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

A. 510(k) Number:
k050593

B. Purpose for Submission:
New product

C. Measurand:
Barbiturates

D. Type of Test:
Qualitative lateral flow immunochromatographic test

E. Applicant:
ACON Laboratories

F. Proprietary and Established Names:
ACON BAR II One Step Barbiturate Test Strip
ACON BAR II One Step Barbiturate Test Device

G. Regulatory Information:
1. Regulation section:
   21 CFR §862.3150: Test System, Barbiturate
2. Classification:
   Class II
3. Product code:
   DIS
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 BAR II One Step Barbiturates Test Strip and the ACON BAR II One Step Barbiturates Test Device are rapid chromatographic immunoassays for the qualitative detection of Barbiturates levels in urine at a designated cutoff concentration of 300 ng/mL (Secobarbital). They are intended for healthcare professionals including professionals at point-of-care sites.

   This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods.

   Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used."

3. Special conditions for use statement(s):
See above.
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 BAR II One Step Barbiturate 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):
ACON BAR One Step Barbiturates Test Strip and Test Device
2. Predicate 510(k) number(s):
k012824
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, manufacturer, and test time. The tests use a different antibody-antigen system which, in turn, affects the cross-reactivity and interference of the assay.

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. Barbiturates, 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 barbiturates-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. <u>Analytical performance:</u>

      a. Precision/Reproducibility:

      Drug-free urine was spiked with secobarbital to concentrations of 150, 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 BAR II Test Strip

BAR Conc (ng/mL)	% of Cutoff	% Correct		
		Lot 1	Lot 2	Lot 3
0	n/a	100	100	100
150	-50 %	100	100	100
450	+50 %	100	100	100
600	+100 %	100	100	100

Precision of Three Lots of ACON BAR II Test Device

BAR Conc (ng/mL)	% of Cutoff	% Correct		
		Lot 1	Lot 2	Lot 3
0	n/a	100	100	100
150	-50 %	100	100	100
450	+50 %	100	100	100
600	+100 %	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 methods):

      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:

      See Assay Cutoff section below.

e. *Analytical specificity:*
A wide variety of compounds (n=251, see package insert for a complete list) at 100 ug/mL were tested in drug-free urine and secobarbital positive urine and showed no cross-reactivity.

f. *Assay cut-off:*
To test the analytical sensitivity of the test around the claimed cutoff concentration, drug-free urine was spiked with secobarbital to concentrations of 150, 225, 300, 375, 450, and 600 ng/mL. Thirty tests were tested from three lots (n=90 total). Results were read after five minutes as 'positive' or as 'negative' and are shown below as the average of the three lots.

Sensitivity of ACON BAR II Test Strip: average lot performance

BAR 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	15	15	50
375	+25%	30	5	25	83
450	+50%	30	0	30	100
600	+100 %	30	0	30	100

Sensitivity of ACON BAR II Test Device: average lot performance

BAR II 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	26	3	87
300	Cutoff	30	16	14	47
375	+25%	30	5	25	83
450	+50%	30	0	30	100
600	+100 %	30	0	30	100

2. Comparison studies:
a. *Method comparison with predicate device:*
Urine samples (n=300) 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 BAR II Test Strip, ACON BAR II Test Device, and the Predicate. The results are shown in the tables below:

Comparison of ACON BAR II Test Strip and the Predicate

		Predicate	
		Pos	Neg
ACON BAR II	Pos	120	24
Test Strip	Neg	0	156

Positive agreement: >99%
Negative agreement: 87 %
Overall agreement: 92 %

Comparison of ACON BAR II Test Device and the Predicate

		Predicate	
		Pos	Neg
ACON BAR II	Pos	120	24
Test Device	Neg	0	156

Positive agreement: >99%
Negative agreement: 87 %
Overall agreement: 92 %

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 BAR II Test Strip to GC/MS Results

		Specimen Cutoff Range by GC/MS Data					
		Negative	< -25% Cutoff	- 25% to Cutoff	Cutoff to +25%	> +25% Cutoff	% Agreement
BAR II Test Strip	+	0	1	2	9	132	99
	-	149	0	6	0	1	98

Comparison of ACON BAR II Test Device to GC/MS Results

		Specimen Cutoff Range by GC/MS Data					
		Negative	< -25% Cutoff	- 25% to Cutoff	Cutoff to +25%	> +25% Cutoff	% Agreement
BAR II Test Device	+	0	1	2	9	132	99
	-	149	0	6	0	1	98

b. *Matrix comparison:*
Not applicable; this device is only for use with urine samples.

3. Clinical studies:
A study was designed to determine if physician's office and laboratory personnel can perform the ACON BAR II test properly and can interpret test results properly. Eighty samples (40 negative, 40 positive ranging from 310 ng/mL to 23, 960 ng/mL ; 10 samples were ±25% cutoff)) from the method

comparison study above were aliquoted, randomized, and blinded and sent to the POL test site. The samples were tested over several days. Only package inserts were provided ; no training was offered. Results are presented in the table below :

ACON BAR II : Results of POL Study Using Clinical Specimens

Barb Conc by GC/MS (ng/mL)		Strip		Device	
	n =	Positive	Negative	Positive	Negative
225	1	0	1	0	1
230 – 295	3	1	2	1	2
310 – 437	6	5	1	5	1
508 – 23,960	34	34	0	34	0
Negative Samples	36	0	36	0	36
Total	80	40	40	40	40

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:
   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.