

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

A. 510(k) Number:

k082080

B. Purpose for Submission:

New device

C. Measurand:

Breath alcohol

D. Type of Test:

Qualitative

E. Applicant:

Alcotest Quebec

F. Proprietary and Established Names:

Alco Tube Plus Alcohol Detector

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJZ	Class I, reserved	862.3050	91, Toxicology

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The Alco Tube Plus Alcohol Detector is an *in vitro* medical device to qualitatively detect the presence of alcohol in the human breath. It is a disposable screening device for one-time use. The detector is available in two cut-offs including 0.05 and 0.08 percent breath alcohol. The device is used only as a

screening device and is only an indication of the possible presence of alcohol in the blood of the test subject.

3. Special conditions for use statement(s):

For over the counter use

4. Special instrument requirements:

Not applicable

I. Device Description:

The Alcotest Quebec Alco Tube Plus Alcohol Detector is a visually read qualitative test for the presence of alcohol in breath. It consists of a glass tube containing yellow indicator crystals. The user is instructed to activate the device by pressing firmly on either end of the plastic tube, and then to blow continuously for 12 seconds into the device. A red indicator dot turns white when a sufficient sample has been provided. Users are then instructed that their blood alcohol concentration (BAC) is greater than the cutoff of the tester if the crystals have changed from yellow to green and extend beyond a black indicator line on the tester. The testers are available at cutoffs of 0.05 and 0.08% BAC.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Akers Biosciences Inc. BreathScan Alcohol Detectors

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

k060761

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Target population	Same	Over the counter
Calibration	Same	Not required
Assay type	Same	Qualitative with visual interpretation
Blowing time	Same	12 seconds

Differences		
Item	Device	Predicate
Number of cutoffs	Two (0.05 and 0.08%)	Four (0.02, 0.04, 0.08, and 0.08%)
Length	10 cm	7 cm
Weight	7 grams	2 grams

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

None referenced

L. Test Principle:

The yellow indicator crystals inside the tube are coated with potassium dichromate and sulfuric acid. In the presence of alcohol, the crystals change color from yellow to green as the alcohol vapors are oxidized to acetic acid and chromium sulfate is produced. The reagents in the tester are adjusted such that the majority of the crystals change color at the designated cutoff.

M. Performance Characteristics (if/when applicable):

In lieu of testing by the National Highway Traffic Safety Administration (NHTSA) (Department of Transportation (DOT)), the sponsor performed their own testing following the NHTSA guidelines.

1. Analytical performance:

a. *Precision/Reproducibility:*

Test samples were prepared using a Breath Alcohol Sample Simulator (BASS), which provided alcohol-in-air test samples with known concentrations.

The testers were read by ten individuals under five different lighting sources (fluorescent, daylight, incandescent, sodium vapor, mercury vapor) using 60 randomized pre-reacted testers.

Results were as follows:

	Concentration tested	0.05% BAC cutoff (# with expected result/total)	0.08% BAC cutoff (# with expected result/total)
Fluorescent	0.00	200/200	200/200
	-60% of cutoff	200/200	200/200
	+60% of cutoff	200/200	200/200
Daylight	0.00	200/200	200/200
	-60% of cutoff	200/200	200/200
	+60% of cutoff	200/200	200/200
Incandescent	0.00	200/200	200/200
	-60% of cutoff	200/200	200/200
	+60% of cutoff	200/200	200/200
Sodium Vapor	0.00	200/200	200/200
	-60% of cutoff	200/200	200/200
	+60% of cutoff	200/200	200/200
Mercury Vapor	0.00	200/200	200/200
	-60% of cutoff	200/200	200/200
	+60% of cutoff	200/200	200/200

b. Linearity/assay reportable range:

Not applicable. This assay is a qualitative assay.

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

The device is traceable to commercially available certified alcohol reference solutions at 100, 80, and 50 mg%.

d. Detection limit:

The NHTSA guidelines do not specifically address the detection limit of breath alcohol devices but require testing at a % BAC of zero (blank reading) to assess the possibility of false positives. The sponsor included zero concentration samples in their precision study above. Non-alcoholic human breath was used as the sample. All of the devices produced the expected result.

e. Analytical specificity:

The sponsor performed the following studies for both cut-off concentrations (0.05 and 0.08% BAC) to evaluate the potential effect of cigarette smoke, temperature and vibration.

Cigarette smoke - Five trials at 0.000 BAC were conducted. An alcohol-free

person who smokes cigarettes performed the test. The subject smoked approximately one half of a cigarette and then tested their breath using the Alco Tube Plus. This was then repeated to produce a total of five trials. No false positive results were obtained under these conditions.

Temperature - The effect of temperature at 15° and 40° C (59° and 104° F) was assessed. Forty (40) different devices were assessed at each temperature for each cut-off. Twenty samples that were 60% below the device cut-off and twenty samples that were 60 % above the cut-off were tested. There were no deviations from the expected results.

Vibration - Forty 0.05% and forty 0.08% devices were mounted on a shake table and vibrated. After vibration, 20 tests at 60% below the cut-off and 20 tests at 60% above the cutoff were performed for each tester. There were no deviations from the expected results.

f. Assay cut-off:

The stated cutoffs are 0.05 and 0.08% BAC.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a consumer study comparing an Alco Tube Plus at a cutoff of 0.05% and 0.08% BAC to a quantitative comparator device (the Alco-Sensor IV). The purpose of the study was to determine if consumers could correctly perform and interpret the test according to the package insert. There were 20 paired volunteers (drinker, non-drinker) who participated in the

study which was conducted over two days. There were 12 males and 8 females and the reported age range was from 19 to 64 years of age. The non-drinker administered the test to the drinker using both the 0.05 and 0.08 testers and then read the results. The drinker then provided another breath sample which was analyzed using the quantitative device operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.03 to 0.155% by the quantitative device. A total of 400 comparisons were performed with the following results:

0.05 tester result (n=200)	Quantitative Results			
	Less than cutoff – 60% (< 0.02%)	Near cutoff negative (0.02 – 0.05%)	Near cutoff positive (> 0.05 – 0.083%)	Greater than cutoff + 60% (> 0.083)
Positive	0	0	70	21
Negative	80	29	0	0

0.08 tester result (n=200)	Quantitative Results			
	Less than cutoff – 60% (< 0.02%)	Near cutoff negative (0.02 – 0.05%)	Near cutoff positive (> 0.05 – 0.083%)	Greater than cutoff + 60% (> 0.083)
Positive	0	0	70	21
Negative	80	29	0	0

b. Matrix comparison:

Not applicable. This device is for one sample 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):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

For this type of device, alcohol should not be detectable in the breath 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.