

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

A. 510(k) Number:

K033566

B. Purpose of the Submission:

This is a new 510(k). The sponsor is expanding the claim for previously cleared test strips to point-of-care settings, including workplace.

C. Analyte:

amphetamine, barbiturates, benzodiazepines, cocaine, methadone, methamphetamine, opiates, phencyclidine, and cannabinoid

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Rapid Diagnostics (a division of MP Biomedicals, Inc.)

F. Proprietary and Established Names:

Micromedic Drugs of Abuse Panel Test (AMP, BAR, BZO, COC, MTD, MET, OPI, PCP, THC)

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, Metamphetamine
862.3650, Enzyme Immunoassay, Opiates
Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

II

3. Product Code:

DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LCM, respectively

4. Panel:

Toxicology (91)

H. Intended Use:1. Intended use(s):

Refer to Indications for use.

2. Indication(s) for use:

The MICROMEDIC[®] *Drugs of Abuse Panel Test* is an immunochromatographic one-step *in-vitro* test intended for the qualitative determination of up to nine different drug substances in human urine at the following cut-off levels (amphetamine, 1000 ng/ml; barbiturate [secobarbital], 300 ng/ml; benzodiazepine [oxazepam], 300 ng/ml; cocaine, 300 ng/ml; methadone, 300 ng/ml; methamphetamine, 1000 ng/ml; opiates, 2000 ng/ml; phencyclidine, 25 ng/ml; and cannabinoid, 50 ng/ml).

The MICROMEDIC[®] *Drugs of Abuse Panel Test* is intended for use in a point-of-care (POC) setting to include emergency hospitals and medical care facilities (i.e., emergency rooms, ambulances, etc.), as well as the workplace, criminal justice and transportation arenas, and walk-in, or mobile drug testing facilities.

The MICROMEDIC[®] *Drugs of Abuse Panel Test* will provide a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

It is the responsibility of those organizations required to follow Department of Transportation (DOT) or the Substance Abuse and Mental Health Administration (SAMHSA) Workplace Drug Testing Guidelines to determine that use of this product satisfies the criteria for workplace testing established under DOT and SAMHSA.

3. Special condition for use statement(s):

The device is for in vitro diagnostic use.

The device is for prescription use.

The assay is intended for use in point-of-care settings.

4. Special instrument Requirements:

Not applicable. The device is a visually read single-use device.

I. Device Description:

The product is a single-use dip-and-read test card. Operators dip the test strip into the urine and the reaction is initiated by movement of the sample through the test strip.

J. Substantial Equivalence Information:

1. Predicate device name(s):

The predicates are all Rapid Diagnostic previously cleared Rx test strips.

2. Predicate K number(s):

The 510(k) numbers belonging to the sponsor's earlier cleared strips are K003809 for amphetamine, benzodiazepine, cocaine, methamphetamine, PCP, and THC. K030211 for barbiturates. K023252 for methadone. K020716 for opiates.

3. Comparison with predicate:

Devices are all the same as the originally cleared products. The configurations (or combinations) may vary in the marketed versions from the originally cleared configuration.

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

The sponsor did not reference any standards in their submission.

L. Test Principle:

The test employs lateral flow immunochromatographic technology.

Each component strip of the MICROMEDIC[®] *Drugs of Abuse Panel Test* is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line to indicate that an adequate volume of sample was added and that the membrane strip is intact.

Description of the test antibody: mouse monoclonal anti-drug antibody

Description of the control line antibody: goat anti-mouse IgG

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Reproducibility was evaluated to support the expanded POC claim.

Specimen description: spiked control samples

Lots of product used: not specified

Number of operators: three

Operator: POC staff

Testing Facility: POC sites

Urine control material was evaluated. Controls were purchased from Biochemical Diagnostics and were verified by GC/MS. A total of 20 samples for each of the seven testing levels were analyzed for each of the nine drugs. Results of the study are presented below:

PRECISION STUDY RESULTS

DRUG	CONTROL ng/ml	#NO	# + Site 1	# +/- Site 1	# - Site 1	# + Site 2	# +/- Site 2	# - Site 2	# + Site 3	# +/- Site 3	# - Site 3
AMP (1000 ng/ml)	0				20			20			20
	500 ng/ml	20			20			20		20	
	750 ng/ml	20			20			20		20	
	1000 ng/ml	20	20			20			20		
	1250 ng/ml	20	20			20			20		
	1500 ng/ml	20	20			20			20		
	3000 ng/ml	20	20			20			20		
BAR (300 ng/ml)	0				20			20			20
	150 ng/ml	20			20			20		20	
	225 ng/ml	20			20			20		20	
	300 ng/ml	20	20			20			20		
	375 ng/ml	20	20			20			20		
	450 ng/ml	20	20			20			20		
	900 ng/ml	20	20			20			20		
BZO (300 ng/ml)	0				20			20			20
	150 ng/ml	20			20			20		20	
	225 ng/ml	20			20			20		20	
	300 ng/ml	20	20			20			20		
	375 ng/ml	20	20			20			20		
	450 ng/ml	20	20			20			20		
	900 ng/ml	20	20			20			20		
COC (300 ng/ml)	0							20			20
	150 ng/ml	20			20			20		20	
	225 ng/ml	20			20			20		20	
	300 ng/ml	20	20			20			20		
	375 ng/ml	20	20			20			20		
	450 ng/ml	20	20			20			20		
	900 ng/ml	20	20			20			20		

DRUG	CONTROL ng/ml	#NO	# + Site 1	# +/- Site 1	# - Site 1	# + Site 2	# +/- Site 2	# - Site 2	# + Site 3	# +/- Site 3	# - Site 3
MTD (300 ng/ml)	0 ng/ml				20			20			20
	150 ng/ml	20			20			20		20	
	225 ng/ml	20			20			20		20	
	300 ng/ml	20	20			20			20		
	375 ng/ml	20	20			20			20		
	450 ng/ml	20	20			20			20		
	900 ng/ml	20	20			20			20		
MET (1000 ng/ml)	0	20			20			20			20
	500 ng/ml	20			20			20		20	
	750 ng/ml	20			20			20		20	
	1000 ng/ml	20	20			18		2	20		
	1250 ng/ml	20	20			20			20		
	1500 ng/ml	20	20			20			20		
	3000 ng/ml	20	20			20			20		
OPI (2000 ng/ml)	0				20			20			20
	1000 ng/ml	20			20			20		20	
	1500 ng/ml	20			20			20		20	
	2000 ng/ml	20	20			20			20		
	2500 ng/ml	20	20			20			20		
	3000 ng/ml	20	20			20			20		
	6000 ng/ml	20	20			20			20		
PCP (25 ng/ml)	0				20			20			20
	12.5 ng/ml	20			20			20		20	
	18.8 ng/ml	20			20			20		20	
	25 ng/ml	20	20			20			20		
	31.3 ng/ml	20	20			20			20		
	37.5 ng/ml	20	20			20			20		
	75 ng/ml	20	20			20			20		
THC (50 ng/ml)	0				20			20			20
	25 ng/ml	20			20			20		20	
	37.5 ng/ml	20			20			20		20	
	50 ng/ml	20	20			17		3	20		
	62.5 ng/ml	20	20			20			20		
	75 ng/ml	20	20			20			20		
	150 ng/ml	20	20			20			20		

Study results appear adequate to support the claim and are consistent with earlier in-house study results.

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

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

Control materials are required but are not specifically identified in the labeling. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

The device has an internal process control which indicates whether an adequate volume of sample was added and whether the membrane strip is intact.

d. Detection limit:

The sponsor indicates that this information was taken from the original 510(k) and the labeling has not changed. Therefore the raw data to support these conclusions was not reviewed. It is summarized below:

Cutoff validation and sensitivity were evaluated in-house. The manufacturer analyzed 175 devices of each of the nine analytes individually in strip format at the following concentrations: 0, 50%, 75%, 100%, 125%, 150% and 300% of cut-off level of the assay.

Table 1 Amphetamine (AMP)

AMP (ng/ml)	# Tested	# Negative	# Borderl ine	# Positive
0	25	25	0	0
500 ng/ml	25	25	0	0
750 ng/ml	25	0	24	1
1000 ng/ml	25	0	0	25
1250 ng/ml	25	0	0	25
1500 ng/ml	25	0	0	25
3000 ng/ml	25	0	0	25

Table 2 Barbiturate (BAR)

BAR (ng/ml)	# Tested	# Negative	# Borderl ine	# Positive
0	25	25	0	0
150 ng/ml	25	25	0	0
225 ng/ml	25	10	15	0
300 ng/ml	25	0	10	15
375 ng/ml	25	0	0	25
450 ng/ml	25	0	0	25
900 ng/ml	25	0	0	25

Table 3 Benzodiazepine (BZO)

BZO (ng/ml)	# Tested	# Negative	# Borderl ine	# Positive
0	25	25	0	0
150 ng/ml	25	25	0	0
225 ng/ml	25	21	4	0
300 ng/ml	25	0	6	19
375 ng/ml	25	0	0	25
450 ng/ml	25	0	0	25
900 ng/ml	25	0	0	25

Table 4 Cocaine (COC)

COC (ng/ml)	# Tested	# Negative	# Borderl ine	# Positive
0	25	25	0	0
150 ng/ml	25	25	0	0
225 ng/ml	25	16	9	0
300 ng/ml	25	0	20	5
375 ng/ml	25	0	2	23
450 ng/ml	25	0	0	25
900 ng/ml	25	0	0	25

Table 5 Methadone (MTD)

MTD (ng/ml)	# Tested	# Negative	# Borderl ine	# Positive
0	25	25	0	0
150 ng/ml	25	25	0	0
225 ng/ml	25	10	15	0
300 ng/ml	25	0	10	15
375 ng/ml	25	0	0	25
450 ng/ml	25	0	0	25
900 ng/ml	25	0	0	25

Table 6 Methamphetamine (MET)

MET (ng/ml)	# Tested	# Negative	# Borderl ine	# Positive
0	25	25	0	0
500 ng/ml	25	25	0	0
750 ng/ml	25	25	0	0
1000 ng/ml	25	0	18	7
1250 ng/ml	25	0	23	2
1500 ng/ml	25	0	3	22
3000 ng/ml	25	0	0	25

Table 7 Opiate (OPI)

OPI (ng/ml)	# Tested	# Negative	# Borderl ine	# Positive
0	25	25	0	0
1000 ng/ml	25	25	0	0
1500 ng/ml	25	25	0	0
2000 ng/ml	25	0	12	13
2500 ng/ml	25	0	0	25
3000 ng/ml	25	0	0	25
6000 ng/ml	25	0	0	25

Table 8 Phencyclidine (PCP)

PCP (ng/ml)	# Tested	# Negative	# Borderline	# Positive
0	25	25	0	0
12.5 ng/ml	25	25	0	0
18.8 ng/ml	25	25	0	0
25 ng/ml	25	3	21	1
31.3 ng/ml	25	0	25	0
37.5 ng/ml	25	0	18	7
75 ng/ml	25	0	0	25

Table 9 Cannabinoid (THC)

THC (ng/ml)	# Tested	# Negative	# Borderline	# Positive
0	25	25	0	0
25 ng/ml	25	25	0	0
37.5 ng/ml	25	25	0	0
50 ng/ml	25	0	3	22
62.5 ng/ml	25	0	0	25
75 ng/ml	25	0	0	25
150 ng/ml	25	0	0	25

e. Analytical specificity:

The sponsor indicates that this information is taken from the original 510(k). It was not reviewed, but is presented below.

The assays were evaluated with samples prepared with drug at the cut-off concentration. Readings were shown not to be interfered with by pH conditions between 4 and 9 and when the specific gravity varied between 1.005 and 1.035.

The following substances were tested in negative samples and samples spiked with drugs at the cut-off concentration, and confirmed to not effect test results:

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

The following table lists compounds that are detected by DOA panel test which produced positive results when tested at levels equal or greater than the concentrations listed below:

<u>Test</u>	<u>Compounds</u>	<u>Cut-off (ng/ml)</u>
Amphetamine	D-Amphetamine	1,000
	D/L-Amphetamine	2,000
	(±)3,4Methylenedioxyamphetamine	2,500
	l-Amphetamine	30,000
	(+)methamphetamine	> 100 µg/ml
	(±)3,4Methylenedioxymethamphetamine	> 100 µg/ml

Test	Compounds	Cut-off (ng/ml)
Barbiturate	Alphenal	100
	Barbital	150
	Pentobarbital	150
	Phenobarbital	150
	Amobarbital	300
	Secobarbital	300
	Butalbital	5,000
Benzodiazepines	Nitrazepam	100
	Chloradiazepoxide HCl	300
	Clobazam	300
	Desmethyldiazepam	300
	Oxazepam	300
	Temazepam	300
	Alprazolam	1000
	Bromazepam	1000
	Diazepam	1000
	Flunitrazepam	1000
	Lorazepam	1000
	Clonazepam	2000
	Flurazepam	100
Cocaine	Benzoylcegonine	300
	Cocaine	30,000
Methadone	Methadone	300
	Methadol	300
Methamphetamine	(+)Methamphetamine	1000
	(±)3,4Methylenedioxymethamphetamine	1000
	d-Amphetamine	> 100 µg/ml
	l-Amphetamine	> 100 µg/ml
	(±)3,4Methylenedioxyamphetamine	> 100 µg/ml
	Chloroquine	> 100 µg/ml
	(-)Ephedrine	> 100 µg/ml
	β-Phenylethylamine	> 100 µg/ml
	Procaine	> 100 µg/ml
	d-Pseudoephedrine	> 100 µg/ml
	Ranitidine	> 100 µg/ml
Opiate	Ethylmorphine	1,000
	Morphine	2,000
	Morphine-3-β-glucuronide	2,000
	Codeine	2,000
	6-Acetylmorphine	2,000
	Dihydrocodone	2,000
	Heroin	5,000
	Hydrocodone	7,500
	Hydromorphone	7,500
	Nalorphine	15,000
	Normorphine	20,000
	Norcodeine	100,000
	Naloxone	100,000
	Oxycodone	100,000
Phencyclidine	PCP	25
THC	11-nor-Δ ⁹ -THC-9-COOH	50
	11-nor-Δ ⁸ -THC-9-COOH	37.5
	11-hydroxy-Δ ⁹ -THC	5000
	Δ ⁸ -Tetrahydrocannabinol	15000
	Δ ⁹ -Tetrahydrocannabinol	25000

The following compounds show no cross-reactivity at concentration up to 100 µg/ml unless specified. There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

4-Acetamidophenol	Cortisone	Homatropine	Perphenazine
Acetaminophen	Deoxyephedrine	Hydrochlorothiazide	Phenylethylamine-α
Acetylsalicylic acid	Dextromethorphan	Ibuprofen	Phenylpropanolamine
Amikacin	Digitoxin	Imipramine	Promethazine
Amitriptyline	Digoxin	Isoproterenol	Pseudoephedrine
Arterenol	Diphenhydramine	Ketamine	Quinine antidine
Ascorbic acid	Ecgonine	Lidocaine	Salicylic acid
Aspartame	Ecgonine methyl ester	Meperidine	Tetracycline
Atropine	Ephedrine	Methaqualone	Tetrahydrozoline
Caffeine	Epinephrine	Methylphenidate	Theophylline
Camphor	Gentisic	Neomycin	Thioridazine
Chlorpheniramine	Guaiacol glyceric ester	Niacinamide	Trifluoperazine
Chloroquine	Histamine	Penicillin G	Tryptophan
			Tyramine

f. Assay cut-off:

These have not changed from the originally cleared products.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision and sensitivity sections, above.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor provided naturalistic samples and prepared spiked samples to a POC employee for analysis. The samples were also analyzed by GC/MS.

Number of study sites: one

Type of study site(s): POC setting

Operator description: POC staff member

Results of the study appear below:

Accuracy was tested in each component strip and compared to GC/MS method at the following concentrations: d-amphetamine 1000 ng/ml (AMP), secobarbital 300 ng/ml (BAR), oxazepam, 300 ng/ml (BZO), benzoylecgonine 300 ng/ml (COC), methadone 300 ng/ml (MTD), (+)methamphetamine 1000 ng/ml (MET), morphine 2000 ng/ml (OPI), phencyclidine 25 ng/ml (PCP) and 11-nor- Δ^9 -THC-9-COOH 50ng/ml (THC).

The results of each component strip are listed below:

Table 1: Amphetamine (AMP)

The accuracy of the amphetamine test was evaluated in comparison to GC/MS method at a cut-off of 1000 ng/ml. Eighty-one (81) specimens with GC/MS confirmed d-amphetamine concentration were evaluated.

Rapid AMP Test	(-)		(+)		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	2	1	8	26	92%
Negative	43	0	1	0	98%
Total	45	1	9	26	N=81

Table 2: Barbiturate (BAR)

The accuracy of the barbiturate test was evaluated in comparison to GC/MS method at a cut-off of 300 ng/ml secobarbital. One-hundred thirteen (113) specimens with GC/MS confirmed barbiturate concentration were evaluated in this study.

Rapid BAR Test	(-)		(+)		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	0	0	6	58	100%
Negative	45	4	0	0	100%
Total	45	4	6	58	N=113

Table 3: Benzodiazepine (BZO)

The accuracy of the benzodiazepine test was evaluated in comparison to GC/MS method at a cut-off of 300 ng/ml oxazepam. Seventy-nine (79) specimens with GC/MS confirmed oxazepam concentration were evaluated.

Rapid BZO Test	(-)		(+)		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	0	1	6	30	97%
Negative	42	0	0	0	100%
Total	42	1	6	30	<i>N=79</i>

Table 4: Cocaine (COC)

The accuracy of the cocaine test was evaluated in comparison to GC/MS method at a cut-off of 300 ng/ml benzoylecgonine. Eighty-one (81) specimens with GC/MS confirmed benzoylecgonine concentration were evaluated.

Rapid COC Test	(-)		(+)		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	0	2	3	31	94%
Negative	41	4	0	0	100%
Total	41	6	3	31	<i>N=81</i>

Table 5: Methadone (MTD)

The accuracy of the methadone test was evaluated in comparison to GC/MS method at a cut-off of 300 ng/ml methadone. Ninety-nine (99) specimens with GC/MS confirmed methadone concentration were evaluated.

Rapid MTD Test	(-)		(+)		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	0	0	4	46	100%
Negative	40	9	0	0	100%
Total	40	9	4	46	N=99

Table 6: Methamphetamine (MET)

The accuracy of the methamphetamine test was evaluated in comparison to GC/MS method at a cut-off of 1000 ng/ml methamphetamine. Eighty (80) specimens with GC/MS confirmed methamphetamine concentration were evaluated in this study.

Rapid MET Test	(-)		(+)		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	0	2	4	31	95%
Negative	40	3	0	0	100%
Total	40	5	4	31	N=80

Table 7: Opiates (OPI)

The accuracy of the opiates test was evaluated in comparison to GC/MS method at a cut-off of 2000 ng/ml morphine. Eighty-three (83) specimens with GC/MS confirmed morphine and codeine concentrations were evaluated.

Rapid OPI Test	(-)		(+))		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	2	2	8	27	90%
Negative	44	0	0	0	100%
Total	46	2	8	27	N=83

Table 8: Phencyclidine (PCP)

The accuracy of the phencyclidine test was evaluated in comparison to GC/MS method at a cut-off of 25 ng/ml phencyclidine. Eighty (80) specimens with GC/MS confirmed morphine and codeine concentrations were evaluated.

Rapid PCP Test	(-)		(+))		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	0	1	1	34	97%
Negative	43	1	0	0	100%
Total	43	2	1	34	N=80

Table 9: Cannabinoid (THC)

The accuracy of the cannabinoid test was evaluated in comparison to GC/MS method at a cut-off of 50 ng/ml 11-nor- Δ^9 -THC-9-COOH. Eighty-eight (88) specimens with GC/MS confirmed 11-nor- Δ^9 -THC-9-COOH concentration were evaluated.

Rapid THC Test	(-)		(+)		Percent agreement with GC/MS
	Negative by GC/MS	Near Cutoff NEG (between -25% and C/O)	Near Cutoff POS (between C/O and +25%)	GC/MS POS (greater than +25% C/O)	
Positive	1	1	3	35	95%
Negative	44	4	0	0	100%
Total	45	5	3	35	N=88

The POC results appear consistent with the performance originally demonstrated in the in-house studies. However, because all of the positive samples for some of the drugs in this study were prepared samples and because of the way the naturalistic samples were selected for inclusion in this study it was decided to limit the presentation of performance to the information from the sponsor's in-house study. This information appearing in the package insert was not reviewed again as the sponsor indicates they have not changed the information from how it was presented at the time of the original prescription clearance.

The sponsor was asked to include only a statement in their package insert indicating that the product was evaluated in a POC setting and results were comparable.

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.