National Survey on Health Information Exchange in Clinical Laboratories

Information Collection Request

Supporting Statement, Part B

Submitted by:

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Table of Contents

B. Collections of Information Employing Statistical Methods

B1. Respondent Universe and Sampling Methods

ONC's contractor, NORC, will collect information for the survey on behalf of ONC. The contractor is responsible for the design and administration of the survey that will be used to collect information about laboratory information exchange.

As discussed in Part A, data will be collected from a national sample of laboratories utilizing a mail out/mail back methodology with email outreach and telephone non-response follow up. The target population for this survey is all hospital and independent laboratories in the 50 states plus D.C. and Puerto Rico. The source for the sampling frame will be the CMS Online Survey, Certification and Reporting (OSCAR) database.[1] The OSCAR database contains information on over 225,000 laboratories in the United States, and includes contact information (phone numbers and addresses) needed for survey data collection. The Clinical Laboratory Improvement Amendments (CLIA) Quality Systems laboratory regulations became effective in April 24, 2003. All laboratories in the United States are required to hold a CLIA certificate if they perform even one test on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings." Certificates are effective for two years. There are 29 different lay types in the CLIA database. In developing a sampling strategy for labs we focused on labs that have a high likelihood of exchanging lab results with outside entities. These lab's include hospital labs, independent labs and public health labs. We intentionally excluded public health labs as they are captured in other data collections. Hospitals and independent laboratories are required to hold a CLIA Certificate to operate. Even laboratories located in exempt states (Washington and New York) are required to hold a CLIA Certificate. Both these states have instituted a program that has been approved by the federal government in place of CLIA. That is, these states have instituted a program that has been approved by CLIA as equal to, or more stringent than, CLIA requirements. Thus, the CLIA database will provide a comprehensive picture of laboratory testing in the United States. Information is updated regularly by state CLIA offices.

The OSCAR database identifies 29 different categories of laboratories, of which two (hospital and independent) will be in scope for this survey. Table B.1 provides selected counts by target category from the OSCAR database as of 12/05/2011. The table also provides distribution percentages for each laboratory category, based on number of laboratories and number of laboratory tests. As can be seen, LabCorp and Quest, while constituting a small percentage of laboratories, process just over one-third of laboratory tests for the combined hospital/independent laboratory market.

Table B.1 Distribution of Laboratories in the OSCAR Database by Category

Lab Category	Number of Labs	Percent of Total Labs	Percent of Total Lab Tests
Hospital	8,925	61.8%	48.8%
Independent - LabCorp/Quest	506	3.5%	36.0%
Independent - Other	5,011	34.7%	15.1%
Total	**14,442**		

[1] Available at http://wwwn.cdc.gov/clia/oscar.aspx

In-scope laboratories will be identified from the OSCAR database based on laboratory type and laboratory type description and state (including the 50 states, D.C., and Puerto Rico).

A stratified random sample design will be utilized for the survey, with strata defined on the basis of state (50 states, D.C., Puerto Rico), category (hospital and independent laboratory), and, for independent laboratories, ownership (LabCorp, Quest, other). The strata are defined to: 1) support estimates and analyses at the state by category level; and 2) provide data collection efficiency for the large chain independent laboratories, LabCorp and Quest.

A target sample size of 4,963 completed interviews for Wave 1 was established to achieve the following precision requirement at the national level: $\pm$1.5 percentage point margin of error (MOE) at the 95% confidence level for both hospitals and independents laboratories. LabCorp and Quest laboratories will be sampled with certainty given the large volume of tests conducted by these two organizations, and data collection for these laboratories will be carried out through headquarters rather than through the individual laboratories.

B2. Procedures for the Collection of Information

ONC's contractor, NORC, will coordinate with the CMS CLIA staff to obtain the sample of laboratories from the most current version of the OSCAR database. The OSCAR database provides a listing of all clinical laboratory locations by state and includes contact information (phone numbers, addresses and email address) for each of the laboratories. CMS has also made available to NORC a listing of contact information for the CLIA offices located in each state. NORC staff will coordinate with LabCorp and Quest headquarters to provide data for all of their laboratories included in the sample. Through preliminary conversations with staff at these corporations, ONC has learned that much of the data necessary to complete the survey are housed centrally at headquarters. This will allow ONC to collect the survey data more efficiently and with lower respondent burden. Specifically, the reporting of data for these laboratories will occur through headquarters instead of mailing each individual laboratory a survey invitation. The means of collecting the data from headquarters will be determined in agreement with LabCorp and Quest separately, with options including electronic transfer, provision of an Excel file for data entry, or other manners preferred by LabCorp or Quest.

Respondents at the sampled laboratories will receive first an advanced letter informing them of the purpose and importance of the survey. A complete mailing packet will soon follow the advanced letter. It will contain a personalized invitation letter informing the respondents about the nature and purpose of the survey and encouraging them to participate. The letter will inform laboratories that they can complete their survey by filling out the hard-copy questionnaire. For cases where an email address is also available, an email containing the above information will also be sent.

All respondent letters will include a toll-free number for respondents who have questions about the survey. The toll-free line and email will be monitored by project-trained staff that can assist respondents with instructions on completing the questionnaire.

A unique respondent identification number will be assigned to each respondent, and this number will be printed on all communications mailed to respondents. The envelope will include NORC's return address, to enable receipt and processing of any returned or undeliverable mail. Mail returned as undeliverable from the USPS will be receipted and processed. Updated address information will be noted, entered into NORC's Case Management System (CMS) and directed to interviewing staff for contacting and updating. Returned mail with no updated information will be sent to NORC's locating staff for review, examination, and determination of status (whether the laboratory has closed, moved, or perhaps changed ownership or consolidated with other companies).

Respondents who do not complete the survey within 2 to 3 weeks of receiving the initial mailing will be sent a reminder email, if an email address is available. Respondents who have not completed the survey within four weeks of the initial mailing will receive a mailing containing a reminder letter and a hardcopy questionnaire with a pre-paid return envelope.

Respondents who have not completed the survey within eight weeks of the initial mailing will receive a postcard reminder. Its purpose is to prompt respondents to complete the survey, return their completed hardcopy questionnaires or call NORC to request another copy. It will also acknowledge and thank those who have already participated but whose hardcopy questionnaires have not been received at the time of the mailing. This mailing will reflect all new address information identified from returned mail (actual questionnaires returned with updated information will be re-mailed immediately upon receipt).

Approximately two weeks following the postcard reminder mailing, a final mailing will be sent to all remaining non-responders. This mailing will include a cover letter, a copy of the hardcopy questionnaire, and pre-paid return mailing materials. The letter will inform the respondent that this is their last chance to complete the survey and remind them of the importance of their participation.

In the last 4 to 5 weeks of data collection, NORC will conduct telephone non-response follow-up prompting for any respondents who have not completed the survey, or for whom the mailings have been returned as undeliverable. These respondents will be contacted by telephone by and prompted to complete the hardcopy survey. Telephone numbers will be obtained from the OSCAR database; NORC staff will conduct additional efforts to obtain current telephone numbers for those that are missing or are in error from the OSCAR database.

B2A. Statistical Methodology for Sample Stratification and Selection

In-scope laboratories will be stratified into one of 107 strata, based on Laboratory Type, State, and Facility Name. Hospital laboratories (Laboratory Type 14) will be stratified by state (resulting in 52 strata).

Independent laboratories (Laboratory Type 15) will first be segmented into three groups based on Facility Name – LabCorp, Quest, and Other. Independent laboratories with the word “Quest” in their Facility Name will be reviewed to ensure they are part of the Quest laboratory system and, if so, classified as Quest. Independent laboratories with the word “LabCorp” or “Laboratory Corporation of America” in their facility name will be reviewed to ensure they are part of the LabCorp laboratory system and, if so, classified as LabCorp. All remaining independent laboratories will be classified as Other. Other laboratories will be stratified by state (resulting in 52 strata).

Completed interview target sample sizes for hospital and independent laboratories will be allocated independently across states using the following criteria: 1) target number of completes first set equal to one-third of the total number of laboratories in the state (assumed response rate); 2) number of completes reduced for states with lowest MOE so as to achieve national target precision within laboratory type. Selected sample size for contact will be three times completed interview target sample size. Sample will be randomly selected within each stratum. LabCorp and Quest Laboratories will be sampled with certainty.

Table B.2 shows the expected national level sample sizes in terms of contacts and completed interviews, along with expected MOE’s by laboratory category. Expected national level MOE’s are provided for each laboratory category, as well as for aggregated laboratory categories.

Note that, although LabCorp/Quest is a separate stratum within the independent laboratory category, estimates will not be generated separately for LabCorp/Quest, to maintain the confidentiality of data

provided for these organizations. All LabCorp and Quest data will be combined with the other independent laboratories.

Table B.2. Distribution of Laboratories on the OSCAR Database by Category, Along with Sample Sizes for Wave 1 of the Lab Survey

Lab Category	Number of Labs in Population	Sample Size of Contacted Facilities	Total Target Number of Completed Interviews	Expected National Margin of Error (MOE)	Number of States with Expected 7.5% MOE	Number of States with Expected 10% MOE
Hospital	8,925	8,687	2,882	1.5%	6	13
Total Independent	5,517	5,270	2,081	1.5%	7	15
Independent: LabCorp/Quest	506	506	506	N/A	N/A	N/A
Independent: Other	5,011	4,764	1,575	N/A	N/A	N/A
Total (Tier 1)	**14,442**	**13,957**	**4,963**	**1.1%**	**20**	**32**

Table B.2 also provides, for hospital and independent laboratory categories, the number of states that will achieve expected MOE's of 7.5 percentage points and 10 percentage points. For hospitals and independent laboratory categories (and for aggregated laboratory categories), the number of states achieving the MOE criteria for 7.5 and 10 percentage points is primarily a function of the population size. Given expected response rates, a minimum population size of 342 would be required to achieve an expected MOE of 7.5 percentage points, and a minimum population size of 192 would be required to achieve an expected MOE of 7.5 percentage points. Table B.3 provides population sizes, target number of completed interviews, and expected MOE at the state level for both hospital and independent laboratories.

Table B.3. Distribution of Laboratories on the OSCAR Database within State by Category, Along with Sample Sizes for Wave 1 of the Lab Survey

State/ Territory	Hospitals			Independents			Combined Hospital/Independents		
	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error
AK	32	10	25.7%	13	6	23.7%	45	16	18.3%
AL	166	55	10.8%	130	63	7.3%	296	118	6.4%
AR	119	39	12.9%	45	16	18.8%	164	55	10.6%
AZ	153	51	11.2%	91	45	8.5%	244	96	7.2%
CA	695	216	5.5%	529	207	4.9%	1,224	423	3.7%
CO	142	47	11.7%	89	39	10.3%	231	86	7.9%
CT	106	35	13.6%	73	36	9.5%	179	71	8.2%
DC	22	7	30.6%	15	6	27.2%	37	13	20.7%
DE	28	9	26.9%	6	2	43.8%	34	11	23.4%
FL	477	159	6.3%	428	153	6.1%	905	312	4.4%
GA	247	82	8.8%	136	49	10.7%	383	131	6.8%
HI	25	8	28.6%	25	8	28.6%	50	16	20.2%
IA	139	46	11.8%	43	17	16.5%	182	63	9.7%
ID	50	16	20.2%	24	9	23.8%	74	25	15.5%
IL	327	109	7.7%	155	59	9.4%	482	168	6.0%
IN	231	77	9.1%	98	36	12.4%	329	113	7.4%
KS	161	53	11.0%	68	38	8.2%	229	91	7.3%
KY	156	52	11.1%	72	30	12.2%	228	82	8.3%
LA	354	118	7.4%	85	33	12.4%	439	151	6.4%

State/ Territory	Hospitals			Independents			Combined Hospital/Independents		
	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error
MA	213	71	9.5%	125	56	8.4%	338	127	6.5%
MD	106	35	13.6%	98	37	11.9%	204	72	9.0%
ME	54	18	18.9%	15	5	35.8%	69	23	16.7%
MI	237	79	9.0%	99	39	11.1%	336	118	7.1%
MN	164	54	10.9%	46	16	18.9%	210	70	9.5%
MO	193	64	10.0%	123	53	8.8%	316	117	6.8%
MS	147	49	11.4%	47	18	16.7%	194	67	9.5%
MT	77	25	16.1%	19	7	26.3%	96	32	13.8%
NC	241	80	9.0%	166	80	6.6%	407	160	5.6%
ND	60	20	17.9%	18	6	32.7%	78	26	15.7%
NE	115	38	13.0%	44	16	18.7%	159	54	10.7%
NH	57	19	18.4%	10	4	30.0%	67	23	16.0%
NJ	138	46	11.8%	92	33	13.1%	230	79	8.8%
NM	68	22	17.2%	33	11	24.1%	101	33	14.0%
NV	81	27	15.4%	36	19	12.0%	117	46	10.3%
NY	300	100	8.0%	260	92	8.0%	560	192	5.7%
OH	372	124	7.2%	133	51	10.0%	505	175	5.9%
OK	184	61	10.3%	57	22	15.1%	241	83	8.5%
OR	96	32	14.1%	87	38	10.4%	183	70	8.6%
PA	350	116	7.4%	164	61	9.4%	514	177	5.9%
RI	29	9	27.1%	17	7	25.6%	46	16	18.9%
SC	130	43	12.2%	42	16	17.6%	172	59	10.1%
SD	66	22	17.1%	31	11	23.0%	97	33	13.7%

State/ Territory	Hospitals			Independents			Combined Hospital/Independents		
	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error	Number of Facilities	Target Number of Completed Interviews	Expected Margin of Error
TN	194	64	10.0%	111	42	11.1%	305	106	7.5%
TX	854	221	5.7%	478	188	5.1%	1,332	409	3.9%
UT	81	27	15.4%	41	16	17.4%	122	43	11.6%
VA	158	52	11.1%	101	40	11.0%	259	92	7.9%
VT	31	10	25.5%	4	1	84.9%	35	11	24.4%
WA	143	47	11.7%	150	70	7.2%	293	117	6.4%
WI	157	52	11.1%	58	20	17.4%	215	72	9.4%
WV	91	30	14.6%	12	5	28.4%	103	35	13.2%
WY	39	13	22.2%	11	4	35.5%	50	17	18.9%
PR	69	23	16.7%	664	145	7.0%	733	168	6.5%
Total	**8,925**	**2,882**	**1.5%**	**5,517**	**2,081**	**1.5%**	**14,442**	**4,963**	**1.1%**

In Wave 2 of the survey, the plan is for all Wave 1 respondents to be re-contacted and asked to complete a Wave 2 survey instrument. In addition, the Wave 2 sample will include a 25% sample of laboratories that did not respond to the Wave 1 survey and all new laboratories and laboratories that were not selected for the Wave 1survey.

Based on expected sample sizes and response rates for Wave 1, and assumed growth of 10% LabCorp and Quest labs and 1.5% growth in hospital and other independent labs, the Wave 2 sample design would be as shown in Table B.4.

Table B.4. Distribution of Sample Laboratories for Wave 2 of the Lab Survey

Lab Category	Number of Labs in Population	Sample Size of Contacted Facilities	Total Target Number of Completed Interviews
Wave 1 Responders			
Hospital	2,882	2,882	2,162
Total Independent	2,081	2,081	1,561
Independent: LabCorp/Quest	506	506	380
Independent: Other	1,575	1,575	1,181
Total	**4,963**	**4,963**	**3,722**
Wave 1 Nonresponders			
Hospital	5,805	1,451	290
Total Independent	3,189	797	159
Independent: LabCorp/Quest	0	0	0
Independent: Other	3,189	797	159
Total	**8,994**	**2,249**	**450**
Wave 1 Nonsample + New Labs			
Hospital	372	372	124
Total Independent	373	373	124
Independent: LabCorp/Quest	51	51	17
Independent: Other	322	322	107
Total	**745**	**745**	**248**
Total			
Hospital	9,059	4,705	2,576
Total Independent	5,643	3,251	1,844
Independent: LabCorp/Quest	557	557	396
Independent: Other	5,086	2,694	1,448

Total	**14,702**	**7,956**	**4,420**

B2B. Estimation Procedure

Sample respondents will be weighted through a multiple step process to derive final survey weights: 1) application of base weights (inverse of probability of selection); 2) nonresponse adjustment; 3) ratio adjustment to population totals within stratum.

Given the need for estimates related to proportion of laboratories with some characteristic (e.g., able to send structured laboratory results electronically to ordering providers) and proportion of laboratory results that are handled in some manner (e.g., sent electronically in coded format to ordering physicians), two sets of weights will be derived: one for use in estimating characteristics associated with laboratories and one for use in estimating characteristics associated with laboratory test results.

B2C. Degree of Accuracy Needed for Purpose Described in Justification

Target national level MOE at the 95% confidence level was established at $\pm$1.5 percentage points for both hospitals and independents laboratories. LabCorp and Quest laboratories will be sampled with certainty given the large volume of tests conducted by these two organizations, and data collection for these laboratories will be carried out through headquarters rather than through individual laboratories.

B2D. Unusual Problems Requiring Specialized Sampling Procedures

There are no unusual problems requiring specialized sampling procedures.

B2E. Use of Periodic (Less Frequent Than Annual) Data Collection Cycles

The first wave of the survey data collection will establish a baseline from which to measure laboratory results exchange activity for the sampled laboratories. The second wave of data collection will occur approximately one year following the first wave and will measure changes in exchange capability and activity at the originally sampled laboratories.

B3. Methods to Maximize Response Rates

Expected unweighted response rates for the survey are conservatively estimated at 33% for hospitals and independents other than LabCorp and Quest, and 100% for LabCorp and Quest (due to data collection through headquarters), resulting in a net expected overall unweighted response rate of 36%. The expected response rate is based upon review of prior experience with establishment surveys with voluntary reporting. While for some individual strata, unweighted response rates are expected to exceed 33%, targeting a higher response rate within each state would require more follow-up effort, time, and costs than was believed worthwhile in terms of the potential gain in precision (due to the limited population size). Therefore, in order to provide conservative estimates of state-level expected margin of error for planning purposes, a 33% response rate within each state was assumed. The sample size does support the national level precision requirement of $\pm$1.5 percentage points at the 95% confidence level for both hospitals and independents laboratories.

As the survey is an establishment survey, weighted response rates taking into account the relative importance assigned to different laboratories should also be considered. The relative importance for laboratories can be stated in terms of number of laboratory results. Based upon the distributions from

Table B.1 and the expected response rates by laboratory category, the weighted response rate (in terms of laboratory tests as the key measure of size) is roughly 57%.

Such levels of nonresponse for the survey allow for potential nonresponse bias. Nonresponse bias will be controlled using nonresponse weighting adjustments at the laboratory category by state level.

Further analysis into the potential for residual nonresponse bias in survey estimates will be carried out through several mechanisms. First, nonresponse rates by laboratory category and state will compared to assess the potential for differential nonresponse bias across strata. Second, results will be compared between early and late reporters to the survey. Finally, results will be compared to any available administrative data collected by individual states to assess whether differences exist and, if so, potential reasons including nonresponse bias.

To maximize response rates, ONC's contractor, NORC, has developed a comprehensive approach to nonresponse follow-up. Utilizing these strategies, ONC is confident that it will achieve its targeted response rates by implementing the following specific, systematic data collection activities includes:

Locating:

To maximize the likelihood of response, respondents whose mailings are returned throughout data collection as undeliverable will be marked for locating to ensure the project has the most current contact information.

Ease of Survey Completion:

The questionnaire will be carefully designed with user-friendly formatting and clear instructions. A Frequently Asked Questions section will be included for reference and definitions will be provided to ensure that respondents understand all technical terms. The length of the questionnaire has been intentionally constrained and only critical questions are included.

Personalized Mailings:

At the start of data collection, NORC, on behalf of ONC, will send personalized advance letters to all laboratories to introduce the survey. The letter will clearly describe the goals and importance of the survey. Laboratories with email addresses will also receive an email version of the letter.

Brochure:

Included in each mailing will be a color brochure that identifies the purpose of the survey; who is performing the data collection; how and why each laboratory was selected; survey content and procedures for completing/returning the questionnaire; intended uses of the data; and confidentiality protections. A copy of the draft Brochure is included in Attachment E.

***Targeted Emails*:**

Emails will be sent to invite laboratories to participate in the survey and to non-responders to remind them to complete the survey. Not only can email reminders be sent for a nominal cost, but past experience has shown that emails sent earlier in the field period increase the number of early responders and reduce the need for subsequent and repeated follow-up attempts. Carefully timed, targeted emails will continue throughout data collection to encourage response.

Questionnaire Mailings:

Respondents will receive an advance letter, an initial mail packet, a second mail packet, a reminder postcard, and a final mail packet. Survey organizations have embraced these methods and have found to improve response rates. The letter from ONC accompanying the questionnaire will be designed to

alert respondents of the scheduled data collection end date and motivate non-responders to complete and return the survey before the end of data collection.

Study endorsements from stakeholders:

ONC will work with organizations to endorse the survey and promote participation. Featuring the benefits of participating in the survey will be sent to State HIE contacts for use in newsletters, websites, and other promotional materials.

Study-specific hotline and email address:

Throughout the project, NORC will maintain and carefully monitor a project-specific toll-free line and email address for respondents who need assistance in completing the questionnaire (whether hard copy or on-line). Project-trained staff will assist respondents with instructions on completing the questionnaire, fax or re-mail replacement surveys to respondents, and monitor the toll-free line and email.

B4. Tests of Procedures

Cognitive Interviews:

Cognitive interviewing is an established technique to pre-test survey instruments and materials, such as cover letters and supplemental information, which will be fielded in a larger sample via hardcopy mail-out. While not as robust or effective as a field test, cognitive research techniques can provide useful information to questionnaire designers seeking to improve wording and response options for complex measures or difficult questions to answer. For this pre-test, we used both personal contacts and data from the Clinical Laboratory Improvement Amendments (CLIA) database collected by the Centers for Medicare & Medicaid Services to identify potential respondents from small and large independent and hospital medical laboratories, which were administratively independent or affiliated with a centralized entity. In July 2012, we conducted one round of interviews for each instrument; nine interviews were conducted for a hospital based instrument and three interviews were conducted for an instrument designed for independent labs. Four experienced, NORC cognitive interviewers were trained for this project, working from structured interview protocols. We used both quantitative coding and open-ended notes to identify questions where there are problems in comprehension, information retrieval, or communication of the response.

Overall, the cognitive interviews suggest that there is still substantial variation in the interpretations of key terms in this instrument. The most important source of confusion is the appropriate term to be used for questions that seek to measure volume of test results. The primary difficulty appears to be identifying the summary term to be used for the lab tests and whether it should be anchored in the patient, the billing unit, or the single elements of any test panel. The term “affiliated physician” appears to pose smaller but similar definitional problems for the hospital version of the questionnaire. Variations in interpretation may reflect true variations in how physicians are attached to hospitals. Similarly, the administrative structure of laboratories, which may include a group of affiliated but distinct laboratories or fully centralized and administratively integrated collection of physical laboratory locations, cause both cognitive issues and uncertainties in reporting. Finally, there are several instances in which the questionnaire did not offer enough response categories or restricted response options and, thus, limited the respondents’ ability to find an appropriate way to map their experience to the questionnaire.

The following key changes were made based on the results from the cognitive interviews and discussions with experts:

- Added a question that clarifies whether the respondent is reporting for a single laboratory or multiple laboratories
- Expanded the response categories for the laboratory's organizational affiliation and the job title of the respondent
- Included a question that provides details on the kinds of clinical pathology tests performed by the laboratory
- Used the phrase 'ordering practioners' rather than 'providers'
- Added instructions defining 'lab tests' and 'electronically in a structured format'

For the full report of findings from the Cognitive Interviews, please see Attachment C.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals consulted on the statistical aspects of the survey:

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Attachments

- Attachment A [Survey Questionnaire A – Hospitals Laboratories]
- Attachment B [Survey Questionnaire B – Independent Laboratories]
- Attachment C [Cognitive Interviewing Report]
- Attachment D [Comments from American Clinical Laboratory Association]
- Attachment E [Brochure]