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

A. 510(k) Number:

k111206

B. Purpose for Submission:

New device

C. Measurand:

Saliva Alcohol

D. Type of Test:

Semi-quantitative, chromogenic, visually read color change

E. Applicant:

Teco Diagnostics

F. Proprietary and Established Names:

Teco Saliva Alcohol Test

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):

   Refer to Indications for Use below

2. Indication(s) for use:

   The Teco Alcohol Saliva Test is a screening test for the semi-quantitative detection of the presence of ethyl alcohol in human saliva. The test strip indicates relative Blood Alcohol Concentrations (BAC) at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% cut-off levels. Results are used for the diagnosis of alcohol intoxication. The test is intended for both prescription and over-the-counter in vitro diagnostic use. The assay is a disposable test for one-time use.

3. Special conditions for use statement(s):

   The device is single use and disposable

4. Special instrument requirements:

   None – each device is single use and self-contained

I. Device Description:

The Saliva Alcohol Reagent Strips consist of an alcohol reagent pad affixed onto a firm plastic strip. Cutoffs available are 0.00, 0.02, 0.04, 0.08, and 0.3% BAC. There will be one test strip packaged into one foil pouch.

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:

Similarities		
Item	Device	Predicate
Intended use/indications for	Same	The Saliva Alcohol Test is a rapid screening test used for measuring alcohol in

Similarities		
Item	Device	Predicate
use		human saliva. Results are used in the diagnosis of alcohol intoxication.
Methodology	Same	Chromogenic; Coupled enzymatic reactions using alcohol oxidase on ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB).
Enzyme	Same	Alcohol Oxidase
Sample Type	Same	Saliva
Cutoffs	Same	Negative 0.02% 0.04% 0.08% 0.30%
Result	Same	Semi-quantitative

Differences		
Item	Device	Predicate
Read Time Window	2 minutes	2 – 3 minutes

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

ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

L. Test Principle:

The test principle of the strip is based on coupled enzymatic reactions that take place on the pad to visualize the BAC. The first reaction is an oxidation reaction where the ethanol in the saliva is coupled with alcohol oxidase and converted into an aldehyde and peroxide. In the second reaction, tetramethylbenzidine (TMB) is oxidized with the peroxide from the first reaction, with peroxidase acting as the catalyst. TMB is the color indicator substrate, and the degree of color change corresponds to the amount of ethanol present in the saliva.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The imprecision of the device was evaluated by reading known spiked alcohol concentrations on three lots of strips, with 20 replicates from each lot and read over 3 days. The alcohol concentrations were confirmed with a clinical chemistry analyzer. The strips were read by trained technicians under

fluorescent light. There were no deviations from the expected results.

Cutoff	BAC	Lot	N	Result from color block				
				Neg	0.02	0.04	0.08	0.3
Neg	**0.0%**	1	20	20	0	0	0	0
		2	20	20	0	0	0	0
		3	20	20	0	0	0	0
Cutoff 1 -60%	0.008%	1	20	20	0	0	0	0
		2	20	20	0	0	0	0
		3	20	20	0	0	0	0
Cutoff 1	**0.02%**	1	20	0	20	0	0	0
		2	20	0	20	0	0	0
		3	20	0	20	0	0	0
Cutoff 1 +60%	0.032%	1	20	0	0	20	0	0
		2	20	0	0	20	0	0
		3	20	0	0	20	0	0
Cutoff 2 -60%	0.016%	1	20	0	20	0	0	0
		2	20	0	20	0	0	0
		3	20	0	20	0	0	0
Cutoff 2	**0.04%**	1	20	0	0	20	0	0
		2	20	0	0	20	0	0
		3	20	0	0	20	0	0
Cutoff 2 +60%	0.064%	1	20	0	0	0	20	0
		2	20	0	0	0	20	0
		3	20	0	0	0	20	0
Cutoff 3 -60%	0.032%	1	20	0	0	20	0	0
		2	20	0	0	20	0	0
		3	20	0	0	20	0	0
Cutoff 3	**0.08%**	1	20	0	0	0	20	0
		2	20	0	0	0	20	0
		3	20	0	0	0	20	0
Cutoff 3 +60%	0.128%	1	20	0	0	0	0	20
		2	20	0	0	0	0	20
		3	20	0	0	0	0	20
Cutoff 4 -60%	0.120%	1	20	0	0	0	20	0
		2	20	0	0	0	20	0
		3	20	0	0	0	20	0
Cutoff 4	**0.3%**	1	20	0	0	0	0	20
		2	20	0	0	0	0	20
		3	20	0	0	0	0	20
Cutoff 4 +60%	0.480%	1	20	0	0	0	0	20
		2	20	0	0	0	0	20
		3	20	0	0	0	0	20

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):*

The sponsor states that the cutoffs are verified during manufacturing using ethanol solutions with known concentrations verified by a clinical chemistry analyzer.

The sponsor provided results from an accelerated stability study to verify the claimed shelf life of 18 months for the strips when stored at 2 – 8^{o} C. The protocol and acceptance criteria were reviewed and found to be acceptable. Real-time stability studies are ongoing.

d. *Detection limit:*

To assess the possibility of false positives, the sponsor performed a study analyzing alcohol-free (0% BAC) saliva samples. Each of 10 samples was analyzed 10 times for a total n of 100. There were no false positives observed when measuring zero concentration samples.

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 10 minutes after consumption or use of the potential interferents. Samples were read by untrained laypersons. There were no false positives or false negatives when samples were read at 10 minutes after use or consumption of the potential interferent. False positives were observed for cigarette smoke, chewing tobacco, and mouthwash when read at one minute. The labeling specifies that users should not consume anything or have anything in the mouth for at least ten 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 0.02, 0.04, 0.08, and 0.30 % BAC. No interference was seen for acetone, 2-butanol, glycerol, or isopropanol at the concentrations listed below.

Volatile Substance	Concentration at which no interference was observed
Acetone	1.000%
2-Butanol	1.000%
Glycerol	1.000%
Isopropanol	1.000%

Methanol was found to cause positive interference at a concentration as low as 0.001 %. The Limitations section of the labeling states that the assay is for the detection of ethanol and that other alcohols may cause positive results if present in the saliva sample.

Temperature:

The effect of temperature on the device was evaluated by reading known spiked alcohol concentrations at 2-8°C, 27°C, and 40°C on three lots of strips, with 5 replicates from each lot and read over 3 days. The strips were read by trained technicians under fluorescent light. There were no deviations from the expected results.

Cutoff	**BAC %**	Temp (°C)	Lot	N	Neg	0.02	0.04	0.08	0.3
Neg	**0.0%**	2-8°C	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		27 °C	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		40 °C	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
	0.008%	2-8°C	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		27 °C	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		40 °C	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0

Cutoff	**BAC %**	Temp (°C)	Lot	N	Neg	0.02	0.04	0.08	0.3
	0.016%	2-8 °C	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		27 °C	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		40 °C	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
Cutoff 1	**0.02%**	2-8 °C	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		27 °C	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		40 °C	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
	0.032%	2-8 °C	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		27 °C	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		40 °C	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
Cutoff 2	**0.04%**	2-8 °C	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		27 °C	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		40 °C	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
	0.064%	2-8 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		27 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		40 °C	1	5	0	0	0	5	0

Cutoff	**BAC %**	Temp (°C)	Lot	N	Neg	0.02	0.04	0.08	0.3
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
Cutoff 3	**0.08%**	2-8 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		27 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		40 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
	0.120%	2-8 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		27 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		40 °C	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0

	0.128%	2-8 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		27 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		40 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
Cutoff 4	**0.30%**	2-8 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		27 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		40 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
	0.480%	2-8 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		27 °C	1	5	0	0	0	0	5

			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		40 °C	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5

Lighting:

The effect of lighting on the device was evaluated by reading known spiked alcohol concentrations in daylight, and under fluorescent, incandescent, and mercury vapor lighting, The study used three lots of strips, with 5 replicates from each lot and read over 3 days. The strips were read by trained technicians. There were no deviations from the expected results.

Cutoff	BAC %	Lighting Source	Lot	N	Neg	0.02	0.04	0.08	0.3
Neg	**0.0%**	Daylight	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		Fluorescent	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		Incandescent	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		Mercury Vapor	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
-60% Cutoff 1	0.008%	Daylight	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		Fluorescent	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		Incandescent	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
		Mercury Vapor	1	5	5	0	0	0	0
			2	5	5	0	0	0	0
			3	5	5	0	0	0	0
-60% Cutoff	0.016%	Daylight	1	5	0	5	0	0	0
			2	5	0	5	0	0	0

			3	5	0	5	0	0	0
		Fluorescent	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		Incandescent	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		Mercury Vapor	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0

Cutoff 1	**0.02%**	Daylight	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		Fluorescent	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		Incandescent	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
		Mercury Vapor	1	5	0	5	0	0	0
			2	5	0	5	0	0	0
			3	5	0	5	0	0	0
+60% Cutoff 1	0.032%	Daylight	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Fluorescent	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Incandescent	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Mercury Vapor	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
Cutoff 2	**0.04%**	Daylight	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Fluorescent	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Incandescent	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Mercury	1	5	0	0	5	0	0

		Vapor	2	5	0	0	5	0	0
			3	5	0	0	5	0	0
+60% Cutoff 2	0.064%	Daylight	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Fluorescent	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Incandescent	1	5	0	0	5	0	0
			2	5	0	0	5	0	0
			3	5	0	0	5	0	0
		Mercury Vapor	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
Cutoff 3	**0.08%**	Daylight	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Fluorescent	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Incandescent	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
-60% Cutoff 4	0.120%	Daylight	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Fluorescent	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Incandescent	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Mercury Vapor	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
+60% Cutoff 3	0.128%	Daylight	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Fluorescent	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Incandescent	1	5	0	0	0	5	0
			2	5	0	0	0	5	0
			3	5	0	0	0	5	0
		Mercury	1	5	0	0	0	0	5

		Vapor	2	5	0	0	0	0	5
			3	5	0	0	0	0	5
+60% Cutoff 4	0.480%	Daylight	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		Fluorescent	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		Incandescent	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		Mercury Vapor	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
Cutoff 4	**0.30%**	Daylight	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		Fluorescent	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		Incandescent	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5
		Mercury Vapor	1	5	0	0	0	0	5
			2	5	0	0	0	0	5
			3	5	0	0	0	0	5

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 their device to results from the predicate Mission Saliva Alcohol Test Strip.

The study included 25 participants designated as the alcohol-drinkers and 25 naïve non-alcohol drinkers designated as the readers. Each drinker provided a negative saliva sample and then consumed varying amounts of alcohol after which saliva samples were tested at 10 minute intervals for a total of 6 samples per drinker. A total of 20 additional samples were spiked with alcohol to achieve concentrations > 0.08% BAC. Therefore a total of 195 strips were read for this

study. All of the reacted strips were randomized and blinded before being presented to the readers. After the study the participants completed a questionnaire regarding the ease of use and interpretation of results.

Results are summarized in the table below:

Mission Results / Teco Results (new device)	Neg	0.02	0.04	0.08	0.30
Neg	49	2	0	0	0
0.02	2	54	3	0	0
0.04	0	3	49	1	0
0.08	0	0	1	11	0
0.30	0	0	0	0	20
% Agreement (complete match)	96%	92%	92%	92%	100%
% Agreement (+/- one color block)	100%	100%	100%	100%	100%

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):

Not applicable

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.