasma specimen, can lead to inaccurate results. It is important to minimize these errors and consider the potential interferences when interpreting the test outcomes. Improved training and quality control measures should be implemented to mitigate these issues.

Thirdly, a positive result from the test indicates the presence of the drug or its metabolites but does not provide information about the level of intoxication, administration route, or concentration in the specimen. To overcome this limitation, the test results should be used in conjunction with additional clinical data to make informed decisions.

Furthermore, a negative result does not necessarily indicate drug-free whole blood, serum, or plasma. Negative results can occur when the drug is present but below the test's cut-off level. It is important to be aware of this possibility when interpreting negative results, and additional confirmatory testing or alternative approaches should be considered to accurately determine drug presence.

CONCLUSION

The analytical performance of the drug detection device was evaluated based on sensitivity, selectivity, and precision. In general, the AllTest Multi-Drug Rapid Test demonstrated excellent sensitivity around the cut-off concentrations. While technological advancements have improved the reliability of results, rapid testing devices remain primarily screening tools. Therefore, employers, officials, physicians, and counselors who utilize these tools must exercise caution in interpreting the results, as with any immunoassay. Confirmatory analysis

through GC-MS is necessary to ensure the identification of analytes in immunological analysis results.

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