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

A. 510(k) Number:
k052115

B. Purpose of the Submission:
New device

C. Analyte:

Marijuana (MAR), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI), Phencyclidine (PCP), Benzodiazepines (BZO), Barbiturates (BAR), Methadone (MTD), Tricyclic Antidepressants (TCA), and Oxycodone (OXY)

D. Type of Test:
Qualitative Lateral Flow Immunochromatographic Test

E. Applicant:
First Check Diagnostics LLC

F. Proprietary and Established Names:
First Check Multi Drug Cup 12

G. Regulatory Information:

1. Regulation section:
   862.3100, Enzyme Immunoassay, Amphetamine
   862.3150, Enzyme Immunoassay, Barbiturate
   862.3170, Enzyme Immunoassay, Benzodiazepine
   862.3870, Enzyme Immunoassay, Cannabinoids
   862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites
   862.3620, Enzyme Immunoassay, Methadone
   862.3610, Thin Layer Chromatography, Methamphetamine
   862.3650, Enzyme Immunoassay, Opiates
   862.3910 Thin Layer Chromatography, Tricyclic Antidepressants
   Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:
   Class II

3. Product Codes:
   DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, 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 12 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI), Phencyclidine (PCP), Benzodiazepine (BZO), Barbiturates (BAR), Methadone (MTD), Tri-cyclic Antidepressants (TCA) and Oxycodone (OXY) is a screening test for the rapid detection of the twelve drugs listed above in human urine. The designated cut-off concentrations of these drugs are as follows: Marijuana at 50 ng/mL, Cocaine at 300 ng/mL, Amphetamine at 1000 ng/mL, Methamphetamine at 1000 ng/mL, Ecstasy at 500 ng/mL, Opiates at 2000 ng/mL, Phencyclidine at 25 ng/mL, Benzodiazepine at 300 ng/mL, Barbiturates at 300 ng/mL, Methadone at 300 ng/mL, Tri-cyclic Antidepressants at 1,000 ng/mL and Oxycodone at 100 ng/mL.

   The BAR, BZO, TCA, OXY assay will yield preliminary positive results when BAR, BZO, TCA and OXY is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant and oxycodone in urine. The Multi Drug Cup 12 shows the drug was or was not present at the cutoff level. 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 for most drugs (HPLC is the preferred confirmatory method for Tri-cyclic Antidepressants). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

   This device is not intended for workplace testing.

   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. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided.

3. Special condition for use statement(s):
   The BAR, BZO, TCA, OXY assay will yield preliminary positive results when BAR, BZO, TCA and OXY is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate,

benzodiazepine, tricyclic antidepressant and oxycodone in urine. The Multi Drug Cup 12 shows the drug was or was not present at the cutoff level.

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 for most drugs (HPLC is the preferred confirmatory method for Tri-cyclic Antidepressants). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

This device is not intended for workplace testing. This device is intended for Home Use.

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. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided.

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 twelve 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

2. Predicate K number:
   k050186

3. Comparison with predicate:

Similarities

Characteristic	New device	Predicate
Principle	Immunochromatographic lateral flow assay	same
Number of tests	12	same
Cutoff concentrations	Marijuana at 50 ng/mL, Cocaine at 300 ng/mL, Amphetamine at 1000 ng/mL, Methamphetamine at 1000 ng/mL, Ecstasy at 500 ng/mL, Opiates at 2000 ng/mL, Phencyclidine at 25 ng/mL, Benzodiazepine at 300 ng/mL, Barbiturates at 300 ng/mL, Methadone at 300 ng/mL, Tri-cyclic Antidepressants at 1,000 ng/mL and Oxycodone at 100 ng/mL.	same

Differences

Characteristic	New device	Predicate
Target Population	Home Use	Prescription Use
Instructions for Use	Lay user labeling written at no higher than a 7th grade level	Labeling for healthcare professions.

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 competitive binding. The device contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate (or antibody) band in the test region and a pad containing colored antibody (or the drug-protein) colloidal gold conjugate. 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 device or the sample should be mailed in for confirmation.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

See Clinical studies section below to see performance data for samples around the cutoff.

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

The device has an internal process control. Users are informed that the control indicates that sufficient urine was added to the test. This is typical of OTC tests. Users are also informed not to interpret the test if the control line does not form.

d. Detection limit:

Performance Characteristics have been addressed in k050186 (Ameditech Immutest Drug Screen Cup).

e. Analytical specificity:

Performance Characteristics have been addressed in k050186 (Ameditech Immutest Drug Screen Cup).

f. Analytical specificity:

Performance Characteristics have been addressed in k050186 (Ameditech Immutest Drug Screen Cup).

g. Assay cut-off:

The cutoff concentrations for methamphetamine, THC, cocaine metabolites, amphetamines, opiates and PCP are recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA).

SAMHSA has not recommended a cutoff concentration for barbiturates, benzodiazepines, methadone, tricyclic antidepressants, 3,4-methylenedioxymethamphetamine, and oxycodone. The cutoff concentrations for these drugs are the same as the cutoff concentrations in k050186, the predicate device.

2. Comparison studies:

a. Method comparison with predicate device:

Performance Characteristics have been addressed in k050186 (Ameditech Immutest Drug Screen Cup)

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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):
A consumer study was conducted to determine the device's performance when used by untrained users following the instructions in the labeling. A questionnaire was used to determine if the untrained users understood the purpose of the test, the conditions for its use, the test's limitations, and the meaning of the results. 250 untrained users read a total of 5,760 assays during the study and 5,731 of 5,760 assays (99.5%) was interpreted correctly. 480 unique tests with sample solutions containing benzoylecgonine, morphine, secobarbital, oxazepam, THC, nortriptyline, phencyclidine, methadone, MDMA, amphetamine, and oxycodone were performed by consumers using drug-free urine spiked with various concentrations and combinations of drugs. Each drug was tested at 0%, 50%, 75%, 125%, 150%, and 200% of the target concentration. Drug concentrations except for TCA were confirmed by GC/MS at a SAMHSA laboratory; recovery ranged between 85.3 to 138.0% of the target concentration. TCA was confirmed by HPLC at an independent laboratory; recovery ranged between 84.3 to 121.2% of the target concentration. Approximately 6.9% of the consumers had used a home drug kit. 10.7% had not finished high school; 42.6% were high school graduates; 34.3% had completed one year of college; and 12/4% of the lay users were college graduates. The ratio of female to male was approximately 2:1. The ages ranged from 18 to over 45 years. 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	480	475	5
COC	300	480	478	2
AMP	1000	480	477	3
MET	1000	480	477	3
MDMA	500	480	479	1
OPI	2000	480	478	2
PCP	25	480	479	1
BAR	300	480	477	3
BZO	300	480	477	3
TCA	1000	480	479	1
MTD	300	480	478	2
OXY	100	480	477	3

*Twenty-six of twenty-nine incorrectly interpreted results that were at target concentrations of ±25% (either 75% or 125% of the cutoff). Three of twenty-nine incorrectly interpreted results (amphetamines, opiates and methadone) that were at -50% of the cutoff.

250 consumers were recruited. A consumer questionnaire was administered to evaluate their experience with home drug tests and labeling effectiveness. The following questions were asked: "Have you purchased a home drug test?" Have you previously used a home drug test?" "Was the test easy to run and were the results easy to read?" "Does it matter how light or dark the colored line is?" "If a sample tests positive for a prescription drug like TCA, does that mean for certain that an individual is abusing that prescription drug?" 2.8 % of the participants had purchased a home drug test. 6.8% previously used a home drug test. 95.2% of the participants said the test was easy to run and the results were easy to read. 90.6% correctly stated that it does not matter how dark or light a colored line is. 94.7% said if a sample tests positive for a prescription drug it does not mean for certain that an individual is abusing that prescription drug.

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.