

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

A. 510(k) Number:

k111322

B. Purpose for Submission:

New device

C. Measurand:

Benzodiazepines, Barbiturates, Ecstasy, Methadone, Opiates and Oxycodone

D. Type of Test:

Qualitative immunoassay

E. Applicant:

Chemtron Biotech, Inc.

F. Proprietary and Established Names:

Chemtrue Single/Multi-Panel Drug Screen Cassette and Dip Card Tests

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JXM	II	862.3170 Benzodiazepine test system	91, Toxicology
DIS	II	862.3150 Barbiturate test system	91, Toxicology
DJC	II	862.6310 Methamphetamine test system	91, Toxicology
DJR	II	862.3620 Methadone test system	91, Toxicology
DJG	II	862.3650 Opiate test system	91, Toxicology

H. Intended Use:

1. Intended use(s):

See indication for use below

2. Indication(s) for use:

The Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of up to six of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and the calibrators used for these drugs are as follows:

Analyte	Abbreviation	Calibrator	Cutoff
Benzodiazepines	BZO	Oxazepam	300 ng/mL
Barbiturates	BAR	Secobarbital/ Pentobarbital	300 ng/mL
Ecstasy	MDMA/ XTC	d,l-Methylenedioxyethamphetamine	500 ng/mL
Methadone	MTD	Methadone	300 ng/mL
Opiates	OPI/MOR	Morphine	2000 ng/mL
Oxycodone	OXY	Oxycodone	100 ng/mL

The Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are intended for the qualitative detection of drugs of abuse for in vitro diagnostic and prescription use ONLY. They are not intended for point-of-care settings or over the counter use. These assays 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.

3. Special conditions for use statement(s):

In vitro diagnostic use, prescription use only
Not for point-of-care or over the counter use

4. Special instrument requirements:

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

I. Device Description:

The devices are for use in human urine. The Chemtrue Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are single-test test strips. The Chemtrue Single/Multi-Panel Drug Screen Cassette and Dip Card Tests contain test cassettes and package inserts (instructions for use).

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON, One Step Drug Screen Test Card For Single and Multi Drug Screen Test Cards

2. Predicate K number(s):

k061718

3. Comparison with predicate:

Item	Device	Predicate
Intended use	Qualitative detection of drugs-of-abuse in urine for prescription and In Vitro Diagnostic Use ONLY	Same
Test Principle	One-Step lateral flow competitive immunoassay	Same
Specimen	Urine	Same
Cutoff	Benzodiazepines 300 ng/mL Barbiturates 300 ng/mL Ecstasy (MDMA) 500 mg/dL Methadone 300 ng/ml Opiates (Morphine) 2000 ng/mL Oxycodone 100 ng/mL	Same
Read time	5 minutes	Same
Storage	2-30 °C (36-86 F)	Same
Time to read results	Do not read after 8 minutes	Results remain stable for up to 4 hours after test initiation

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

None were referenced

L. Test Principle:

Chemtron Biotech’s Chemtrue Single/Multi-Panel Drug Screen Cassette and Dip Card Tests employs lateral flow immunochromatographic technology.

Benzodiazepine, Barbiturates, Ecstasy, Methadone, Opiates and Oxycodone are detected in human urine by competitive binding between rabbit monoclonal

antibodies to one of its respective drug and drug-labeled conjugate (containing a chromagen). Binding of the drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control (goat monoclonal anti-rabbit IgG) which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Dip Card

Drug	Concentration Tested	Operator 1/ Lot One	Operator 2/ Lot Two	Operator 3/ Lot Three	Total
		Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
BZO	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	9/1	9/1	9/1	27/3
	Cutoff	6/4	4/6	6/4	16/14
	+25%	1/9	2/8	1/9	4/26
	+50%	0/10	0/10	0/10	0/30
BAR	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	9/1	9/1	9/1	27/3
	Cutoff	5/5	5/5	7/3	17/13
	+25%	2/8	2/8	1/9	5/25
	+50%	0/10	0/10	0/10	0/30
MDMA	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	10/0	9/1	10/0	29/1
	Cutoff	6/4	7/3	6/4	19/11
	+25%	1/9	0/10	1/9	2/28
	+50%	0/10	0/10	0/10	0/30
MTD	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	10/0	10/0	10/0	30/0
	Cutoff	7/3	4/6	2/8	13/17
	+25%	1/9	1/9	0/10	2/28
	+50%	0/10	0/10	0/10	0/30
OPI	Negative	10/0	10/0	10/0	30/0

	-50%	10/0	10/0	10/0	30/0
	-25%	10/0	10/0	10/0	30/0
	Cutoff	7/3	8/2	8/2	23/7
	+25%	2/8	0/10	1/9	3/27
	+50%	0/10	0/10	0/10	0/30
OXY	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	9/1	10/0	10/0	29/1
	Cutoff	4/6	7/3	5/5	16/14
	+25%	0/10	2/8	1/9	27/3
	+50%	0/10	0/10	0/10	0/30

Cassette

Drug	Concentration Tested	Operator 1/ Lot One	Operator 2/ Lot Two	Operator 3/ Lot Three	Total
		Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
BZO	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	9/1	9/1	9/1	27/3
	Cutoff	6/4	6/4	5/5	17/13
	+25%	2/8	2/8	1/9	5/25
	+50%	0/10	0/10	0/10	0/30
BAR	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	9/1	9/1	10/0	28/2
	Cutoff	5/5	5/5	6/4	16/14
	+25%	3/7	2/8	2/8	7/23
	+50%	0/10	0/10	0/10	0/30
MDMA	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	9/1	9/1	10/0	28/2
	Cutoff	5/5	5/5	6/4	16/14
	+25%	2/8	0/10	1/9	3/27
	+50%	0/10	0/10	0/10	0/30
MTD	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	10/0	8/2	10/0	28/2
	Cutoff	4/6	4/6	6/4	14/16
	+25%	0/10	1/9	0/10	1/29
	+50%	0/10	0/10	0/10	0/30
OPI	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	10/0	10/0	10/0	30/0
	Cutoff	3/7	7/3	6/4	16/14
	+25%	2/8	2/8	1/9	5/25

	+50%	0/10	0/10	0/10	0/30
OXY	Negative	10/0	10/0	10/0	30/0
	-50%	10/0	10/0	10/0	30/0
	-25%	8/2	10/0	10/0	28/2
	Cutoff	5/5	3/7	4/6	12/18
	+25%	0/10	1/9	0/10	1/29
	+50%	0/10	0/10	0/10	0/30

b. *Linearity/assay reportable range:*

Not applicable, the device is intended for qualitative use

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

This device has internal process controls. A colored line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are informed that the test is invalid if a line fails to appear in the control region.

Control materials are not supplied with this device; however it is good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow all applicable guidelines for testing QC materials.

Stability:

Accelerated studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:

When stored at 2–30 °C product is stable until expiration date which is 24 months.

Real time studies have been conducted and are on-going.

Read time stability was performed for Chemtrue Single/Multi-Panel Drug Screen Dip Card and Cassette. A drug-free urine was spiked with the appropriate drug at 50% cutoff, 150% cutoff, as well as a negative urine was used to perform the study. All samples were analyzed fifteen times at each concentration with three lots of test strips at 1-5 minute intervals from 1-20 minutes. Data supports the recommended read time of 5 minutes for each device.

d. *Detection limit:*

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

e. Analytical specificity:

Cross-reactivity was established by spiking structurally related compounds into drug-free urine and diluting each to obtain various concentrations. 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. Testing was performed on both devices (dip card and cassette). Both devices produced similar results. The percent cross-reactivity of those compounds are presented below:

Structurally related:

Benzodiazepines

Substances	Concentration (ng/mL)	% Cross-reactivity
Oxazepam	300	100
Alprazolam	3000	100
Alpha-Hydroxyalprazolam	100	300
Bromazepam	500	60
Chlordiazepoxide	2,500	12
Clobazam	200	150
Clonazepam	10,000	3
Clorazepate	350	85.7
Desalkylflurazepam	65	462
Diazepam	200	150
Estazolam	500	60
Flunitrazepam	375	80
Flurazepam	90	333
Lorazepam	600	50
Lormetazepam	7,500	4
Midazolam	900	33.3
Nitrazepam	200	150
Nordiazepam	150	200
Sertraline		
Temazepam	350	85.7
Triazolam	1,000	30

Barbiturates

Substances	Concentration (ng/mL)	% Cross-reactivity
Secobarbital	300	100
Pentobarbital	300	100
Alphenal	500	60
Amobarbital	400	75
Aprobarbital	350	85.7
Barbital	5,000	6
Butobarbital Butisol	250	120

Butalbital	3,000	10
Cyclopentobarbital	750	40
Phenobarbital	250	120

Ecstasy (MDMA)

Substances	Concentration (ng/mL)	% Cross-reactivity
D,1 (3,4)-Methylenedioxyamphetamine (MDMA)	500	100
3,4-Methylenedioxyamphetamine (MDA)	15,000	3.3
3,4-Methylenedioxyethylamphetamine (MDEA)	1,000	50
d-Methamphetamine	100,000	0.5

Methadone

Substances	Concentration (ng/mL)	% Cross-reactivity
Methadone	300	100
Doxylamine	100,000	0.3
EDDP	100,000	0.3
Pheniramine	100,000	0.3

Opiates

Substances	Concentration (ng/mL)	% Cross-reactivity
Morphine	2000	100
Codeine	2000	100
6-Acetylmorphine	1500	133.3
Diacetyl morphine (Heroin)	2000	100
Ethylmorphine	1500	133.3
Hydrocodone	50,000	4
Hydromorphone	50,000	4
Norcodeine	100,000	2
Normorphine	100,000	2
Oxycodone	100,000	2
Oxymorphone	100,000	2
Paracetamol	100,000	2
Thebaine	100,000	2

Oxycodone

Substances	Concentration (ng/mL)	% Cross-reactivity
Oxycodone	100	100
Codeine	100,000	0.1
Hydrocodone	100,000	0.1
Oxymorphone	100,000	0.1

Structurally un-related:

This 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 substances at 100 µg/mL concentration were also tested at +/- 50% respective drug cutoff concentrations, if a false result was observed at +/- 25% cutoff levels. Testing was performed on both devices (dip card and cassette). The following compounds showed no interference when tested at the +/-50% drug concentration:

Acetaminophen	5,5-Diphenylhydantoin	Oxalic Acid
Acetylsalicylic Acid	Dopamine	Papaverine
Albumin	(-)-ephedrine	Perphenazine
Amoxicillin	l-Erythromycin	Phenelzine
R(-)-Apomorphine	Estradiol	L-Phenylephrine
L-Ascorbic Acid	Estrone	Phenylethylamine
Atropine	Ethanol	Phenylpropanolamine
Baclofen	Fenofibrate	Prednisone
Benzocaine	Fentanyl	Promazine
Benzoic Acid	Fotemustine	Promethazine
Bilirubin	Furosemide	D-Propoxyphene
Buprenorphine	Gemfibrozil	d,l Propranolol
Cannabidiol	Gentisic acid	d-Pseudoephedrine
Carisoprodol	Glucose	Pyridoxal-5-phosphate
Cholesterol	Guaiacol glyceryl ether	Pyridoxine
Chloral hydrate	Hemoglobin	Pyrilamine
Chloramphenicol	Hydralazine	Pyrogallol
Chlordiazepoxide	Hydrocortisone	Quinidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Quinine
Chlorpromazine	(+/-)-Isoproterenol	Quinolinic Acid
Chlorprothixene	Ketamine	Riboflavin
Clofibrate	Meprobamate	Salicylic Acid
Clonidine	Methapyrilene	Sodium Chloride
Cortisone	Methylphenidate	Sulfamethazine
(-)-Cotinine	Nalidixic Acid	Sulindac
Creatine Hydrate	Naloxone	Tetracycline
Creatinine	Naltrexone	Tetrahydrozoline
Cyclobenzaprine	(+)-Naproxen	Thiamine
Cyclodextrin-r	Niacinamide	Thioridazine
Cyproheptadine	Nicotinic Acid	Tramadol
Deoxycorticosterone	Nifedipine	Trifluoperazine
Dextromethorphan	19-Norethindrone	Tryptamine
Diclofenac	Norpropoxyphene	Tyramine

Diflunisal	Nortriptyline	Uric Acid
4-Dimethyl-aminoantipyrine	Noscapine	Zomepirac sodium salt
Diphenhydramine	Octopamine	

Evaluation of SG and pH on test results:

To evaluate the effect of pH value on the test results, urine controls at 50%, 75%, 125% and 150% of the cutoff value were used. Each control level was adjusted by either 1N NaOH solution or 1N HCl to the pH levels at 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 and 8.5. Each test sample was tested in duplicate.

To evaluate the effect of specific gravity, urine controls at +/-25% and +/-50% of the cut-off values were spiked with DI water or sugar to obtain specific gravities of 1.002, 1.010, 1.015, 1.020, 1.025, and 1.030. Each test sample was tested in duplicate.

The testing results demonstrate that varying pH's and specific gravities do not affect urine testing results around each analyte cut-off.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, M1.a, above.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study was conducted to evaluate the performance of the device for detection of benzodiazepine, barbiturate, MDMA, opiates, methadone and oxycodone, with 2 operators (1 operator/device). In the method comparison study, 203 unaltered clinical samples (85 negative and 118 positive) benzodiazepine, 190 unaltered clinical samples (85 negative and 105 positive) barbiturate, 100 unaltered clinical samples (60 negative and 40 positive) MDMA, 106 unaltered clinical samples (65 negative and 41 positive) opiates, 104 unaltered clinical samples (60 negative and 44 positive) methadone, 106 unaltered clinical samples (59 negative and 47 positive) oxycodone were tested with the proposed devices and compared against the results obtained with GC/MS. The results of the studies are presented below:

Benzodiazepine

		Negative	Low Negative by GC/MS (less than - 50%)	Near Cutoff Negative by GC/MS (Between - 50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Dip Card	Positive	0	0	1	35	82	99.2%
	Negative	43	9	32	1	0	98.8%
Cassette	Positive	0	0	1	34	82	98.3%
	Negative	43	9	32	2	0	98.8%

Barbiturates

		Negative	Low Negative by GC/MS (less than - 50%)	Near Cutoff Negative by GC/MS (Between - 50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Dip Card	Positive	0	0	1	42	62	99.1%
	Negative	43	8	33	1	0	98.8%
Cassette	Positive	0	0	1	41	62	98.1%
	Negative	43	8	33	2	0	98.8%

MDMA

		Negative	Low Negative by GC/MS (less than - 50%)	Near Cutoff Negative by GC/MS (Between - 50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Dip Card	Positive	0	0	1	12	28	97.6%
	Negative	43	5	11	1	0	98.3%
Cassette	Positive	0	0	1	12	28	97.6%
	Negative	43	5	11	1	0	98.3%

Opiates

		Negative	Low Negative by GC/MS (less than - 50%)	Near Cutoff Negative by GC/MS (Between - 50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Dip Card	Positive	0	0	0	19	22	100%
	Negative	43	10	12	0	0	100%
Cassette	Positive	0	0	0	19	22	100%

	Negative	43	10	12	0	0	100%
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Methadone

		Negative	Low Negative by GC/MS (less than - 50%)	Near Cutoff Negative by GC/MS (Between - 50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Dip Card	Positive	0	0	1	15	28	97.7%
	Negative	43	5	11	1	0	98.3%
Cassette	Positive	0	0	1	16	28	100%
	Negative	43	5	11	0	0	98.3%

Oxycodone

		Negative	Low Negative by GC/MS (less than - 50%)	Near Cutoff Negative by GC/MS (Between - 50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Dip Card	Positive	0	0	1	11	36	100%
	Negative	43	6	9	0	0	98.3%
Cassette	Positive	0	0	1	11	36	100%
	Negative	43	6	9	0	0	98.3%

Discordant Tables:

Dip Card

Cutoff value (ng/mL)	Assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug/Metabolite	GC/MS value (ng/ml)
Benzodiazepine 300	positive	Oxazepam	298
Benzodiazepine 300	negative	Alprazolam	322
Barbiturate 300	positive	Pentobarbital	290
Barbiturate 300	negative	Pentobarbital	302
MDMA 500	positive	MDMA	498
MDMA 500	negative	MDMA	526
Methadone 300	positive	Methadone	298
Methadone 300	negative	Methadone	334
Oxycodone 100	positive	Oxycodone	94

Cassette

Cutoff value (ng/mL)	Assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)
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		Drug/Metabolite	GC/MS value (ng/ml)
Benzodiazepine 300	positive	Oxazepam	298
Benzodiazepine 300	negative	Oxazepam	303
Benzodiazepine 300	negative	Alprazolam	322
Barbiturate 300	positive	Pentobarbital	290
Barbiturate 300	negative	Pentobarbital	309
Barbiturate 300	negative	Butalbital	328
MDMA 500	positive	MDMA	498
MDMA 500	negative	MDMA	526
Methadone 300	positive	Methadone	298
Oxycodone 100	positive	Oxycodone	94

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix, urine

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):

Not applicable

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.