LABORATORY QUALIFICATION SELF-AUDIT

INSTRUCTIONS:

This laboratory qualification self-audit is intended to aid a laboratory's clients in requesting the proper information to asses the quality of scientific results being reported by the laboratory to the client. An audit allows both the client and the laboratory a formal and well-documented procedure to examine and validate the accuracy and reliability of the laboratory results reported to the client.

This procedure is initiated by the client and completed by the laboratory. The client fills out the client information, the date of the audit request, and the sections of the audit requested. The laboratory then receives this document, fills out the appropriate laboratory information, the date the audit is returned to the client, and the sections that for which answers were provided.

The laboratory can provide the answers to the question on a separate sheet and or document, and return it to the client enclosed with the original completed audit form. For simplicity of tracking, we ask that lab responses follow the numbering scheme adopted in the audit questionnaire. Copies should be kept by the laboratory for its own records.

Client Company Name					
-Client Point of Contact					
-Client Phone Number					
-Client Address					
-Client Email					
Client Date Requested					
Sections Requested	I.	II.	III.	IV.	V.

Laboratory Name					
-Lab Point of Contact					
-Lab Phone Number					
-Lab Address					
-Lab Email					
Lab Date Returned					
Sections Provided	I.	II.	III.	IV.	V.

I. Basic Information

1. Please list all analyses performed in the lab.
2. For each analysis, please provide the following:
   A. Instruments and methods
   B. List of analytes
   C. LOD, LOQ, Reporting Limits
   D. How often are blank, standards, and spiked matrix samples analyzed?
   E. How often are facilities tested for possible analyte contamination?

II. Documentation

Please provide copies of the following:

1. Index of Standard Operating Procedures
2. Company Organizational Chart
3. Equipment List
4. Accreditations and Certifications

III. General Qualifications

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. Has management defined, documented, and communicated its Quality Policy to its organization?
2. Has management appointed quality responsibility and authority to appropriate personnel?
3. Does the lab have a documented Quality System?
4. Does the management regularly review the Quality System at scheduled intervals?
5. Does the lab have a quality manual approved by management?
6. Are quality reports issued to management and used as a basis for continual improvement?
7. What accreditations does the laboratory maintain? Please list and attach copies.
8. Is there an SOP for sample submittal and receiving?
9. Is each sample assigned a unique laboratory identification number? How is it assigned?
10. Are samples stored securely and labeled with proper identity?
11. Is there a log of stored samples? For how long are samples stored?
12. Are temperature and humidity of sample storage area recorded?
13. Is a Certificate of Analysis (CofA) issued for each test performed?
14. Is all data on CofA's traceable to raw data stored by the laboratory?
15. How are CofA's for each customer stored? For how long?
16. Are clients notified of any method deviations taken during analysis? Is there a system for obtaining customer agreement to these changes?
17. Are there procedures to control, revise, and change documents?
18. Are all appropriate documents controlled and identified by revision level or date?
19. Do authorized personnel approve controlled documents prior to issue?
20. Are there SOP's available for handling reference standards and working standards?
21. Are CofAs and/or reference data for these standards available?

22. Are storage data and conditions available for these standards?
23. How often are standards re-analyzed or re-certified?
24. Do you have SOPs or guidelines on continual improvement?
25. Are SOPs and manuals available for handling all instruments?
26. Does the laboratory have a subcontractor list and approval system?
27. Does the laboratory conduct subcontractor audits? How often?
28. Are all reagents and chemicals sourced from approved suppliers?
29. Are reference standards certified (NIST or other)?
30. Are all reagents and chemicals marked with date of receipt, date opened, and expiration date? How are expiration dates assigned?
31. Does the laboratory have a documented calibration system?
32. Are there SOP's for calibration?
33. When calibration are performed by an outside contractor, does the laboratory require certifications and test data?
34. Are all calibrations traceable to NIST?
35. Are all analytical methods validated?
36. Are analytical method validation test data available?
37. Are all instruments currently certified to perform within the scope required for each analysis?
38. Are instruments calibrated? What is the calibration schedule?
39. Are weights used certified?
40. Is calibration data available for verification?
41. What are the procedures for re-testing a sample?
42. Are test results / chromatograms signed and dated by the analyst?
43. Is there a log for each instrument and piece of equipment? Is the log up to date?
44. Are laminar air flow stations validated for: velocity, filter integrity, linearity? How often?
45. Are records kept of temperature / pressure of each autoclave run?
46. Have you done heat distribution studies on the autoclave?
47. Are there SOP's for destruction of samples, media, and reagents?
48. Does the laboratory perform internal quality audits to verify that departmental personnel comply with established procedures?
49. Are follow-up audits performed in the case of any corrective action findings?
50. Are records of internal audits available?
51. Is there an SOP for observations that are outside of operating specifications?
52. Do you have an SOP for guidelines on Good Laboratory Practices (GLP)?
53. Are training records on each SOP available?
54. Is a training assessment of each analyst complete and certified?

IV. <u>Cannabis Qualifications</u>

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. What instruments are used for the analysis of cannabinoids?
2. How are cannabinoids reported?
3. Are cannabinoid acids and free form combined for a total potential free form cannabinoid calculations? How is this calculation performed?
4. What instruments are used for the analysis of terpenes?
5. How are terpenes reported?

6. How is moisture content of cannabis determined?
7. Are results reported on a dry weight basis? If so, how is the calculation performed?
8. Are any results reported other than direct analytes physically observed in the sample? (Such as total cannabinoids, total terpenes, total ocimene, etc) Please explain.

V. Pesticide Qualifications

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. What is the full list of pesticides analyzed by the lab?
2. Pesticide Instrumentation
   A. Are all pesticides able to be analyzed on a single instrument?
   B. If not, which analytes are assigned to which instrument?
3. How is the instrument(s) calibrated for pesticide analysis?
   A. Are pesticides calibrated individually or as a combined standard?
   B. Are pesticides calibrated in solvent standard or in spiked matrix?
   C. What are the concentrations used to generate a calibration curve for each pesticide?
   D. What are the correlation coefficients of the slopes generated from each analyte's curves?
4. What are the blank matrices use by the laboratory for pesticide analysis?
   A. From where is this matrix blank material sourced?
   B. Does this matrix blank material come with documentation certifying that is free of the pesticide residues being analyzed by the lab?
5. Extraction Procedures
   A. What method of extraction is used for extraction in each matrix analyzed by the laboratory for pesticides?
   B. Which equipment and reagents are used for this extraction?
   C. Has the laboratory performed experimentation to generate data on the spike recoveries of each pesticide in the corresponding matrix? If this data cannot be found in the quality manual or other requested laboratory documents, please attach it when submitting this form.
   D. Does the laboratory use the percentage recovery data to make any calculations used in final reported results? If so, please explain.
6. Quality Control
   A. How frequently does the laboratory perform QC checks on its pesticide analysis?
   B. What types of QC samples are performed for pesticide analysis?
   C. What are the mean recoveries, precisions and sample sizes of each type of QC sample from the previous calendar year?
   D. What are the mean recoveries, precisions and sample sizes of each type of QC sample from the current calendar year up to the present? (use client date of request or nearest practical date as 'the present')
7. Interfering Peaks
   A. What is the range in retention time seen from solvent standards?
   B. Is there a formal criteria for deviation in retention time during a client sample?
   C. If so, where is it cited, If not, which employees make this judgment call?