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

A. 510(k) Number:

k093879

B. Purpose for Submission:

New Device

C. Measurand:

Saliva Alcohol

D. Type of Test:

Chromogenic assay; semi-quantitative; visually read color change

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

Mission Saliva Alcohol Test Strip

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.3040, Alcohol Test System

2. Classification:

   Class II

3. Product code:

   DIC

4. Panel:

   Toxicology (91)

H. Intended Use:

1. Intended use(s):
   See Indications for use, below.

2. Indication(s) for use:

   The Mission Saliva Alcohol Test Strip is a screening test used to semi-quantitatively measure alcohol in human saliva. The test strip indicates relative Blood Alcohol Concentration (BAC) at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% cut-off levels. Results are used in the diagnosis of alcohol intoxication. For in vitro diagnostic use only.

3. Special conditions for use statement(s):

   The device is for over the counter use

   The assay is a disposable test for one-time-use.

4. Special instrument requirements:

   Mission Saliva Alcohol Test Strip

I. Device Description:

The Mission Saliva Alcohol Test Strip is a visually read semi-quantitative test for the detection of alcohol in saliva. The test strip indicates the relative Blood Alcohol Concentration (BAC) at 5 different cut-off levels (negative, 0.02%, 0.04%, 0.08% and 0.3%). The device consists of a saliva collection cup and test strip (25 each per package). The resultant color on the test strip is compared to the color blocks printed on the pouch.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Saliva Alcohol Test; Enzymatics Inc.

2. Predicate 510(k) number(s):

   k894001

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate device	Predicate device (k894001)
Intended use/indications for use	The Saliva Alcohol Test Strip is a rapid screening test used for measuring alcohol in human saliva. Results are used in the diagnosis of alcohol intoxication.	Same
Methodology	Chromogenic	Same
Enzyme	Alcohol oxidase	Alcohol dehydrogenase
Sample Types	Saliva	Same
Measuring Units	Blood Alcohol Concentration (BAC%)	BAC% and mg/dL
Measuring Range	Negative 0.02% 0.04% 0.08% 0.30%	0.01% to 0.145% (and 10 to 145 mg/dL)
Result	Semi-quantitative	Quantitative
Read Time Window	2 to 3 minutes	2 to 15 minutes

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

- NHTSA/DOT Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, (Federal Register/Vol. 59, No. 147, August 2, 1994/Notices/39382.
- NHTSA/DOT Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, (Federal Register/Vol. 73, No. 62, March 3, 2008/Notices.

L. Test Principle:

The Mission Saliva Alcohol Test Strip is a firm plastic strip with a reagent pad attached at the tip that contains tetramethylbenzidine, alcohol oxidase, and peroxidase. The test is based on two coupled enzymatic reactions. In the first reaction step ethanol in the sample is oxidized to aldehyde by alcohol oxidase. The second step uses the enzyme peroxidase to catalyze the oxidation of TMB, a color indicator substrate. The color change corresponds to the amount of alcohol present. The results are read by comparing the color of the test with the color chart printed on the pouch.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Negative saliva samples were collected from three volunteers who provided the sample for each day of testing. Each volunteer was instructed to abstain from consuming alcohol for 24 hours and not to smoke or consume any food or drink 15 minutes prior to sample collection. The alcohol test solutions were prepared from a stock solution containing ethanol standards in an aqueous solution (from Sigma) diluted to each of the four cut off levels and within +/- 60% of each cut off**.** The concentration of the alcohol in the solution was confirmed on the Roche C501 using alcohol test reagent ETOH Gen. 2. The test strip was saturated with each sample and allowed to stand for 2 min and was then compared to the color chart. A total of 20 replicates were tested for over the course of three days. Three test strip lots were tested by 3 technicians, 10 replicates of which were tested on day 1 and the 5 replicates on days 2 and 3 for a total of 60 tests per concentration.

The study results demonstrated 100% correct results rate, see table below:

Cutoff	BAC	Lot	N	Result from Lay-user compared to color block					
				Neg	0.02	0.04	0.08	0.3	% Correct Results
Neg	**0.0%**	1	20	20	0	0	0	0	100%
		2	20	20	0	0	0	0	100%
		3	20	20	0	0	0	0	100%
-60% cutoff	0.008%	1	20	20	0	0	0	0	100%
		2	20	20	0	0	0	0	100%
		3	20	20	0	0	0	0	100%
Cutoff	**0.02%**	1	20	0	20	0	0	0	100%
		2	20	0	20	0	0	0	100%
		3	20	0	20	0	0	0	100%
+60% cutoff	0.032%	1	20	0	0	20	0	0	100%
		2	20	0	0	20	0	0	100%
		3	20	0	0	20	0	0	100%
-60% cutoff	0.016%	1	20	0	20	0	0	0	100%
		2	20	0	20	0	0	0	100%
		3	20	0	20	0	0	0	100%
Cutoff	**0.04%**	1	20	0	0	20	0	0	100%
		2	20	0	0	20	0	0	100%
		3	20	0	0	20	0	0	100%
		1	20	0	0	20	0	0	100%

+60% cutoff	0.064%	2	20	0	0	20	0	0	100%
		3	20	0	0	20	0	0	100%
-60% cutoff	0.032%	1	20	0	0	20	0	0	100%
		2	20	0	0	20	0	0	100%
		3	20	0	0	20	0	0	100%
Cutoff	**0.08%**	1	20	0	0	0	20	0	100%
		2	20	0	0	0	20	0	100%
		3	20	0	0	0	20	0	100%
+60% cutoff	0.128%	1	20	0	0	0	20	0	100%
		2	20	0	0	0	20	0	100%
		3	20	0	0	0	20	0	100%
-60% cutoff	0.120%	1	20	0	0	0	20	0	100%
		2	20	0	0	0	20	0	100%
		3	20	0	0	0	20	0	100%
Cutoff	**0.3%**	1	20	0	0	0	0	20	100%
		2	20	0	0	0	0	20	100%
		3	20	0	0	0	0	20	100%
+60% cutoff	0.480%	1	20	0	0	0	0	20	100%
		2	20	0	0	0	0	20	100%
		3	20	0	0	0	0	20	100%

b. Linearity/assay reportable range:

Not applicable. The assay is semi-quantitative and does not report a numerical concentration.

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

Each lot of test strips is verified during manufacturing by using control solutions that have been prepared from purchased ethanol solutions that are confirmed using a chemistry analyzer. The control results from the test strips are read visually by comparing to the color chart and then the color intensity verified using a spectrophotometer. New lots are also visually checked in comparison to the previously released lot.

The sponsor performed a study to determine the storage conditions for the saliva samples. Samples were prepared from a pool of negative saliva samples collected from alcohol-free volunteers and by adding ethanol from a stock solution to obtain 0.02% and 0.08% ethanol. Each samples was divided into 12 aliquots and stored at room temperature (15-25°C) and refrigerated (2-8°C) ranging from 1 to 24 hours. An aliquot of each sample was tested immediately to serve as the 0 hour time point. A total of 20 replicates were tested for each concentration at each temperature at each time point.

The results support the claims in the labeling that the samples can be stored for up to 4 hours at room temperature (15-25°C) or up to 8 hours refrigerated (2-8°C).

d. Detection limit:

The sponsor performed a study where 20 negative saliva samples obtained from 20 non-alcoholic volunteers were tested. Each volunteer collected their own saliva and read the results on the test strip. A total of 20 replicates were tested for each sample using three lots of test strips. The same tests were also read by a laboratory technician. The results demonstrated that 100% of the negative samples were correctly identified, therefore demonstrating that this device had no false positives in this study.

e. Analytical specificity:

The sponsor performed the following studies to evaluate the effect of cigarette smoke, volatile substances, lighting and temperature on the results of the test.

Cigarette smoke:
The effect of cigarette smoke on the Mission Saliva Alcohol Test Strip was evaluated by selecting 10 volunteers, 5 of which were not alcohol drinkers and 5 who were designated alcohol-drinkers. On the day of testing each participant was smoked ½ to 1 cigarette then provided saliva samples at 1 minute and 15 minutes after smoking. For the alcohol drinking participants, saliva samples were also collected and tested 15 minutes after alcohol consumption and prior to smoking. The non-alcohol drinkers collected saliva from the alcohol drinking participants and performed the test in 5 replicates at each time point. The same tests were also read by a laboratory technician for comparison. Additionally, the technician also checked that BAC level of each alcohol-drinker using the Alco-Sensor IV at each time point. Results from the lay-users are as follows:

ID	Alco-Sensor IV	Time after smoking	Result compared to color block					
			Neg	0.02	0.04	0.08	0.3	% Correct Results
1	0.070%	Before	0	0	0	5	0	100%
	0.076%	<1 min	0	0	0	5	0	100%
	0.085%	15 min	0	0	0	5	0	100%
2	0.072%	Before	0	0	0	5	0	100%
	0.065%	<1 min	0	0	0	5	0	100%
	0.035%	15 min	0	0	5	0	0	100%
3	0.065%	Before	0	0	0	5	0	100%
	0.062%	<1 min	0	0	0	5	0	100%
	0.083%	15 min	0	0	0	5	0	100%

4	0.110%	Before	0	0	0	5	0	100%
	0.095%	<1 min	0	0	0	5	0	100%
	0.091%	15 min	0	0	0	5	0	100%
5	0.025%	Before	0	5	0	0	0	100%
	0.022%	<1 min	0	5	0	0	0	100%
	0.019%	15 min	0	5	0	0	0	100%

Results demonstrate a 100% correct call rate for non-alcohol drinkers 15 min after smoking. False positive results were obtained when the test was performed less than 1 minute following smoking. The package insert contains the limitation that the user is instructed to wait 20 minutes after smoking before performing the test.

Temperature:
The effect of temperature on the Mission Saliva Alcohol Test Strip was evaluated using alcohol-free saliva from volunteers and control solutions prepared at each cutoff level and at +/-60% of each cut off level tested at six different temperature conditions: 2-8, 10, 15, 27, 30, and 40°C. The concentration of the alcohol in the prepared solution was confirmed using the Roche C501 chemistry analyzer. All samples and test strips were placed at different temperatures and allowed to equilibrate for 2 hours prior to testing. The test pad of each strip was saturated with each sample and allowed to stand for 2 minutes prior to reading the result. A total of 20 replicates were tested for each sample at each temperature.

There were no deviations from the expected results for temperatures between 15 and 40°C. The labeling instructs the user to bring all test items to room temperature for 15 minutes before use.

Lighting:
The effect of different lighting conditions on the Mission Saliva Alcohol Test was evaluated using alcohol-free saliva and control solutions prepared at each cut off level and at +/-60% of each cut off level and tested under five lighting conditions: daylight, incandescent, fluorescent, mercury vapor, sodium vapor. The negative samples were prepared from a pool of alcohol-free saliva samples collected form five volunteers. An alcohol control solution was used to obtain the desired alcohol concentrations. The solutions with different concentrations were randomly labeled and tested. A total of 20 replicates for each sample were tested by technicians, with 5 replicates per lighting condition. Results are provided in the following table:

Cutoff	Alcohol %	Light	Result compared to color chart				
			Neg	0.02	0.04	0.08	0.3
		Daylight	20	0	0	0	0
		Mercury Vapor	20	0	0	0	0

Neg	Neg	Incandescent	20	0	0	0	0
		Fluorescent	20	0	0	0	0
		Sodium Vapor	20	0	0	0	0
-60% cutoff	0.008%	Daylight	20	0	0	0	0
		Mercury Vapor	20	0	0	0	0
		Incandescent	20	0	0	0	0
		Fluorescent	20	0	0	0	0
		Sodium Vapor	20	0	0	0	0
Cutoff	**0.02%**	Daylight	0	20	0	0	0
		Mercury Vapor	0	20	0	0	0
		Incandescent	0	20	0	0	0
		Fluorescent	0	20	0	0	0
		Sodium Vapor	0	20	0	0	0
+60% cutoff	0.032%	Daylight	0	0	20	0	0
		Mercury Vapor	0	0	20	0	0
		Incandescent	0	0	20	0	0
		Fluorescent	0	0	20	0	0
		Sodium Vapor	0	0	20	0	0
-60% cutoff	0.016%	Daylight	0	20	0	0	0
		Mercury Vapor	0	20	0	0	0
		Incandescent	0	20	0	0	0
		Fluorescent	0	20	0	0	0
		Sodium Vapor	0	20	0	0	0
Cutoff	**0.04%**	Daylight	0	0	20	0	0
		Mercury Vapor	0	0	20	0	0
		Incandescent	0	0	20	0	0
		Fluorescent	0	0	20	0	0
		Sodium Vapor	0	0	**10**	**10**	0
+60% cutoff	0.064%	Daylight	0	0	20	0	0
		Mercury Vapor	0	0	20	0	0
		Incandescent	0	0	20	0	0
		Fluorescent	0	0	20	0	0
		Sodium Vapor	0	0	0	**20**	0
-60% cutoff	0.032%	Daylight	0	0	20	0	0
		Mercury Vapor	0	0	20	0	0
		Incandescent	0	0	20	0	0
		Fluorescent	0	0	20	0	0
		Sodium Vapor	0	0	20	0	0
Cutoff	**0.08%**	Daylight	0	0	0	20	0
		Mercury Vapor	0	0	0	20	0
		Incandescent	0	0	0	20	0
		Fluorescent	0	0	0	20	0
		Sodium Vapor	0	0	0	20	0
		Daylight	0	0	0	20	0

+60% cutoff	0.128%	Mercury Vapor	0	0	0	20	0
		Incandescent	0	0	0	20	0
		Fluorescent	0	0	0	20	0
		Sodium Vapor	0	0	0	20	0
-60% cutoff	0.120%	Daylight	0	0	0	20	0
		Mercury Vapor	0	0	0	20	0
		Incandescent	0	0	0	20	0
		Fluorescent	0	0	0	20	0
		Sodium Vapor	0	0	0	20	0
Cutoff	**0.3%**	Daylight	0	0	0	0	20
		Mercury Vapor	0	0	0	0	20
		Incandescent	0	0	0	0	20
		Fluorescent	0	0	0	0	20
		Sodium Vapor	0	0	0	0	20
+60% cutoff	0.480%	Daylight	0	0	0	0	20
		Mercury Vapor	0	0	0	0	20
		Incandescent	0	0	0	0	20
		Fluorescent	0	0	0	0	20
		Sodium Vapor	0	0	0	0	20

The study demonstrates a 100% agreement with the expected results for all lighting conditions except sodium vapor. The labeling contains a limitation to not read the test under streetlights as sodium vapor from streetlights can cause colors to appear differently and cause false results.

The effect of different lighting conditions on the Mission Saliva Alcohol Test was also tested by ten volunteers who performed the test under the five lighting conditions (daylight, incandescent, fluorescent, mercury vapor, sodium vapor) using negative saliva samples and saliva containing 0.008% and 0.032%. The samples were prepared from a pool of negative saliva samples collected from five non-alcoholic volunteers. The volunteers was instructed to abstain form consuming alcohol for 24 hours and not to smoke or consume any food or drink 15 minutes prior to sample collection. The alcohol test solutions were prepared form a stock solution. Each of the volunteers performed the test according to the package insert under each lighting condition. Each volunteer tested each sample using 20 strips for a total of 200 readings for each lighting condition using three lots of test strips. The results of this study demonstrated that the volunteers were able to obtain the correct result using the device under the different lighting conditions.

Interfering Substances:
The effect of common food and products on the Mission Saliva Alcohol Test Strip was evaluated by selecting 10 volunteers, 5 of which were not alcohol drinkers and 5 who were designated alcohol-drinkers. On the day of testing each participant consumed one piece of chewing gum, mouth wash, one spray

of breath spray, and cough syrup and then provided saliva samples at 1 minute and 15 minutes after consumption. For the alcohol drinking participants, saliva samples were also collected and tested 15 minutes after alcohol consumption and prior to consumption of the substances listed above. The non-alcohol drinkers collected saliva from themselves and the alcohol drinking participants and performed the test in 5 replicates at each time point. Additionally, the technician also checked that BAC level of each alcohol-drinker using the Alco-Sensor IV at each time point.

Results from these studies demonstrated a 100% correct call rate with the samples from the non-alcohol drinkers and alcohol-drinkers at the 15 minute time point. The results at the <1 min time point demonstrated interference from chewing gum, mouth wash, cough syrup, and breath spray. The labeling states that the user should wait 20 minutes after using over-the-counter products, eating, smoking, or chewing gum before testing. Such items may cause false positive results.

Volatile Substances:
The effect of volatile substances on the Mission Saliva Alcohol Test Strip was evaluated by spiking negative saliva samples from 5 alcohol-free volunteers with the following volatile substances: acetone, 2-butanol, 1-butanol, glycerol, isopropanol and methanol at an initial concentration of 1.0%. A total of 20 replicates were tested for each substance. Volatile substances at 1.0% resulting in a positive result were further diluted to determine the lowest level at which the correct result is found. The substances were also tested for each cut off level and at +/-60% of each cut off. Substances at 1.0% resulting in a positive result were diluted further tested to determine the lowest level at which a correct result was found. The conclusion from these studies is that the Mission Saliva Alcohol Test Strip will generate positive results in the presence of methanol at 0.01% and 1-butanol at 0.1% whereas substances at the following concentrations, which are included in the labeling, do not interfere with the testing results at each of the cut off levels:

Substance	Concentration at which no interference was observed
1-Butanol	0.05%
Methanol	0.0001%
2-Butanol	1.00%
Acetone	1.00%
Glycerol	1.00%
Isopropanol	1.00%

f. Assay cut-off:

The device will produce a different color from light blue/green to dark blue at

the following cut-offs: Negative, 0.02, 0.04, 0.08 and 0.3% BAC.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a consumer study comparing the Mission Saliva Alcohol test to results from the Alco-Sensor IV (Intoximeters Inc.) which is an alcohol breath test which is listed on the NHTSA/DOT Conforming Products List for Evidential Breath Testing Devices. After reading the package insert 32 participants, designated as the alcohol-drinkers, and 32 non-alcohol drinkers provided their own saliva to Mission saliva alcohol test strips. The participants designated as the non-alcohol drinker and a technician then performed the test using the alcohol-drinker's saliva. The technician also performed the breath alcohol test using the Alco-Sensor IV. The studies were performed under regular incandescent light with a total of 296 test strips used for the study. The process was repeated approximately every 15 minutes for a total of 4 times, therefore each participant provided 4 saliva samples and 4 breath samples for a total of 128 saliva samples for the study. After the study the participants completed a questionnaire regarding the ease of use and interpretation of results.

The sponsor performed a separate study with 41 non-alcohol drinkers who performed the Mission Saliva Test with their own saliva. Technicians also tested the saliva and breath from the participants using the Mission Saliva Test and Alco-Sensor IV, respectively. In this study 100% of the results were negative using the Mission Saliva Test and correlated with 0.0% results from the Alco-Sensor IV. The results are complied and presented in the following table:

The results obtained by the lay-user compared to the Alco-Sensor IV readings are presented in the following table:

	Alco-Sensor Concentration (%)							
Mission Saliva Result	0.0	0.007 to 0.015	0.016 to 0.026	0.026 to 0.04	0.041 to 0.05	0.051 to 0.07	0.071 to 0.085	0.086 to 0.116
Neg	41	6	1	0	0	0	0	0
0.02	0	12	18	7	3	0	0	0
0.04	0	0	0	13	17	11	0	0
0.08	0	0	0	0	3	19	7	6
0.3	0	0	0	0	0	0	0	0

b. Matrix comparison:

Not Applicable, saliva is the only indicated matrix.

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):

Reading Time Study:
The effect of various reading times on the Mission Saliva Alcohol Test Strip were evaluated using negative saliva samples and saliva spiked with control solutions to obtain alcohol concentrations at each cut off and at +/-60% of each cut off. The test pad for each strip was saturated with sample and read at 2, 3, 4, and 5 minutes. A total of 20 replicates were tested for each read time for each sample.

The results support the suggested read time of 2 to 3 minutes in the labeling. The labeling states that the test should not be read after 3 minutes.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable. Alcohol should not be detectable by this device in the saliva of individuals who have not consumed alcohol.

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.