

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

**A. 510(k) Number:** K033299

**B. Analyte:** methamphetamine

**C. Type of Test:** lateral flow immunochromatographic

**D. Applicant:** ACON Laboratories, Inc.

**E. Proprietary and Established Names:** ACON® mAMP 500 One Step Methamphetamine Test Strip and ACON® mAMP 500 One Step Methamphetamine Test Device

**F. Regulatory Information:**

1. Regulation section: 21 CFR § 862.3610
2. Classification: Class II
3. Product Code: LAF
4. Panel: Clinical Toxicology

**G. Intended Use:**

1. Indication(s) for use:

The ACON® mAMP 500 One Step Methamphetamine Test Strip and ACON® mAMP 500 One Step Methamphetamine Test Device are rapid immunochromatographic assays for the qualitative detection of methamphetamine in human urine at a cutoff concentration of 500 ng/mL. Measurements obtained by the strip and device are used in the diagnosis and treatment of methamphetamine use or overdose.

2. Special condition for use statement(s):

The ACON® mAMP 500 One Step Methamphetamine Test Strip and Test Device provide 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 judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used. For prescription use only.

3. Special instrument Requirements: N/A

**H. Device Description:** The test strip is held at one end while the other end (indicated by a line) is dipped in the urine specimen. The control (C) and test (T) areas are in the middle of the strip and are used to read the test result. The test device uses a strip enclosed in a plastic cassette. The urine is applied to a sample well (S) by means of a dropper. Control and test regions in the middle are similar to the strip.

**I. Substantial Equivalence Information:**

1. Predicate device name(s): Instant-View Methamphetamine (500) Urine Test
2. Predicate K number(s): K994406
3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Indications for Use	Same	Qualitative detection of methamphetamine in urine
Methodology	Same	Lateral flow immunoassay
Endpoint	Same	Visible Lines
Cutoff	Same	500 ng/mL
Antibodies	Same	Goat, Mouse
<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Read Time	5 minutes to 4 hours	4 to 7 minutes

**J. Standard/Guidance Document Referenced (if applicable):**

None referenced

**K. Test Principle:**

The mAMP 500 One Step Methamphetamine Test Strip and Test Device are immunoassays based on the principle of competitive binding. Methamphetamine which may be present in the urine specimen competes with the drug conjugate for binding sites on the antibody.

During testing with the strip or device, a urine specimen is applied by dipping or using a dropper and migrates by capillary action. Methamphetamine, if present in the urine specimen below 500 ng/mL, will not saturate the binding sites of antibody-coated particles in the strip or device. The antibody-coated particles will then be captured by immobilized Methamphetamine conjugate and a visible colored line will appear in the test line region. The colored line will not form in the test line region if the Methamphetamine level exceeds 500 ng/mL because the methamphetamine present will saturate all the binding sites of anti-Methamphetamine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

**For the test strip:**

A study was conducted at 3 physician's offices by untrained operators using 3 different lots of product. An identical panel of coded specimens containing no Methamphetamine, 25% Methamphetamine above and below the cut-off and 50% Methamphetamine above and below the 500 ng/mL cut-off was provided to each site. Results were as follows:

Methamphetamine concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

**For the test device:**

A study was conducted at 3 physician's offices by untrained operators using 3 different lots of product. An identical panel of coded specimens containing no Methamphetamine, 25% Methamphetamine above and below the cut-off and 50% Methamphetamine above and below the 500 ng/mL cut-off was provided to each site. Results were as follows:

Methamphetamine concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	1	14	2	13
750	15	0	15	0	15	0	15

b. *Linearity/assay reportable range:*

N/A

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

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

The manufacturer does not supply control materials with these devices, but recommends that a positive and negative control be tested to confirm the test procedure and to verify proper test performance.

d. *Detection limit:*

These assays are designed to produce a positive result for methamphetamine at a concentration of 500 ng/mL or greater.

e. *Analytical specificity:*

The specificity of these assays was evaluated using several methamphetamine-related compounds. Results were as follows:

Compound	Concentration (ng/mL)	% Cross Reactivity
D-Methamphetamine	500	100%
D-Amphetamine	50,000	1%
D/L-Amphetamine	75,000	<1%
Chloroquine	12,500	4%
(±)-3,4-Methylenedioxymethamphetamine	1,000	50%
P-Hydroxymethamphetamine	15,000	<1%
Mephentermine	25,000	2%
(1R,2S)-(-)-Ephedrine	50,000	1%
L-Phenylephrine	100,000	<1%
β-Phenylethylamine	75,000	<1%

In addition, approximately 150 common drugs and endogenous substances were tested for possible cross-reactivity at 100 µg/mL. None

of the substances tested caused a positive result with the methamphetamine strip or device.

f. *Assay cut-off:*

See detection limit above.

2. Comparison studies:

a. *Method comparison with predicate device:*

Performance was compared with the predicate device with the following results:

**For the test strip:**

Method	Results	Other mAMP Rapid Test		Total Results
		Positive	Negative	
mAMP 500 One Step Test Strip	Positive	108	39*	147
	Negative	0	153	153
<b>Total Results</b>		108	192	300
<b>% Agreement with this commercial kit</b>		>99%	80%	87%

\*32 specimens were shown by GC/MS to be greater than 500 ng/mL in concentration.

**For the test device:**

Method	Results	Other mAMP Rapid Test		Total Results
		Positive	Negative	
mAMP 500 One Step Test Device	Positive	108	34*	142
	Negative	0	158	158
<b>Total Results</b>		108	158	300
<b>% Agreement with this commercial kit</b>		>99%	82%	89%

\*32 specimens were shown by GC/MS to be greater than 500 ng/mL in concentration.

Performance was also compared with the reference method GC/MS, with the following results:

**For the test strip:**

Method	Results	GC/MS		Total Results
		Positive	Negative	
mAMP 500 One Step Test Strip	Positive	140	7	147
	Negative	0	153	153
<b>Total Results</b>		140	160	300
<b>% Agreement with GC/MS Analysis</b>		>99%	96%	98%

**For the test device:**

Method	Results	GC/MS		Total Results
		Positive	Negative	
mAMP 500 One Step Test Device	Positive	139	7	146
	Negative	1	153	154
<b>Total Results</b>		140	160	300
<b>% Agreement with GC/MS Analysis</b>		>99%	97%	98%

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical sensitivity:*

N/A

*b. Clinical specificity:*

N/A

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

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Methamphetamine is not found in the urine of individuals who have not ingested methamphetamine or a related substance.

**M. Conclusion:**

Based upon the information provided for the file, I recommend that the ACON® mAMP 500 One Step Methamphetamine Test Strip and ACON® mAMP 500 One Step Methamphetamine Test Device be found substantially equivalent to the predicate device.