

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

**A. 510(k) Number:**  
k041822

**B. Purpose for Submission:**  
New Product

**C. Analyte:**  
Amphetamine

**D. Type of Test:**  
Qualitative lateral flow immunochromatographic test

**E. Applicant:**  
ACON Laboratories

**F. Proprietary and Established Names:**  
ACON AMP 300 One Step Amphetamine Test Strip  
ACON AMP 300 One Step Amphetamine Test Device

**G. Regulatory Information:**

1. Regulation section:  
21 CFR §862.3100: Test System, Amphetamine
2. Classification:  
Class II
3. Product Code:  
DKZ
4. Panel:  
Toxicology (91)

**H. Intended Use:**

1. Intended use(s):  
This device is used in the diagnosis and treatment of drug use or overdose.
2. Indication(s) for use:  
“The ACON AMP 300 One Step Amphetamine Test Strip and the ACON AMP 300 One Step Amphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of amphetamine in human urine at a cutoff concentration of 300 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.”

3. Special condition for use statement(s):  
This test strip and test device provides only a preliminary analytical test result. A more specific alternative chemical method, such as GC/MS, must be used to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.
4. Special instrument Requirements:  
Not applicable, as the test strip and the test device are visually-read single-use devices.

**I. Device Description:**

The ACON AMP 300 One Step Amphetamine Test has two formats: Test Strip and Test Device. These two formats are manufactured with the same formulation, components, and manufacturing processes. The Test Strip is labeled and has a maximum dip line indicator. The Test Device contains a testing strip with minor cosmetic changes (no dip indicator) in a plastic housing with a specimen well and a window to read the test results. A dropper is included with the Test Device, but a specimen collection container is not included with either test format.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
SureStep Drug Screen AMP II Test
2. Predicate K number(s):  
k003466
3. Comparison with predicate:  
The device is similar to or the same as to the previously cleared predicate(s) in the following ways: test principles, indication for use, cut-off concentration(s), use in a professional and point-of-care setting, sample matrix, endpoint, and test time. The tests differ in their manufacturer and cosmetic appearance.

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

The sponsor did not reference any standards in the submission.

**L. Test Principle:**

The devices employ lateral flow immunochromatographic technology and are based on the principle of competitive binding. Amphetamine, if present in concentrations below the cutoff level, will not saturate the binding sites of antibody-coated particles in the device. The antibody-coated particles will then be captured by immobilized amphetamine-specific conjugate and a colored line will appear in the test line region. A line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody. Each strip in the device contains a procedural control. Formation of a line in the control line region indicates that the proper volume of urine has been added and membrane wicking has

occurred. If a line does not form in the control region then the test is not valid and users are cautioned to repeat the test. A 'presumptive positive' is determined by the appearance of a procedural control line AND no line appearing next to the test region.

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

1. Analytical performance:

*a. Precision/Reproducibility:*

Drug-free urine was spiked with d-Amphetamine to concentrations of 150, 225, 375, 450, and 600 ng/mL; three lots of test strip and test device were tested in replicates of 10 for three days. Results were read after five minutes as 'positive' or as 'negative'. The tables below summarize the results for both test formats:

**Precision of Three Lots of ACON AMP 300 Test Strip**

AMP Conc (ng/mL)	% Correct Result			
	n	Lot 1	Lot 2	Lot 3
0	30	100	100	100
150	30	100	100	100
225	30	90	90	86.7
375	30	86.7	86.7	83.3
450	30	100	100	100
600	30	100	100	100

**Precision of Three Lots of ACON AMP 300 Test Device**

AMP Conc (ng/mL)	% Correct Result			
	n	Lot 1	Lot 2	Lot 3
0	30	100	100	100
150	30	100	100	100
225	30	83.3	83.3	90
375	30	86.7	83.3	80
450	30	100	100	100
600	30	100	100	100

*b. Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

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

This device has an internal process control. A red line appearing in the control region confirms sufficient sample volume, adequate membrane wicking, and that the correct technique has been used. Users are informed not to interpret the test if a line does not form in the control region.

Control standards are not supplied with this device but the manufacturer recommends the use of commercially available controls. It is good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow all applicable guidelines for testing QC materials.

**d. Detection limit:**

To test the analytical sensitivity of the test, drug-free urine was spiked with d-Amphetamine to concentrations of 150, 225, 300, 375, 450, and 600 ng/mL. Results were read after five minutes as 'positive' or as 'negative'.

**Sensitivity of ACON AMP 300 Test Strip**

AMP Conc (ng/mL)	% of Cutoff	n	Visual Reading		% Correct
			Negative	Positive	
0	0	30	30	0	100
150	-50%	30	30	0	100
225	-25%	30	27	3	90
300	Cutoff	30	13	17	43
375	+25%	30	4	26	87
450	+50%	30	0	30	100
600	+100 %	30	0	30	100

**Sensitivity of ACON AMP 300 Test Device**

AMP Conc (ng/mL)	% of Cutoff	n	Visual Reading		% Correct
			Negative	Positive	
0	0	30	30	0	100
150	-50%	30	30	0	100
225	-25%	30	25	5	83
300	Cutoff	30	16	14	53
375	+25%	30	4	26	87
450	+50%	30	0	30	100
600	+100 %	30	0	30	100

**e. Analytical specificity:**

AMP and its related compounds (listed below) were spiked into drug-free urine at a concentration of 100 ug/mL, then serially diluted and tested with the AMP 300 Test Strip and Test Device until the concentration at which the initial negative result was obtained. The following table lists the lowest concentration which yields a positive result for the compound being tested when read at five minutes. Cross-reactivity was calculated by dividing the concentration at which the compound yielded a positive result by the designated cut-

off concentration. Benzphetamine, Ephedrine, l-Ephedrine, l-Epinephrine, d/l-Epinephrine, d-Methamphetamine, and l-Methamphetamine produced negative results when spiked at 100 ug/mL.

#### **ACON AMP 300 Test: Cross-reactivity of Compounds**

<b>Compound</b>	<b>Concentration (ng/mL)</b>	<b>Cross Reactivity (%)</b>
d-Amphetamine	300	100%
d/l-Amphetamine	390	77%
l-Amphetamine	50,000	0.6%
(±) 3,4 Methylenedioxyamphetamine	1,560	19%
β-Phenylethylamine	100,000	0.3%
Phenylpropanolamine	100,000	0.3%
Tyramine	100,000	0.3%
p-Hydroxynorephedrine	100,000	0.3%
(±) Phenylpropanolamine	100,000	0.3%
p-Hydroxyamphetamine	1,560	19%
d/l-Norephedrine	100,000	0.3%

204 compounds were tested for possible interference with the ACON AMP 300 test strip and test device in drug-free urine, in a urine pool spiked with -50% of the cutoff levels of the drugs of abuse, and in a urine pool spiked with +50% of the cutoff levels of the drugs of abuse. The compounds tested for possible interference are listed in the package insert; no compound caused an incorrect test result in any of the three urine pools or in either device when tested at 100 ug/mL.

A drug-free urine pool was aliquoted so the pH could be adjusted to a range of 5 to 9 in 1 pH unit increments; three of the four aliquots at each pH were spiked with a drug to -50%, +50%, and +100% of the cutoff concentration. The spiked, pH-adjusted urine was tested in duplicate with the AMP 300 Test Strip and the Test Device. Altering the pH of the urine sample did not affect the expected results of any of the tests.

Fifteen (15) urine samples of specific gravity ranging from 1.004 to 1.034 were aliquoted into four samples each; one sample remained neat while the other three aliquots were spiked with each drug to the concentration of -50%, +50%, and +100% of the cutoff respectively. Each sample was tested in duplicate with the AMP 300 Test Strip and the Test Device. Variations in specific gravity did not affect the expected results of any of the tests.

**f. Assay cut-off:**

The identified cutoff concentration is lower than that recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA); the current recommended cutoff is 1000 ng/mL. The test will yield a positive result when a given drug exceeds 300 ng/mL in the urine sample. Analytical performance of the device around the cutoff is described in Section M.1.d above.

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

Urine samples were collected from presumed non-user volunteers and known positive specimens were obtained from several clinical laboratories. Drug positive samples and about 10% of the negative samples were confirmed by GC/MS or HPLC. Specimens were coded, randomized, and blinded for side-by-side comparisons between ACON AMP 300 Test Strip, ACON AMP 300 Test Device, and the Predicate. The results are shown in the tables below:

**Comparison of ACON AMP 300 Test Strip and the Predicate**

		Predicate	
		Pos	Neg
ACON AMP 300 Test Strip	Pos	127	0
	Neg	0	173

Positive agreement: 100%

Negative agreement: 100%

Overall agreement: 100%

**Comparison of ACON AMP 300 Test Device and the Predicate**

		Predicate	
		Pos	Neg
ACON AMP 300 Test Device	Pos	127	0
	Neg	0	173

Positive agreement: 100%

Negative agreement: 100%

Overall agreement: 100%

Test results above were compared to their known GC/MS results in the tables below. Samples were considered positive if they were at or higher than the cutoff of 300 ng/mL.

**Comparison of ACON AMP 300 Test Strip to GC/MS Results**

		Specimen Cutoff Range by GC/MS Data					% Agreement
		Negative	< -25% Cutoff	- 25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
AMP 300 Test Strip	+	0	1	1	2	123	100
	-	150	18	5	0	0	99

### Comparison of ACON AMP 300 Test Device to GC/MS Results

		Specimen Cutoff Range by GC/MS Data					% Agreement
		Negative	< -25% Cutoff	- 25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
AMP 300 Test Device	+	0	1	1	2	123	100
	-	150	18	5	0	0	99

Comparison of the predicate to GC/MS results yielded similar results (positive agreement 100%, negative agreement 99%). Eight of the samples (2.7%) were  $\pm 25\%$  of the cutoff; 25 (8.3%) of the samples were  $\pm 50\%$  of the cutoff.

**b. Matrix comparison:**

Not applicable; this device is only for use with urine samples.

**3. Clinical studies:**

**a. Clinical sensitivity:**

The device's reproducibility in the hands of professional users was tested at three doctor's office sites. A registered medical assistant at each site tested urine that was spiked with drug at the following concentrations: 0, -50% of the cutoff concentration, -25% cutoff, +25% cutoff, and +50% cutoff. Ninety blinded and randomized specimens were tested at each site, which included 15 samples for each of the five drug levels and 15 samples that generated invalid results. A total of 45 samples were tested for each level of drug.

### Summary of POL Study Results: ACON AMP 300 Test Strip

AMP Conc (ng/mL)	% Cutoff Conc	n	# Neg	# Pos	% Correct
0	0	45	45	0	100
150	- 50%	45	45	0	100
225	- 25%	45	34	11	76
375	+ 25%	45	4	41	91
450	+ 50%	45	0	45	100
Total		225	128	97	
Overall agreement of Test Strip Results with expected results: 210/225 = 93%					

**Summary of POL Study Results: ACON AMP 300 Test Device**

<b>AMP Conc (ng/mL)</b>	<b>% Cutoff Conc</b>	<b>n</b>	<b># Neg</b>	<b># Pos</b>	<b>% Correct</b>
<b>0</b>	0	45	45	0	100
<b>150</b>	- 50%	45	45	0	100
<b>225</b>	- 25%	45	34	11	76
<b>375</b>	+ 25%	45	4	41	91
<b>450</b>	+ 50%	45	0	45	100
<b>Total</b>		<b>225</b>	<b>128</b>	<b>97</b>	
Overall agreement of Test Device with expected results: $210/225 = 93\%$					

***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:**

Not applicable.

**N. Conclusion:**

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