Characterization of Mainstream Tobacco Smoke

Labstat International Inc.
Test Report

Prepared for
Institute of Environmental Science and Research Limited

Project Code: NZ4 **Date: May 26, 2005**

1 Use of Labstat's[1] Analytical Reports[2]

Normally Labstat International Inc.'s contractual obligations extend ***only*** to the provision of data and related reports.

It should be noted[3], in this regard, that

> ***All analytical data and reports, provided by Labstat International Inc., are for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the data, the report nor the name of the laboratory (Labstat International Inc.) nor any member of its staff may be used in connection with the advertising or sale of any product or process without written authorization from the CEO of the company or his designate. Labstat International Inc. is not responsible for unauthorized use of test reports.***

The following also applies to reported data.

> ***All Labstat reports on testing relate only to the sample received and tested by it at the time of testing. Labstat warrants that all samples submitted were tested in accordance with its standard chemical test procedures. Except as stated herein, there is no warranty expressed or implied, statutory or other wise, as to the results of Labstat tests. Labstat does not warrant or guarantee the fitness of the materials from which the samples have been drawn for any particular purpose including without limitation for consumption as cigarettes, cigars, smokeless tobacco or any other form of tobacco or tobacco-related product.***

[1] Labstat International Inc.,
262 Manitou Drive, Kitchener, ON Canada N2C IL3
Phone: (519) 748-5409; Fax: (519) 748-1654; Email: labstat@labstat.com

[2] *This document may not be reproduced, in whole or in part in any form, without the written consent of the author(s) on behalf of Labstat International Inc.*

[3] *Unless superseded by a specific contractual obligation or other written agreement.*

2 Administrative Information[4]

2.1 Quotation Reference

Quotation Number: T1716R1
Date: May 16, 2005
Recipient's Name: Dr. Rod Lea

2.2 Client Identification

Institute of Environmental Science and Research Limited
Kenepuru Science Centre
Kenepuru Drive
P.O.Box 50-348
Porirua, New Zealand

2.3 Date of Sample Receipt

The samples to be tested for NZ4 were received on March 02, 2005 and April 05, 2005 via Canada Post.

2.4 Sample Characteristics

The shipment received on March 02, 2005 consisted of one cigarette package of one product. The shipment received on April 05, 2005 consisted of one pouch of tobacco for each of 5 products. Plain and filtered cigarettes were made from the pouch tobacco to generate a total of 10 brands. There was no physical damage to the cigarette package or tobacco pouches. Individual cigarettes and whole tobacco were normal in appearance.

2.5 Test Article Identification

The following sample codes have been used to identify the products associated with the results in each of the tables that are part of this report.

Sample ID	Sample Description
050541	Drum Milde Shag (Filter)
050542	Drum Milde Shag
050543	Gallaher's Park Drive Fine Cut Regular (Filter)
050544	Gallaher's Park Drive Fine Cut Regular
050545	Drum Halfzware Shag (Filter)
050546	Drum Halfzware Shag
050547	Gallaher's Park Drive Mild (Filter)
050548	Gallaher's Park Drive Mild
050549	Holiday (Filter)
050550	Holiday
050551	Holiday Special Filter

[4] Provided in accord with International Standard ISO/IEC 17025 "*General requirements for the competence of testing and calibration laboratories*" Section 5.10

2.6 Special Instructions

No special instructions, with respect to the selection of the test sample and/or compositing, were received.

2.7 Date of Test Report

May 26, 2005

3 Accreditation

3.1 Scope

Labstat International Inc. has been accredited by the Standards Council of Canada to International Standard ISO/IEC 17025 "*General requirements for the competence of testing and calibration laboratories"* with a scope that includes all of the mandated tobacco-related Health Canada methods (see Tobacco Reporting Regulations dated 26 June 2000, Canada Gazette Part II, Vol. 134, No. 15 Schedules 1, 2 and 3 pages 1780 – 1785). The testing included in this report is within the scope of this accreditation.

Standards Council of Canada
Accredited Laboratory
Scope of Accreditation 368

Conseil canadien des normes
Laboratoire accrédité
Portée d'accréditation 368

TM

3.2 International Recognition of Tests

Our accrediting organization, Standards Council of Canada, is one of 36 such member bodies participating in a global mutual recognition agreement (MRA), known as the ILAC (International Laboratory Accreditation Cooperation) Arrangement. The arrangement, effective January 31, 2001, requires acceptance of technical test data from accredited laboratories by member bodies in 28 economies worldwide.

4 Acceptance of Data

4.1 Overview

In most cases, data are evaluated in two stages. The first consists of a comparison of results for control materials with certified values or Labstat's historical in-house database. If the control results are acceptable and there are three (3) or more samples per analysis brand, then the data obtained from the analysis of samples is subjected to an outlier test. Values identified as outliers are then scrutinized for an assignable cause and, if one is found, the value is removed from the data set. If none is found, the value is assumed to be a legitimate member of the data set and included in all subsequent calculations.

4.2 Evaluation of Results from Control Materials

Data obtained using control materials are deemed acceptable if the data are in keeping with Labstat's database for the control material and the specific method of analysis[5]. This is not a simple problem since there is no "yes" or "no" answer but rather one which is phrased in terms of probabilities. In the approach taken by Labstat, the measure of random variation in the procedure is taken to be the sample standard deviation (S.D. or "s"). A "*Z score"* is then determined as follows:

$$Z = \frac{\text{Sample Average} - \text{Historical Average}}{\text{Historical Standard Deviation}}$$

P values are generated and the cut off point (α) chosen in such a way as to minimize the chance of rejecting data which are legitimate members of the set (i.e. type 1 error). Thus, in most cases where the number of observed control samples is greater than or equal to 5, p-values are generated from the Standard Normal distribution. In rare cases, when the number of observed control samples is less than 5, p-values are generated from a t-distribution.

The standard deviation rather than the standard error for the mean has been chosen when determining the 'Z score'. This allows for both project-to-project variation, which is inherent in the historical data, and the 'normal' run-to-run variability, which is present in the data set. The cut-off point for P values is a matter of judgment and has been set at 0.005 (assuming the probability of falsely rejecting a data point is 0.5% (i.e. α=0.005) or less for a two tailed test.

In instances where expected values are not known, a decision to accept the data is made based on observed levels of precision in comparison with that determined for similar analyses. Also, there are circumstances where the expected value may be "Below Detection Limits". In this case the decision to accept or reject the data is made upon the ability of the method to recover the analyte of interest either in the form of a laboratory fortified blank (LFB) or laboratory fortified matrix (LFM). Acceptable recoveries fall in the range of 85% to 105%.

4.3 Identification of Outliers[6]

4.3.1 Definition

An outlying observation, or "outlier," is one that appears to deviate markedly from other members of the sample in which it occurs. In this case, there are two alternatives:

1. An outlying observation may be merely an extreme manifestation of the random variability inherent in the data. If this is true, the value is retained and processed in the same manner as the other observations in the sample.
2. The observation may be the result of gross deviation from prescribed experimental procedure or an error in calculating or recording the numerical value. In such cases, an investigation must be carried out. When the experimenter is clearly aware that a gross deviation from prescribed experimental procedure has taken place, the resultant observation is discarded (assignable cause) without recourse to a statistical test. A statistical test may always be used to support a judgment that a physical reason does actually exist for an outlier, or the statistical criterion may be used routinely as a basis to initiate action to find a physical cause.

[5] A minimum of 50 results is normally required for the purpose of this comparison.

[6] The term "outlier" has been defined in International Standard ISO 3534-1 (1993) entitled "*Statistics - Vocabulary and symbols - Part 1: Probability and general statistical terms"* section 2.64

4.3.2 Statistical Criteria

There are a number of criteria for testing outliers. In all of these, the doubtful observation is included in the calculation of the numerical value of a sample criterion (or statistic) that is then compared with a critical value. The critical value is that which would be exceeded by chance with some specified (small) probability on the assumption that all the observations did indeed constitute a random sample from a single parent population, distribution or universe. The specified small probability is called the "significance level" and can be thought of as the risk of erroneously rejecting a good observation. A level of significance of 0.02 has been chosen in conjunction with the statistical test and tables described in ASTM E178-02[7].

Significant departures from the expected results (i.e. “outliers”) are viewed seriously, requiring an investigation for an assignable cause. This is a documented procedure that, at a minimum, consists of the following steps:

- Review of all associated calculations to ensure that arithmetic errors have not been made
- Review of linearity range for any standards
- Assessment of instrument status
- Review of reagents, columns, standards etc. to ensure that contamination or decomposition has not occurred
- Review of sample preparation and handling procedures as they relate to the result in question

If the outlier is present in the analyte data and an assignable cause is found, the test result is removed from the data set but recorded in the quality control section of the laboratory’s record of test results for that project. The analysis must then be repeated. If the outlier is present in the ancillary[8] data and an assignable cause is found, the test result is not removed, but rather the outlying observation is replaced by the designation “AC” (Assignable Cause). If this investigation fails to determine an assignable cause, the test result is assumed to be a legitimate member of the data set and is included in all subsequent calculations.

5 Methods

5.1 General References

Test methods for the analysis of mainstream tobacco smoke are referenced in the table below and were practiced as written unless otherwise indicated (see “Test Method Deviations”).

OFFICIAL METHODS FOR THE COLLECTION OF EMISSION DATA ON MAINSTREAM SMOKE[9]

Item	Emission	Official Method
1.	(*a*) Tar (*b*) Nicotine (*c*) Carbon Monoxide	Official Method T-115, *Determination of "Tar", Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke*

[7] ASTM Designation: E178-02. *Standard Practice for Dealing with Outlying Observations*

[8] Data, which are related, but not normally required as part of the reporting process (e.g. puff counts, TPM, cigarette weights etc.). Outliers in the analyte data that have an assignable cause are always repeated.

[9] Canadian Tobacco Reporting Regulations: 2000-01-19 *Canada Gazette Part II, Vol. 134, No. 15* Part 3: Emissions from Designated Tobacco Products. Test method numbers refer to Health Canada methodologies which have been posted by Health Canada on the internet at site http://www.hc-sc.gc.ca/hecs-sesc/tobacco/legislation/index_testmethods.html

5.2 Cigarette Conditioning and Smoking Environments

Cigarettes were conditioned and smoked under the environmental conditions specified in ISO 3402 (1999) *"Tobacco and tobacco products – Atmosphere for conditioning and testing".* With respect to conditioning, this document states "*The conditioning atmosphere shall be as follows: temperature 22 ± 1°C; relative humidity 60 ± 3%.* Smoking requires an environment in which the temperature is 22 ± 2°C and the relative humidity 60 ± 5%.

5.3 Standard Machine Smoking Conditions

Smoking of test and reference cigarettes carried out on either a rotary smoking machine or a linear smoking machine. The smoking parameters and smoking machine specifications which were used are set out in the International Organization for Standardization standard ISO 3308, Fourth Edition 2000-04-15, ***Routine analytical cigarette-smoking machine - Definitions and standard conditions, 2000 (E)*** with modifications as noted in the table below.

5.4 Machine Parameters

The following table is a summary of the smoking parameters that were employed in this project.

Variable	"ISO"
Puff Volume (ml)	35
Interval (sec)	60
Duration (sec)	2
Vents	"open"

Mainstream yields (MS) were obtained under "ISO" conditions (as defined above). Yields obtained using "ISO" smoking parameters are referred to as "standard" (s). Data files ending in (s) denote results obtained under the condition as noted in the previous sentence and in the above table.

6 Results

6.1 Quality Control

The control results for the variables of interest were acceptable as defined in section 4.2. Consequently it is reasonable to assume that the values determined for the test samples are reflective of the characteristics of the products as received and tested as described in the Methods Section.

6.2 Test Method Deviations

Test methods followed as written (see Section 5)

6.3 Analytical Data

Individual results and the corresponding sample statistics may be found on the compact disk (CD) that accompanies this report. The data file has been labeled *NZ4_ms_dataCF.xls*.

6.3.1 Sample Statistic Calculations

In cases where a sample result is below the limit of detection (LOD), the value zero (0) is used in the sample statistic calculation. In cases where a sample result is between the LOD and the limit of quantification (LOQ), the average of the LOD and the LOQ is used in the sample statistic calculation.

7 Authorization

This report has been reviewed by me and is certified, to the best of my knowledge, to be a true and accurate description of the procedures, protocols and test methods used to arrive at the data and/or findings that accompany this report.

Dated: May 26, 2005

W.S. (Bill) Rickert, Ph.D.,
Laboratory Director,
Labstat International Inc.

Appendix

"Raw" Data and Summary Statistics (See Enclosed CD)