Proposed Protocol For New Instrument Evaluation

Washington State Patrol
Breath Test Program

November 2006

A. Introduction

1. Purpose
   a. to evaluate new breath alcohol instrumentation and technology for establishing type approval and possible implementation within Washington State
   b. to develop a forensically sound breath alcohol test program in Washington State centered around an instrument that has been found to be fit-for-purpose
   c. to develop documented evidence having a high degree of assurance that a particular instrument type with perform according to pre-determined specifications and analytical attributes
   d. to provide documented evidence for the validity and subsequent selection of a particular instrument type that has been shown to fit-for-purpose with a high degree of confidence
2. Manufacturers will be asked to come to Seattle and present an overview of their instrument and leave one for evaluation
3. Manufacturers will be provided with a copy of this proposed evaluation protocol
4. The evaluation results will be available to all interested individuals
5. The evaluation is expected to take approximately six months to complete
6. The instruments will be tested together as much as possible in order to minimize any differences due to experimental design, procedure or the use of other equipment.
7. A Datamaster CDM will also be included in the testing protocol.

B. Desirable Instrumental Features

1. Infrared and/or Electrochemical analytical method
2. Data collection
3. Re-cycle tubing for simulator analysis
4. Ability to continue using Guth 2100 digital simulators
   a. minimize length of simulator tubing
   b. ability to heat simulator tubing
   c. future purchase of new instruments must include a Guth

model 2100 simulator
   d. instrument must monitor simulator temperature value
   e. instrument must report simulator temperature on printout
5. Flash EPROM capability
6. External laser printer capability
   a. instrument must be provided with an external laser printer for evaluation purposes
   b. instrument must be capable of using existing external laser printers
   c. future purchase of new instruments must include an external laser printer
7. Adjustable threshold levels for interference detection
8. Data to collect
   a. breath exhalation attempts
   b. breath volume
   c. breath exhalation times
   d. all three digit results
   e. data currently being collected by Washington State
   f. breath exhalation profiles
   g. simulator profiles
   h. allow for the decision not to collect profiles as well
   i. simulator temperature value
9. Independent evaluation of software
   a. possibly by the CMX Group (New Jersey hearing)
10. Short sampling time for simulator control standard
   a. determine the algorithm for simulator sample acceptance
11. No results in the third digit should be suppressed
   a. instrument should record even the noise levels in the third digit (i.e., 0.001, 0.002, etc.)
12. Instrument must be on NHTSA Conforming Products List
13. Instrument should allow for the sequential measuring of a selected number of breath samples from 1 to 20
14. Instrument should allow for the sequential measuring of a selected number of simulator samples from 1 to 20
15. Data should be retained in memory even when a complete and valid test is not accomplished
16. Technician must be able to calibrate
   a. provide full details of calibration procedure and computations involved
17. Determine the analytical range of the instrument
18. Instrument should have the capability of displaying the analytical results or not
19. Instrument should have the capability of retaining and subsequently printing the breath alcohol exhalation profile
   a. either at the time of the test or through data collection
20. Data collection should have the ability to be activated or Suppressed
21. Provide ability to default to field evidentiary settings

Multiple breath test model

Int. Ext. Blk Spl Blk Ext. x10 adjust

No time outs, user cutoff available.

Get list of error codes w/ definitions

22. Provide list of pre-determined error codes
23. Capability for remote communications with the instrument to allow various diagnostic testing
24. Ability to download data to a jump drive at the instrument
25. Instrument must perform the same analytical computation for the determination of an external control standard and a breath alcohol result
    a. this must also apply to an internal standard if present
26. Ability of the instrument to default to normal field operating settings
    a. can these default settings be revised, would this require a revision to the software
27. Instrument must be able to perform tests for software and memory data integrity (i.e., checksum, CRC, etc.)
    a. this test should be done at the beginning of each subject analysis
28. Instrument should have the demonstrated ability to compute 99% confidence intervals and print onto the printout
    a. this should first correct the mean subject results according to the bias determined at the time of installing a new solution and performing the first measurement
    b. the technician will need to enter the reference value for the solution
    c. the bias should be determined from the mean of all simulator results performed on the instrument since the time of the last solution change
    d. the confidence interval will be computed around the corrected mean result
    e. the printout should show the raw measurement results along with the corrected mean and the confidence interval limits
    f. the instrument must have the ability to turn on or off this feature as selected by the technician (this may not become a standard feature of the instrument in all locations)
29. The instrument should employ the following breath sampling parameters to ensure an end-expiratory sample
    a. minimum flow rate of 4 L/min
    b. minimum continuous exhalation time of 5 seconds
    c. minimum volume of 1.5L
    d. minimum slope to the breath alcohol exhalation curve
    e. if the parameters are not met the instrument should continue to allow for sample provision without doing another purge cycle
    f. the instrument should allow a total of two minutes opportunity for sample provision
    g. if a valid sample is not provided the instrument must allow the operator to indicate: Refusal or Incomplete

Test

30. The instrument should have the capability of a driver's license and operator card 2D bar code reader that automatically enters specific data into the system for downloading to the host computer and printing selected portions at the instrument
    a. at the time of solution change, there should be the ability to read a bar code on the solution bottle that the technician will scan and indicate solution batch number, reference value, expiration date
31. Reporting of measurement results
    a. does the instrument truncate the first unobserved digit?
    b. what is the resolution of the reported result and what is the resolution limiting step?
32. Printout results for evidential document
    a. the printout should appear generally as follows:

WASHINGTON STATE PATROL
BAC DATAMASTER CDM 140115
SOFTWARE VERSION 76043-004 (04/28/04)
NOVEMBER 22, 2006
SIMULATOR TEMPERATURE (34 ± 0.2^{0}C): 34.02^0 C
OBSERVATION TIME BEGAN: 22:34
CITATION NUMBER: 12345
OPERATOR'S NAME (L/F/M):
GULLBERG/R/G
SUBJECT'S NAME (L/F/M):
SMITH/T/A
SUBJECT'S DOB: 12/23/1945
EXTERNAL STANDARD BATCH#: 06031

--- BREATH ANALYSIS ---

BLANK TEST	0.000	10:40
INTERNAL STANDARD	VERIFIED	10:40
SUBJECT SAMPLE	0.125	10:40
BLANK TEST	0.000	10:41
EXTERNAL STANDARD	0.082	10:41
BLANK TEST	0.000	10:42
SUBJECT SAMPLE	0.129	10:42
BLANK TEST	0.000	10:43

ALL RESULTS IN g/210L

OPERATOR _____
AGENCY _____

C. Manufacturer Evaluation

1. Technical training provided by the manufacturer
   a. available within Washington State
   b. inform manufacturer that the Washington State Patrol intends to provide instrument maintenance within the state
2. Technical materials available
3. Parts cost and availability
   a. manufacturer should provide a complete list of parts and their cost
4. Will source code be made available to defense under a protective order?
   a. how will this request or court order be addressed
5. If instrument employs a fuel cell:
   a. what is the cost of replacement?
   b. how much time to replace?
6. If manufacturer also sells customized communications and/or database software, this should be provided to allow for evaluation
7. Provide technical details regarding method of RFI detection and/or prevention

Testing Report RF Susceptability

8. If instrument employs fuel cell technology
   a. what is the cost and time for replacement
   b. local technician must be capable of accomplishing
   c. is there diagnostic capability regarding fuel cell, what are its details
   d. does the fuel cell result involve some type of adjustable gain
9. Provide list of users along with phone numbers and emails
10. Does the manufacturer recommend some quantitative measure of overall instrument efficiency
    a. number of tests/error record
    b. number of tests/dollar repair
11. How are software versions numbered and documented
    a. if an update is provided by flash EEROM, how is this documented
12. Manufacturer must provide detailed steps of analytical computation performed in the software or firmware to convert analytical voltages to breath alcohol results
13. Provide details on simulator sample acceptance algorithm
14. The manufacturer must submit the instrument to an independent laboratory (i.e., DLS Electronic Systems, Inc., Wheeling, IL) for determining the susceptibility of the instrument to Radio Frequency Interference (RFI). A certificate of acceptability must be provided.
15. What accreditations do the manufacturers possess?
16. Determine the technical details of the instrument during the time of orientation prior to evaluation
    a. analytical method and details

b. mouth alcohol detection
c. RFI detection
d. sampling parameters for breath and simulator - allow for revision of breath sampling parameters

17. Do not allow a test to be performed after 60 days following last solution change
18. Require at least 16 minutes between "observation time began" and the current time the test is initiated

D. Analytical Evaluation

1. Determine from manufacture the proper voltage settings and critical test points
   a. ensure these are proper prior to beginning
2. Accuracy
   a. obtain traceable simulator solutions from Toxicology Lab
   b. obtain solutions with reference values near: 0.02, 0.04, 0.08, 0.10, 0.15, 0.20, 0.30, 0.40 g/210L
   c. obtain certificates of analysis from the Toxicology Lab for these solutions
   d. perform n=10 measurements on each using a new solution for each separate instrument
   e. use same simulator for each instrument and for all concentrations
   f. compute systematic error or bias for each instrument
   g. compute standard deviations
   h. save all printout results and clearly identify all serial numbers, personnel, location, dates, etc.
   i. plot means with error bars for all instruments comparing with reference values and method mean
   j. perform analyses initially without re-calibration of the instrument
   k. re-calibrate the instruments and perform the analyses again - plot means and error bars and compare to initial results
   l. plot the total error (TE) against the reference concentration (Petersen, et.al., 2001)
3. Precision
   a. compute standard deviation estimates and use to plot error bars in accuracy chart
   b. compute ANOVA along with components of variance for each instrument at all concentrations
   c. precision as a function of concentration
      1) add approximately 0.1ml ethanol to 500ml water in simulator and perform n=10 measurements
      2) add approximately 0.2ml ethanol to same solution and perform n=10 measurements
      3) continue until near 0.40 g/210L obtained
      4) plot standard deviation estimates against mean for

Calc
[X]

all instruments

d. obtain duplicate breath test data from jurisdictions using each instrument type and compute the uncertainty function
   1) is this an acceptable fitness function?

e. perform a large number of replicate simulator measurements (n>100) and plot results - evaluate standard deviation - how do instruments compare in depletion rates
   1) do a runs test
   2) do simple linear regression

f. perform n=10 replicates on each instrument using the same simulator and with a solution value of 0.30 g/210L - then do same test using two simulators in tandem - plot sequential results and look for significant trend in depletion

g. at all concentrations compute the ratio of the largest variance to the smallest variance among the instruments
   1) $F = S^2_{max}/S^2_{min}$

h. for each of the five instruments, take the variances determined at each concentration (0.04, 0.08, 0.10, 0.15, 0.20, 0.25, 0.30 and 0.40) and determine the ln S, ln S^2, and ln range - put these into a table and compute the oneway ANOVA - this evaluates for differences in variances (see Nelson, L.)

i. perform at least n=100 sequential simulator tests using 0.08 solution
   1) compute:

$$\frac{D^2}{S^2} \qquad D^2 = \sum_{i=l}^{n} d_i^2 \ (d_i = \textit{diff between successive results}) \qquad S^2 = \sum_{i=1}^{n} \left(Y_i - \bar{Y}\right)^2$$

   2) the ratio should be near 2.0 if no trends
   3) above or below 2.0 indicates a trend or lack of Randomness
   4) see article (Youden, 1954)

j. look at n=10 simulator results on the Datamaster DMT where the standard deviation is < 0.001 g/210L - obtain the fourth digit and re-compute the SD - what is the difference - should we be reporting the fourth digit with such precise results

k. on the ECIR II, perform n=20 simulator tests with the full one minute delay between results and then n=20 with no time delay - do a linear plot of each over time - compare results - test for trends

l. explain why precision might vary between instruments - first test might be low, non-heated tubing

m. do n=30 simulator tests at high concentrations (i.e., 0.30 or 0.40 g/210L) - plot sequentially and do linear regression - calculate S_{yx} and S_x and compare between instruments

n. select one of the concentrations at which ten measurements were made on each instrument and do a oneway ANOVA with instrument being the fixed effect

4. Linearity
   a. using the mean responses and mean reference values, develop the sensitivity response for each instrument in an Excel file (see example)
   b. plot mean response against reference values
   c. plot sensitivity against $\log_{10}$ reference (see example)
   d. sensitivity plot should be relatively flat
5. Interfering substances
   a. determine concentration at which acetone will yield a 0.01 g/210L ethanol equivalent (relevant for IR only)
   b. introduce volatile organic compounds alone from simulator devices as well as mixed with known levels of ethanol
      1) measure the ethanol first, n=3
      2) include: acetone, isopropanol, methanol, toluene, ethylene glycol, propylene glycol
      3) save aliquots of the solutions and have Tox Lab Quantity
      4) compare results on fuel cell instruments to results in paper by House and Gorezynski
   c. introduce iso-propanol with ethanol and determine if the fuel cell instruments distinguish between the two or not (iso-propanol may simply add to the ethanol equivalent result)
   d. what toluene concentrations are necessary to obtain 0.01 g/210L ethanol equivalent
   e. add increasing amounts of acetone to ethanol standard
      1) perform n=5 measurements on just ethanol
      2) add 0.05ml acetone and do n=5
      3) add 0.05ml acetone and do n=5
      4) continue this for several points
      5) plot mean and error bars against acetone levels
   f. other compounds to consider evaluating: n-butanol, n-propanol, i-propanol, methanol
6. Levels of Detection/Levels of Quantitation
   a. from plot of SD estimates against mean results, determine the intercept and then $3S_0$ and $10S_0$
   b. estimate LOD and LOQ
   c. obtain duplicate data from jurisdictions currently using each instrument type and estimate LOD and LOQ
   d. perform n=10 measurements on a solution having approximately 0.01 g/210L, from the SD determine the LOD and LOQ, use same solution on all instruments
7. Develop a 2^3 factorial design
   a. factors to consider: simulator solution volume, simulator leaks, simulator tubing length, concentration,

Dave → filter testing?

MDL

heated/non-heated tubing
b. each factor at two levels
c. perform n=10 measurements for all eight conditions
d. analyze by standard methods

8. Between-day simulator precision
a. perform n=10 tests per day over a period of at least 40 days
b. plot sequential mean results
c. evaluate precision and accuracy
d. use reference solutions from toxicology lab
e. evaluate for any depletion trend
f. have one simulator assigned to each instrument

9. Evaluate simulator leaks
a. perform n=10 tests on instrument
b. loosen simulator jar by specified amount and perform another n=10 results
c. use same simulator solutions for both steps a and b
d. repeat protocol for all instruments
e. plot mean and error bars for all instruments on one plot including all experimental conditions
f. do a two-way ANOVA as described in #19 below

10. Perform n=10 measurements using simulator with water only
a. use same simulator and water source for all instruments
b. document simulator serial number and technician
c. set instrument to four digits if possible

test on 1 inst Sim ↑↓ 32 – 36

11. Determine the analytical range for the instrument
a. measure simulator ethanol concentrations above 0.40 g/210L until the limit is reached
b. how does instrument respond to concentrations over the limiting range?
c. important to know dynamic range of the instrument

1 time at .6 work up to

12. Evaluate carryover effect
a. perform n=10 simulator measurements on solutions of approximately 0.04 and 0.40 g/210L
b. using same solutions, perform alternating simulator tests of 0.04 g/210L and 0.20 g/210L
b. obtain n=10 at each concentration
c. evaluate mean and precision and compare to n=10 replicates performed at each concentration

13. Recalibrate the instrument and perform a set of n=10 measurements at 0.04, 0.08, 0.10 and 0.15 g/210L
a. evaluate difficulty to recalibrate
b. are multiple attempts necessary
c. evaluate the different number of calibration runs allowed on the Datamaster DMT
d. is there any apparent improvement with the multi-point calibration over the single point

14. Radio Frequency Interference Testing
a. using simulator control standards, transmit handheld

radio signals during analytical test
b. determine if test aborted or result obtained
c. evaluate exhalation profiles if available

15. In a run of n=10 simulator tests, record the length of time for each sample, what is the average length of time for samples to be accepted by the simulator, what is the total time required to perform n=10 simulator tests

Inst
2x 2 test seq. ✓ for ext. sim

16. Perform at least two simulator control tests as part of a test sequence per day over a period of at least 60 days
    a. this is to evaluate the differences between duplicate simulator control tests as part of a complete breath test
    b. select a + or - for the case where the first or second test is higher and do a runs test
    c. evaluate the trend over at least 60 days
    d. plot sequential differences (Y_1-Y_2) against test sequence - look for trends, bias
17. Compare results using heated and non-heated simulator tubing
    a. do only on instruments with heated simulator tubing
    b. perform n=10 simulator results of a 0.15 g/210L solution using the non-heated simulator tubing
    c. then immediately perform n=10 simulator results on a 0.08 g/210L solution with the heated tubing
    d. is there any effect on the 0.08 g/210L results
18. Mouth alcohol testing in vitro
    a. employ two simulators in tandem - one with 0.08 g/210L and the other representing the oral cavity
    b. employ a six-way tubing arrangement so each sample can be provided to all five instruments simultaneously
    c. provide an initial sample with no mouth alcohol to observe baseline response due to the 0.08 g/210L simulator
    c. perform several tests to evaluate response to this simulated mouth alcohol condition
19. Do a two-way ANOVA design
    a. instrument type and simulator type are the two main effect factors
    b. do n=10 measurements for each combination
    c. set up data table as:

	Instrument				
	1	2	3	4	5
Simulator					
1	0.078	.	.		
	0.079				
	.				
2	0.081	.	.		
	0.083				

d. consider the fixed effects model
e. look at interaction terms
f. do the same set-up for simulator leak and non-leak, use same simulator
g. do the same set-up for instrument type and simulator concentration - block on concentration (C) - use the mixed effect model:

$$Y_{ijk} = \mu + I_i + C_j + IC_{ij} + \varepsilon_{ijk}$$

E. Quality Assurance Protocol Evaluation

1. Perform a complete Quality Assurance Protocol according to the existing Breath Test Section Manual on each instrument
2. Determine from the manufacturer the critical voltage settings within the instrument
   a. evaluate the ease of removing covers to perform voltage checks
3. Determine calibration details and procedures and have technicians perform the calibration
   a. compare the calibration methods between instruments
4. How will the presence of acetone be evaluated in an instrument employing fuel cell technology
5. Have at least five different technicians perform the QAP on each instrument
   a. obtain input regarding time, difficulties, etc.
6. Note the time necessary to do the QAP on each instrument

F. Data Collection Evaluation

1. Does manufacture provide communications software
2. Is communications software available to test and evaluate
3. Put an instrument in the field at a location difficult to poll and evaluate the polling capabilities
   a. ensure compatibility between data storage format and existing database management tools within the Washington State Patrol
4. Compare downloaded results to printout documents at the instrument for a few examples
5. Instrument should have the capability of storing data or not as selected by the technician
6. Instrument should have the capability in the software to compute and print the 99% confidence intervals for the subject results - the printing of these results must be capable of being selected or not by the technician
7. There must be the capability either at the instrument or at the host computer to printout a previously performed test
   a. the instrument must have the capability if the test

record is still within memory
   b. the host computer must have the capability if the record is within its memory
   c. the printout must be in the identical form as that normally produced by the instrument
8. A list of all possible error codes must be provided
9. Critical voltage values must also be stored with each breath test record and downloaded to the host computer
   a. determine from the manufacturer what are the critical voltage values
10. Is the instrument capable of providing a look-up table for local drinking establishments
   a. can this list be updated by flash EEROM
11. Instrument should have the capability of preserving in memory the full breath exhalation profile for each subject tested
   a. even where full test is not completed or valid, the breath exhalation profile should be preserved
12. Instrument should be capable of preserving the result of breath alcohol measurements even where the full acceptable test sequence is not complete. This should then be available for the host computer.
13. Does the instrument have the ability to provide look-up tables for several of the data entry options .
14. The database should retain
   a. breath exhalation attempts
   b. breath exhalation time on final accepted sample
   c. breath volume on final accepted sample
15. Revise the software in the instrument remotely through use of the flash EEROM devices
   a. how is the record of such changes to software recorded?
16. Collect all data currently obtained by the Datamaster

G. Subject Testing Evaluation

1. Design a drinking lab with all of the usual controls
2. Prior to alcohol consumption have subjects provide n=10 samples into each instrument
3. After alcohol consumption have subjects provide replicates (n=10) into each of the instruments (four or less) in a random order
   a. estimate components of variance
   b. record order of each breath sample and look for trends
   c. block on subjects in a two-way ANOVA
4. Have subjects provide abnormal breath samples to generate "Invalid Samples"
   a. determine messages provided for abnormal breath sampling
5. Collect breath alcohol profiles
6. Have subjects provide n=10 breath samples at multiple

concentrations and perform n=10 simulator samples near each concentration also

a. concentrations from approximately 0.10 g/210L down to 0.02 g/210L
b. evaluate components of variance - ensure $CV_A < 0.5\ CV_B$
c. plot standard deviation estimates against means

7. If possible, evaluate the influence of individuals on weight reducing diets
   a. test subjects before and after special diet
   b. does the increase in acetone yield measurable increases in isopropanol that might be measured on fuel cell instruments
8. Evaluate different abnormal breath exhalation conditions
   a. have subject try to suck sample back
   b. have subject start and stop exhalations rapidly
9. Mouth alcohol testing:
   a. obtain mean breath alcohol concentrations on subjects after dosing and obtaining a specified BrAC
   b. administer mouth alcohol
   c. have subjects immediately begin to provide samples into the different instruments and record results
   d. continue over time
   e. plot results for each instrument over time along with the mean results prior to administering mouth alcohol
   f. evaluate the elimination rates on each instrument
   g. what is the response of each instrument to mouth alcohol
10. Breath alcohol exhalation curve analysis
   a. download exhalation curves for replicate (n=10) tests
   b. download CO_2 curves for Intoximeter ECIR also
   c. evaluate curves for reproducibility - is the CO_2 curve more reproducible than the ethanol curve
   d. does hyper and hypo-ventilation effect the CO_2 curve

H. Field Application Evaluation

1. train specific troopers in use of new instruments
2. place instruments at locations to be used by trained troopers
3. use in association with emphasis patrols or weekends
4. obtain feedback from troopers
   a. obtain copies of printouts
   b. compare to Datamaster test administered as well
5. Plot differences against their mean for duplicate results
   a. do same analysis comparing IR and EC if relevant
6. Plot sequential simulator results
   a. is there evidence of depletion
   b. compute standard deviations
   c. compare standard deviations to that of some field Datamaster simulator results (F-test)

7. Set instrument to perform two simulator tests
   a. compare differences

8. Evaluate the instruments and determine their suitability for use in the DUI/DRE Motor Home
9. Evaluate the space needed and any security features when each instrument is located in different field locations
   a. obtain input from technicians

I. Evaluations/Considerations From Other Jurisdictions

1. Identify at least five jurisdictions currently using the specified equipment
2. Obtain input from these jurisdictions regarding:
   a. manufacturer support
   b. time in service for equipment
   c. test protocol
   d. training provided
   e. legal challenges
   f. data collection
   g. who provides equipment maintenance
   h. number of instruments
3. Obtain duplicate data if available to estimate the uncertainty function
4. Employ a questionnaire where users will rate several manufacturer and instrument features on a scale of 1 to 10

J. Training Considerations

1. What will be required to train existing operators
2. Obtain training outlines from other jurisdictions using each type of equipment
3. Will 12 to 16 hour basic course continue to be adequate

K. Legal Community Evaluation

1. Prosecutors will be presented an overview and demonstration regarding the new instruments and asked to provide their opinions and impressions
2. The pro and con considerations for each instrument will be Noted
3. Prosecutors will be asked to comment regarding several Considerations:
   a. usability
   b. printout appearance
   c. data collection
   d. technology capability
   e. possible legal challenges
   f. legal experience of other states

g. impact on our current legislation and case law

L. Records to Retain

1. Note on all records the date, time, technician and other relevant information
2. Retain all records
3. Record the occurrence of any problems with the instruments
4. Record the occurrence of conversations with the manufacturer regarding instrument issues
5. Records of interviews with other users

M. Scoring of Results

1. A method of scoring results may be developed and employed
2. If used, the scoring method will employ
   a. proportional scoring (PS): range from 0 to 100
   b. weighing factor (WF): use a scale from x 1 to x 10
   c. a subtotal is obtained by multiplying PS x WF

Glossary

accuracy - The property of a measurement result describing is "trueness" or degree of correspondence to the known true value of the measurand. Accuracy is quantified by the bias or systematic error.

bias - Also known as systematic error, this is the difference (either in absolute units or percent) between the mean of replicate measurements and the traceable reference value. The bias describes the more general concept of accuracy.

fit-for-purpose - Where an instrument or analytical procedure yields results that are acceptable for a given context or ultimate purpose.

limit of detection - the concentration at which the presence of the analyte of interest can be statistically distinguished from the inherent noise of the system. (LOD=3S where S = the standard deviation of the measurement of blanks)

limit of quantitation - The concentration at which results can be reported with confident assessment of accuracy and precision (LOQ=10S)

linearity - The acceptable accuracy and precision of an instrument at several levels throughout its relevant concentration range.

measurand - The specific property being measured. In breath alcohol measurement, for example, the measurand would be an individual's end-expiratory breath alcohol concentration.

precision - The repeatability amongst replicate measurements. Precision is typically quantified by the standard deviation

or variance.

selectivity - the ability of the instrument to accurately measure the analyte of interest in the presence of an interfering substance.

validation - a process by which an analytical method or instrument type are shown to be suitable for their intended use or fit-for-purpose

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