

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

A. 510(k) Number:

k050594

B. Purpose for Submission:

New Device

C. Measurands:

Cannabinoids, Opiates, Cocaine, Methamphetamine, and Phencyclidine

D. Type of Test:

Qualitative immunoassay

E. Applicant:

Nano-Ditech Corporation

F. Proprietary and Established Names:

In vitro Nano-Check™ DAT 5 Multi Drug Screening Test
THC/OPI/COB/mAMP/PCP

G. Regulatory Information:

Regulation section:

Regulation Number	Standard Product Nomenclature	Panel	Product Code	Class
862.3870	Enzyme Immunoassay Cannabinoids	Toxicology (91)	LDJ	II
862.3250	Enzyme Immunoassay, Cocaine and Cocaine Metabolites	Toxicology (91)	DIO	II
862.3610	Thin Layer Chromatography, Methamphetamine	Toxicology (91)	DJC	II
862.3650	Enzyme Immunoassay, Opiates	Toxicology (91)	DJG	II
Unclassified	Enzyme Immunoassay, Phencyclidine	Toxicology (91)	LCM	

H. Intended Use:

1. Intended use(s):

Refer to Indications for use.

2. Indication(s) for use:

The Nano-Check™ DAT 5 Multi Drug Screening Test for Marijuana, Opiates, Cocaine, Methamphetamine and Phencyclidine is a rapid, self-controlled immunoassay for the qualitative detection of Cannabinoids (THC), Opiates (OPI), Benzoylcegonine (COC), Methamphetamine (mAMP) and Phencyclidine (PCP) compounds and their metabolites in human urine. The detection limits (cut-off concentrations of this test are as follows: Cannabinoids at 50 ng/ml, Opiates at 2000 ng/ml, Cocaine at 300ng/ml, Methamphetamine at 1000 ng/ml and Phencyclidine at 25 ng/ml). This assay is intended for Professional and Laboratory In-Vitro Use Only.

3. Special condition for use statement(s):

The Nano-Check™ DAT 5 Multi Drug Screening Test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The assay is not designated for use in point-of-care settings.

Tests for opiates cannot distinguish between abused drugs and certain prescribed medications.

Certain foods or medications may interfere with tests for amphetamines and opiates and cause false positive results.

4. Special instrument Requirements:

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

I. Device Description:

The product is a single-use device in a cassette format. Operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON THC One Step Marijuana Test Strip
ACON OPI One Step Opiates Test Strip
ACON COC One Step Cocaine Test Strip
ACON mAMP One Step Methamphetamine Test Strip
ACON PCP One Step Phencyclidine Test Strip

2. Predicate K number(s):

k003557
k040274
k010841
k011672
k011730

3. Comparison with predicate:

Both devices are for the qualitative determination of the same analytes in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices.

Similarities		
Item	Device	Predicate Devices
Test Principle	Same	Immunochromatographic, lateral flow, competitive assay
Type of test	Same	Qualitative
Assay time	Same	5-10 minutes
Matrix	Same	Human urine
Indications for use	Same	Prescription use
Cutoffs	Same	THC: 50 ng/mL OPI: 2000 ng/mL COC: 300 ng/mL mAMP: 1000 ng/mL PCP: 25 ng/mL
Differences		
Item	Device	Predicate
Number of assays per device	5	1
Format	Cassette; user adds urine with dropper provided	Dipstick; user immerses strip in urine sample

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

The sponsor referenced the following guidance document(s) in their submission:

Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff, published December 2003

Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications, published November 2000.

L. Test Principle:

The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of 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 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:*

Drug free samples were spiked with the five drugs to achieve the concentration of either -50% cutoff or +50% cutoff levels. Ten samples, each containing a different set of concentration combinations for the 5 drugs and blind –labeled samples, were tested on duplicated devices by three operators. All tests that applied the +50% cutoff urine sample were detected positive by all three operators, and all tests of -50% cutoff urine samples were detected negative by all three operators. Results of study presented below.

Drug	Conc.	Result Expected	No. of device tested	No. of device of expected result			agreement
				Operator 1	Operator 2	Operator 3	
THC c/o 50	-50% cutoff	neg	10	10	10	10	100%
	+50% cutoff	pos	10	10	10	10	100%
OPI c/o 2000	-50% cutoff	neg	10	10	10	10	100%
	+50% cutoff	pos	10	10	10	10	100%
COC c/o 300	-50% cutoff	neg	10	10	10	10	100%
	+50% cutoff	pos	10	10	10	10	100%
mAMP c/o1000	-50% cutoff	neg	10	10	10	10	100%
	+50% cutoff	pos	10	10	10	10	100%
PCP c/o 25	-50% cutoff	neg	10	10	10	10	100%
	+50% cutoff	pos	10	10	10	10	100%
Total agreement							100%

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.

The device has an internal process control. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

Stability studies are summarized for the controls. The sponsor specifies the concentrations of materials evaluated in the studies, the frequency of testing, the method for testing the materials, environmental conditions of storage, and acceptance criteria for the study. Accelerated studies are being used by the sponsor to estimate the expiration date; however, on-going real time studies are being performed.

d. *Detection limit:*

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result.

This information appears in the table below.

Compound Name	Cut off level
11-Nor- Δ^9 -Tetrahydrocannabinol carboxylic acid (THC)	50 ng/ml
Morphine (OPI)	2000 ng/ml
Benzoylecgonine (COC)	300 ng/ml
D-Methamphetamine (mAMP)	1000 ng/ml
Phencyclidine (PCP)	25 ng/ml

Cut off Validation Study

Drug	Level ng/ml	Negative	Positive	Coincidence (%)
THC	0	25	0	100
	25	25	0	100
	37.3	20	5	80
	50	15	10	N/A
	62.5	1	24	96
	75	0	25	100
OPI	0	25	0	100
	1000	25	0	100
	1500	23	2	92
	2000	10	15	N/A
	2500	4	21	84
	3000	0	25	100

Drug	Level ng/ml	Negative	Positive	Coincidence (%)
COC (Benzoyllecgonine)	0	25	0	100
	150	25	0	100
	225	21	4	84
	300	11	14	N/A
	375	1	24	96
	450	0	25	100
Methamphetamine	0	25	0	100
	500	25	0	100
	750	25	0	100
	1000	14	11	N/A
	1250	3	22	88
	1500	0	25	100
PCP	0	25	0	100
	12.5	25	0	100
	18.5	20	5	80
	25	10	15	N/A
	31.5	1	24	96
	37.5	0	25	100

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

Methamphetamine

Drug Compound	Response equivalent to cutoff in ng/mL
d-Amphetamine	>100,000
l-Amphetamine	>100,000
d-Methamphetamine	1,000
dl-Amphetamine	>100,000
(±) Ephedrine	>100,000
(-) Ephedrine	>100,000
d,l 3,4-Methylenedioxymethamphetamine (MDMA)	1,000
3,4-Methylenedioxyamphetamine (MDA)	>100,000

Opiates

Drug compound	Response equivalent to cutoff in ng/mL
Codeine	1,000
Hydrocodone	1,000
Hydromorphone	2,500
Oxycodone	25,000
Morphine	2,000
Morphine-3- β -glucuronide	25,000
Nalorphine	750
Procaine HCL	>100,000
Oxymorphone	>100,000
Ofloxacin	>100,000
Thebaine	100,000
6-Acetylmorphine	1,000

Cocaine

Compound	Response equivalent to cutoff in ng/mL
Benzoylecgonine	300
Ecgonine	25,000
Cocaine HCL	250

Cannabinoids (THC)

Compound	Response equivalent to cutoff in ng/mL
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	50
11-Nor- Δ^8 -Tetrahydrocannabinol carboxylic acid	75
11-Nor- Δ^9 -Tetrahydrocannabinol carboxylic acid	>100,000
Δ^8 -Tetrahydrocannabinol	>100,000
Δ^9 -Tetrahydrocannabinol	> 10,000
Cannabinol	>100,000

Phencyclidine

Compound	Response equivalent to cutoff in ng/mL
4-hydroxyphencyclidine	25
Ibuprofen	>100,000
Thienylcyclohexylpiperidine (TCP)	4,000
Hydromorphone	50,000

There is the 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.

f. Assay cut-off:

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

2. Comparison studies:*a. Method comparison with predicate device:*

Because the candidate device was compared to a reference method, GC/MS, it was not compared to a predicate device. According to the sponsor accuracy was determined by taking clinical samples containing THC/ Cannabinoids, Morphine, Benzoylcegonine, Methamphetamine and /or Phencyclidine, confirmed by GC/MS and then analyzed using the Nano-Check™ DAT 5M THC/OPI/COC/mAMP/PCP test panel. The results are shown below.

		GC/MS	
		Positive	Negative
Nano-Check™ DAT 5M THC	Positive	80	5
	Negative	3	262
	Total	83	267
	Agreement	96.4%	98.1%
	Total agreement	97.7%	
Nano-Check™ DAT 5M OPI	Positive	82	1
	Negative	3	264
	Total	85	265
	Agreement	96.5%	99.6%
	Total agreement	98.9%	
Nano-Check™ DAT 5M COC	Positive	86	4
	Negative	1	259
	Total	87	263
	Agreement	98.9%	98.5%
	Total agreement	98.6%	
Nano-Check™ DAT 5M mAMP	Positive	76	2
	Negative	2	270
	Total	78	272
	Agreement	97.4%	99.3%
	Total agreement	98.9%	
Nano-Check™ DAT 5M PCP	Positive	50	1
	Negative	1	298
	Total	51	299
	Agreement	98.0%	99.7%
	Total agreement	99.4%	

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. 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.