

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

A. 510(k) Number:

k060896

B. Purpose for Submission:

Clearance of a device for drugs of abuse with a new cutoff (300 ng/mL) for methamphetamine.

C. Measurand:

Methamphetamine (d-Methamphetamine), Amphetamines, Benzodiazepines, Cocaine metabolites, Morphine, Phencyclidine (PCP), and Tetrahydrocannabinols

D. Type of Test:

Qualitative, visually read, immunochromatographic test

E. Applicant:

Varian, Inc.

F. Proprietary and Established Names:

OnTrak TesTcup® II Pro 5-AS and OnSite CupKit™ Pro 5-AS

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.3610, Methamphetamine Test System

21 CFR § 862.3100, Amphetamine Test System

21 CFR § 862.3170, Benzodiazepine Test System

21 CFR § 862.3250, Cocaine and Cocaine Metabolite Test System

21 CFR § 862.3640, Morphine Test System

Unclassified, Enzyme Immunoassay, Phencyclidine

21 CFR § 862.3870, Cannabinoids Test System

2. Classification:

Class II

3. Product code:

DJC, DKZ, JXM, DIO, DNK, LCM, and LDJ respectively.

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

TesTcup II and OnSite CupKit products are in vitro diagnostics tests intended for professional use for the qualitative detection of drug or drug metabolite in urine at or above the stated cutoff concentrations.

Cutoff Concentrations:

Amphetamines: 1000 ng/mL

Benzodiazepines: 200 ng/mL

Cocaine metabolite: 300 ng/mL

Methamphetamine: 300 ng/mL

Methamphetamine: 500 ng/mL

Morphine: 300 ng/mL

Morphine (M2K): 2000 ng/mL

Phencyclidine (PCP): 25 ng/mL

Tetrahydrocannabinols: 50 ng/mL

2. Indication(s) for use:

See Intended Use above.

3. Special conditions for use statement(s):

The device is for in vitro diagnostic prescription use. TesTcup II and OnSite CupKit products provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

4. Special instrument requirements:

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

I. Device Description:

The OnTrak TesTcup II and OnSite Cupkit assays are in vitro diagnostic tests intended for professional use for the qualitative detection of amphetamines (d,l-amphetamine 1000 ng/mL), benzodiazepines (oxazepam 200 ng/mL), cocaine metabolite (benzoylecgonine 300 ng/mL), methamphetamine (d-methamphetamine 500 ng/mL), morphine (morphine 300 ng/mL), morphine 2000 (morphine 2000 ng/mL), PCP (phencyclidine 25 ng/mL), and THC (1 1-nor-A9-THC-9-carboxylic acid 50 ng/mL) and were previously cleared under k033902. The OnTrak TesTcup II and OnSite Cupkit product lines have several different types that use varying combinations of the above drugs of abuse test strips.

This submission (k060896) is for the clearance of methamphetamine (d-methamphetamine) at a 300 ng/mL cut-off to be packaged with the drugs of abuse test strips above. The methamphetamine assay with a 300 ng/mL cutoff has exactly the same antibody and antigen as the previously cleared 500 ng/mL methamphetamine

assay. The label system (polystyrene beads), nitrocellulose membrane, control-line antibody, and sample pad are also identical between the two. The difference between the two assays is a slight difference in the typical volume of polystyrene bead labeled antibody and capture antigen.

J. Substantial Equivalence Information:

1. Predicate device name(s):
OnTrak TesTcup® II and OnSite CupKit™
2. Predicate 510(k) number(s):
k033902
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	TesTcup II and OnSite CupKit products are in vitro diagnostics tests intended for professional use for the qualitative detection of drug or drug metabolite in urine at or above the stated cutoff concentrations.	TesTcup II and OnSite CupKit products are in vitro diagnostics tests intended for professional use for the qualitative detection of drug or drug metabolite in urine at or above the stated cutoff concentrations.
Cutoff	Amphetamines: 1000 ng/mL Benzodiazepines: 200 ng/mL Cocaine metabolite: 300 ng/mL Methamphetamine: 500 ng/mL Morphine: 300 ng/mL Morphine (M2K): 2000 ng/mL Phencyclidine (PCP): 25 ng/mL Tetrahydrocannabinols: 50 ng/mL	Amphetamines: 1000 ng/mL Benzodiazepines: 200 ng/mL Cocaine metabolite: 300 ng/mL Methamphetamine: 500 ng/mL Morphine: 300 ng/mL Morphine (M2K): 2000 ng/mL Phencyclidine (PCP): 25 ng/mL Tetrahydrocannabinols: 50 ng/mL
Sample Types	Urine	Urine
Test Method	Immunochromatographic	Immunochromatographic

Differences		
Item	Device	Predicate
Cutoff	Methamphetamine: 300 ng/mL included	Methamphetamine: 300 ng/mL not included

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

None were identified by the applicant.

L. Test Principle:

The assays are based on the principle of microparticle capture inhibition. The test relies on the competition between drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane in the test chamber. Urine is collected directly in the test cup provided. The drug profile card is placed in the samples by inserting it into the lid holder, then securing the lid onto the cup. Urine is drawn in the profile card by capillary action and reacts with antibody coated microparticles and drug conjugate present on the membrane. In the absence of drug, the antibody is free to interact with the drug conjugate, causing the formation of a blue band.

When drug is present in the specimen, it binds to the antibody-coated microparticles. If sufficient drug is present, the microparticles are inhibited from binding the drug conjugate and no blue band is formed at the result window. A preliminary positive ("non-negative" result is the absence of a blue band).

An additional antibody/antigen reaction occurs at the "VALID" area. The "VALID" blue band forms when antibodies, which are imbedded in the reagent membrane, interact with and bind to the antigen on the blue microparticles.

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

The precision of the assay for methamphetamine (300 ng/mL cut-off) was determined by testing 63 replicates across three different days with 6 different concentrations: 0, 75, 150, 225, 375, and 450 ng/mL (21 replicates for each concentration per day, for a total of 378 devices tested) using a Methamphetamine urine standard containing drug at different concentrations. Results were read by the three operators. Samples were randomized and blind with respect to the operators. Results are summarized below.

Methamphetamine (ng/mL) Cutoff = 300 ng/mL	Precision Results (%)			
	Lot 1		Lot 2	
	+	-	+	-
0	0	100	0	100
75	0	100	0	100
150	1	100	1.6	98.4
225	17.5	82.5	60.3	39.7
375	100	0	98.4	1.6
450	100	0	100	0

b. *Linearity/assay reportable range:*
Not applicable.

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

The sponsor did not indicate any degree of traceability for their devices. Control materials are required but are not specifically identified in the labeling. No calibrators are required. The device is calibrated during the manufacturing process.

d. *Detection limit:*

Sensitivity of qualitative assays may be characterized by validating performance around the claimed cutoff concentration of the assay, and demonstrating the lowest concentration of drug that is capable of or consistently producing a positive result. This information appears in the precision section, a., above.

e. *Analytical specificity:*

Each substance was tested starting with a 100,000 ng/mL solution or a 1000 ng/mL solution in a negative urine control. Each compound was diluted and tested negative result appeared for methamphetamine. Three OnSite CupKit devices were tested per substance by pipetting approximately 100 to 200 uL of spiked urine onto the appropriate feedhole. Devices were color rated according to the QC color rating scale. If at least 2 out of 3 negative results were seen for methamphetamine, then the sponsor defines this as no interference at that level. The entire protocol was repeated for each of the two lots. Results are summarized below.

Methamphetamine-related Compounds	Minimum Concentration Required to give a Positive result (ng/mL)
d,I-Methamphetamine	500
3,4-Methylenedioxymethamphetamine (MDMA)	1000
Propylhexedrine	2000
Fenfluramine	2000
I-Methamphetamine	3000
p-Hydroxymethamphetamine	5000
3,4-Methylenedioxyethylamphetamine (MDEA)	10,000
Ranitidine	25,000
d-Amphetamine	50,000
I-Phenylephrine	50,000

Methamphetamine-related Compounds	Minimum Concentration Required to give a Positive result (ng/mL)
B-Phenethylamine	50,000
d,I-Amphetamine	50,000
d,I-Ephedrine	100,000
3,4-Methylenedioxymphetamine (MDA)	>100,000
I-Amphetamine	>100,000
I-Pseudoephedrine	>100,000
d-Pseudoephedrine	>100,000

f. Assay cut-off:
See Intended Use above.

2. Comparison studies:

a. Method comparison with predicate device:

The methamphetamine strip within the TesTcup II /CupKit was evaluated in a SAMHSA certified laboratory using clinical specimens. The clinical negative samples were screened negative by automated immunoassay and reported as negatives according to SAMSHA guidelines. Clinical specimens screened positive by automated immunoassay were subsequently analyzed by GC/MS. Ten samples were diluted once with negative human urine to achieve the appropriate test range.

A total of 100 negative urine samples were tested, 10% of these specimens, chosen at random were confirmed negative by GC/MS. A total of 50 positive urine samples were tested. 10% of the samples were between 75% and 100% of the analyte cutoff; another 10% of the samples were between 100% and 125% of the cutoff. The remainders of the samples were at concentrations greater than 125% of the cutoff. Results are summarized below.

TesTcup II/CupKit Methamphetamine Cutoff = 300 ng/mL		Negative Samples	GC/MS Values ng/mL		
			Near Cutoff		>125% of Cutoff
			75% - 100%	100% - 125%	
	+	0	0	3	39
	-	100	5	3	0

b. Matrix comparison:
Not applicable.

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:

No illicit drugs should be present in urine.

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.