

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k051966

B. Purpose of the Submission:

New device

C. Analyte:

Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP)

D. Type of Test:

Qualitative Lateral Flow Immunochromatographic Test

E. Applicant:

Worldwide Medical LLC

F. Proprietary and Established Names:

First Check Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP)

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3100, Enzyme Immunoassay, Amphetamine

21 CFR 862.3870, Enzyme Immunoassay, Cannabinoids

21 CFR 862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites

21 CFR 862.3610, Thin Layer Chromatography, Methamphetamine

21 CFR 862.3650, Enzyme Immunoassay, Opiates

Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

Class II

3. Product Codes:

DKZ, LDJ, DIO, LAF, DJG and LCM

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to the Indications for use below.

2. Indication(s) for use:

The First Check Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) is a screening test for the rapid detection of one to seven of the above listed drugs in a variety of combinations in urine. The designated cut-off concentration of these drugs are as follows: Marijuana at 50 ng/mL, Cocaine at 300 ng/mL, Amphetamine at 1,000 ng/mL, Methamphetamine at 1,000 ng/mL, Ecstasy at 500 ng/mL, Opiates at 2,000 ng/mL, and Phencyclidine at 25 ng/mL. The test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample.

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 indicated.

3. Special condition for use statement(s):

The First Check Multi Drug Cup 7 test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

This assay is for OTC use.

The materials necessary for the confirmatory test are provided with the screening device. Materials, as well as the confirmatory test, are provided to the consumer at no additional cost. The consumer pays for shipment of the sample to the laboratory.

4. Special instrument Requirements:

Not applicable.

I. Device Description:

The device is a two piece plastic cup consisting of a plastic specimen collection cup and a plastic lid with between one and seven test strips sealed in plastic housing which is attached to the underside of the lid. To perform the test, you collect a urine sample with the collection cup provided. Secure the test list lid onto the specimen collection cup and rest the cup on its side to activate testing. The product also

includes an instruction booklet, a numbered sticker for confidential confirmation testing, a transportation pouch and a pre-addressed mailing box.

J. Substantial Equivalence Information:

1. Predicate device name:
Ameditech Immutest Drug Screen Cup/ImmuTest Multi-Drug Screen Panel II
2. Predicate K numbers:
k040092/k042975
3. Comparison with predicate:
This device and the predicates are identical in product design, performance characteristics, materials, manufacturing, matrix used and are intended for use as an initial screening method subject to confirmation. The proposed device is intended to be sold over-the-counter (OTC) while the predicate devices are intended for prescription use only.

K. Standard/Guidance Document Referenced (if applicable):

The sponsor did not reference any standards or guidance documents in their pre-market submission.

L. Test Principle:

This device uses a one step, rapid chromatographic immunoassay which operates under the principle of recognition and formation of specific antibody/target drug complexes. 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 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 if the test has been performed properly. If a control line does not appear for any reason, the results are considered invalid and should not be interpreted. The sample should either be retested using a new First Check Multi Drug Cup 7 or the sample should be mailed in for confirmation.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Performance Characteristics have been addressed in k040092 and k042975 (Ameditech Immutest Drug Screen Cup and Ameditech ImmuTest Multi-Drug Screen Panel II).
 - b. *Linearity/assay reportable range:*
Not applicable
 - c. *Traceability (controls, calibrators, or method):*

The device has an internal procedural control; a colored line will always appear at the control line region if the test has been performed properly. The labeling informs users to check that the test is working properly by looking for a red or pink line next to the word control on all test strips. If a control line does not appear for any reason, the results are considered invalid and should not be interpreted. The sample should either be retested using a new First Check Multi Drug Cup 7 or the sample should be mailed in for confirmation.

d. Detection limit:

Performance Characteristics have been addressed in k040092 and k042975 (Ameditech Immutest Drug Screen Cup and Ameditech ImmuTest Multi-Drug Screen Panel II).

e. Analytical specificity:

Performance Characteristics have been addressed in k040092 and k042975 (Ameditech Immutest Drug Screen Cup and Ameditech ImmuTest Multi-Drug Screen Panel II).

f. Analytical specificity:

Performance Characteristics have been addressed in k040092 and k042975 (Ameditech Immutest Drug Screen Cup and Ameditech ImmuTest Multi-Drug Screen Panel II).

g. Assay cut-off:

The identified cutoff concentrations are those recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA). Analytical performance of the device around the cutoff is described in the precision section above.

2. Comparison studies:

a. Method comparison with predicate device:

Performance Characteristics have been addressed in k040092 and k042975 (Ameditech Immutest Drug Screen Cup and Ameditech ImmuTest Multi-Drug Screen Panel II).

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable

b. Clinical specificity:

Not applicable.

- c. *Other clinical supportive data (when a and b are not applicable):*
The accuracy and precision of the test was demonstrated in a study performed by 240 untrained users. 375 unique tests with sample solutions containing methamphetamine, morphine, phencyclidine, amphetamine, MDMA and benzoylecgonine were performed by consumers using drug-free urine that had been spiked with various concentrations and combinations of drugs. 355 unique tests with sample solutions containing THC were performed by consumers using drug-free urine that had been spiked with various concentrations and combinations of drugs. A total of 2,605 assays were performed. Each drug was tested at 0%, 50%, 75%, 125%, 150%, and 200% of the target concentration. Some samples contained as many as four drugs; there were samples that contained no drugs at all. Drug concentrations were confirmed by GC/MS at a SAMHSA laboratory; recovery ranged between 88.9% to 130.6% of the target concentration. Approximately 2.5 % of the consumers had used a home drug kit before. 90% reported they were high-school graduates and the ratio of female to male was approximately 2:1. The study was conducted at three different locations (Phoenix, AZ; Johnson City, NY; and Bemidji, MN).

The results of the study are summarized below:

DRUG	Cutoff Concentration (ng/ml)	Number of Studies	Correctly Interpreted	Incorrectly Interpreted
THC	50	355	353	2
COC	300	375	366	9
AMP	1000	375	373	2
MET	1000	375	372	3
MDMA	500	375	364	11
OPI	2000	375	369	6
PCP	25	375	375	-

2572 of 2605 tests were interpreted correctly (98.7%). All samples that were interpreted incorrectly were within $\pm 25\%$ of the cutoff value (75% or 125% of cutoff).

A consumer questionnaire was administered to evaluate labeling effectiveness. The following questions were asked: “Was the test easy to run and were the results easy to read?” and “Does it matter how light or dark the colored line is?”. Seven participants (2.9%) answered that the test was not easy to run and the results were not

easy to read. Fifteen participants (6.25%) answered that it does matter how light or how dark the colored line is.

4. Clinical cut-off:
Not applicable.
5. Expected values/Reference range:
Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.