

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

A. 510(k) Number:

k041712

B. Purpose of the Submission:

New 510(k)

C. Analyte:

Oxycodone
Benzodiazepines
Barbiturates
Methadone
Propoxyphene
Tricyclic Antidepressants

D. Type of Test:

Qualitative immunoassay

E. Applicant:

American Bio Medica

F. Proprietary and Established Names:

'RapidTec 4'

G. Regulatory Information:

1. Regulation section:
862.3150, Enzyme Immunoassay, Barbiturate
862.3170, Enzyme Immunoassay, Benzodiazepine
862.3620, Enzyme Immunoassay, Methadone
862.3650, Enzyme Immunoassay, Opiates
862.3700, Enzyme Immunoassay, Propoxyphene
862.3910, Thin Layer Chromatography, Tricyclic Antidepressant Drugs
2. Classification:
All Class II
3. Product Code:
DIS; JXM; DJR; DJG; JXN; LFG
4. Panel:
Toxicology (91)

H. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
'RapidTec 4' is a one-step, lateral flow immunoassay for the simultaneous detection of four abused substances in urine. 'RapidTec 4' is intended for use in the qualitative detection of any four (4) of the following drugs of abuse in human urine at the following levels: (The calibrating analyte is in parentheses)

Oxycodone	100 ng/ml	(Oxycodone)
Benzodiazepines	300 ng/ml	(Oxazepam)
Barbiturates	300 ng/ml	(Butalbital)
Methadone	300 ng/ml	(Methadone)
Propoxyphene	300 ng/ml	(Norproxyphene)
Tricyclic Antidepressants	1000 ng/ml	(Nortriptyline)

'RapidTec 4' is intended for professional use. It is not intended for over-the-counter sale to non-professionals. The assays are easy to perform, but should not be used without proper supervision. This immunoassay is a simplified screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas-chromatography/mass spectrometry (GC/MS.)

3. Special condition for use statement(s):
'RapidTec 4' provides only a preliminary analytical result. A more specific alternate method must be used in order to obtain a more confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse result, particularly when preliminary positive results are used.

The assay is for Rx use.

The assay was not evaluated in point-of-care settings.

4. Special instrument Requirements:
None

I. Device Description:

'RapidTec 4' is a single strip for the rapid, visual competitive immunoassay for the simultaneous detection of 4 drugs selected from the following: oxycodone, benzodiazepines, barbiturates, propoxyphene, tricyclic antidepressants and methadone in urine.

J. Substantial Equivalence Information:

1. Predicate device name(s):
RapidTec 5A; RapidTec 5M
2. Predicate K number(s):
K021114; K023869
3. Comparison with predicate:
The devices and their predicates are for the qualitative determination of the same analyte(s) in the same matrix, and utilize the same cutoff concentrations. All are visually-read single use devices.

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

The sponsor did not identify any in the submission

L. Test Principle:

Lateral flow immunoassay

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

OXYCODONE

Reproducibility studies were carried out using commercially available standards. Each sample, at each concentration of oxycodone, was tested 4 times, twice daily, for 5 days by 2 different operators at 2 different locations. A total of 80 determinations, at each concentration, were made.

Concentration (ng/ml)	Total number of Determinations	# Positive	# Negative
No Drug Present	80	0	80
25	80	2	78
50	80	8	72
75	80	65	15
100	80	80	0
125	80	80	0

Barbiturates

Reproducibility studies were carried out using commercially available standards. Each sample, at each concentration of butalbital, was tested 4 times, twice daily, for 5 days.

Concentration (ng/ml)	Total number of Determinations	Result
No drug present	40	40 negative
150	40	40 negative
225	40	36 positive
300	40	40 positive
375	40	40 positive

Benzodiazepines

Reproducibility studies were carried out using commercially available standards. Each sample, at each concentration of oxazepam, was tested 4 times, twice daily, for 5 days.

Concentration (ng/ml)	Total number of Determinations	Result
No drug present	40	40 negative
150	40	39 negative
225	40	36 negative
300	40	40 positive
375	40	40 positive

Methadone

Reproducibility studies were carried out using commercially available standards. Each sample, at each concentration, was tested 4 times, twice daily for 5 days. A total of 40 determinations were made at each concentration.

Concentration (ng/ml)	Total number of Determinations	Result
No drug present	40	40 negative
150	40	39 negative
225	40	36 positive
300	40	40 positive
375	40	40 positive

Propoxyphene

Reproducibility studies were carried out using commercially available control materials. Each sample, at each concentration of norpropoxyphene, was tested 4 times, twice daily for 5 days.

Concentration (ng/ml)	Total number of Determinations	Result
No drug present	40	40 negative
150 ng/ml	40	35 negative
225 ng/ml	40	24 positive
300 ng/ml	40	40 positive
375 ng/ml	40	40 positive

Tricyclic Antidepressants

Studies were carried out using commercially available standards. Each sample, at each concentration of nortriptyline, was tested 4 times, twice daily, for 5 days. A total of 40 determinations, at each concentration, were made.

Concentration (ng/ml)	Total number of Determinations	# Positive	# Negative
No drug present	40	0	40
500	40	0	40
750	40	32	8
1000	40	36	4
1250	40	40	0

- b. *Linearity/assay reportable range:*
Not applicable. The assay is for qualitative use.
- c. *Traceability (controls, calibrators, or method):*
Traceability is not specified. External controls are commercially available.
- d. *Detection limit:*

Oxycodone

'RapidTec 4' will detect 100 ng/ml of oxycodone in urine. Known concentrations of oxycodone were added to certified drug-free urine. Ten (10) determinations were made at each concentration of this single analyte. Sensitivity is defined as the lowest concentration of oxycodone that will produce positive results in all 10 replicates. At 100 ng/ml of oxycodone, all 10 replicates were positive.

Concentration (ng/ml)	Result
No drug present	10 neg / 10 determinations
50	9 neg / 10 determinations
75	8 pos / 10 determinations
100	10 pos / 10 determinations
125	10 pos / 10 determinations

Barbiturates

'RapidTec 4' detects the presence of 300 ng/ml of butalbital in urine. Known concentrations of butalbital were added to certified drug-free urine and tested with 'RapidTec4.' Each concentration was tested ten (10) times. Sensitivity is defined as the lowest concentration of butalbital that produced positive results in all 10 replicates. At 300 ng/ml of butalbital all 10 replicates were positive.

Concentration (ng/ml)	Total number of Determinations	# Positive	# Negative
No Drug Present	10	0	10
150	10	0	10
225	10	8	2
300	10	10	0
375	10	10	0

Benzodiazepines

'RapidTec 4' will detect 300 ng/ml of oxazepam in urine. Known concentrations of oxazepam were added to certified drug-free urine and tested with 'RapidTec4.' Each concentration was tested ten (10) times with 'Rapid Tec 4.' Sensitivity is defined as the lowest concentration of oxazepam that produced positive results in all 10 replicates. At 300 ng/ml of oxazepam, all 10 replicates were positive.

Concentration (ng/ml)	Total number of Determinations	# Positive	# Negative
No drug present	10	0	10
150	10	0	10
225	10	8	2
300	10	10	0
375	10	10	0

Methadone

'RapidTec 4' will detect 300 ng/ml of methadone in urine. Known concentrations of methadone were added to certified drug-free urine.

Ten (10) determinations were made at each concentration of methadone. Sensitivity is defined as the lowest concentration of methadone that produced positive results in all 10 replicates. At 300 ng/ml of methadone, all 10 replicates were positive.

Concentration (ng/ml)	Total number of Determinations	# Positive	# Negative
No drug present	10	0	10
150	10	1	9
225	10	7	3
300	10	10	0
375	10	10	0

Propoxyphene

'RapidTec 4' will detect 300 ng/ml of propoxyphene (norpropoxyphene) in urine. Known concentrations of norpropoxyphene were added to certified drug-free urine. Ten (10) determinations were made at each serial dilution of this single metabolite. Sensitivity is defined as the lowest concentration of norpropoxyphene that produced positive results in all 10 replicates. At 300 ng/ml of norpropoxyphene, all 10 replicates produced positive results.

Concentration (ng/ml)	Total number of Determinations	# Positive	# Negative
No drug present	10	0	10
150	10	1	9
225	10	5	5
300	10	10	0
375	10	10	0

Tricyclic Antidepressants

'RapidTec 4' detects tricyclic antidepressants (nortriptyline) in urine at 1000 ng/ml. Known concentrations of nortriptyline were added to drug-free urine. Ten (10) determinations were made at each serial dilution of this single analyte. Sensitivity is defined as the lowest concentration of nortriptyline that will produce positive results in all 10 replicates. At 1000 ng/ml of nortriptyline, all 10 replicates were positive.

Concentration (ng/ml)	Result
No drug present	10 neg/10 determinations
500	10 neg/10 determinations
750	8 pos/10 determinations
1000	9 pos/10 determinations
1250	10 pos/10 determinations

e. Analytical specificity:

Cross-reactivity:

Oxycodone

'RapidTec 4' detects 300 ng/ml oxazepam in urine. A high concentration stock solution for each of the analytes was serially diluted (1:1) until negative results were obtained. The lowest concentration that gave a positive result was listed as the cross-reactivity concentration.

Compounds that will produce a positive results:

<u>Compound</u>	<u>Conc. (ng/ml)</u>
6-Acetylcodeine	25,000
6-Acetylmorphine	75,000
Codeine	12,500
Dihydromorphone	3,125
Hydromorphone	2,500
Hydrocodone	625
Morphine	6,250
Noroxycodone	50,000
Oxycodone	100
Oxymorphone	100
Thebaine	25,000

Barbiturates

'RapidTec 4' detects 300 ng/ml butalbital in urine. A high concentration stock solution for each of the analytes was serially diluted (1:1) until negative results were obtained. The lowest concentration that gave a positive result was listed as the cross-reactivity concentration.

Compounds that will produce a positive results:

Compound	Conc. (ng/ml)
Allobarbitol	300
Amobarbitol	1000
Aprobarital	150
Barbitol	1250
Butabarbitol	750
Butalbital	300
Butethal	500
5,5-Diphenylhydantoin	2500
Pentobarbitol	300
Phenobarbitol	1500
Secobarbitol	150
Talbutal	75

Benzodiazepines

'RapidTec4' detects 300 ng/ml of oxazepam in urine. A high concentration for each of the analytes was diluted (1:1) until negative results were obtained. The lowest concentration that gave a positive result was listed as the cross-reactivity concentration.

Compounds that will produce a positive result:

Compound	Conc. (ng/ml)
Alprazolam	75
Bromazepam	400
Chlordiazepoxide	150
Clobazam	100
Clonazepam	300
Desmethlydiazepam	100
Diazepam	100
Estazolam	500
Flunitrazepam	150
Lorazepam	2200
Lormetazepam	500
Nitrazepam	75
Nordiazepam	150
Oxazepam	300
Sulindac	7500
Temazepam	100
Triazolam	1500

Methadone

'RapidTec 4' detects 300 ng/ml of methadone in urine. A high concentration stock solution for each of the analytes was serially diluted (1:1) until negative results were obtained. The lowest concentration that gave a positive result was listed as the cross-reactivity concentration.

Compounds that will give a positive result:

Compound	Conc. (ng/ml)
Benzotropine Methane Sulfonate	30000
Diphenhydramine	50000
Diisopyramide	60000
Isopropamide	500
Methadone	300
(-)-alpha-Methadol	300
(-)-alpha-Acetylmethadol (LAAM)	2500
Procyclide	50000
Suxibuzone	25000

Propoxyphene

'RapidTec 4' detects 300 ng/ml propoxyphene/norpropoxyphene in urine. A high concentration stock solution of each of the analytes was serially diluted (1:1) until negative results were obtained. The lowest concentration that gave a positive result was listed as the cross-reactivity concentration.

Compounds that will produce a positive result:

Compound	Conc. (ng/ml)
Propoxyphene	300
Norpropoxyphene	300

Tricyclic Antidepressants

'RapidTec 4' detects 1000 ng/ml of nortriptyline in urine. A high concentration stock solution for each of the analytes as serially diluted (1:1) until negative results were obtained. The lowest concentration that gave a positive result was listed as the cross-reactivity concentration

Compounds that will produce a positive result:

Compound	Conc. (ng/ml)
Amitriptyline	1000
Clomipramine	5000
Cyclobenzaprine	8000
Cyproheptadine	50000
Desipramine	800
Doxepin	5000
Imipramine	1000
Norclomipramine	2500
Nordoxepin	500
Nortriptyline	1000
Promazine	12500
Protriptyline	2000
Trimipramine	3000

Interference:

Studies were conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drugs positive urine. The compounds were found not to interfere at concentration up to 100,000ng/ml are listed in package insert.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the detection limit section, above. The identified cutoff concentration of the assay is standard for the industry.

2. Comparison studies:

a. Method comparison with predicate device:

Oxycodone

Ninety (90) specimens were tested with 'RapidTec 4'. Of the 90 samples, 50 were found to be drug-free and 40 were screened as positive by EMIT II. 'RapidTec 4' correctly identified all of the specimens that contained no drug as negative. The 40 specimens (19 clinical samples, 21 diluted samples with concentrations near the cutoff), screened as positive by EMIT II, confirmed and quantified by GC/MS for presence of oxycodone, ranged in concentration from 40 to 1025 ng/ml. All specimens containing 54 ng/ml or greater were found to be positive by 'RapidTec 4.'

RapidTec4	Negative by EMIT II	Near cutoff Negative (between – 50% and cutoff)	Near cutoff Positive (between cutoff and +50%)	GC/MS Positive (greater than +50%)	Percent Agreement
Positive	0	7	1	30	82
Negative	50	2	0	0	100

Barbiturates

Ninety (90) clinical specimens were tested with ‘RapidTec 4’. Of the 90 samples, 50 were found to be drug-free and 40 screened as positive by EMIT II. ‘RapidTec 4’ correctly identified all of the specimens that contained no drug as negative. GC/MS analyses of the 40 positive specimens (15 clinical samples, 25 diluted samples with concentrations near the cut-off) showed barbiturate (Alprazolam, Nordiazepam, Oxazepam, and Temazepam) concentrations of 114 to 3034/ml. All specimens containing barbiturate concentrations greater than 180 ng/ml were found to be positive by ‘RapidTec 4.’

RapidTec4	Negative by EMIT II	<u>Near cutoff</u> Negative (between – 50% and cutoff)	<u>Near cutoff</u> Positive (between cutoff and +50%)	GC/MS Positive (greater than 50%)	Percent Agreement
Positive	0	6	8	22	83
Negative	50	2	0	0	100

Benzodiazepines

Ninety (90) specimens were tested with ‘RapidTec 4.’ Of the 90 specimens, 50 were found to be drug-free and 40 screened as positive by EMIT II. ‘RapidTec 4’ correctly identified all of the specimens that contained no drug as negative. GC/MS analyses of the 40 positive specimens (14 clinical samples, 26 diluted samples with concentrations near the cut-off) showed benzodiazepine (Butalbital, Phenobarbital, Pentobarbital) concentrations of 100 to 3000 ng/ml. The specimens containing 100 to 125ng/ml were determined to be negative by ‘RapidTec 4.’ All other specimens containing greater than 150 ng/ml of benzodiazepines were shown to be positive.

RapidTec4	Negative by EMIT II	<u>Near cutoff Negative</u> (between-50% and cutoff)	<u>Near cutoff Positive</u> (between cutoff and +50%)	GC/MS Positive (greater than +50%)	Percent Agreement
Positive	0	15	5	15	57
Negative	50	2	0	0	100

Methadone

Ninety (90) specimens were tested with ‘RapidTec 4.’ Of the 90 specimens, 50 were found to be drug-free and 40 were screened as positive by EMIT II. ‘RapidTec 4’ correctly identified all of the specimens that contained no drug as negative. GC/MS analyses of the 40 positive specimens (30 clinical samples, 10 dilutes samples with concentrations near the cut-off) showed methadone concentrations of 75 to 1072 ng/ml. All specimens containing 174 ng/ml of methadone or greater were found to be positive by ‘RapidTec 4.’

RapidTec4	Negative by EMIT II	<u>Near cutoff Negative</u> (between –50% and cutoff)	<u>Near cutoff Positive</u> (between cutoff and +50%)	GC/MS Positive (greater than +50%)	Percent Agreement
Positive	0	8	7	31	82
Negative	56	6	0	0	100

Propoxyphene

Ninety (90) specimens were tested with ‘RapidTec 4’ Of the 90 specimens, 50 were found to be drug-free and 40 were screened as positive by EMIT II. ‘RapidTec 4’ correctly identified all of the specimens that contained no drug as negative. The 40 specimens, screened as positive by EMIT II, confirmed and quantified by GC/MS, showed propoxyphene/norpropoxyphene concentrations of 143 to 621 ng/ml. All specimens containing 233 ng/ml or greater, were found to be positive by ‘RapidTec 4.’ The 9 specimens that contained levels of propoxyphene/norpropoxyphene below 213 ng/ml were determined to be negative by ‘RapidTec 4.’

RapidTec4	Negative by EMIT II	<u>Near cutoff</u> Negative between – 50% and cutoff)	<u>Near cutoff</u> Positive (between cutoff and +50%)	GC?MS Positive (greater than +50%)	Percent Agreement
Positive	0	7	12	22	83
Negative	50	2	7	0	89

Tricyclic Antidepressants

Ninety (90) clinical specimens were tested with ‘Rapid Tec 4.’ Of these, 50 were shown to be drug-free and 40 were screened as positive by EMIT II. Confirmation (identification, but not quantification) was accomplished by HPLC. ‘RapidTec 4’ determined the 50 drug-free specimens as negative and identified the 40 specimens that contained tricyclic antidepressants (Amitriptyline, Desipramine, Nortriptyline, Imipramine) as positive.

		HPLC		
		+	-	
	+	40	0	40
RapidTec				
	-	0	50	50

b. Matrix comparison:

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

3. Clinical studies:

a. Clinical sensitivity:

Not applicable. Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Not applicable. Clinical studies are not typically submitted for this device type.

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Conclusion:

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