A JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This request is an extension with a revision of a previously approved project collection (0920-0274) from the Office of Management and Budget (OMB), to conduct a voluntary survey of laboratories that participate in the Centers for Disease Control and Prevention's Model Performance Evaluation Program (MPEP) for laboratories conducting testing related to (HIV) retroviral infection.

The Laboratory Practice Evaluation and Genomics Branch, Division of Laboratory Systems (DLS), National Center for Preparedness, Detection, and Control of Infectious Diseases, CCID, Centers for Disease Control and Prevention (CDC) has developed a Model Performance Evaluation Program (MPEP) for assessing the quality of testing performed by laboratories that test for recognized infections of public health significance.

CDC selected antibody testing for HIV-1, the virus that has been determined to be the etiologic agent of AIDS, as the first specific area of concentration used to develop the performance evaluation program. The evaluation of HIV testing is especially relevant because of rapidly changing technology (as evidenced by the introduction of new tests), modifications in technical aspects of existing tests, and the application of testing to new populations. Data already gathered under previously approved census surveys have allowed MPEP personnel to identify overall testing problems, such as diverse interpretive criteria for Western blot test results, and specific laboratory testing problems, such as screening and supplemental result interpretation inaccuracies due to varying reagent quality. It is necessary to extend the investigation that has already been initiated so that the MPEP can continue to identify and address the needs of the laboratory community as they develop.

The current request for OMB approval consists of the HIV-1 Antibody Test Data Collection Form – Result Booklet (attachment 10), and the specially prepared enrollment forms for laboratories to participate in the MPEP (attachments 3). Thus, the MPEP for HIV and AIDS related testing will contain the following voluntary forms:

The MPEP laboratory enrollment form and the accompanying enrollment letter (attachment 3) is for use in enrolling laboratories located in the United States, Canada, and laboratories located outside of North America. The Welcome Letters for New Laboratories and for adding a new laboratory to a new program (Attachment 4 & 5), HIV-1 Antibody Test Data Collection Form Pre-shipment and Password Letters (Attachment 6 & 7), Laboratory Information Change form (Attachment 8), Result Booklet Cover Letter (Attachment 9), Test Data Collection Form – Result Booklet (Attachment 10), and HIV-1 Antibody Test Report Cover Letter (Attachment 11).

Information presented at national conferences sponsored by CDC, the Association of Public Health Laboratories (APHL), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA), have led to changes in certain recommendations and guidelines. The revised survey document reflects current knowledge about testing for HIV infection and subsequent changes in laboratory practices in performing this testing. Minor changes include a name and address change for the MPEP manager and coordinator. These changes have no effect on the time required to complete the forms. The MPEP no longer contains programs for HIV-1 RNA Viral Load and CD4+ T-cell determinations due to budgetary constraints.

In addition to the MPEP enrollment, a results form for HIV-1 antibody (attachment 10) is included. The CDC recognized the need for standardized report forms for this test in order to better evaluate the results.

This study is authorized under the Public Health Service Act, (42 USC 241) Section 301. A copy is included in the attachments (attachment 1).

2. Purpose and Use of Information Collection

Since May 1988, CDC has conducted periodic census surveys of laboratories participating in the MPEP. The successful completion of the voluntary census surveys to date has resulted in the partial achievement of one of CDC's major objectives: a database of information describing the testing practices and the physical and technical characteristics of a large number of HIV testing laboratories. As CDC continues to identify testing laboratories, the focus has turned to the remaining objectives. Test results from performance evaluation surveys and completion of the census surveys are necessary in order to provide CDC with the comprehensive data needed to achieve the major objectives of the MPEP.

The laboratory census surveys provide CDC with necessary information on laboratory characteristics, including the qualifications of each laboratory's staff, the testing methods employed, and the types of samples tested. In addition, the surveys provide CDC with information regarding laboratory experience, including the length of experience with each of the major tests performed by laboratories, the total numbers of screening and confirmatory tests that have been performed by the laboratories, the numbers of such tests performed on a weekly basis, and the total number of reactive specimens. CDC uses the survey information to evaluate factors that affect the performance of testing laboratories. This knowledge will enable CDC to establish methods for further identifying and defining problems in the retroviral and AIDS-related testing processes, and assist CDC in developing strategies to continue to maintain and improve quality in these aspects of retroviral testing worldwide.

In order to maintain a current source of information and due to the rapid development of new technologies the survey questions may vary slightly from time to time for example to include a new test kit or new application of a test kit, or new practices in use of test kits. The information obtained in the laboratory census surveys will allow CDC to maintain an accurate and up-to-date database reflecting the recent changes in retroviral and AIDS-related testing technologies. Testing manufacturers are continuing to develop new retroviral tests utilizing alternative technologies such as recombinant DNA, synthetic peptides, DNA probes, alternate EIA formats such as rapid testing or single use diagnostic devices, and indirect immunofluorescence assays (IFA). In addition, manufactured EIA test kits including rapid tests have demonstrated increased sensitivity and specificity and may serve as alternate supplemental testing techniques. Also, retroviral tests have improved to facilitate differentiation between HIV-1 and HIV-2; therefore, it is important for CDC to track the effects these developments are having on laboratory testing practices.

Without the information obtained in the laboratory census surveys, CDC would not know the internal characteristics of the testing laboratories, would not be aware if testing problems exist, and would therefore be unable to investigate relationships between testing practices and laboratory performance. CDC would also be unable to extend the investigation that has already been initiated. It is essential that CDC continue investigating these relationships in order to identify specific areas within the total testing process for improvement, develop effective intervention strategies, and benefit laboratorians and the public by improving the quality of testing.

After information is collected from MPEP participant laboratories, it is developed into national reports and mailed to each program participant so they can also benefit through the sharing of information. An example of the recent HIV-1 Antibody Test Report is provided (attachment 12). The CDC MPEP also publishes information in peer reviewed journals and presents information at national and international conferences. Additionally, the CDC MPEP is a primary resource for information about laboratory characteristics, testing practices, and the volume of retroviral and AIDS-related testing. In the past, information has been shared and will continue to be shared with organizations including other Centers, Institute, and Offices (CIOs) located in CDC, National Institutes of Health (NIH), Department of Defense (DoD), Food and Drug Administration (FDA), Association of Public Health Laboratories (APHL), American Association of Bioanalysts (AAB), American Association of Blood Banks (AABB), World Health Organization (WHO), Pan American Health Organization (PAHO), and commercial test kit

manufacturers.

3. Use of Improved Information Technology and Burden Reduction

To reduce the burden on each participant, CDC has made the MPEP enrollment forms available on line (http://www.phppo.cdc.gov/mpep/enrollment.aspx). Through the CDC Internet Web Page, there are links to the performance evaluation programs conducted by the MPEP. Currently all information concerning enrollment is located on the MPEP web page linkage. Interested laboratories may enroll either on-line or contact the MPEP via telephone. The CDC has provided a toll-free telephone number, allowing communication of responses by voice to a trained interviewer. Only the minimum amount of information needed for the purposes of the project will be collected. Through the CDC Internet Web Page, the final report is available for viewing.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has taken the following steps to ensure that this information collection will not duplicate information otherwise accessible to CDC. CDC announced plans for the project well in advance of its initiation, thereby ensuring that duplicate efforts would not take place elsewhere within CDC. CDC also assembled an internal AIDS Task Force of professionals highly knowledgeable of AIDS-related activities within CDC, and these professionals ensured the MPEP that no sources of similar information exist within CDC.

In addition, CDC conducted research efforts during 1992 and 1993 to identify possible external sources of the required information. This research confirmed that sources, including the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), the Society for Analytical Cytology (SAC), the American Association of Blood Banks (AABB), and Centers for Medicare & Medicaid Services (CMS), can provide names and addresses of many of the potential respondents, but are unable to provide CDC with individual laboratory information at the level of detail required by CDC to achieve the goals of its MPEP. No information collections are currently conducted to provide specific information on the characteristics of laboratories and their testing practices.

Similar nationwide information pertaining to the total testing process is not available from the sources identified above [in Item 4]. CAP, AABB, AAB and private organizations such as Fast Systems, Inc. sponsor proficiency testing programs. However, some of these programs are regulatory in nature, address only portions of the analytical testing process, and none provide the scope of information pertaining to the total testing process required by CDC. In spite of this limitation, the name and address information that is available from these sources is valuable and was used as a starting point in CDC's information collecting activities.

5. Impact on Small Businesses or Other Small Entities

Some of the laboratories and clinician offices addressed by the census surveys can be classified as small business entities. To reduce the burden on these entities, CDC offers a choice of response methods, streamlines the data collection instruments and keeps the number of questions to the minimum required for the intended use of the data. Also, respondents are only expected to report information for which they currently maintain records. Therefore, each participant's voluntary involvement in the HIV-1 MPEP imposes no additional record-keeping burden.

6. Consequences of Collecting the Information Less Frequently

The CDC intends to collect information through HIV-1 Antibody Test Result Form bi-annually. It is

necessary to collect the HIV-1 result booklet information on a bi-annual basis in order to maintain an accurate and up-to-date database reflecting recent changes in HIV testing issues, including new technologies, testing algorithms and quality control procedures.

Testing manufacturers are continuing to develop new retroviral tests for detecting tests which include recombinant DNA, synthetic peptides, DNA probes, alternate EIA formats, and indirect immunofluorescence assays (IFA). In addition, manufactured EIA test kits, have demonstrated increased sensitivity and specificity and may serve as alternative supplemental testing techniques. Also, retroviral tests have improved to facilitate differentiation between HIV-1 and HIV-2; therefore, it is important for the CDC to track the effects these developments are having on laboratory testing practices.

If information collection in either of these program components were to be performed less frequently, the CDC's database would present an inaccurate picture of the current activity at these laboratories, adversely affecting the CDC's ability to properly interpret their performance evaluation results.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information collection activity fully complies with the Guidelines 5 CFR 1320.5. There are no special circumstances related to the proposed surveys.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A notice soliciting comments was published in the Federal Register on February 26, 2007 (Vol. 72, page 8385) and a copy is attached to this document (attachment 2). No responses to this notice were received. In order to collect and process data for the surveys and project, CDC solicited the advice and help of the following industry personnel within the past three years:

Mr. Wayne Meyers, Project Manager (email: wmeyers@constellagroup.com)

Ms. Courtney Rodi, Research Programmer (email: crodi@constellagroup.com)

Constella Health Sciences, LLC

3 Corporate Blvd., Suite 600

Atlanta, GA 30329

404-325-2660

Dr. Greg Chiklis, Vice-President of Product Development

ZeptoMetrix, Inc.

25 Kenwood Circle

Suite 14A

Franklin, MA 02038-3201

508-520-0588

Email: chiklis@zeptometrix.com

9. Explanation of Any Payment or Gift to Respondents

No remuneration is to be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Officer reviewed this submission and determined that the Privacy Act does not apply to this data collection. Respondents are organizations that provide HIV testing services. While the data collection forms include the name and job title of the individual who completes the forms on behalf of the respondent organization, that individual is responding from their role as a staff person knowledgeable about performance testing and laboratory practices, and does not provide personal information. At no time does the HIV-1 MPEP possess any information about the persons whose samples are used for the sample performance panels.

A contractor, Constella LLC, is responsible for processing registration forms for the MPEP, collecting the data collection instruments, and sending de-identified data to CDC. The contractor assigns a unique identification number to each respondent organization upon its enrollment in the HIV-R MPEP, and maintains records that link the unique ID number to the respondent organization's name. The contractor provides for anonymity of laboratories enrolled in the MPEP by isolating the Laboratory MPEP number (MPEPNUM) from all other data pertaining to the laboratory identification. Thus the Laboratory MPEP Number is associated with laboratory performance records only. The Laboratory MPEP Number link to the Master Laboratory Identification Number link is stored in a separate data set, accessible only by the contractor, allowing only the contractor to connect the Laboratory MPEP Number to laboratory identity. The contractor uses this Master Laboratory Identification Number to link the Laboratory MPEP number to the laboratory address for the purpose of connecting files and creating reports for the MPEP as needed. No software has been or will be written which produces an output linking the Master Laboratory Identification Number to the Laboratory MPEP Number or linking the Master Laboratory Identification Number to any laboratory performance information. All report generation which requires the use of the laboratory identity is the responsibility of the contractor.

Response data is primarily filed and retrieved by the HIV-1 MPEP identification number. All data provided by the contractor contains no laboratory identifiers. The master copy of the data base to be maintained by the contractor resides on the CDC mainframe computer, an IBM 3090 running the MVS operating system. The facilities of the TOP SECRET mainframe security package will be used to restrict access to the data to designated DLS personnel and the contractor. The contractor is responsible for ensuring that adequate backup and recovery procedures are in place to ensure that accidental or natural occurrences will not result in loss of project data. These procedures, as a minimum, include regular generation of two (2) backup copies of the data base, with one copy transferred to a secure, off-site facility. In addition, backups are made after major updates to the data base are performed.

The data collection procedures allow CDC to conduct primary analyses on de-identified data. However, since CDC is offering consultation for testing sites, we maintain the capability of asking the contractors to re-link identification information if an individual testing site seeks CDC's help in elucidating testing problems. In addition, if we encounter results on the result booklet which indicate that a laboratory is consistently providing incorrect interpretations, we may ask the contractor to re-link identification information so that we can offer help for that testing site. If incorrect results are reported by a significant number of testing sites for a particular challenge sample, or if adverse laboratory practices are reported by most laboratories, we may ask the contractors to re-link identifiers so that we may offer quick and expedient help. As a rule, this would only be done if the questionable results are likely to have an adverse public health impact, and therefore intervention is necessary to protect the public. Thus far, since program inception, the need for re-linking has not occurred. While we do not anticipate the need for re-linking

identifiers to be a regular occurrence, no one can be sure exactly how these tests will perform in real-world applications. We envision that the re-linking function will persist only for the brief length of time needed to address the performance issues of high public health impact associated with any given result booklet.

The name and address of the participating testing sites appear on a cover page for the HIV-1 Result Form. The cover page is removed by the contractor prior to forwarding any result forms to the CDC.

Hard copies of the HIV-1 Result Booklet with identifiers removed are secured in locked, fire-proof file and storage cabinets whose access is strictly limited. Thus data is treated in a secure manner, and is not disclosed unless compelled by law.

Individual participants are not identified in any way in the published national reports.

11. Justification for Sensitive Questions

While testing sites may view their laboratory performance as sensitive, no individualized reports are generated and published. The data of de-identification (described in A10) has been done purposely because we encourage sites to compare data results to the average results and to perform self-assessments.

12. Estimates of Annualized Burden Hours and Cost

754 respondents will receive two MPEP HIV-1 Ab PE Result Booklet and cover letter per year. The estimated annualized burden hours will be 10 minutes per respondent to complete the HIV-1 Ab PE Result Form. Based on field testing, the burden for the electronic form and the paper from are the same. This yields a response burden of 251 hours total.

A.12.1 Estimates of Annualized Burden Hour				
Form Name	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response**	**Total Burden Hours**
Enrollments (new)	100	1	3/60	5
Laboratory Change Form	20	1	3/60	1
HIV-1 Ab PE Results Form	754	2	10/60	251
Totals	874			257

A.12.2 Estimates of Annualized Cost to Respondents					

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Type of Respondents	**Number of Respondents**	**Frequency of Response**	**Hourly Wage Rate**	**Total Burden Hours**	**Respondent Cost**
Enrollments (new)	100	1	$25.00	5	$125.00
Laboratory Change Form	20	1	$25.00	1	$25.00
HIV-1 Ab PE Results Form	754	2	$25.00	251	$6,275.00
Totals	874				$6,425.00

Approximately 100 respondents will receive the MPEP enrollment form and cover letter (Laboratory Change Form). The estimated annualized burden hours will be 3/60 minutes to complete the enrollment form, yielding a response burden of five hours total.

Since complete anonymity is maintained in the MPEP, it is impossible to know the specific type of laboratory personnel responding. It is assumed that the MPEP forms are being completed by upper level laboratory technicians. The average hourly rate for respondents participating in MPEP was obtained from the following resources listed below:

Pallatroni L. and P. Brittritts 1999. MLO's National Salary Survey Compensation and Respondent Profiles. Clinical Laboratory Reference Supplement: Medical Laboratory Observer

Guilles H. J. et. al. 1999. Work and Lifestyles Variables Affect National Medical Technologist Earnings. Laboratory Medicine. 30:478-482

13. Estimates of Other Total Annual Cost Burden to Respondent or Record Keepers

There is no additional cost to the respondents other than their time.

14. Annualized Costs to the Federal Government

The estimated cost to the Government by the Contractor is shown in the following table. This cost includes wages for staff hours involved in formatting, printing, mailing, data collection, data input, data analysis, and overhead expenses. The estimated cost is based on the projected number of HIV-1 Ab Testing sites that will participate in the CDC HIV-1 Ab Testing Program.

Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Costs (dollars)
Direct Cost to the Federal	CDC Project Officer (2% effort)	$ 2,000

Government		
	CDC Health Scientist (2% effort)	$ 15,000
Contractor and Other Expenses	Contractor Cost and Fees	$ 20,500
	TOTAL COST TO THE GOVERNMENT	$ 37,500

15. Explanation for Program Changes or Adjustments

This request is a revision of a previous data collection (0920-0274). This data collection is currently approved for 1,057 burden hours. With this request, CDC is requesting approval for 257 burden hours, a net decrease of 800 hours. The decrease is due to discontinuation of the following data collection instruments:

- HIV Testing Survey (-500 hours)
- CD4+ T-Cell Survey (-82 hours)
- HIV-1 Ab PE Results Form (-49 hours due to fewer participants)
- HIV RNA PE Results Form (-70 hours)
- CD4+ T-Cell PE Results Form (-100 hours)

The discontinuation of these forms results in a decrease of 801 hours.

This request is seeking approval to add a form, Laboratory Change Form, to this information collection request. This form has a burden of 1 hour.

With approval of the new form and the discontinuation of the five forms listed above, this information collection request has a net decrease of 800 hours from the previous approval.

This information collection request also includes revision of previously approved data collection instruments. The revisions are necessitated by additional test kit manufacturers coming to market and the employment of new testing procedures by participants. The time to complete the HIV-1 Ab PE Results Forms remains the same despite the fact the additional test kit choices have been added.

16. Plans for Tabulation and Publication and Project Time Schedule

Surveys are mailed to participants in January and July of each year. Participants report their results to CDC and CDC processes the completed surveys approximately 60-75 days after the survey was been mailed. Analysis of the results data occurs approximately 75-90 days after the survey was been mailed. After the data have been analyzed, a report is prepared and published approximately 90-120 days after the survey was been mailed.

Participants are surveyed using the HIV-1 Ab Testing Form twice per year (in January and July) for five years. Descriptive statistics, done by the contractor, are used to analyze the generated data. The proportions of different types of specimens used for the tests will be determined. Aggregate data regarding type of laboratory vs. testing volume are reported. Further, the proportions of different types of testing sites reporting results to patients and using specific algorithms for confirmatory testing are calculated. The data from the HIV-1 Ab Testing Form is returned to respondents and made public domain through a national report that contains CDC description and interpretation of results as well as graphic representations of frequency distributions.

The results may be published in peer reviewed journals (such as the Journal of Clinical Microbiology) by project officers and scientists from CDC.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Exemption is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification.