

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k153192

B. Purpose for Submission:

New device

C. Measurands:

Amphetamine, barbiturates, benzodiazepines, buprenorphine, cocaine, marijuana, methadone, methamphetamine, methylenedioxymethamphetamine (MDMA), morphine, opiates, oxycodone, phencyclidine, propoxyphene, and tricyclic antidepressants.

D. Type of Test:

Qualitative lateral flow chromatographic immunoassay

E. Applicant:

Chemtron Biotech, Inc.

F. Proprietary and Established Names:

Chemtrue® Multi-Panel Drug Screen Cup Tests
Chemtrue® Multi-Panel Drug Screen Cup with OPI2000 Tests
Chemtrue® Multi-Panel Drug Screen Dip Card Tests
Chemtrue® Multi-Panel Drug Screen Dip Card with OPI2000 Tests

G. Regulatory Information:

Assay	Product Code	Classification	Regulation Section	Panel
Amphetamine	DKZ	Class II	21CFR 862.3100, Amphetamine Test System	Toxicology (91)
Barbiturates	DIS	Class II	21 CFR 862.3150, Barbiturates Test System	Toxicology (91)

Assay	Product Code	Classification	Regulation Section	Panel
Benzodiazepines	JXM	Class II	21 CFR 862.3170, Benzodiazepines Test System	Toxicology (91)
Buprenorphine	DJG	Class II	21 CFR 862.3650, Opiate test system	Toxicology (91)
Cocaine	DIO	Class II	21 CFR 862.3250, Cocaine and metabolites Test System	Toxicology (91)
Marijuana	LDJ	Class II	21 CFR 862.3870, Cannabinoids Test System	Toxicology (91)
Methadone	DJR	Class II	21 CFR 862.3620, Methadone Test System	Toxicology (91)
Methamphetamine	LAF	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
MDMA	DJC	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
Morphine	DNK	Class II	21 CFR 862.3640, Morphine Test System	Toxicology (91)
Opiates	DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)
Oxycodone	DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)
Phencyclidine	LCM	Class II	Unclassified, Enzyme immunoassay Phencyclidine	Toxicology (91)
Propoxyphene	JXN	Class II	21 CFR 862.3700 Propoxyphene test system	Toxicology (91)
Tricyclic Antidepressants	LFG	Class II	21 CFR 862.3910, Tricyclic antidepressant drugs test system	Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to Indications for Use below

2. Indication(s) for use:

Chemtrue® Multi-Panel Drug Screen Dip Card Tests

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Morphine, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene and Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoyllecgonine	150
Cocaine	COC	Benzoyllecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- Δ^9 -THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should

be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Multi-Panel Drug Screen Dip Card with OPI2000 Tests

The Chemtrue® Multi-Panel Drug Screen Dip Card with OP2000 Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Opiates, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene and Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoyllecgonine	150
Cocaine	COC	Benzoyllecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- Δ^9 -THC-9-COOH	50
Methadone	MTD	Methadone	300
Opiates	OPI	Morphine	2000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method

must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Multi-Panel Drug Screen Cup Tests

The Chemtrue® Multi-Panel Drug Screen Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Morphine, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene and Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoyllecgonine	150
Cocaine	COC	Benzoyllecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- Δ^9 -THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. The

tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Multi-Panel Drug Screen Cup with OPI2000 Tests

The Chemtrue® Multi-Panel Drug Screen Cup with OPI2000 Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Opiates, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene and Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoyllecgonine	150
Cocaine	COC	Benzoyllecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	300
Methamphetamine	MAMP	d-Methamphetamine	500
Methamphetamine	MAMP	d-Methamphetamine	1000
Marijuana	THC	11-nor- Δ^9 -THC-9-COOH	50
Methadone	MTD	Methadone	300
Opiates	OPI	Morphine	2000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The multi test panels can consist of up to fourteen (14) of the above listed analytes in any combination. Only one cutoff concentration will be included per analyte per device. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone, Propoxyphene and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

3. Special conditions for use statement(s):

For in vitro diagnostic use only.

4. Special instrument requirements:

Not applicable, as the devices are visually-read single-use devices.

I. Device Description:

The devices consist of:

- A test cup or a test card with 1 to 14 drug test strips
- Transport vial, transport bag, and mailing box (for confirmation testing)
- Package insert (instructions for use)

J. Substantial Equivalence Information:

1. Predicate device name(s):

Innovacon Spectrum II Test Card, Innovacon Spectrum II Test Card with Integrated Cups
Phamatech QuickScreen Cocaine 150 Test

2. Predicate 510(k) number(s):

k061718
k103295

3. Comparison with predicate:

Similarities - k103295		
Item	Candidate Devices Chemtrue® Drug Screen Dip Card Tests, Chemtrue® Drug Screen Dip Card with OPI2000 Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests with OPI2000 Tests	Predicate - k103295 Phamatech QuickScreen Cocaine 150 Test
Indications for Use	Same	Qualitative detection of drugs of abuse in urine
Analytes	Same	COC at 150 ng/mL
Methodology	Same	Qualitative lateral flow chromatographic immunoassay

Similarities – k061718		
Item	Candidate Devices Chemtrue® Drug Screen Dip Card Tests, Chemtrue® Drug Screen Dip Card with OPI2000 Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests with OPI2000 Tests	Predicate – k061718 Innovacon Spectrum II Test Card, Innovacon Spectrum II Test Card with Integrated Cups
Indications for Use	Same	Qualitative detection of drugs of abuse in urine
Analytes	Same	AMP at 300, 500, and 1000 ng/mL BAR at 200 and 300 ng/mL BZO at 200 and 300 ng/mL BUP at 10 ng/mL COC at 300 ng/mL MDMA at 500 ng/mL MET at 300, 500, and 1000 ng/mL THC at 50 ng/mL MTD at 300 ng/mL MOR at 300 ng/mL OPI at 2000 ng/mL OXY at 100 ng/mL PCP at 25 ng/mL PPX at 300 ng/mL TCA at 1000 ng/mL

Similarities – k061718		
Item	Candidate Devices Chemtrue® Drug Screen Dip Card Tests, Chemtrue® Drug Screen Dip Card with OPI2000 Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests with OPI2000 Tests	Predicate – k061718 Innovacon Spectrum II Test Card, Innovacon Spectrum II Test Card with Integrated Cups
Methodology	Same	Qualitative lateral flow chromatographic immunoassay

Differences – k103295		
Item	Candidate Devices Chemtrue® Drug Screen Dip Card Tests, Chemtrue® Drug Screen Dip Card with OPI2000 Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests with OPI2000 Tests	Predicate - k103295 Phamatech QuickScreen Cocaine 150 Test
Intended Use	For prescription and Over-The-Counter (OTC)	For prescription and point-of-care use only

Differences - k061718		
Item	Candidate Devices Chemtrue® Drug Screen Dip Card Tests, Chemtrue® Drug Screen Dip Card with OPI2000 Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests, Chemtrue® Multi-Panel Drug Screen Cup Tests with OPI2000 Tests	Predicate – k061718 Innovacon Spectrum II Test Card, Innovacon Spectrum II Test Card with Integrated Cups
Intended Use	For prescription and Over-The-Counter (OTC)	For prescription use only

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

Guidance for Industry and Food and Drug Administration Staff: Design Considerations for Devices Intended for Home Use, November 24, 2014

L. Test Principle:

The devices are rapid lateral flow immunoassays in which drug-protein conjugates in the test device compete with drugs or drug metabolites that may be present in urine. On each test strip, a drug-protein conjugate is added to the test band of the membrane – known as the test region (T), and the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. If target drugs are present in the urine specimen below its cut-off concentration, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible precipitant in the test band indicates a negative result. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result. A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Dipcard format

Drug	Concentration Tested	Operator 1/ Lot 1	Operator 2/ Lot 2	Operator 3/ Lot 3	Total of the three operators
		Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
AMP 300	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	5/5	4/6	5/5	14/16
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
BAR 200	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	5/5	5/5	6/4	16/14
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30

BZO 200	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	3/6	5/4	6/6	14/16
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
COC 150	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	3/4	4/7	7/5	14/16
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
MAMP 300	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	6/4	4/5	6/5	16/14
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
AMP 500	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	4/3	4/6	8/5	16/14
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
MAMP 500	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	4/5	3/4	9/5	16/14
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
PPX 300	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	4/5	4/5	7/5	15/15
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30

Cup format

AMP 300	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	1/4	7/5	9/4	17/13
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30

BAR 200	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	5/4	5/7	5/4	15/15
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
BZO 200	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	6/7	3/3	6/5	15/15
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30

COC 150	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	5/2	4/5	4/10	13/17
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
MAMP 300	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	1/4	8/5	6/6	15/15
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
AMP 500	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	3/5	6/2	7/7	16/14
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
MAMP 500	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	4/7	5/4	4/6	13/17
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30
PPX 300	Negative	10/0	10/0	10/0	30/0
	50% of cutoff	10/0	10/0	10/0	30/0
	75% of cutoff	10/0	10/0	10/0	30/0
	cutoff	5/4	2/5	8/6	15/15
	125% of cutoff	0/10	0/10	0/10	0/30
	150% of cutoff	0/10	0/10	0/10	0/30

Precision performance for the remaining fourteen drugs (AMP 1000, BAR 300, BZO

300, BUP 10, COC 300, MDMA 500, MAMP 1000, THC 50, MTD 300, MOR 300, OP 2000, OXY 100, PCP 25, and TCA 1000) was established in k142396.

b. Linearity/assay reportable range:

Not applicable. These devices are intended for qualitative use only.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Stability: Device stability has been evaluated through accelerated and real-time studies. The real-time studies are ongoing. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims that the devices are stable for two years (24 months) when stored at 2–30° C.

Quality control: Control materials are not supplied with the devices; however the labeling provides information on how to obtain quality control materials.

d. Detection limit:

See Precision/Reproducibility section in M.1.a above.

e. Analytical specificity:

For each drug and cutoff, specificity was evaluated by spiking various concentrations of similarly structured drug compounds into drug-free urine. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross-reactivity of those compounds is listed below:

Target Drug and Cutoff	Compound	Concentration Equivalent to the Cutoff (ng/mL)	Cross-Reactivity (%)
AMP 300	D,L-AMP	600	50.0
	L-AMP	>30000	<1
	D-Methamphetamine	>30000	<1
	L-Methamphetamine	>30000	<1
	D,L-Methamphetamine	>30000	<1
	+/- MDMA	>30000	<1
	Ephedrine	>30000	<1
	D,L-MDA	300	100.0
	D,L-MDEA	>30000	<1
	Pseudoephedrine	>30000	<1
	Phentermine	4000	7.5
	Phenylephrine	>30000	<1
	Tyramine	>30000	<1

AMP 500	D,L-AMP	700	62.5
	L-AMP	50000	<1
	D-Methamphetamine	50000	<1
	L-Methamphetamine	50000	<1
	D,L-Methamphetamine	50000	<1
	D,L MDMA	50000	<1
	D,L-MDA	700	100.0
	D,L-MDEA	50000	<1
	Ephedrine	50000	<1
	Pseudoephedrine	50000	<1
	Phentermine	4000	10.0
	Phenylephrine	50000	<1
	Tyramine	50000	<1
AMP 1000	D,L-AMP	1500	62.5
	L-AMP	100000	<1
	0-Methamphetamine	100000	<1
	L-Methamphetamine	100000	<1
	D,L-Methamphetamine	100000	<1
	D,LMDMA	100000	<1
	D,L-MDA	900	100.0
	D,L-MDEA	100000	<1
	Ephedrine	100000	<1
	Pseudoephedrine	100000	<1
	Phentermine	6000	14.3
	Phenylephrine	100000	<1
	Tyramine	100000	<1
BAR 200	Alphenal	300	66.7
	Amobarbital	400	50.0
	Aprobarbital	400	50.0
	Barbital	6000	3.3
	Butabarbital	300	66.7
	Butalbital	1000	20.0
	Cyclopentobarbital	240	83.3
	Phenobarbital	1400	14.3
BAR 300	Alphenal	500	60.0
	Amobarbital	600	50.0
	Aprobarbital	500	60.0
	Barbital	10000	3.0
	Butabarbital	500	60.0
	Butalbital	2000	15.0
	Cyclopentobarbital	500	60.0
	Phenobarbital	2000	15.0

BENZ 200	Alprazolam	200	100.0
	Alphahydroxyalprazolam	200	100.0
	Bromazepam	200	100.0
	Chlordiazepoxide	400	50.0
	Clobazam	600	33.3
	Clonazepam	20000	1.0
	Clorazepate	1800	11.1
	Desalkylflurazepam	800	25.0
	Diazepam	300	66.7
	Estazolam	200	100.0
	Flunitrazepam	4600	4.3
	Flurazepam	200	100.0
	Lorazepam	600	33.3
	Lormetazepam	2800	7.1
	Midazolam	8000	2.5
	Nitrazepam	800	25.0
	Nordiazepam	5200	3.8
	Temazepam	400	50.0
	Triazolam	1200	16.7
	BENZ 300	Alprazolam	300
Alphahydroxy alprazolam		300	100.0
Bromazepam		300	100.0
Chlordiazepoxide		600	50.0
Clobazam		800	37.5
Clonazepam		30000	1.0
Clorazepate		2000	15.0
Desalkylflurazepam		1000	30.0
Diazepam		500	60.0
Estazolam		300	100.0
Flunitrazepam		4800	6.3
Flurazepam		300	100.0
Lorazepam		800	37.5
Lormetazepam		3600	8.3
Midazolam		10000	3.0
Nitrazepam		1000	30.0
Nordiazepam		8000	3.8
Temazepam		600	50.0
Triazolam		1800	16.7
BUP 10		Buprenorphine	10
	Norbuprenorphine	10	100
	Morphine	1000	<1
	Codeine	1000	<1

COC 150	Cocaethylene	150	100.0
	Cocaine	180	83.3
	Ecgonine	15000	<1
	Ecgonine HCl	15000	<1
COC 300	Cocaethylene	300	100.0
	Cocaine	300	100.0
	Ecgonine	30000	<1
	Ecgonine HCl	30000	<1
MDMA 500	MDA	15000	3.3
	MDEA	1000	50
	d-Methamphetamine	50000	<1
	d-Amphetamine	50000	<1
MAMP 300	L-Methamphetamine	2000	15.0
	D,L-Methamphetamine	1600	18.8
	D-Amphetamine	30000	<1
	L-Amphetamine	30000	<1
	D,L-Amphetamine	30000	<1
	MDA	30000	<1
	MDEA	20000	1.5
	MDMA	2000	15.0
	Ephedrine	30000	<1
	Pseudoephedrine	30000	<1
	Phenylephrine	30000	<1
	Phentermine	30000	<1
MAMP 500	L-Methamphetamine	2500	20.0
	D,L-Methamphetamine	2000	25.0
	D-Amphetamine	50000	<1
	L-Amphetamine	50000	<1
	D,L-Amphetamine	50000	<1
	MDA	50000	<1
	MDEA	25000	2.0
	MDMA	2600	19.2
	Ephedrine	50000	<1
	Pseudoephedrine	50000	<1
	Phenylephrine	50000	<1
	Phentermine	50000	<1

MAMP 1000	L-Methamphetamine	5000	20.0
	D,L-Methamphetamine	5000	20.0
	D-Amphetamine	100000	<1
	L-Amphetamine	100000	<1
	D,L-Amphetamine	100000	<1
	MDA	100000	<1
	MDEA	30000	3.3
	MDMA	3000	33.3
	Ephedrine	100000	<1
	Pseudoephedrine	100000	<1
	Phenylephrine	100000	<1
	Phentermine	100000	<1
PPX 300	d-Propoxyphene	300	100
	d-Norpropoxyphene	300	100

The sponsor also evaluated the potential for positive and negative interference from non-structurally related compounds, endogenous compounds, pH, and specific gravity. The structurally unrelated compounds and endogenous substances study was performed by spiking structurally unrelated compounds and endogenous substances at a concentration of 100 µg/mL into urine samples containing drug at ± 25% of the respective drug cutoff concentrations.

The following substances showed no positive or negative interference in this study:

Albumin	Creatinine	Riboflavin
Bilirubin	Glucose	Sodium Chloride
Cholesterol	Hemoglobin	Uric Acid
Acetaminophen	Diphenylhydantoin	Octopamine
Acetone	Dopamine	Oxalic Acid
Acetylsalicylic Acid	Erythromycin	Papaverine
Amoxicillin	Estradiol	Penicillin-G
Ampicillin	Estrone	Perphenazine
Apomorphine	Ethanol	Phenelzine
Ascorbic Acid	Fenofibrate	Phenylethylamine
Aspirin	Fentanyl	Prednisone
Aspartame	Fotemustine	Promazine
Atropine	Furosemide	Promethazine
Baclofen	Gemfibrozil	Propoxyphene
Benzocaine	Guaiacolglyceryl ether	Propranolol
Benzoic Acid	Gentisic Acid	Pyridoxine
Carisoprodol	Hydralazine	Pyrilamine

Chloramphenicol	Hydrocortisone	Pyrogallol
Chlordiazepoxide	Hydroxytyramine	Quinidine
Chlorpheniramine	Isoproterenol	Quinine
Chlorpromazine	Ketamine	Quinolinic Acid
Clofibrate	Meprobamate	Ranitidine
Clonidine	Methapyrilene	Salicylic Acid
Cortisone	Methylphenidate	Sulfamethazine
Cotinine	Nalidixic Acid	Sulindac
Creatine Hydrate	Naloxone	Tetracycline
Cyclobenzaprine	Naltrexone	Tetrahydrozoline
Cyclodextrin-r	Naproxen	Thiamine
Cyproheptadine	Niacinamide	Thioridazine
Deoxycorticosterone	Nicotinic Acid	Tramadol
Dextromethorphan	Nifedipine	Trifluoperazine
Diclofenac	Norethindrone	Tryptamine
Diflunisal	Norpropoxyphene	Tyramine
Dimethyl-aminoantipyrine	Noscapine	Zomepirac sodium salt
Diphenhydramine		

To evaluate the effect of pH value on the test results, urine controls at $\pm 25\%$ of the cutoff value were used. Each control level was adjusted by either 1N NaOH solution or 1N HCl to pH levels of 2.0, 3.0, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 and 9.0. Each test sample was tested in duplicate.

To evaluate the effect of specific gravity, urine controls at $\pm 25\%$ of the cutoff values were spiked with deionized water or sugar to obtain specific gravities of 1.001, 1.010, 1.015, 1.020, 1.025, and 1.030. Each test sample was tested in duplicate.

The results demonstrated that pH and specific gravity do not affect the results from the device.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, M.1.a., above.

2. Comparison studies:

The sponsor performed a method comparison study comparing performance of the test strips of the cup devices to the GC/MS reference method. Results are summarized below:

a. Method comparison with predicate device:

Dipcard Format

AMP 300

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	14	27
NEG	31	11	0	0

Agreement among positives = 41/41 = 100%

Agreement among negatives = 42/42 = 100%

AMP 500

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	12	31
NEG	31	14	0	0

Agreement among positives = 43/43 = 100%

Agreement among negatives = 45/45 = 100%

BAR 200

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	26	14
NEG	34	9	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 43/44 = 98%

*Sample contained pentobarbital at 185 ng/mL

BENZ 200

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	26	14
NEG	31	16	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 47/47 = 100%

COC 150

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	15	28
NEG	31	10	0	0

Agreement among positives = 43/43 = 100%

Agreement among negatives = 41/41 = 100%

MAMP 300

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	14	34
NEG	31	9	0	0

Agreement among positives = 48/48 = 100%

Agreement among negatives = 40/41 = 98%

* Sample contained methamphetamine at 296 ng/mL

MAMP 500

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	11	30
NEG	31	11	0	0

Agreement among positives = 41/41 = 100%

Agreement among negatives = 42/43 = 98%

*Sample contained methamphetamine at 494 ng/mL

PPX 300

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	12	33
NEG	31	10	0	0

Agreement among positives = 45/45 = 100%

Agreement among negatives = 41/41 = 100%

Cup Format

AMP 300

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	14	27
NEG	31	10	0	0

Agreement among positives = 41/41 = 100%

Agreement among negatives = 41/42 = 98%

*Sample contained amphetamine at 229 ng/mL

AMP 500

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	11	31
NEG	31	13	1†	0

Agreement among positives = 42/43 = 98%

Agreement among negatives = 44/45 = 98%

*Sample contained amphetamine at 441 ng/mL

†Sample contained amphetamine at 510 ng/mL

BAR 200

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	26	14
NEG	34	9	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 43/44 = 98%

*Sample contained pentobarbital at 185 ng/mL

BENZ 200

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	26	14
NEG	31	16	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 47/47 = 100%

COC 150

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	15	28
NEG	31	10	0	0

Agreement among positives = 43/43 = 100%

Agreement among negatives = 41/41 = 100%

MAMP 300

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	14	34
NEG	31	9	0	0

Agreement among positives = 48/48 = 100%

Agreement among negatives = 40/41 = 98%

*Sample contained methamphetamine at 296 ng/mL

MAMP 500

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	11	30
NEG	31	12	0	0

Agreement among positives = 41/41 = 100%

Agreement among negatives = 43/43 = 100%

PPX 300

Candidate Device Result	Concentration by reference method (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	12	33
NEG	31	10	0	0

Agreement among positives = 45/45 = 100%

Agreement among negatives = 41/41 = 100%

b. *Matrix comparison:*

Not applicable. These devices are for use with urine samples only.

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 performed for all analytes to evaluate the ability of untrained users to interpret the devices properly when given only the labeling (package insert) provided with the devices. One hundred and thirty (130) lay-users participated in this study from three (3) intended user sites with GC/MS confirmed urine samples in the following concentration ranges: negative, 50%, 75%, 125% and 150% of the cutoff. Samples were created by spiking drugs into drug-free urine pool. Each sample was aliquoted into an individual blind-labeled container. Each lay-user was provided with a package insert in English only and up to two (2) random blind labeled samples with the tests of each device format. The results are summarized below:

Chemtrue® Cup Test	Candidate Device Result	(-)			(+)		% Agreement with reference method
		<50% of the C/O	Negative (50% of the C/O)	Near cutoff Negative (50% of the cutoff to the cutoff)	Near cutoff positive (cutoff to 125% of the cutoff)	Positive (≥125% of the C/O)	
AMP1000	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
AMP500	+	0	0	0	26	21	100%
	-	60	23	39	0	0	100%
AMP300	+	0	0	0	23	48	100%
	-	51	21	25	0	0	100%
BAR300	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
BAR200	+	0	0	0	43	22	100%
	-	194	26	22	0	0	100%
BUP	+	0	0	0	39	23	100%
	-	189	35	21	0	0	100%
BZO300	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
BZO200	+	0	0	0	22	24	100%
	-	184	37	40	0	0	100%
COC300	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
COC150	+	0	0	0	37	41	100%
	-	182	25	22	0	0	100%
MDMA	+	0	0	1	37	39	100%
	-	189	21	20	0	0	99.50%

Chemtrue® Dipcard Test	Candidate Device Result	(-)			(+)		% Agreement with reference method
		<50% of the C/O	Negative (50% of the C/O)	Near cutoff Negative (50% of the cutoff to the cutoff)	Near cutoff positive (cutoff to 125% of the cutoff)	Positive (≥125% of the C/O)	
MET 1000	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
MET 500	+	0	0	0	26	22	100%
	-	55	41	25	0	0	100%
MET 300	+	0	0	0	23	42	100%
	-	56	22	25	0	0	100%
MTD	+	0	0	0	21	20	100%
	-	208	21	37	0	0	100%
MOR300	+	0	0	0	19	58	100%
	-	56	19	18	0	0	100%
OPI2000	+	0	0	0	20	20	100%
	-	58	20	20	0	0	100%
OXY	+	0	0	0	39	21	100%
	-	176	21	20	0	0	100%
PCP	+	0	0	0	21	20	100%
	-	192	39	35	0	0	100%
PPX	+	0	0	1	38	40	100%
	-	185	22	21	0	0	99.60%
TCA	+	0	0	1	20	36	100%
	-	177	21	22	0	0	99.60%
THC	+	0	0	0	21	37	100%
	-	190	39	20	0	0	100%

Chemtrue® Dipcard Test	Candidate Device Result	(-)			(+)		% Agreement with reference method
		<50% of the C/O	Negative (50% of the C/O)	Near cutoff Negative (50% of the cutoff to the cutoff)	Near cutoff positive (cutoff to 125% of the cutoff)	Positive (≥125% of the C/O)	
AMP1000	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
AMP500	+	0	0	0	28	21	100%
	-	54	39	41	0	0	100%
AMP300	+	0	0	1	24	46	100%
	-	53	21	23	0	0	99%
BAR300	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
BAR200	+	0	0	0	43	22	100%
	-	194	26	22	0	0	100%
BUP 10	+	0	0	0	35	26	100%
	-	202	35	23	0	0	100%
BZO300	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
BZO200	+	0	0	0	21	25	100%
	-	184	37	40	0	0	100%
COC300	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%
COC150	+	0	0	0	37	40	100%
	-	183	25	22	0	0	100%
MDMA	+	0	0	0	38	39	100%
	-	204	20	20	0	0	100%
MET1000	+	0	0	0	10	10	100%
	-	60	10	10	0	0	100%

Chemtrue® Dipcard Test	Candidate Device Result	(-)			(+)		% Agreement with reference method
		<50% of the C/O	Negative (50% of the C/O)	Near cutoff Negative (50% of the cutoff to the cutoff)	Near cutoff positive (cutoff to 125% of the cutoff)	Positive (≥125% of the C/O)	
MET500	+	0	0	0	22	36	100%
	-	55	44	26	0	0	100%
MET300	+	0	0	1	24	43	100%
	-	57	20	23	0	0	99%
MTD 300	+	0	0	0	20	20	100%
	-	222	21	38	0	0	100%
MOR 300	+	0	0	0	19	59	100%
	-	51	34	19	0	0	100%
OP2000	+	0	0	0	19	19	100%
	-	59	21	20	0	0	100%
OXY	+	0	0	0	39	21	100%
	-	191	20	20	0	0	100%
PCP	+	0	0	0	35	22	100%
	-	194	35	35	0	0	100%
PPX	+	0	0	0	38	40	100%
	-	185	22	22	0	0	100%
TCA	+	0	0	0	21	36	100%
	-	174	35	25	0	0	100%
THC	+	0	0	0	21	38	100%
	-	203	39	20	0	0	100%

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.