HBI INTERNATIONAL ®

www.hbiinternational.com

a BBK Tobacco & Foods, LLP company

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October 31, 2018

SUBMITTED ELECTRONICALLY

Comment: Review of Existing Center for Tobacco Products Regulatory and Information Collection Requirements

I.   Introduction

BBK Tobacco & Foods, LLP d/b/a HBI International is an importer of rolling papers for roll-your-own tobacco. We sell our own paper brands that are manufactured oversees, and we also sell products manufactured and imported by 3rd parties. With the implementation of the deeming rule in August 2016, our papers are regulated as tobacco products.

HBI International addressed the challenge the transition from working in an unregulated environment to a regulated environment, and we are determined to comply with all applicable regulations. We also want to be a responsible corporate citizen, and as such we aim to not only follow the minimum regulatory requirements, but we also want to develop a deeper scientific understanding of our products.

This public comment opportunity centers on the following topics:

1. whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility
2. the accuracy of the FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. ways to enhance the quality, utility, and clarity of the information to be collected
4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

We want to comment on the collection of of smoke delivery data in support of SE reports for RYO cigarette paper. We submit that the data has only limited practical utility and scientific value and puts a large burden on the respondents. We assert that the burden is disproportionally high for the level of information gained from obtaining smoke delivery data for RYO papers.

In brief, when smoke data is collected for RYO cigarette paper SE applications, RYO cigarettes are made in the lab using fine-cut tobacco. Then the cigarettes are smoked on a smoking machine and the gas and/or particulate phase are analyzed in the same way as factory-made cigarettes. We will show that there are significant differences between RYO cigarettes and factory-made cigarettes. These differences result in a large workload for the lab in making the cigarettes and in highly variable data. There is a point where the data is so variable that small to medium differences in the RYO paper itself are overshadowed by the differences in the rolled cigarette test results.

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We will also demonstrate mathematically that the rolling paper contributes only to a small degree to the smoke deliveries; differences seen in the rolling paper, most commonly differences in the amount of cellulose, become so small in the final RYO cigarettes, that any impact on smoke deliveries is obliterated by the variability of the data.

We therefore question the usefulness of smoke delivery data for the characterization of RYO rolling papers. Even more importantly, we will show that the data can be misleading and result in erroneous conclusions.

HBI proposes that cigarette rolling papers not be tested with artificial cigarettes using tests designed for standardized manufactured cigarettes. Because the variability of RYO cigarettes nullifies the usefulness of the tests the FDA currently requires, HBI suggests instead that cigarette rolling papers be analyzed by themselves in order to obtain data that is not contaminated by injecting the high variability of lab-made RYO cigarettes.

II.   **Contribution of Rolling Paper to Overall Cigarette Material**

Rolling papers contain predominantly cellulose. It is well established that the incomplete combustion and pyrolysis of cellulose generates some of the HPHC compounds such as CO, CO_2, aldehydes, etc. There may be small amounts of binders and fillers, but in general the cellulose content of a single rolling paper can be assumed to be at least 90%.

Rolling papers have low basis weights, which means one single paper is very light. Standard rolling paper dimensions are "Single wide" (37x70 mm), "1 1/4" (44x78 mm) and "KS SLIM" (44x110 mm). Our papers broadly weigh between 40 and 75 mg, depending on size and exact nature of the paper.

Per the ISO standard 15592-3, the RYO cigarette is rolled to a diameter of 7.2 mm and the amount of tobacco used to fabricate the cigarette depends on the length of the paper. The amount used is between 750 mg (for a single wide RYO cigarette) to 1175 mg (for a KSSLIM RYO cigarette).

Below we will mathematically approximate the contribution of the rolling paper to the total amount of cellulose in the finished cigarette. We will use a KSSLIM paper as an example. We will also assume that the paper is 100% cellulose (which is the most conservative assumption possible) and weighs 75 mg. If we assume that 1175 mg of tobacco are used to make the cigarette, the tobacco contains 470 mg cellulose. This is based on Leffingwell's estimate that tobacco contains about 40% cellulose. The total

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amount of cellulose in the RYO cigarette is (75+470) = 545 mg of cellulose. The contribution of the paper cellulose to the overall amount of cellulose is 14%.

Therefore, when smoke data is collected, the data reflects most predominantly the tobacco used for the RYO cigarettes and only to a small degree the paper that is used. Significantly, if two papers are compared in an SE submission (for example one predicate and one SE product), any small changes in the weight of one rolling paper translates into an even small percentage of change for the complete cigarette.

In the following example we take two KSSLIM papers with paper weights of 75 mg and 65 mg. This is a difference of 14% in the weight of the paper. But if both cigarettes are made with 1175 mg of tobacco (corresponding to 470 mg of cellulose), the total amounts of cellulose in the RYO cigarette is (65+470) = 535 mg cellulose for the one RYO cigarette and (75+470) = 545 mg cellulose for the other RYO cigarette. The difference in cellulose of the finished RYO cigarette is less than 2%. This cannot be differentiated by smoke delivery testing, especially in the case of RYO cigarettes, which have a greater variability (see below).

The above mathematical analysis shows that a larger difference in cellulose amount of the paper itself translates only into a small difference in the finished RYO cigarette. Collecting smoke data from rolled cigarettes containing tobacco to characterize the difference in rolling paper weight does not adequately address differences in the paper because it measured predominantly the delivery from the combustion/pyrolysis of the cellulose in tobacco.

III.   Machine Smoking of Factory-Made Cigarettes vs. RYO Cigarettes

In general, for the determination of smoke delivery data for RYO cigarettes, the paper and fine-cut tobacco are sent to the lab (internal or 3rd party). and trained lab personnel prepares the cigarettes. The resulting RYO cigarettes are then treated like factory-made cigarettes. They are smoked on smoking machines and the gas and/or particulate phase is tested for the desired chemical compounds.

Lab-smoking is standard practice for the testing of smoke analytes in factory-made cigarettes. The use of smoking machines and smoking standards is accepted as the best possible way to compare different factory-made cigarettes. However, it is also acknowledged that the deliveries seen in machine smoking are not a true reflection of analyte exposure. For factory-made cigarettes, at least the smoking article that is tested on the machine is identical to the smoking article used by the consumer. We will show below that this is not the case for RYO cigarettes.

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A.   **Variability of Factory-Made Cigarettes**

A large amount of scientific papers characterize factory-made cigarettes, especially the different generations of the standard cigarettes like 3R4F. The error for TPM, nicotine and CO for 3R4F cigarettes is broadly generally 5-10%; it can reach up to 20% for analytes that are present in very small quantities. The data for factory-made cigarettes exhibit a similar degree of variability.

The low variability is a direct reflection of the uniformity of factory made cigarettes. Paper porosity, tobacco weight, cigarette circumference and pressure drop are important physical product parameters that determine smoke deliveries. These parameters are tightly controlled parameters for machine-made cigarettes. Typical cigarette makers include built-in modules that conduct on-the-fly quality control and eject any cigarette that doesn't meet specifications.

B.   **Variability of RYO Cigarettes**

Compared to the uniform factory-made cigarettes, RYO cigarettes have no specifications for physical parameters because the consumer makes each cigarette individually. Essentially, each RYO cigarette is a unique specimen.

In the following paragraphs we will discuss the challenges we face when measuring smoke delivery data for RYO cigarettes.

1.   **Making of the RYO-Cigarettes**

We have just pointed out the inherent variability of RYO cigarettes. When RYO cigarettes are made in the lab, certain limitations are put upon the cigarettes. For example, the diameter is fixed to 7.2 mm. This is purely practical and ensures that the cigarette fits in the standard labyrinth seal on the smoking machine. As discussed above, the amount of tobacco is also regulated through ISO 15592-3. It is up to the lab's discretion to set a limit on the allowed weight variance. Lastly, also by discretion of the lab, the cigarettes can be selected by pressure drop. These measures all reduce the variability of the RYO cigarette and should reduce the variability in the smoke data.

However, the more tightly controlled the making parameters for the RYO cigarette are, *the less representative the cigarette is of the real-life RYO cigarettes that are being made by the consumer*. Thus, the smoke data obtained from lab-made RYO cigarettes are doubly removed from real life exposures because 1) they are machine smoked; and 2) the standard lab-made RYO cigarette does not reflect actual consumer-made RYO cigarettes.

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We submit that machine generated smoke delivery data for RYO cigarettes has little practical utility since the RYO cigarettes made for testing have no resemblance to RYO cigarettes made by the consumer.

2.   Physical Parameters of Lab-Prepared RYO Cigarettes:

We submitted several papers to Global Laboratories, an ISO certified laboratory located in Wilson, North Carolina. Global is one of two contract laboratories in the US that can make and machine smoke RYO cigarettes.

Attachment 1 shows a 2 page excerpt from Global's report. The sample was a 1 ¼ size rolling paper. We have redacted the sample name to maintain confidentiality. 154 cigarettes were rolled by trained lab personnel. The predetermined weight of the finished cigarette was between 0.08425 and 0.8625 mg. We eliminated all cigarettes that were not 76 mm long and outside that weight range.

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Table 1: Remaining cigarettes meeting specifications

data point	#	Weight, g	PDc, mm Wg
1	152	0.846	33
2	146	0.8508	34
3	153	0.8458	36
4	49	0.846	38
5	45	0.8517	47
6	23	0.8597	49
7	151	0.8567	58
8	79	0.8592	59
9	33	0.8603	60
10	44	0.8484	63
11	27	0.8444	64
12	54	0.8603	64
13	31	0.8564	68
14	7	0.8484	71
15	4	0.8497	71
16	34	0.8468	74
17	88	0.8449	76
18	99	0.8503	76
19	85	0.8426	82
20	86	0.8482	87
21	52	0.853	87
22	87	0.8561	87
23	30	0.8429	90
24	117	0.8612	90
25	70	0.8498	92
26	8	0.8496	95
27	38	0.8623	95
28	3	0.8519	102
29	63	0.8623	102
30	65	0.853	105
31	101	0.8483	107
32	81	0.8624	107
33	41	0.8471	113
34	100	0.8454	116
35	71	0.8612	116
36	69	0.8428	118
37	9	0.8445	118
38	25	0.8484	119
39	42	0.8601	122
40	39	0.8568	123
41	10	0.8576	129
42	64	0.852	133
43	106	0.8522	135
44	119	0.8607	141
45	80	0.8552	143
46	46	0.8436	144
47	12	0.8435	145
48	74	0.8462	149
49	58	0.8537	154
50	62	0.8522	168
51	90	0.8426	216
52	103	0.8579	242
53	104	0.8562	255
	Mean	0.8519	103
	SD	0.0063	48
	CV	0.7347	46
	Min	0.8426	33
	Max	0.8624	255

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Table 1 above shows the data points that remained after the elimination. About two thirds of the prepared cigarettes did not match the acceptance criteria.

These remaining 53 cigarettes meet very tight specifications with respect to cigarette diameter, cigarette length and tobacco weight. However, the pressure drop varies between 33 and 255 mm H2O. This difference reflects the variability of the tobacco density distribution inside the cigarette. The pressure drop is known to have a significant influence on the smoke deliveries. It is very difficult to select about 20 cigarettes with a tight range of pressure drops for TNCO analysis.

This illustrates the large amount of work and material is needed to make cigarettes that are sufficiently uniform to obtain reasonable data.

We submit this constitutes **a high burden on us to collect information with questionable validity of the methodology.**

3.   TNCO Data Variability for RYO Cigarettes

We also submitted cigarettes to be prepared and machine smoked to Enthalpy Analytics. We submitted 25 samples to be analyzed for TPM, nicotine and CO delivery. The samples were actually all the same paper. **Attachment 2** has the original data (sample names redacted to preserve confidentiality). The data shows the increased variability of the RYO cigarette data compared to the 3R4F standard cigarette (labeled "913" in the report, not redacted). We see this higher variability in spite of all the specifications attached to the making of the RYO cigarettes.

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Figure 1: TPM for repeated testing of an RYO cigarette
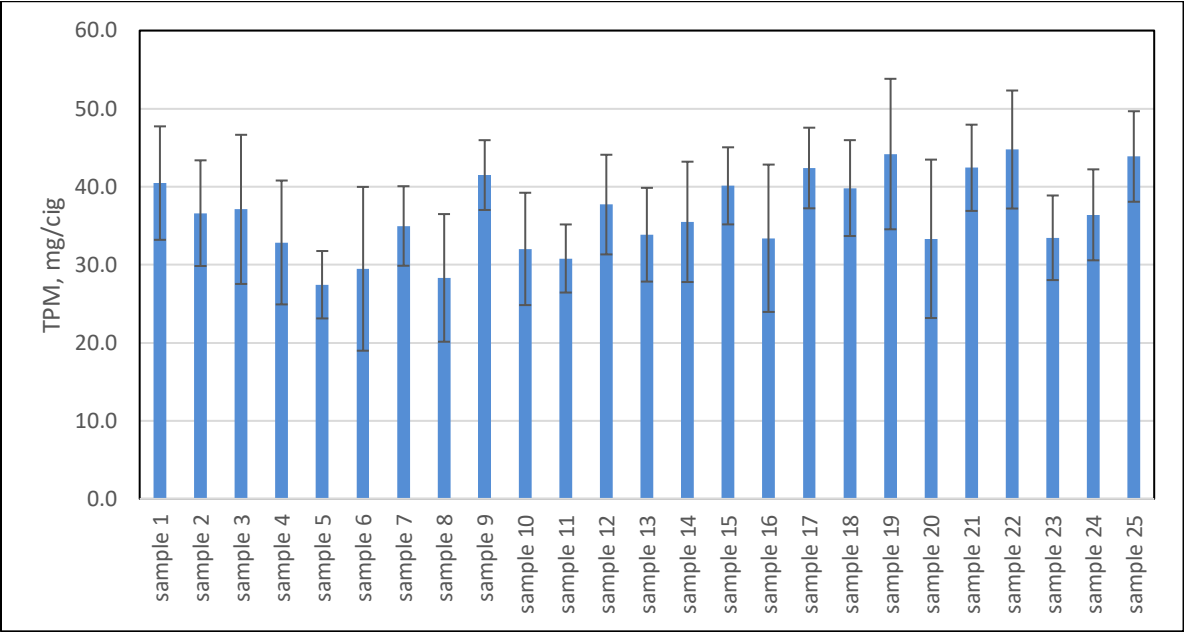
Figure 1 above shows the average and standard deviation collected from the 25 samples. We hypothesize that the large variability of the data is due to the uneven tobacco distribution in the cigarette rod. The tobacco density in the rod cannot be controlled in RYO cigarettes as it is in factory-made cigarettes. This results in larger variabilities of the pressure drop which in turn influence the smoking behavior.

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Figure 2: nicotine delivery for 25 samples of the same kind
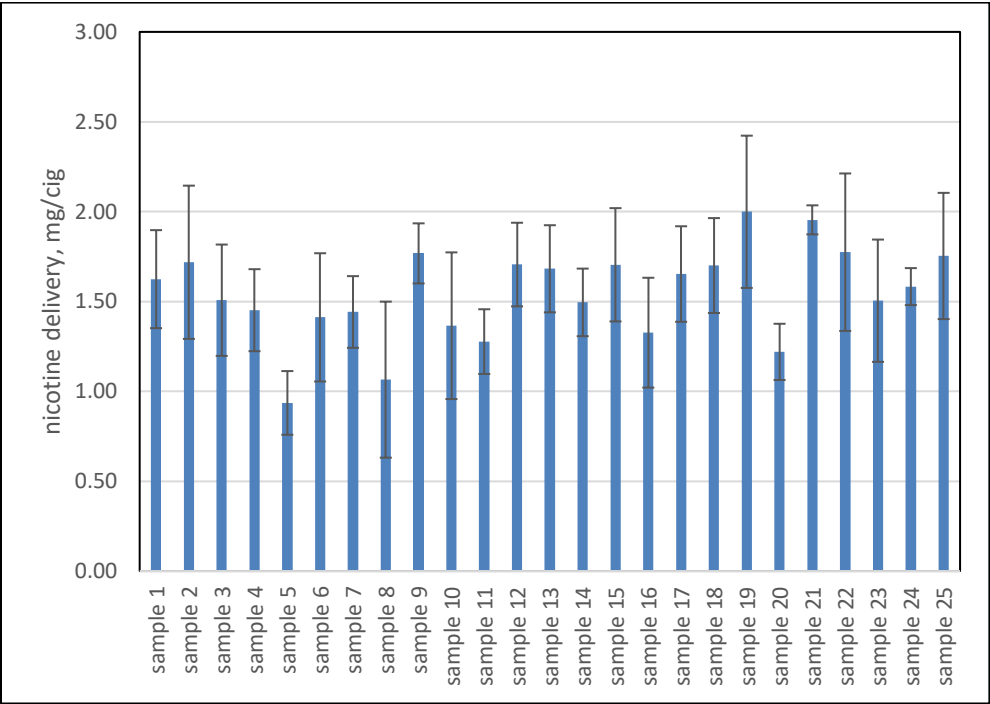
Figure 2 above shows the nicotine delivery for the same samples. Nicotine is found almost exclusively in the particulate matter, so it is to be expected to see a similar variability in the data.

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Figure 3: CO delivery in 25 samples
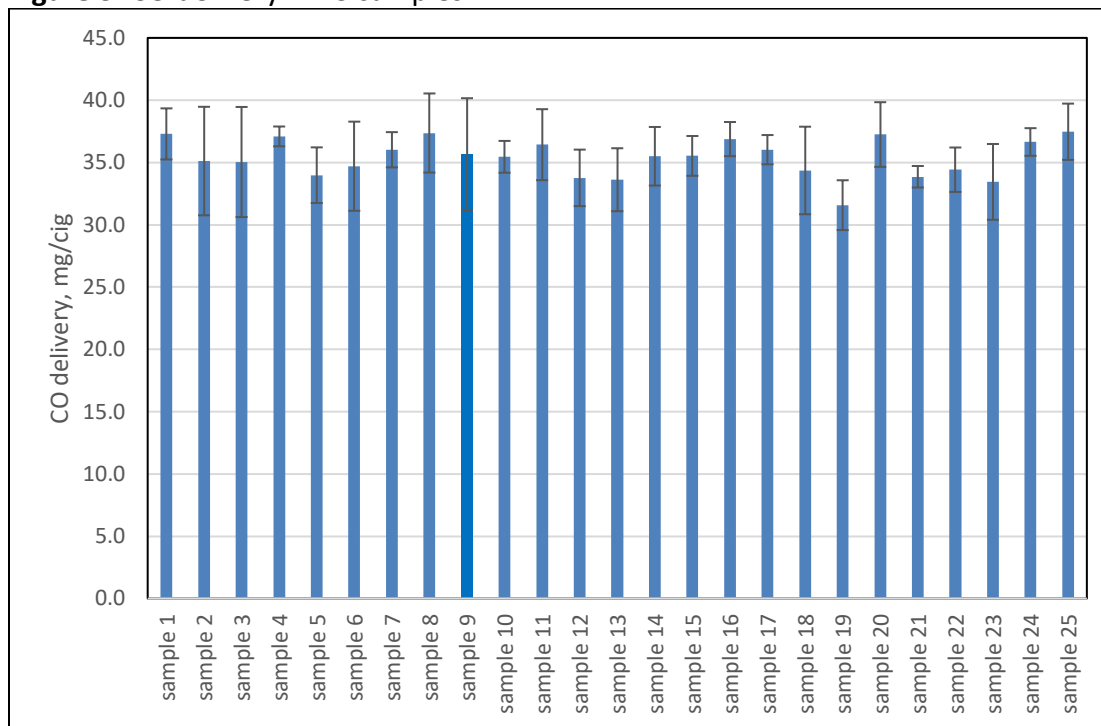
Figure 3 above illustrates the CO delivery for the 25 samples. CO is a persistent gas, so it is a good marker for gas phase analytes. There is also significant variability in the CO delivery.

We have analyzed the individual analyte data using one-way ANOVA and there are statistically significant differences between the samples for TPM, nicotine and CO delivery respectively.

Table 2: p-values from one-way ANOVA analyses for TNCO analysis

smoke parameter	p-value
TPM, mg/cig	0.00058
nicotine, mg/cig	0.000014
CO, mg/cig	0.036

Table 2 above shows the p-values from the ANOVA analysis for the smoke parameters. All samples are the same sample, so it is illogical to have statistically significant differences. We assert that the results are due to the variability of the RYO cigarettes. As shown above, even with strong lab-imposed specifications, it is very laborious and difficult to obtain consistent cigarettes for testing and the variability of the product results in variability of the data.

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In the case above, we would conclude that certain samples are statistically different. However, the cigarettes use the same RYO paper and as such should not be different. This is an erroneous conclusion based on the limitations of the test. In a similar fashion, we also hypothesize that the data could show 2 samples to be statistically the same, even if they are truly different.

We conclude that there are significant limitations to the collection of smoke data from RYO-cigarettes and **question the validity of the methodology and assumptions used.**

C.   Laboratory Shortage

As seen in the discussion above, we utilize two different labs to conduct smoke analyses. HBI international is not set up to conduct smoke testing. Setting up a lab with instrumentation, utilities and personnel and obtaining ISO certification would be a multi-year and multi-million dollar undertaking, and it would be a too heavy burden on our company.

Engaging a 3rd party lab also involves cost. And as mentioned above, there are only two labs available. At the same time, there are a lot of samples to be tested. This can result in long waiting times. HBI International has directly experienced that. Another client had submitted a big project just before we submitted our samples to the lab and we were told that our samples wouldn't even be looked at for several months.

We assert that some of the required testing does not add any value to SE applications. It unnecessarily clogs up labs. Equally significant, the inconsistent data increases the FDA's own burden.

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IV.   **Summary**

We have discussed the usefulness of collecting and using smoke analysis data for SE submissions for RYO rolling papers. To obtain smoke data, RYO cigarettes are made using the rolling papers under discussion in the SE. We have shown that this approach puts an **undue burden on the submitter** and delivers **data that is not a true reflection of the rolling paper itself and can lead to incorrect conclusions**:

- The amount of cellulose in the rolling paper is very small compared to the finished RYO cigarette; any differences in the rolling paper translate to even smaller differences in the finished cigarettes which cannot be detected in a reliable way.

- RYO cigarettes are very variable; the great variability translates into variable smoke data which can led to incorrect conclusions.

- In order to reduce the variability of RYO cigarette smoke deliveries somewhat, specifications are attached to their making; as result, a large amount of cigarettes have to be hand-rolled in order to obtain a small population somewhat suited for testing.

- The more the lab rolling of RYO cigarettes is controlled, the further the resulting cigarettes are from the real-life rolling of RYO cigarettes by the consumer. Thus the resulting cigarettes have less and less practical utility.

As shown above, the current testing the FDA requires does not produce useful and reliable data. The data can even lead to incorrect conclusions. Instead, the FDA should examine cigarette rolling papers with testing that does not introduce the variables and unreliability of lab-made RYO cigarettes. Cigarette rolling papers should be tested without tobacco.

Attachment 1 (2 pages)

Table 5. ███████████████

#	Weight (g)	Length (mm)	PDc (mmWg)	#	Weight (g)	Length (mm)	PDc (mmWg)
1	0.862	75.5	128	45	0.8517	76	47
2	0.8014	76	66	46	0.8436	76	144
3	0.8519	76	102	47	0.8016	76	81
4	0.8497	76	71	48	0.8557	75.5	42
5	0.8077	76	105	49	0.846	76	38
6	0.8007	76	89	50	0.8022	75.5	9
7	0.8484	76	71	51	0.8424	76	210
8	0.8496	76	95	52	0.853	76	87
9	0.8445	76	118	53	0.794	76	55
10	0.8576	76	129	54	0.8603	76	64
11	0.8073	76	130	55	0.8444	75	60
12	0.8435	76	145	56	0.8548	75.5	51
13	0.8639	76	57	57	0.8044	75.5	61
14	0.8591	75	72	58	0.8537	76	154
15	0.8014	76	109	59	0.7968	76	61
16	0.7991	75	101	60	0.8053	76	133
17	0.8502	75.5	91	61	0.8419	76	68
18	0.7947	76	121	62	0.8522	76	168
19	0.7948	76	99	63	0.8623	76	102
20	0.7997	76.5	77	64	0.852	76	133
21	0.8487	75	64	65	0.853	76	105
22	0.7948	76	118	66	0.8568	75.5	155
23	0.8597	76	49	67	0.8435	75.5	178
24	0.8437	76.5	126	68	0.851	76.5	202
25	0.8484	76	119	69	0.8428	76	118
26	0.7995	76	61	70	0.8498	76	92
27	0.8444	76	64	71	0.8612	76	116
28	0.849	75.5	73	72	0.863	76	235
29	0.8635	76	68	73	0.7945	76.5	82
30	0.8429	76	90	74	0.8462	76	149
31	0.8564	76	68	75	0.8031	76.5	116
32	0.8602	76.5	75	76	0.8017	76	288
33	0.8603	76	60	77	0.8612	75.5	43
34	0.8468	76	74	78	0.864	76	87
35	0.8446	75	43	79	0.8592	76	59
36	0.8562	75	165	80	0.8552	76	143
37	0.8596	75.5	58	81	0.8624	76	107
38	0.8623	76	95	82	0.8416	76	157
39	0.8568	76	123	83	0.8441	76.5	58
40	0.8545	76.5	115	84	0.8018	75.5	147
41	0.8471	76	113	85	0.8426	76	82
42	0.8601	76	122	86	0.8482	76	87
43	0.7463	76	59	87	0.8561	76	87
44	0.8484	76	63	88	0.8449	76	76

GLOBAL LABORATORY
Services, Inc.

Table 5 (cont.).

#	Weight (g)	Length (mm)	PDc (mmWg)	#	Weight (g)	Length (mm)	PDc (mmWg)
89	0.8019	76	211	133	0.7963	76	90
90	0.8426	76	216	134	0.799	76	162
91	0.8001	76	218	135	0.8019	75.5	146
92	0.8119	76	53	136	0.8428	75	97
93	0.8581	76.5	111	137	0.8106	76	71
94	0.7955	76	110	138	0.7965	76	123
95	0.8412	76	78	139	0.8587	74	32
96	0.8003	76	44	140	0.8063	76	162
97	0.8016	75	62	141	0.7472	76	63
98	0.7924	76	182	142	0.86	75	93
99	0.8503	76	76	143	0.8073	75.5	79
100	0.8454	76	116	144	0.805	76	176
101	0.8483	76	107	145	0.8449	75	42
102	0.842	76	51	146	0.8508	76	34
103	0.8579	76	242	147	0.8079	76	171
104	0.8562	76	255	148	0.7596	76	29
105	0.8086	76	24	149	0.8423	76	68
106	0.8522	76	135	150	0.798	76	43
107	0.806	76	187	151	0.8567	76	58
108	0.8603	76.5	57	152	0.846	76	33
109	0.8104	76	202	153	0.8458	76	36
110	0.8056	76	21	154	0.842	74	52
111	0.798	76	23	Mean	0.8313	75.9	101.8
112	0.808	76	129	SD	0.0283	0.4	54.7
113	0.8109	76	23	CV	3.4	0.5	53.7
114	0.8011	76	94	Min	0.7463	74	9
115	0.8521	75.5	137	Max	0.864	77	288
116	0.7943	76	20				
117	0.8612	76	90				
118	0.8612	75	124				
119	0.8607	76	141				
120	0.8422	76	216				
121	0.8024	76	171				
122	0.7595	75	107				
123	0.8415	75	100				
124	0.8606	75	168				
125	0.8018	76	67				
126	0.7992	76	53				
127	0.7949	76	148				
128	0.8519	75	234				
129	0.7612	76	86				
130	0.811	76	90				
131	0.8088	76	25				
132	0.8117	76	38				

Attachment 2 (5 pages)

Summary

Sample Name	Sample Code	Run No	Port	Cigs	Puffs/Cig	TPM mg/cig	Tar mg/cig	Nicotine mg/cig	CO mg/cig	Water mg/cig
▮▮▮▮	AM-001 R1C P7 0217-028 30582	1	7	3	18.2	44.7	32.8	1.84	36.6	10.1
	AM-001 R2C P10 0217-028 30582	2	10	3	18.3	44.4	30.7	1.64	38.9	12.1
	AM-001 R3C P12 0217-028 30582	3	12	3	18.5	47.4	34.8	1.93	35.1	10.7
	AM-001 R4C P6 0217-028 30582	4	6	3	19.0	30.3	22.8	1.39	35.8	6.04
	AM-001 R5C P17 0217-028 30582	5	17	3	21.9	35.5	26.4	1.31	40.0	7.75
	Average				19.2	40.5	29.5	1.62	37.3	9.34
	StdDev				1.6	7.3	4.9	0.27	2.1	2.42
	RSD				8.2%	18.0%	16.4%	16.8%	5.5%	25.9%
▮▮▮	AM-001 R1C P4 0217-028 30583	1	4	3	21.3	31.8	27.4	1.61	31.5	2.84
	AM-001 R2C P14 0217-028 30583	2	14	3	20.6	32.7	23.5	1.10	42.5	8.07
	AM-001 R3C P17 0217-028 30583	3	17	3	19.0	47.9	36.9	2.22	35.4	8.78
	AM-001 R6C P1 0217-028 30583	6	1	3	16.9	32.7	20.8	2.01	32.9	9.85
	AM-001 R7C P17 0217-028 30583	7	17	3	17.9	38.0	29.3	1.65	33.2	7.01
	Average				19.1	36.6	27.6	1.72	35.1	7.31
	StdDev				1.8	6.8	6.2	0.43	4.4	2.71
	RSD				9.5%	18.5%	22.4%	24.8%	12.4%	37.0%
▮▮▮▮▮	AM-001 R1C P17 0217-028 30584	1	17	3	19.5	46.2	32.9	1.69	38.2	11.7
	AM-001 R4C P10 0217-028 30584	4	10	3	19.5	22.9	20.7	0.955	27.7	1.26
	AM-001 R5C P9 0217-028 30584	5	9	3	17.9	40.3	30.5	1.61	37.4	8.22
	AM-001 R6C P19 0217-028 30584	6	19	3	15.2	32.2	19.1	1.64	34.1	11.5
	AM-001 R7C P9 0217-028 30584	7	9	3	17.9	43.8	33.1	1.64	37.7	9.07
	Average				18.0	37.1	27.2	1.51	35.0	8.34
	StdDev				1.8	9.6	6.8	0.31	4.4	4.23
	RSD				9.8%	25.8%	25.0%	20.5%	12.6%	50.7%
▮▮▮▮	AM-001 R2C P2 0217-028 30585	2	2	3	22.2	39.8	28.5	1.77	36.8	9.58
	AM-001 R3C P20 0217-028 30585	3	20	3	17.9	39.2	29.6	1.60	36.9	7.95
	AM-001 R4C P2 0217-028 30585	4	2	3	19.7	34.2	27.6	1.29	38.3	5.34
	AM-001 R5C P12 0217-028 30585	5	12	3	19.1	30.7	23.8	1.21	36.2	5.68
	AM-001 R6C P5 0217-028 30585	6	5	3	19.6	20.3	10.5	1.39	37.4	8.49
	Average				19.7	32.9	24.0	1.45	37.1	7.41
	StdDev				1.6	7.9	7.9	0.23	0.8	1.83
	RSD				8.0%	24.2%	32.8%	15.7%	2.1%	24.8%
▮▮▮▮	AM-001 R1C P15 0217-028 30586	1	15	3	18.5	34.7	27.3	1.22	35.0	6.14
	AM-001 R2C P13 0217-028 30586	2	13	3	19.4	24.7	18.5	0.768	36.9	5.39
	AM-001 R3C P7 0217-028 30586	3	7	3	20.9	28.1	26.2	0.833	30.9	1.04
	AM-001 R4C P8 0217-028 30586	4	8	3	21.5	24.3	21.2	0.873	33.4	2.15
	AM-001 R7C P2 0217-028 30586	7	2	3	19.2	25.5	20.7	0.984	33.7	3.81
	Average				19.9	27.4	22.8	0.935	34.0	3.71
	StdDev				1.3	4.3	3.8	0.177	2.2	2.14
	RSD				6.3%	15.7%	16.6%	18.9%	6.6%	57.7%
▮▮▮	AM-001 R1C P12 0217-028 30587	1	12	3	19.9	43.4	32.8	2.00	34.8	8.64
	AM-001 R2C P20 0217-028 30587	2	20	3	20.4	27.6	22.1	1.14	39.2	4.33
	AM-001 R5C P7 0217-028 30587	5	7	3	17.6	33.5	26.4	1.43	34.2	5.66
	AM-001 R6C P6 0217-028 30587	6	6	3	19.5	14.5	9.20	1.11	29.3	4.19
	AM-001 R7C P10 0217-028 30587	7	10	3	17.5	28.3	19.9	1.38	36.1	7.01
	Average				19.0	29.5	22.1	1.41	34.7	5.97
	StdDev				1.3	10.5	8.7	0.36	3.6	1.88
	RSD				7.0%	35.6%	39.5%	25.3%	10.3%	31.6%

Summary

Sample Name	Sample Code	Run No	Port	Cigs	Puffs/Cig	TPM mg/cig	Tar mg/cig	Nicotine mg/cig	CO mg/cig	Water mg/cig
▬	AM-001 R3C P10 0217-028 30588	3	10	3	19.1	31.2	26.2	1.24	34.6	3.78
	AM-001 R4C P5 0217-028 30588	4	5	3	17.2	41.4	30.4	1.71	34.9	9.27
	AM-001 R5C P10 0217-028 30588	5	10	3	16.4	36.0	25.5	1.33	35.8	9.11
	AM-001 R6C P18 0217-028 30588	6	18	3	16.6	37.6	25.9	1.59	36.6	10.2
	AM-001 R7C P4 0217-028 30588	7	4	3	18.3	28.6	20.7	1.34	38.1	6.60
	Average				17.5	35.0	25.7	1.44	36.0	7.78
	StdDev				1.1	5.1	3.5	0.20	1.4	2.60
	RSD				6.6%	14.6%	13.4%	13.8%	3.9%	33.4%
▬	AM-001 R1C P13 0217-028 30589	1	13	3	20.5	35.0	29.3	1.50	32.7	4.18
	AM-001 R2C P17 0217-028 30589	2	17	3	20.1	25.2	18.5	0.770	39.5	5.90
	AM-001 R3C P4 0217-028 30589	3	4	3	22.5	19.8	16.5	0.674	39.6	2.63
	AM-001 R4C P3 0217-028 30589	4	3	3	20.3	22.8	18.8	0.808	35.4	3.22
	AM-001 R5C P15 0217-028 30589	5	15	3	19.2	38.8	27.6	1.57	39.6	9.62
	Average				20.5	28.3	22.1	1.07	37.4	5.11
	StdDev				1.2	8.2	5.9	0.43	3.2	2.81
	RSD				5.9%	28.9%	26.5%	40.8%	8.5%	55.0%
▬	AM-001 R1C P1 0217-028 30590	1	1	3	21.6	36.0	28.8	1.76	28.5	5.46
	AM-001 R2C P18 0217-028 30590	2	18	3	16.7	40.7	29.9	1.71	36.9	9.13
	AM-001 R3C P6 0217-028 30590	3	6	3	15.9	38.7	28.2	1.53	40.2	9.02
	AM-001 R6C P4 0217-028 30590	6	4	3	15.3	45.1	30.9	1.96	34.5	12.3
	AM-001 R7C P15 0217-028 30590	7	15	3	17.0	46.8	33.7	1.89	38.2	11.2
	Average				17.3	41.5	30.3	1.77	35.6	9.42
	StdDev				2.5	4.5	2.2	0.17	4.5	2.62
	RSD				14.4%	10.8%	7.2%	9.5%	12.7%	27.8%
▬	AM-001 R1C P3 0217-028 30591	1	3	3	19.5	40.6	30.1	1.70	34.9	8.76
	AM-001 R4C P15 0217-028 30591	4	15	3	17.8	35.4	27.0	1.63	33.6	6.70
	AM-001 R5C P16 0217-028 30591	5	16	3	18.6	33.1	23.9	1.36	37.1	7.86
	AM-001 R6C P13 0217-028 30591	6	13	3	19.1	29.8	19.3	1.47	35.9	9.05
	AM-001 R7C P5 0217-028 30591	7	5	3	19.2	21.2	18.8	0.676	35.7	1.78
	Average				18.8	32.0	23.8	1.37	35.5	6.83
	StdDev				0.7	7.2	4.9	0.41	1.3	2.97
	RSD				3.6%	22.5%	20.6%	29.9%	3.6%	43.5%
▬	AM-001 R2C P11 0217-028 30592	2	11	3	18.2	32.0	24.7	1.26	36.4	5.99
	AM-001 R3C P5 0217-028 30592	3	5	3	19.4	26.6	21.9	1.06	34.9	3.61
	AM-001 R4C P14 0217-028 30592	4	14	3	19.7	37.7	28.1	1.56	35.7	8.09
	AM-001 R5C P8 0217-028 30592	5	8	3	17.6	29.8	23.5	1.25	33.9	5.05
	AM-001 R6C P15 0217-028 30592	6	15	3	18.4	27.9	16.2	1.26	41.2	10.4
	Average				18.7	30.8	22.9	1.28	36.4	6.64
	StdDev				0.9	4.4	4.4	0.18	2.9	2.68
	RSD				4.7%	14.2%	19.1%	14.1%	7.8%	40.4%
▬	AM-001 R1C P16 0217-028 30593	1	16	3	19.9	29.0	24.5	1.42	34.1	3.07
	AM-001 R2C P8 0217-028 30593	2	8	3	18.0	37.0	28.1	1.63	33.5	7.26
	AM-001 R3C P15 0217-028 30593	3	15	3	19.4	41.2	32.1	1.76	37.4	7.35
	AM-001 R4C P9 0217-028 30593	4	9	3	14.9	46.0	34.1	2.06	32.1	9.89
	AM-001 R7C P13 0217-028 30593	7	13	3	18.0	35.3	28.3	1.66	31.7	5.30
	Average				18.0	37.7	29.4	1.71	33.8	6.57
	StdDev				1.9	6.4	3.7	0.23	2.3	2.55
	RSD				10.7%	16.9%	12.7%	13.6%	6.7%	38.7%

Summary

Sample Name	Sample Code	Run No	Port	Cigs	Puffs/Cig	TPM mg/cig	Tar mg/cig	Nicotine mg/cig	CO mg/cig	Water mg/cig
▓▓▓▓▓	AM-001 R1C P8 0217-028 30594	1	8	3	17.0	39.0	29.5	1.89	31.2	7.66
	AM-001 R2C P6 0217-028 30594	2	6	3	15.3	41.1	29.3	1.93	32.0	9.83
	AM-001 R5C P19 0217-028 30594	5	19	3	16.8	29.1	22.9	1.48	32.5	4.76
	AM-001 R6C P10 0217-028 30594	6	10	3	15.2	32.6	22.1	1.73	35.1	8.76
	AM-001 R7C P7 0217-028 30594	7	7	3	18.2	27.4	20.0	1.38	37.3	6.00
	Average				16.5	33.8	24.8	1.68	33.6	7.40
	StdDev				1.3	6.0	4.4	0.24	2.5	2.05
	RSD				7.7%	17.7%	17.6%	14.4%	7.5%	27.7%
▓▓▓▓	AM-001 R3C P3 0217-028 30595	3	3	3	19.2	30.6	24.6	1.32	33.1	4.70
	AM-001 R4C P20 0217-028 30595	4	20	3	18.6	41.9	30.4	1.67	34.9	9.79
	AM-001 R5C P5 0217-028 30595	5	5	3	20.8	32.0	26.9	1.31	33.9	3.75
	AM-001 R6C P11 0217-028 30595	6	11	3	18.0	27.6	18.2	1.47	36.4	7.94
	AM-001 R7C P1 0217-028 30595	7	1	3	18.5	45.4	32.7	1.71	39.1	11.0
	Average				19.0	35.5	26.6	1.49	35.5	7.43
	StdDev				1.1	7.7	5.6	0.19	2.4	3.14
	RSD				5.7%	21.7%	21.2%	12.6%	6.6%	42.2%
▓▓▓▓▓▓	AM-001 R1C P5 0217-028 30596	1	5	3	20.9	48.8	36.0	2.20	33.8	10.6
	AM-001 R2C P15 0217-028 30596	2	15	3	19.8	38.4	28.5	1.44	38.0	8.45
	AM-001 R3C P18 0217-028 30596	3	18	3	17.7	36.5	28.2	1.45	35.9	6.85
	AM-001 R4C P17 0217-028 30596	4	17	3	18.8	38.0	30.4	1.63	35.5	5.99
	AM-001 R5C P1 0217-028 30596	5	1	3	20.6	38.8	29.4	1.80	34.5	7.55
	Average				19.6	40.1	30.5	1.70	35.5	7.89
	StdDev				1.3	4.9	3.2	0.32	1.6	1.78
	RSD				6.7%	12.3%	10.4%	18.5%	4.5%	22.5%
▓▓▓▓	AM-001 R1C P9 0217-028 30597	1	9	3	19.3	46.4	32.4	1.73	37.8	12.3
	AM-001 R2C P3 0217-028 30597	2	3	3	21.3	26.6	22.3	1.10	34.5	3.20
	AM-001 R3C P9 0217-028 30597	3	9	3	19.8	32.0	26.3	1.33	37.5	4.38
	AM-001 R6C P14 0217-028 30597	6	14	3	20.3	23.0	17.9	0.967	36.8	4.19
	AM-001 R7C P12 0217-028 30597	7	12	3	20.6	38.9	29.0	1.51	37.7	8.40
	Average				20.3	33.4	25.6	1.33	36.9	6.50
	StdDev				0.7	9.4	5.7	0.31	1.4	3.82
	RSD				3.7%	28.3%	22.2%	23.0%	3.7%	58.7%
▓▓▓▓	AM-001 R1C P10 0217-028 30598	1	10	3	16.6	44.4	33.1	1.80	36.6	9.50
	AM-001 R4C P12 0217-028 30598	4	12	3	15.0	50.6	36.0	1.95	35.3	12.6
	AM-001 R5C P11 0217-028 30598	5	11	3	16.5	38.7	28.6	1.36	37.7	8.71
	AM-001 R6C P8 0217-028 30598	6	8	3	16.5	40.0	27.2	1.76	34.6	11.1
	AM-001 R7C P6 0217-028 30598	7	6	3	16.9	38.3	27.8	1.38	36.0	9.09
	Average				16.3	42.4	30.5	1.65	36.0	10.2
	StdDev				0.8	5.2	3.8	0.27	1.2	1.6
	RSD				4.6%	12.2%	12.5%	16.1%	3.3%	16.0%

Summary

Sample Name	Sample Code	Run No	Port	Cigs	Puffs/Cig	TPM mg/cig	Tar mg/cig	Nicotine mg/cig	CO mg/cig	Water mg/cig
▇▇▇▇	AM-001 R2C P9 0217-028 30599	2	9	3	19.6	44.4	31.7	1.82	37.4	10.9
	AM-001 R3C P8 0217-028 30599	3	8	3	18.2	40.2	33.7	1.87	30.7	4.60
	AM-001 R4C P1 0217-028 30599	4	1	3	17.5	46.2	37.0	1.96	30.4	7.26
	AM-001 R5C P6 0217-028 30599	5	6	3	19.1	37.7	29.7	1.32	37.2	6.67
	AM-001 R6C P17 0217-028 30599	6	17	3	18.6	30.6	20.9	1.54	36.2	8.24
	Average				18.6	39.8	30.6	1.70	34.4	7.53
	StdDev				0.8	6.1	6.1	0.26	3.5	2.29
	RSD				4.3%	15.4%	19.9%	15.5%	10.2%	30.5%
▇▇▇▇	AM-001 R1C P6 0217-028 30600	1	6	3	19.3	43.2	34.0	2.18	29.7	7.03
	AM-001 R2C P16 0217-028 30600	2	16	3	20.3	29.6	22.4	1.28	32.9	5.84
	AM-001 R3C P11 0217-028 30600	3	11	3	18.1	51.3	40.1	2.30	29.7	8.91
	AM-001 R4C P16 0217-028 30600	4	16	3	16.8	54.3	41.9	2.28	34.3	10.1
	AM-001 R7C P18 0217-028 30600	7	18	3	17.7	42.5	32.9	1.95	31.3	7.66
	Average				18.4	44.2	34.3	2.00	31.6	7.91
	StdDev				1.4	9.6	7.7	0.42	2.0	1.65
	RSD				7.5%	21.8%	22.4%	21.2%	6.3%	20.9%
▇▇▇▇	AM-001 R1C P11 0217-028 30601	1	11	3	22.9	32.0	26.4	1.33	34.0	4.31
	AM-001 R2C P4 0217-028 30601	2	4	3	23.5	50.7	43.1	1.43	38.9	6.17
	AM-001 R5C P14 0217-028 30601	5	14	3	20.4	28.9	23.7	1.14	34.9	4.08
	AM-001 R6C P9 0217-028 30601	6	9	3	20.1	24.2	15.3	1.14	38.9	7.72
	AM-001 R7C P8 0217-028 30601	7	8	3	19.9	30.8	24.1	1.05	39.6	5.65
	Average				21.4	33.3	26.5	1.22	37.2	5.58
	StdDev				1.7	10.1	10.2	0.16	2.6	1.48
	RSD				7.9%	30.5%	38.3%	12.8%	7.0%	26.6%
▇▇▇▇	AM-001 R3C P14 0217-028 30602	3	14	3	17.2	43.3	33.7	2.06	33.3	7.52
	AM-001 R4C P13 0217-028 30602	4	13	3	18.5	35.1	27.3	1.87	35.0	5.88
	AM-001 R5C P4 0217-028 30602	5	4	3	17.3	48.6	34.1	1.88	34.5	12.6
	AM-001 R6C P12 0217-028 30602	6	12	3	17.1	38.7	25.7	2.01	33.0	11.0
	AM-001 R7C P16 0217-028 30602	7	16	3	17.2	46.4	35.4	1.96	33.5	9.04
	Average				17.5	42.4	31.3	1.95	33.9	9.21
	StdDev				0.6	5.5	4.4	0.08	0.9	2.69
	RSD				3.4%	13.0%	14.0%	4.1%	2.5%	29.2%
▇▇▇▇	AM-001 R1C P14 0217-028 30603	1	14	3	18.6	38.1	26.3	1.23	37.1	10.5
	AM-001 R2C P12 0217-028 30603	2	12	3	17.5	43.7	32.9	1.81	33.7	8.94
	AM-001 R3C P13 0217-028 30603	3	13	3	15.0	42.3	31.6	1.71	32.4	8.94
	AM-001 R4C P11 0217-028 30603	4	11	3	14.5	42.0	30.6	1.68	33.7	9.69
	AM-001 R5C P2 0217-028 30603	5	2	3	16.7	57.8	43.0	2.45	35.2	12.3
	Average				16.5	44.8	32.9	1.77	34.4	10.1
	StdDev				1.7	7.6	6.2	0.44	1.8	1.4
	RSD				10.4%	16.9%	18.8%	24.7%	5.2%	13.9%

Summary

Sample Name	Sample Code	Run No	Port	Cigs	Puffs/Cig	TPM mg/cig	Tar mg/cig	Nicotine mg/cig	CO mg/cig	Water mg/cig
▉▉▉▉▉▉	AM-001 R1C P2 0217-028 30604	1	2	3	16.3	39.8	31.2	1.94	28.2	6.64
	AM-001 R2C P5 0217-028 30604	2	5	3	19.3	32.4	24.1	1.39	35.4	6.90
	AM-001 R3C P16 0217-028 30604	3	16	3	18.0	29.6	23.9	1.16	34.2	4.55
	AM-001 R6C P2 0217-028 30604	6	2	3	18.6	27.3	17.0	1.78	33.6	8.49
	AM-001 R7C P3 0217-028 30604	7	3	3	17.5	38.2	28.3	1.26	35.8	8.69
	Average				17.9	33.5	24.9	1.50	33.4	7.05
	StdDev				1.1	5.4	5.4	0.34	3.0	1.67
	RSD				6.3%	16.2%	21.6%	22.6%	9.1%	23.7%
▉▉▉▉▉▉	AM-001 R1C P19 0217-028 30605	1	19	3	18.2	40.3	29.6	1.62	35.9	9.10
	AM-001 R4C P7 0217-028 30605	4	7	3	17.0	40.0	29.6	1.67	37.2	8.73
	AM-001 R5C P3 0217-028 30605	5	3	3	19.5	41.5	31.0	1.66	38.3	8.84
	AM-001 R6C P3 0217-028 30605	6	3	3	16.5	30.8	22.7	1.42	35.7	6.71
	AM-001 R7C P19 0217-028 30605	7	19	3	18.2	29.3	20.0	1.54	36.1	7.75
	Average				17.9	36.4	26.6	1.58	36.6	8.23
	StdDev				1.2	5.8	4.9	0.10	1.1	0.99
	RSD				6.6%	16.0%	18.5%	6.5%	3.0%	12.0%
▉▉▉▉▉▉	AM-001 R2C P19 0217-028 30606	2	19	3	18.4	35.9	26.9	1.29	41.3	7.74
	AM-001 R3C P19 0217-028 30606	3	19	3	17.5	39.5	30.0	1.56	37.2	7.93
	AM-001 R4C P18 0217-028 30606	4	18	3	16.0	49.3	36.0	1.95	36.6	11.3
	AM-001 R5C P13 0217-028 30606	5	13	3	17.2	47.2	33.7	1.76	35.2	11.8
	AM-001 R6C P7 0217-028 30606	6	7	3	18.6	47.4	31.8	2.20	37.0	13.3
	Average				17.5	43.9	31.7	1.75	37.5	10.4
	StdDev				1.0	5.8	3.5	0.35	2.3	2.5
	RSD				6.0%	13.2%	10.9%	20.0%	6.0%	23.8%
913	AM-001 R1C P20 0217-028 913	1	20	3	10.6	44.7	27.3	1.94	30.8	15.5
	AM-001 R2C P1 0217-028 913	2	1	3	10.7	44.6	26.8	2.02	29.6	15.8
	AM-001 R3C P1 0217-028 913	3	1	3	10.5	51.1	30.6	2.08	30.8	18.4
	AM-001 R4C P19 0217-028 913	4	19	3	10.1	43.6	27.0	1.86	30.2	14.7
	AM-001 R5C P18 0217-028 913	5	18	3	9.87	46.5	27.9	1.96	30.3	16.6
	AM-001 R6C P16 0217-028 913	6	16	3	10.2	41.3	25.0	2.05	29.7	14.2
	AM-001 R7C P11 0217-028 913	7	11	3	9.60	37.4	25.1	1.92	28.1	10.4
	Average				10.2	44.2	27.1	1.98	29.9	15.1
	StdDev				0.4	4.2	1.9	0.08	0.9	2.5
	RSD				3.8%	9.6%	6.9%	3.8%	3.0%	16.4%