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Selection Criteria for Alcohol Detection Methods

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16. Abstract

The potential need for testing workers in the aviation industry for job-related alcohol abuse requires the development of a testing strategy based, in part, on selection of alcohol test instruments appropriate to the specific goals of the Federal Aviation Administration. The extensive availability of test instruments with varying capabilities and limitations makes selection of alcohol test instruments difficult technologically, with a considerable potential for choosing test instruments of inappropriate character. The considerations outlined herein are intended to assist in the selection process.

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SELECTION CRITERIA FOR ALCOHOL DETECTION METHODS

INTRODUCTION

Analysis of the amount of ethanol a person has consumed can now be provided by an abundance of equipment utilizing several different technologies. Instruments are available to test ethanol content of blood, breath, and/or saliva; among these are fixed-location devices for testing of blood through enzymatic or gas chromatographic analysis and infrared electronic devices for testing of exhaled breath samples. Portable devices are also available for breath and saliva testing; these devices use either electronic technology based on fuel-cell or tin-oxide sensor techniques, enzymatic reactions similar to the fixed blood test method, or chemical analysis based on oxidative reactions between a crystalline medium and the test sample.

Selection of a particular device or technology requires consideration of the performance required of equipment within various domains and the intended environment. Relevant domains of performance criteria include the general, but critical, qualities that all alcohol detection methods should possess, such as high specificity and selectivity. Certain boundary conditions upon which selection of a potential alcohol detection method would be merited include more unique attributes such as portability and cost-per- test. The relative values assigned to the performance domains are also important, since the combination of traits existent for any particular detection method/device being evaluated may create dissonance about its selection. For example, a unique quality such as portability, which may make one method extremely desirable, may also cause that method to be easily rejected because of violation of one of the more essential domains, such as specificity. Thus, the selection of a "method of choice" requires careful analysis of three important factors: 1) the intended situation or purpose, 2) the performance domains that are particularly relevant or irrelevant for that situation or purpose, and 3) how any particular method, or exemplar thereof, fulfills the requirements. Within this context, a schema for selection of an alcohol detection method(s) may be developed.

CRITICAL PERFORMANCE DOMAINS

SPECIFICITY. Alcohol detection methods should measure only the ethanol level *in vivo*, since false positives would likely prejudice any person so labeled. Many substances other than ethanol can produce false positives in certain types of equipment. Among these, naturally occurring aldehydes and ketones are particularly important because of inherently high levels associated with certain medical conditions. Similarly, exposure to compounds found in various industrial environments is also a common source of false positives; included are other alcohols, such as methanol and isopropanol, as well as hydrocarbons and industrial solvents found abundantly in many aviation environments.

The specificity of ethanol detection methods varies greatly; blood test methods provide the greatest confidence. Infrared and fuel-cell electronic methods, as well as enzymatic methods, also enjoy high specificity, although interactions with other

TABLE 1. ALCOHOL DETECTION METHODS SPECIFICITY

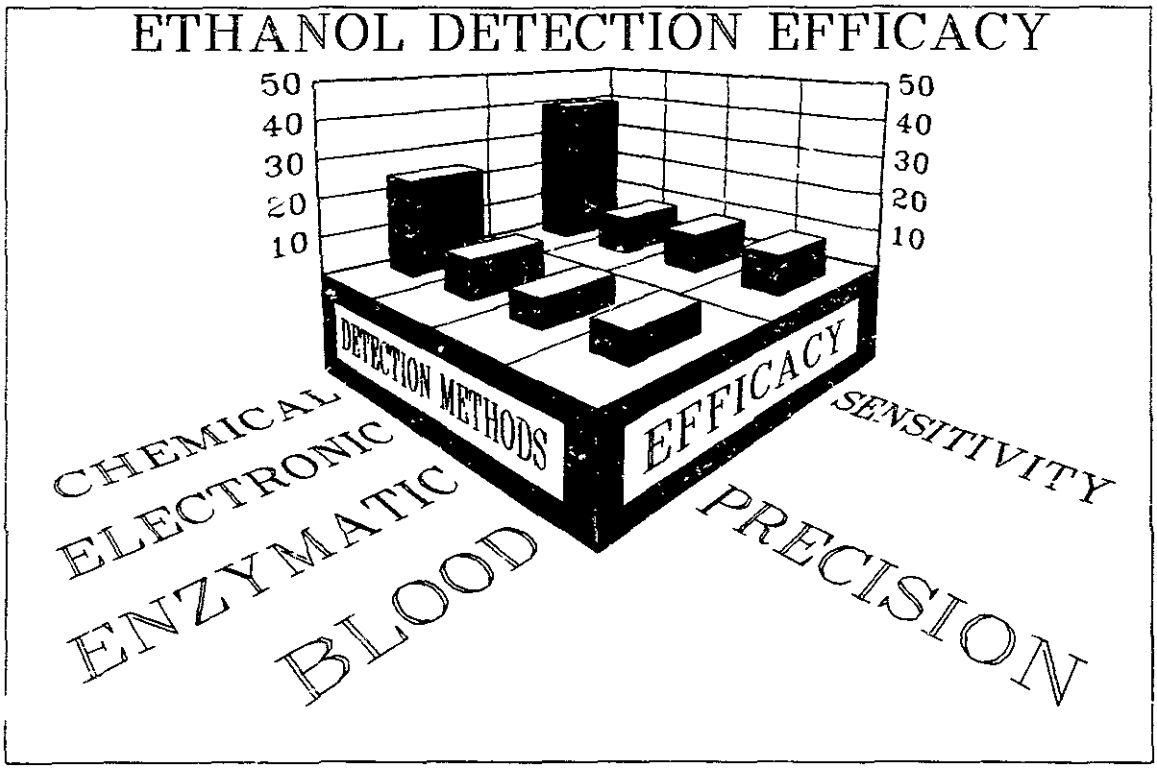
FIXED METHODS	
BLOOD TEST	High specificity. Uses enzymatic reactions or gas chromatographic techniques.
ELECTRONIC (INFRARED)	High specificity. Interactions with other substances have been shown only in the presence of high ethanol.
PORTABLE METHODS	
ENZYMATIC	High specificity. Uses same reactions as blood test.
ELECTRONIC (FUEL CELL)	High specificity. No interactions with substances other than ethanol have been found.
ELECTRONIC (TIN OXIDE)	Low specificity. Reacts with hydrocarbons and other alcohols
CHEMICAL	Low specificity. Reacts with other commonly found aldehydes and ketones, as well as other alcohols .

alcohols have been shown in the presence of high ethanol for the infrared method, and are possible for enzymatic methods. Lower specificity is also seen for the portable chemical methods, all of which use an oxidant such as potassium dichromate which reacts with aldehydes, ketones, and other alcohols. The tin oxide ceramic (Taguchi) electronic sensor reacts indiscriminately with hydrocarbons. Table 1 provides a quick reference for comparisons of specificity.

SENSITIVITY. The minimum quantity of ethanol *in vivo* that alcohol detection equipment can detect accurately varies, although this measure needs to be as exacting as possible. The application of alcohol detection equipment in law enforcement activities requires a minimum quantitative sensitivity of 10 mg% for evidential purposes, as affirmed in many States by the statutory approval of alcohol detection equipment with this level of sensitivity. Methods with less quantitative and/or qualitative sensitivity can only be used forensically to show cause for further analytical testing with more sensitive methods.

Using the most sensitive blood test techniques, some analytical laboratories can measure as little as 2 mg% ethanol, although the average sensitivity is at or near 10 mg%. This is also the average sensitivity level for equipment with infrared and fuel-cell electronic sensors, and the likely level for the portable enzymatic devices, which are new and remain basically unproven. The electronic tin oxide ceramic sensor sensitivity is in the 10 to 15 mg% range; the minimum detectable resolution of portable chemical equipment is in the 20 to 40 mg% range and is generally qualitative in nature. Figure 1 displays information on sensitivity.

PRECISION. The amount (coefficient) of variation in the repeated measurement of a given test sample with a known percentage defines the precision of alcohol detection. In practice, this quality is generally tied closely to sensitivity, reflecting the statistical reliability of the alcohol levels obtained. The coefficient of variation for blood test methods averages about ± 5 mg%; the coefficient of variation for infrared and fuel-cell electronic methods approaches ± 10 mg% (the level of sensitivity).



Detection efficacy shown in mg%· higher #'s = less sensitivity

FIGURE 1: ETHANOL DETECTION EFFICACY

Electronic tin oxide ceramic sensors provide slightly more variable data on ethanol levels than the other electronic methods. As is the case for sensitivity, only qualitative indications of precision are available for portable chemical detection methods; this is also the case for portable enzymatic methods. Figure 1 displays information on precision of alcohol detection methods.

BOUNDARY PERFORMANCE DOMAINS

READINESS. The availability of any method to perform testing upon demand determines whether the method is continually useful. In general, blood test and infrared electronic methods are kept in chronically high states of readiness because of their fixed locations in certified analytical laboratories. The fuel-cell and tin oxide ceramic sensor electronic methods are also ready to use quickly, having solid state circuitry and battery power to provide short warm-up times. Failure of the batteries can be a problem, but some instruments operate on typical 9-volt disposable batteries that can be replaced quickly and without tools. The enzymatic and portable chemical methods are also readily available, unless they become contaminated in some manner, which should be rare with minimum care.

LOCATION/PORTABILITY. The issue of portability forms one of the most important additional qualifications for selection of an ethanol test method. Use in FAA facilities or in the aviation environment precludes the ready availability of a certified analytical laboratory and/or fixed ethanol testing facility, making the blood test and infrared electronic test methods generally untenable. The remaining methods are all portable, although there are differences in weight and size. The electronic (fuel-cell and tin oxide ceramic sensor) methods are generally hand-sized and weigh about one pound; the enzymatic and portable chemical methods are generally about the size and weight of a pencil.

CALIBRATION. The assurance of calibration for alcohol detection equipment determines whether a specific set of test data can be used in the prosecution of a person suspected of using ethanol illegally. Stated recalibration periods are typical for blood test, infrared, electronic fuel-cell and tin oxide ceramic sensor instruments. Instruments used for blood tests typically require more sophisticated and timely calibration procedures, because of their use as general analytical instruments. This contrasts with the lesser need for calibration of infrared and portable electronic devices in which calibration can generally be accomplished easily in the field if a breath alcohol simulator is available. The calibration of enzymatic and portable chemical methods is apparently predetermined and hopefully unnecessary, since no method for verification of calibration of these devices is generally available.

LEGALITY. The evidential status of alcohol detection equipment determines whether ethanol test data can be used in a court of law for prosecution of a person suspected of using ethanol illegally. Blood test methods are the only universal source of evidential data, although several of the electronic test instruments with data archival features have been certified in some states. Among these, infrared test methods have the best status. However, these instruments are typically located in a fixed or mobile certified alcohol testing laboratory. Portable electronic methods, such as the fuel cell and tin oxide sensor devices, are also certified for evidential purposes in some states. In places where they do not enjoy evidential status, they can generally be used to demonstrate cause for further analytical testing. Portable enzymatic methods are currently being tested, but are only certified to show cause for further testing at this time. Portable chemical methods, because of their qualitative nature, may never enjoy evidential status.

OPERATOR STATUS. The qualifications to administer any particular ethanol test method vary widely on educational level, training, and experience. Blood test methods should only be conducted by someone who is thoroughly trained to work in a certified analytical laboratory. Typical qualifications for this type of operator would include a Bachelor of Science degree in chemistry or one of the biological sciences, a one-week course on the operation of the specific instrument to be used, and familiarity with the analytical procedure. The other test methods would require no specific educational criteria, but would require at least a one-day training seminar on the operation, results, and reporting procedures associated with administration of the test. A yearly recurrent training seminar would be advisable for all testing methods.

COST. Blood test instruments and the infrared electronic instruments each cost several thousand dollars per instrument, making the administration of literally thousands of tests necessary to justify the monetary outlay. Similarly, the cost of electronic fuel-cell and tin oxide ceramic sensor instruments is several hundred dollars per instrument,

with a small cost per test ($0.25 to $0.50) necessary to pay for disposable mouthpieces. The unit cost for the enzymatic test instruments is currently $3.00 per test; the cost per test instrument for the typical portable chemical instrument is about $2.00, decreasing to about $1.15 in quantities of 1000 or more. Operator costs are assumed to be equivalent for all portable methods in this analysis.

These costs make the administration of only a few enzymatic and/or portable chemical tests relatively inexpensive, although these methods can only be used once per test instrument. Compared to the portable electronic test methods, the relative cost escalates rapidly with an increase in the number of tests conducted. When the number of tests administered *per portable electronic instrument* reaches about 350, the portable electronic methods achieve the same low cost per test associated with the portable enzymatic and chemical methods. Beyond that number, portable electronic methods gain an ever-increasing cost advantage (Figure 2).

STORAGE. Problems with storage are mainly relevant to portable instruments. Electronic test instruments are essentially impervious to almost any insult, except extreme temperatures and water, and they have an indefinite shelf life. Enzymatic test instruments should also be relatively resistant to insult except water and chemicals, especially if stored in the original sealed packaging. However, puncture of the package makes them suspect, and they have a specified shelf life. Portable chemical instruments are hermetically sealed and resistant to water and chemicals, but they are likely to be susceptible to ultraviolet (UV) light and extreme temperatures.

D.O.T. APPROVAL. Specific test instruments approved to date by the Department of Transportation are based on the National Highway Traffic Safety Administration specifications as published in the *Federal Register* (1); these specifications require prospective test instruments to pass a full range of qualification tests of engineering, construction and performance criteria. A conforming products list has also been published and recently updated in the *Federal Register* (3). Of all the portable instruments available, only electronic test instruments appear on the conforming products

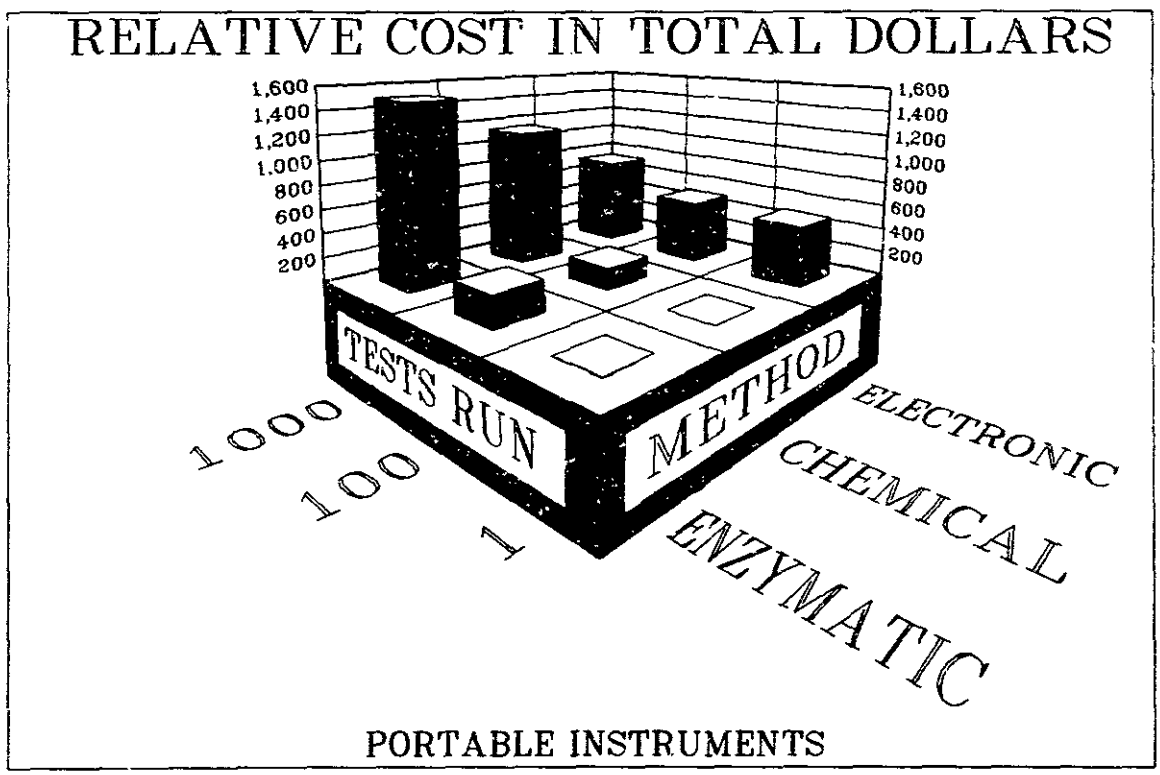


FIGURE 2. COST OF PORTABLE ALCOHOL DETECTION TESTS

list. This fact is grounded in the demonstrated specificity, sensitivity, and precision of the methods.

SELECTION STRATEGY

The degree to which any test method appears desirable should depend primarily on the degree to which it possesses the qualities necessary to perform acceptably in the Critical Performance Domains. These qualities form the basis of whether any test can produce valid data. Certainly specificity, sensitivity, and precision are qualities that would be routinely specified when considering desirable attributes for any test in any situation. Together, these attributes combine to establish the level of confidence that can be assigned to the test data, which is perhaps the most elemental requirement of all.

Appreciation of confidence in the test is basic to the Boundary Performance Domain of *Legality*, a long-standing issue for alcohol testing, and perhaps the most critical boundary issue for the FAA. An important question in this area is whether the ethanol test data will be used in a court of law for prosecution, or merely to determine the status of affected persons in administrative hearings. In either case, however, legal challenges concerning the validity of the test data will likely be forthcoming. It would appear that obtaining the highest quality alcohol test data possible would help guard against improper accusations. This can best be accomplished by using a test method with superior qualities in the Critical Performance Domains.

After assuring that the methods under consideration possess the qualities to meet these requirements, the strategy for selecting a test method(s) must then define which of the Boundary Performance Domains are relevant to the intended purpose. For example, *Portability* would only be relevant for field applications, where no location for a fixed instrument would be likely or desirable, where a single person was responsible for testing large numbers of persons in many locations, or where quick results are needed.

Cost-Per-Test would also be an important consideration. In the case where only one or a few tests would be required, the methods with initial costs of only two or three dollars would be more cost-effective. However, when large numbers of persons are to be tested, or when a single person is responsible for testing persons at many locations, the methods with higher initial cost, but long-term economy, would be preferable.

The question of who would administer such tests must also be studied. For the portable test methods, education and training on specific instruments are not such large considerations, as those instruments can be mastered in about one day. However, a related, and more important concept, is whether someone who has not been educated in forensic methods and the evidential aspects of administering tests and testifying about the results in legal proceedings can be considered competent. This issue impacts the *Legality* domain.

The juxtaposition of these requirements, together with consideration of the degree to which a test method must meet the Critical Performance requirements, forces a path(s) for selection of the test method(s).

In many situations a single method would appear to be the best choice. For example, a fixed-location blood test capability or infrared electronic instrument could be available in a FAA clinic or FAA-approved forensic laboratory; portable instruments of evidential quality could also be given to specially trained inspectors for more widely distributed field applications. In other situations two or more methods might be combined to assure proper testing. This is especially true when a method of lesser stature, such as a portable chemical instrument, is used as a field test, and then must be verified by a more esteemed procedure (e.g., blood test). Such a diversity of test methods application may be necessary for the FAA, which is responsible for regulatory activities in many environments.

Within this context, selection of alcohol test equipment can proceed. First, selection of the test method technology requires comparison of the degree to which the generic qualities of prospective test method technologies meet the requirements of the Critical and Boundary Performance Domains relevant to the environments of usage and goals of the FAA. Assignment of relative values to each performance domain, and analysis of the degree to which each technology performs within the domain, provides comparative ratios of the relative efficacies of alcohol test method technologies. Second, the selection of any particular test instrument within a chosen test methodology can be enhanced by analyzing the degree to which individual instruments exemplify the generic qualities embodied by the test method technology. Comparison of the degree to which the individual attributes for any

instrument compare with those of any other provides ratios of the relative performance efficacies of alcohol test instruments.

The prerequisite for this process, of course, is a thorough identification of the intended purpose and target environment, as well as a thorough understanding of the compliance of alcohol test methods with the relevant Performance Domains. Without such an approach, the selection process may fail to satisfy the necessary requirements and possibly lead to acquisition of test instruments with limited value or excessive costs.

Appendix I provides a comparison of fixed and portable alcohol test methods compliance with the Critical Performance Domains. Appendix II provides a quick reference for comparison of portable alcohol tests methods compliance with both Critical and Boundary Performance Domains. Appendix III provides a complete assessment of both fixed and portable alcohol test methods compliance.

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APPENDIX I

SUGGESTED ORDER OF COMPLIANCE WITH CRITICAL DOMAINS *

FIXED METHODS

1. Blood test methods
2. Electronic infrared methods

PORTABLE METHODS

1. Fuel-cell electronic methods
2. Enzymatic methods
3. Tin oxide ceramin sensor methods
4. Chemical methods

*Order of compliance for boundary domains for portable methods also conforms to this sequence if cost-per-test is figured on a long-term, many-tests-per-instrument basis. See Appendix II.

APPENDIX II

PORTABLE ALCOHOL DETECTION INSTRUMENTS

	ELECTRONIC FUEL CELL	ENZYMATIC	CHEMICAL
SPECIFICITY	High	High	Minimum
SENSITIVITY	~ 10 mg %	~ 10 mg %	> 20 mg %
PRECISION	± 5 mg%	± 5 mg%	Unknown
RELIABILITY	High	High	Medium
LEGALITY	Evidential	Evidential	Cause
CALIBRATION	Verified	Unknown	Unknown
SIZE	Hand	Pencil	Pencil
PORTABILITY	Excellent	Excellent	Excellent
STORAGE	Indefinite	Specified	Indefinite
DOT APPROVED	Yes	No	No
TEST COST: 1	~$ 500.00	~$3.00	~$2.00
TEST COST: 100	~$550.00	~$250.00	~$175.00
TEST COST: 1000	~$750.00	~$1500.00	~$1150.00

APPENDIX III

SUMMARY COMPARISON OF ALCOHOL TESTING METHODS

*(Possibly significant limitations **BOLDED**)*

FIXED TEST METHODS

I. BLOOD TEST:

A. Sensitivity	The lowest valid quantification this type of test can achieve is about 10 mg% (10 mg/dl).
B. Specificity	Highly specific for ethanol; uses alcohol dehydrogenase enzymatic reactions or gas chromatographic techniques.
C. Precision	The average coefficient of variance is abo ± 5 mg%, with some labs much better than others.
D. Operator	Needs BS degree in science, 1 week preliminary training, 6 months experience and certification is desirable. Must work in an analytical lab, and receive a recurrent training seminar yearly.
E. Cost	**Initial instrumentation cost is about $15,000, with an added cost of a few dollars per specimen tested to cover supplies.** Each instrument can be used thousands of times, **making a single test very expensive,** but many tests relatively inexpensive.
F. Legality	This is the most accepted method to provide evidence in the prosecution of a person suspected of using ethanol illegally. The analytical laboratory should have a well-documented quality control and proficiency testing program.
G. Location	**This type of instrumentation should be in a certified analytical laboratory.**
H. Storage	This type of instrumentation should not be stored and should be kept operational at all times.
I. Calibration	**Calibration is required about every six months to maintain certification.**
J. Reliability	This instrumentation is generally reliable.

II. INFRARED ELECTRONIC:

A. Sensitivity	The lowest valid quantification achieved with this type of instrumentation is equivalent to the blood test methods (10 mg%).
B. Specificity	This method is generally impervious to false positives by substances other than ethanol. Only in the presence of **large ethanol levels have interferences been shown.**
C. Precision	The average coefficient of variance obtained with this type of instrumentation approaches that of blood tests at about ± 8 mg%.
D. Operator	Degree is not required, but needs one day of preliminary training in conduct of test and evaluation of results and reporting; yearly recurrent seminar is desirable.
E. Cost	**Initial cost of instrument is about $5000.00,** with less than a dollar required for supplies to support each test. Each instrument can be used thousands of times, **making a single test very expensive,** but many tests inexpensive.
F. Legality	In most states this method has evidential status equivalent to the blood alcohol test, **when calibration and operator competence are assured.**

G. Location	This type of instrumentation should be in a certified breath alcohol testing laboratory.
H. Storage	This type of instrumentation requires no special storage, and is designed for continual operation.
I. Calibration	Demonstration of calibration is required every six months to maintain certification. Actual calibration is rarely necessary, but an internal heat source is required to dry the tested breath sample.
J. Reliability	This instrumentation is extremely reliable.

PORTABLE TEST METHODS

III. ENZYMATIC:

A. Sensitivity	The lowest valid quantification level for this type of test should be about 10 mg%, the same as a blood test.
B. Specificity	Is highly specific for ethanol; uses alcohol dehydrogenase.
C. Precision	The coefficient of variance afforded by this method should equal that of the blood test.
D. Operator	Degree is not required, but needs one hour of preliminary training in conduct of test and evaluation of results and reporting, recurrent one hour seminar is desirable yearly, may administer test in the field.
E. Cost	A single test costs $3.00, with the estimated cost for purchase of 1000 units at about $1500. Each instrument can be used one time, making the administration of many tests very expensive, while a single test is relatively inexpensive.
F. Legality	This method has qualitative reliability for use as evidence in the prosecution of a person suspected of using ethanol illegally. This type of evidence could also be used to show cause for further analytical testing.
G. Location	This type of screening device may be used at any location.
H. Storage	This type of test has a specified shelf life.
I. Calibration	The calibration is set by the manufacturer, with no field calibration practicable.
J. Reliability	This is a new method with face validity and apparent reliability, but it is essentially unproven in portable form.

IV. ELECTRONIC:

FUEL CELL

A. Sensitivity	The lowest valid quantification level obtained with this type of instrumentation is nearly equivalent to the blood test and enzymatic methods (about 10 mg%).
B. Specificity	This method is impervious to false positives by substances other than ethanol.
C. Precision	The coefficient of variance obtained with this type of instrumentation approaches that of blood tests at about ± 8 mg%.
D. Operator	Degree not required, one day preliminary training in conduct of test and evaluation of results and reporting; recurrent seminar desirable yearly.

E. Cost — **Initial cost for the typical portable unit is between $500.00 and $800.00.** For each test conducted, a disposable mouthpiece costing about $0.35 is required. Each instrument can be used hundreds of times, making a single test very expensive, **but many tests very inexpensive.**

F. Legality — In some states this method has evidential status equivalent to the blood alcohol test, **when calibration, operator competence and data archival are assured.** Certain of these portable devices come with printers and/or data storage capability for data archival. Such evidence has been used to show cause for further analytical testing.

G. Location — This type of screening device can be used at any location.

H. Storage — This type of instrument requires no special storage, and is ready for use continually if the batteries are charged.

I. Calibration — Demonstration of calibration is required about every six months to maintain certification. Actual calibration is rarely necessary, but can be done in the field with an ethanol breath simulator.

J. Reliability — This type of instrument is very reliable.

TIN OXIDE CERAMIC (TAGUCHI) SENSOR

A. Sensitivity — The lowest valid quantification achieved by this type of instrumentation is comparable to the other electronic methods (about 15 mg%) .

B. Specificity — **Poor: reacts with hydrocarbons and other alcohols.**

C. Precision — The coefficient of variance obtained with this type of instrumentation is about ± 10 mg%.

D. Operator — Degree not required, one day preliminary training in conduct of test and evaluation of results/reporting, recurrent yearly seminar is desirable.

E. Cost — **Initial cost for the typical portable unit is from about $500.00 to $800.00 each.** For each test, a disposable mouthpiece costing about $0.35 is required. Each device can be used hundreds of times, **making one test highly expensive,** but many tests inexpensive.

F. Legality — **The evidential status of this method is not as complete as the other electronic methods. The lack of specificity renders this evidence more applicable to showing cause for further analytical testing.**

G. Location — This type of screening instrument can be used at any location.

H. Storage — This type of instrument should require no special storage and be ready for use continually.

I. Calibration — Demonstration of calibration is required about every six months to maintain certification. Actual calibration is rarely necessary, but can be done in the field with an ethanol breath simulator.

J. Reliability — This instrumentation is generally reliable.

V. CHEMICAL:

A. Sensitivity — The lowest valid quantification level for a reliable "positive" response is somewhere between 20 to 40 mg%; this type of test works best at high breath alcohol levels.

B. Specificity — **Poor: reacts positively with aldehydes, ketones, and other alcohols.**

C.	Precision	**Qualitative - coefficient of variance depends on integrity of chemicals and color vision of operator. Response is especially difficult to judge at alcohol levels approaching zero.**
D.	Operator	Needs one hour training seminar; must have adequate color vision; normal color vision is desirable.
E.	Cost	**Cost per single sample is about $2.00, with discounting to about $1.15 for purchase of1000 units or more. Each instrument can be used one time, making administration of many tests very costly,** but one test very inexpensive.
F.	Legality	**This test method provides the least valid evidence for use in prosecution of a person suspected of using ethanol illegally;** such evidence has been used to show cause for further analytical testing.
G.	Location	This type of screening device may be used at any location.
H.	Storage	This type of instrument can be stored for an indefinite period in a closed container. **It may be susceptible to high heat and UV light.**
I.	Calibration	**The calibration is set by the manufacturer, with no field calibration practicable.**
J.	Reliability	**Reliability is generally satisfactory, but it depends on the conditions of storage and use. Degradation of the specific instrument and/ or data obtained can occur over time.**

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