Documentation Required for Independent External Scientific Validation for Reported and Alleged Test Results Involving Blood Tests for EtOH not made by Enzymatic Process

Please provide,

The Following Items Concern General Matters:

1. A copy of any accreditation certificates for the laboratory that were in effect at the time of the analysis.

2. The laboratory's overall policies as to testing and calibration.

3. The laboratory's overall procedures as to testing and calibration.

4. The policy that applies to the section of the laboratory where this particular testing or calibration event occurred.

5. The procedure that applies to the section of the laboratory where this particular testing or calibration event occurred.

The Following Items Concern Pre-analytical Matters:

6. Validation studies (both internal and external) that proves the validation of the method and instructions used.

7. The policy that applies to the assay performed in this particular test or calibration event that covers the calibration or the achieving of a calibra-

tion curve.

8. The procedure that applies to the assay performed in this particular test or calibration event that covers the calibration or the achieving of a calibration curve.

9. The instructions that apply to the assay performed in this particular test or calibration event that covers the calibration or the achieving of a calibration curve.

10. The calibration curves and all chromatograms generated on the batch on the machine on which the sample in this case was tested.

11. The identification and source of all internal standards, standards, standard mixtures (separation matrix), verifiers, blanks, and controls that were run within the batch in which the sample in this case was run.

12. All records reflecting internal testing or quality control testing of all solutions, reagents, or standard mixtures used as, as part of, or in relation to internal standards, controls, standard mixtures, or standards in the batch in which the sample in this case was run.

13. All refrigeration logs, reports, or other documents in whatever form, for all refrigerated compartments in which this sample, other unknowns within the run, internal standards, controls, standard mixtures, standards, and reagents used in or in relation to the analysis in this case were stored or kept at any time.

14. All proficiency testing results for the section of the laboratory testing the sample in this case as well as for the person who conducted the testing in this case – since the last date of accreditation inspection preceding the test, and for any such testing since the testing in this case. This specifically includes the summary report of expected results for the proficiency testing (and the manufacturer's information sheet) against which the proficiency test results are judged.

15. Quarterly balance quality control records on any balance instrument related to the calibration of the alcohol standard solution or the preparation of knowns or unknowns used in the blood alcohol testing of the samples in this case. The records reflecting the calibration of weights on any balance or instrument related to this case as well as the control charts kept.

The Following Items Concern Analytical Matters:

16. The instructions that apply to the assay that was used in this particular testing or calibration event occurred.

17. The employee training record, curriculum vitae, and resume for any person listed on chain of custody documents in this case or who performed the analysis.

18. Indentify the make, model, and brand/manufacturer of the instruments and other supporting instruments (i.e. balance, pipette, etc.) used during the analysis and/or preparation of the samples in this case and the variables used in its installation and operation.

19. The policy concerning the sample selection criteria used in this particular case.

20. The procedure concerning the sample selection criteria used in this particular case.

21. The instructions concerning the sample selection criteria used in this particular case.

22. The source and type of all consumables used in collection, preparation, and analysis of the samples run in the batch.

23. If a Gas or Liquid Chromatograph is used, the reporting of t0 time according to the method.

The Following Items Concern Reporting Matters:

24. The particular records for this testing or calibration event.

25. The quality control policy and protocol for the laboratory, the section, and the assay performed.

26. The quality assurance policy and protocol for the laboratory, the section, and the assay performed.

27. The full reporting and the underlying validation of the valuation of the uncertainty measurement (UM) in the ultimate reported result.

28. If a Mass Spectrometer is used, then the following additional materials should be provided:

> 28.1 If a spectral library is used to examine spectra and elucidate spectra, the source of the library spectra.
>
> 28.2 The hit list, and the hit histogram for the spectra examined and reported.
>
> 28.3 All "tune" reports ran within one year if a MS detector was used.

