

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

A. 510(k) Number:

k121247

B. Purpose for Submission:

New Device

C. Measurand:

Saliva Alcohol

D. Type of Test:

Chromogenic, semi-quantitative, visually read color change

E. Applicant:

Chematics Inc.

F. Proprietary and Established Names:

ALCO-SCREEN[®] Saliva Alcohol Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIC	II	Alcohol Test System 21 CFR 862.3040	Toxicology (91)

H. Intended Use:

1. Intended use(s):

Please see indications for use below.

2. Indication(s) for use:

ALCO-SCREEN[®] Saliva Alcohol Test is a semi-quantitative screening test used to estimate the Blood Alcohol Concentration (BAC) using human saliva. The test strip estimates BAC at the 0.00%, 0.02%, 0.04%, 0.08% and 0.3% levels. Results are used in the diagnosis of alcohol use or intoxication.

For in vitro diagnostic use.

3. Special conditions for use statement(s):

Over the counter use

4. Special instrument requirements:

None – each device is single use and self-contained

I. Device Description:

ALCO-SCREEN Saliva Alcohol Test 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 (0.00%, 0.02%, 0.04%, 0.08% and 0.3%). The device consists of a box of 24 individually packaged single test strips each designed for single use,, and instructions for use. The resultant color on the test strip is compared to the color blocks and BAC percentages printed on the test package.

The active reagents in the enzymatic solution include: alcohol oxidase enzyme from yeast, peroxidase enzyme from horseradish, and tetramethylbenzidine.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Mission Saliva Alcohol Test Strip

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

k093879

3. Comparison with predicate:

	Alco-Screen [®] Saliva Alcohol Test (Candidate Device)	Mission Saliva Alcohol Test Strip (Predicate Device, k093879)
Similarities		
Indications for use	ALCO-SCREEN [®] Saliva Alcohol Test is a semi-quantitative screening test used to estimate the Blood Alcohol Concentration (BAC) using human saliva. The test strip estimates BAC at the 0.00%, 0.02%, 0.04%, 0.08% and 0.3% levels. Results are used to diagnose alcohol use or intoxication. For in vitro diagnostic use.	Same
Concentrations	0.00%, 0.02%, 0.04%, 0.08%, and 0.30%	Same
Interpretation	Visual color change	Same
Reading Time	2 minutes	Same
Calibration	None required	Same
Differences		
Technological Characteristics	Chromogenic reaction	Chromogenic reaction
Enzyme Used	alcohol oxidase	alcohol dehydrogenase
Measuring Units	BAC%	BAC% (and mg/dL)
Shelf Life	12 months at 10-27°C (50-80°F)	Same at 2-27°C (36-81°F)

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

None were referenced.

L. Test Principle:

The ALCO-SCREEN[®] Saliva Alcohol Test consists of a plastic strip with a containing alcohol oxidase on the tip. On contact with saliva a pair of coupled enzymatic reactions that catalyze the oxidation of tetramethylbenzidine in the presence of short-chain, linear aliphatic alcohols such as methanol or ethanol will take place. A semi-quantitative estimation of blood alcohol concentration (BAC) can be made at 5 different cut-off levels (negative, 0.02%, 0.04%, 0.08% and 0.3%) by comparing the resultant color on the test strip to a color chart printed on the foil package.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Device precision was evaluated by reading standards prepared by volumetric ethanol addition to saliva to concentrations corresponding to 0, 0.002, 0.004, 0.008, 0.012, 0.016, 0.02, 0.04, 0.032, 0.064, 0.08, 0.120, 0.128 0.30 and 0.480 % ethanol. Three lots of test strips were used, with 20 replicates from each lot read over 3 days. The alcohol concentrations were confirmed with a commercially available enzymatic NAD-ADH reagent kit. The strips were read by untrained volunteers (lay-users). Samples were presented blindly from each of the fifteen saliva alcohol standards and were randomly presented for testing. The results are presented in the tables below:

Percent Decision Level	Ethanol Concentration %	Lot	Readings	Negative	Combined Lay-User Alco-Screen [®] Results			
					0.02	0.04	0.08	0.3
Negative	0.000%	1	60	60	0	0	0	0
		2	60	60	0	0	0	0
		3	60	60	0	0	0	0
0.002%	0.002%	1	60	60	0	0	0	0
		2	60	60	0	0	0	0
		3	60	60	0	0	0	0
0.004%	0.004%	1	60	60	0	0	0	0
		2	60	60	0	0	0	0
		3	60	60	0	0	0	0
0.008%	0.008%	1	60	53	7	0	0	0
		2	60	58	2	0	0	0
		3	60	56	4	0	0	0
0.012%	0.012%	1	60	0	60	0	0	0
		2	60	0	60	0	0	0
		3	60	0	60	0	0	0
-60%	0.008%	1	60	53	7	0	0	0
		2	60	58	2	0	0	0
		3	60	56	4	0	0	0
Cutoff	0.020%	1	60	0	60	0	0	0
		2	60	0	58	2	0	0
		3	60	0	55	5	0	0

+60%	0.032%	1	60	0	11	49	0	0
		2	60	0	6	54	0	0
		3	60	0	7	53	0	0
-60%	0.016%	1	60	0	60	0	0	0
		2	60	0	60	0	0	0
		3	60	0	60	0	0	0
Cutoff	0.040%	1	60	0	3	56	1	0
		2	60	0	2	57	1	0
		3	60	0	1	59	0	0
+60%	0.064%	1	60	0	0	7	53	0
		2	60	0	0	4	56	0
		3	60	0	0	3	57	0
-60%	0.032%	1	60	0	11	49	0	0
		2	60	0	6	54	0	0
		3	60	0	7	53	0	0
Cutoff	0.080%	1	60	0	0	5	55	0
		2	60	0	0	3	57	0
		3	60	0	0	4	56	0
+60%	0.128%	1	60	0	0	0	59	1
		2	60	0	0	0	56	4
		3	60	0	0	0	57	3
-60%	0.120%	1	60	0	0	0	57	3
		2	60	0	0	0	60	0
		3	60	0	0	0	59	1
Cutoff	0.300%	1	60	0	0	0	0	60
		2	60	0	0	0	0	60
		3	60	0	0	0	0	60
+60%	0.480%	1	60	0	0	0	0	60
		2	60	0	0	0	0	60
		3	60	0	0	0	0	60

b. Linearity/assay reportable range:

Not applicable. The device 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

previously cleared enzymatic NAD-ADH Reagent kit. 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.

The sponsor states the shelf-life of the device is 12 months. Shelf-life stability protocols and acceptance criteria were reviewed and deemed acceptable.

d. Detection limit:

As part of the precision study, the sponsor analyzed 180 “zero” concentration samples using three strip lots. No false positives were observed.

e. Analytical specificity:

The sponsor performed studies to evaluate the effect of substances which may be present in the saliva sample as well as a range of lighting and temperature conditions.

Substances that are consumed or used orally:

The sponsor evaluated the effect of cigarette smoke, chewing tobacco, mouthwash, chewing gum, cough syrup and breath spray on the assay. For each potential interferent, samples were collected from ten volunteers, of which five were drinkers and five were non-drinkers. Results were read at 1 minute and 15 minutes after consumption or use of the potential interferents. Samples were read by trained technicians. There were no false positives or false negatives when samples were read at 15 minutes after use or consumption of the potential interferent. False positives were observed for cigarette smoke, chewing tobacco, and alcohol containing mouthwash, breath spray and cough syrup when read at one minute. The labeling specifies that users should not consume anything or have anything in the mouth for at least fifteen minutes prior to use.

Volatile Substances:

The sponsor conducted a study to assess the potential for positive or negative interference from volatile substances. The volatile substance was spiked into alcohol-free saliva samples and samples with alcohol concentrations of 0.008, 0.016, 0.02, 0.04, 0.032, 0.064, 0.08, 0.120, 0.128 0.30 and 0.480 % BAC. No interference was seen for acetone, 2-butanol, glycerol, isopropanol, or methanol at the concentrations listed below.

Volatile Substance	Concentration at which no interference was observed
Acetone	1.2%
1-Butanol	0.0006%
2-Butanol	1.0%
Glycerol	1.2%
Isopropanol	0.6%

Methanol	0.0003%
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Those substances and their concentrations are documented in the Package Insert.

Temperature:

The effect of temperature on the Alco-Screen[®] Saliva Alcohol Test was evaluated using alcohol-free saliva from volunteers and control solutions prepared at concentration levels of 0%, -60%, 100% and +60% of the 0.02%, 0.04%, 0.08% and 0.3% BAC tested at 2 different temperature conditions: 10 and 40°C. The concentration of the alcohol in the prepared solution was confirmed using an enzymatic NAD-ADH reagent supplied by Pointe Scientific. 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 was no additional variability due to the different temperatures tested. The labeling instructs the user to bring all test items to room temperature before use.

Lighting:

The effect of lighting on the device was evaluated by reading known spiked alcohol concentrations in daylight, under fluorescent, incandescent, sodium vapor and mercury vapor lighting. The study used three lots of strips. Twenty replicates were tested for each of the standards (0%, 0.008, 0.016, 0.020, 0.032, 0.04%, 0.064, 0.08, 0.0120, 0.128, 0.300 and 0.480% BAC) under each of five different lighting conditions using the standard test procedure. The strips were read by trained technicians. There were no deviations from the expected results using daylight, under fluorescent and incandescent lighting. When Alco-Screen[®] was evaluated under mercury vapor lighting some interpretation variation was found, but the results were within one color block of the actual sample concentration. Under the sodium vapor lighting for the negative and 0.008% sample, the undeveloped reactive chemical stripe was more evident as noted by the trained technician. In the hands of an untrained user, this may be erroneously identified as a positive signal. The labeling for the Alco-Screen instructs the user not to read the test results under mercury or sodium vapor light. The labeling also states that the test should not be interpreted by persons who are color-blind or visually impaired.

f. Assay cut-off:

Each device provides cutoffs at 0.02%, 0.04%, 0.08%, and 0.30% BAC.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a consumer study comparing the Alco-Screen device 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. The study was performed at 3 sites. After reading the package insert forty two volunteers, designated as the testing volunteers performed the Alco-Screen test on forty three participants (32 drinkers and 11 non-alcohol drinkers). Results were interpreted by the testing volunteers (lay user). The trained facilitators also performed the breath alcohol test on the participants using the Alco-Sensor IV. The studies were performed with a total of 210 test strips used for the study. Results obtained by the lay-user compared to Alco-Sensor IV are provided below:

Alco-Screen Result	Reference Concentration - %BAC (Alco-Sensor IV)				
	0.0	>0.0 to 0.030	0.031 to 0.060	0.061 to 0.190	>0.191
Negative	50	1			
0.02		39	2		
0.04		5	51	4	
0.08			6	40	
0.30				3	9

b. Matrix comparison:

Not applicable. The device can only be used to test saliva samples.

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 Alco-Screen Saliva Alcohol Test were evaluated using negative saliva samples and saliva spiked with control solutions to obtain alcohol concentrations at the cut off and at +/-60% of the cut off for each of the color blocks. The test pad for each strip was saturated with sample and read at 2 and 2 ½ minutes. A total of 20 replicates were tested for each read time for each sample.

The results support the suggested read time of 2 minutes. The labeling states that the test results must be interpreted 2 minutes after sample application, and no longer than 2 ½ minutes after sample application.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Using these types of devices, alcohol is not detectable in the saliva of persons who have not ingested 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.