



Effectiveness of the
Dry-veControl[®] Saliva Alcohol Test as a
Screen for the Presence of Alcohol in Blood

Introduction

The immediate determination of inappropriate alcohol consumption has become increasingly important in many situations involving mental health, occupational safety, educational and law enforcement personnel. Traditionally, screening of individuals for alcohol consumption often requires expensive equipment, trained operators and invasive or semi-invasive sample collection techniques, often under sub-optimal conditions. A more valuable screening method for alcohol ingestion must be simple to use and interpret, be minimally invasive, and provide highly reliable results with minimal or no special knowledge or training required of the individual administering the test.

The **Dry-veControl**[®] saliva alcohol test is intended as a simple, inexpensive, non-invasive method for objective determination of alcohol ingestion. It is a dipstick style test device that uses saliva as the test specimen. In the absence of alcohol, the reagent pad remains an off-white colour, indicating a negative result. In the presence of alcohol, the reagent pad at the tip of the dipstick will change to a green or blue colour within two minutes of application of the test specimen, thereby indicating a positive result. The intensity of the green or blue colour can be used to obtain a rough approximation of the relative blood alcohol concentration by comparison with a colour chart. If a situation requires an evidentiary blood alcohol concentration using standard methodologies should be performed.

Objective

The intent of this study is to evaluate the effectiveness of the **Dry-veControl**[®] saliva alcohol test when used by both a professional medical technologist and an untrained lay person as an objective determinant for the alcohol ingestion and the presence of a measurable blood alcohol concentration as quantitated using a standardized gas headspace chromatography as a reference methodology.

Materials and Methods

The **Dry-veControl**[®] salival alcohol test has been used for many years in a variety of fields to screen for unauthorized or inappropriate alcohol consumption. To quantify its utility in this qualitative screening application, a field study was performed in January 1994 to measure the accuracy and effectiveness of the **Dry-veControl**[®] in distinguishing between individuals with positive blood alcohol concentrations and individuals with no alcohol present in their blood.

Two hundred and thirty male and female volunteers with informed consent, self-administered the **Dry-veControl**[®] saliva alcohol test according to the standard procedure:

1. abstain from placing anything in the mouth of the individual to be tested for at least fifteen (15) minutes prior to beginning the test. This includes alcoholic and non-alcoholic drinks, tobacco products, coffee, breath mints, food, etc.
2. open the foil package and remove the test strip for a cream or off-white colour.
3. saturate the reagent pad with saliva from mouth or sputum cup. Immediately start a timer.
4. at two (2) minutes, observe for a colour change on the reagent pad. A green or blue colour indicates the presence of alcohol and a positive result. A reagent pad that remains colourless indicates the absence of alcohol and a negative result. Results obtained after 2 minutes and 30 seconds may be erroneous.
5. an approximation of blood alcohol concentration may be obtained by comparison of the developed reagent pad with the colour chart included with the test.

Dry-veControl[®] test results were evaluated for positive indication of the presence of alcohol by both the lay volunteer and a professional medical technologist familiar with the test, each observing for a green or blue colour change in the reagent pad of each test strip. Absence of a colour change was classified as a negative for the presence of alcohol. The results for both the laboratory professional and the lay person were compared to those obtained by the reference gas chromatography method. Results obtained by the professional were also compared with self-interpreted results obtained by the layperson.

Samples of the whole blood from fingerstick were collected within 5 minutes of administration of the test to be used for determination of blood alcohol concentration by the reference method. Reference values for blood alcohol concentrations (g / dL) were measured by whole blood head space gas chromatography using a Hewlett Packard (HP) Model 5890 equipped with a flame ionization detector and HP 530 series megabore capillary chromatographic column (50% phenyl methyl silicone; 1.0µm film thickness; 30 m x 0.53 mm) along with a HP model 3393A integrator.

GC operating conditions:

Oven temperature, 35°C; injection temperature, 150°C; detector temperature, 200°C; Hydrogen flow rate, 3 mL/min; carrier gas, nitrogen; column flow rate, 4 mL/min; make-up flow rate, 26 mL/min, column head pressure, 2.7 psig; septum purge, 2 mL/min, total flow, 67.5 mL/min;

Reagents:

Sigma Diagnostics aqueous ethanol standards, 0.0 g/dL, 0.1 g/dL and 0.30 g/dL. Internal standard; n-propanol, analytical grade, saturated with NaCl at a concentration of 40mg/dL (0.04%).

Reference Method Procedure:

A sample of whole blood from fingerstick was collected, within 5 minutes of administration of the saliva test into 1.5ml microfuge tubes containing heparin to prevent clotting and sodium fluoride to inhibit metabolism of alcohol.

Samples and calibration standards were prepared by pipetting 200 µl of standard or sample (whole blood) into a 20 ml glass vial. 800 µl of internal standard was added to the vial and a rubber septum quickly crimped into place over the opening of the vial. The contents were then mixed by inversion. Sealed vials containing calibration standards and volunteer samples were allowed to equilibrate for a minimum of 2 hours at 8°C. For analysis, 20 µl of headspace gas was injected into the GC, within 2 minutes of removal of sample from refrigerator, with care taken to prevent warming of sample vial prior to sampling. Headspace was sampled using a calibrated gas tight volumetric syringe pipette.

Results

The study sample consisted of 230 **Dry-veControl**[®] saliva alcohol dipstick test readings for comparison with 230 blood alcohol concentrations as determined by GC headspace assay. Results were categorized as positive or negative according to the following criteria.

Method

	Dry-veControl [®] Saliva Dipstick	Reference Method GC Headspace Assay
Positive Result	Appearance of any green or blue colour in reagent pad at 2 minutes	Assay result greater than 0 g / dL
Negative Result	No colour change in reagent pad at 2 minutes	Assay result of 0 g/ dL

Alcohol was found to be present (positive) in the blood samples from 176 individuals using the GC reference method. 51 blood samples were found to be free of alcohol (negative) by the reference method. Positive blood alcohol concentrations as measured by the reference method ranged from a minimum of 0.009 g / dL to a maximum of 0.092 g / dL. Interpretation of **Dry-veControl**[®] results as positive or negative by the layperson (self-test) and the professional reader produced matching results on 100% of the tests interpreted. The study population included 45 women and 185 men. The following 2X2 table was constructed to evaluate and categorize the results¹.

		GC REFERENCE RESULT	
		Positive Result	Negative Result
Dry-veControl®	Positive Result	176	8
	Negative Result	3	43

The above table illustrates strong agreement between qualitative results obtained using the Dry-veControl® saliva alcohol test and results obtained using the GC reference method. Using a standard for positive as being any blood alcohol concentration greater than zero, the Dry-veControl® demonstrated the following measures of screening effectiveness.

n	230
Sensitivity	0,983
Specificity	0,843
Positive Predictive Value	0,956
Negative Predictive Value	0,935
Accuracy	0,952

Discussion

It has been long established that the concentration of alcohol in saliva is comparable to that in blood^{2,3,4,5}. The Dry-veControl® dipstick is a simple, inexpensive colorimetric test used to detect the presence of alcohol in saliva. An approximation of blood alcohol concentration may be obtained by comparison of the developed colour with a colour chart. However, definitive diagnosis of relative alcohol intoxication requires confirmatory breath or blood alcohol concentrations by standard methodologies. Dry-veControl® utilizes a highly sensitive enzymatic methodology that has been previously described⁶. In addition to ethanol, the Dry-veControl® detection method is also sensitive to the presence of methanol. Care must be taken when administering the test to ensure the absence of alcohol vapors in the air, a condition that can be present in certain settings due to the ubiquitous presence of alcohol in many laboratories, cleaning solutions, deodorizers and disinfectants.

The **Dry-veControl**[®] test comes conveniently packaged in individual pouches each containing one test. The tests are stored at room temperature not to exceed 27°C. The tests may also be stored refrigerated. The **Dry-veControl**[®] test is extremely easy to use, is non-invasive and is suitable for use by untrained individuals. Timing steps include abstinence in placing anything in the mouth by the test subject for 15 minutes prior to administration of the test, along with a 2-minute incubation period following the wetting of the reagent pad with saliva, prior to interpreting the results.

Conclusions

This study demonstrates the usefulness of **Dry-veControl**[®] for purposes of screening for the presence of alcohol in blood indicating alcohol ingestion. **Dry-veControl**[®] is highly effective as an objective determinant for alcohol ingestion as demonstrated by an accuracy of greater than 95 percent in correctly identifying the presence or absence of measurable alcohol in the blood. It has been shown to be highly sensitive having lower detection limit of less than 0.009 g / dL. There were 3 false negatives in the study sample of 230 test interpretations (1.3 %). **Dry-veControl**[®] is somewhat less specific, exhibiting 8 false positives from 230 interpretations (3,5%). Therefore a positive **Dry-veControl**[®] result is somewhat less useful than a negative result.

By virtue of its simplicity in both the procedure for use and the qualitative colorimetric interpretation method, **Dry-veControl**[®] is suitable as a hometest. Qualitative test results interpreted by untrained lay test subjects agreed with results interpreted by a trained medical technologist, 100 percent of the time.

References

1. Ingelfinger, J. A., Mosteller, F., Thibodeau, L. A. and Ware, J. H. Biostatistics in Clinical Medicine, New York: Macmillan Publishing Co., Inc., 1983, pp 4-10
2. Blanke, R. V. in Fundamentals of Clinical Chemistry, ed by Tietz, N. W., W. B. Saunder Co., Philadelphia, 1970, p. 1114
3. McCall, K. E. L, Whiting, B., Moore, M. R. & Goldberg, A., CLIN.SCI., 56 283-286, 1979
4. Haeckel, R. and Bucklitsch, I. The Comparability of Ethanol Concentrations in Peripheral Blood and Saliva: The Phenomenon of Variation of Saliva to Blood Concentration Ratios. J. CLIN.CHEM.CLIN.BIOCHEM. 5: 199-204, 1987
5. Jones, A., W., CLIN.CHEM. 25 1394-1398, 1979
6. Bergmeyer, J. U., Grabl, M. & Walter H. in Methods of Enzymatic Analysis, 3rd ed. Vol. II, ed. by Bergmeyer, H. U., Verlag Chemie, Weinheim, 1983, p. 143.