Performance Evaluation Program for Rapid HIV Testing
(OMB Control Number 0920-0595)

Request for Revision
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Performance Evaluation Program for HIV Rapid Testing
OMB Control No. 0920-0595

CDC is requesting OMB approval of a revision to a currently approved data collection. This information collection request is currently approved for 750 respondents and 625 burden hours. This submission requests approval for 660 respondents and 387 burden hours. The decrease in burden (-238 hours) is due to the elimination of foreign laboratories in this Model Performance Evaluation Program. This request also includes 2 new forms and changes to existing forms. The changes to the existing forms do not result in an increase in burden. CDC is requesting OMB approval for 3 years for the information collection request. Current OMB approval is scheduled to expire March 31, 2010.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This request is a revision of a previously approved data collection under OMB Control Number 0920-0595. The request includes two previously approved forms, HIV Rapid Testing form EZ (Attachment 3a); and an HIV Rapid Testing Laboratory Practices Questionnaire (LPQ) (Attachment 4a) and two new forms, an Enrollment form (Attachment 5a) and an Information Change form (Attachment 6a). Participation in this program is voluntary. Respondents are HIV testing sites.

Healthcare providers rely on the accuracy of HIV testing results to diagnose HIV infection and in determine appropriate treatment. Accurate and reliable testing results are paramount to intervention and prevention efforts. Diagnosis, treatment, and disease control are dependent upon fast and accurate HIV test results. Thus, assessing the quality of HIV- and AIDS-related testing is a vital component to AIDS prevention. Furthermore, accurate and reliable information regarding application and testing practices among sites performing HIV testing is crucial to recommending meaningful and effective quality assurance practices.

HIV rapid test (HIV-RT) kits have been approved by the HHS Food and Drug Administration (FDA) and marketed in the U.S. for several years. These test kits offer testing sites the capability of providing preliminary positive (reactive) test results to clients and patients within one hour. Several of these test kits are waived (i.e. does not have to be performed by a CLIA inspected laboratory) under the Clinical Laboratory Improvement Act (CLIA). This means that quality assurance and personnel requirements for performing the tests are much less stringent than for traditional HIV tests.

The advent of HIV-RT kits in the U.S. has dramatically changed the spectrum of HIV testing and the laboratory practices surrounding HIV testing. Since the test kits are mobile, self-contained, stable without refrigeration, and CLIA-waived, they are used in a variety of non-traditional testing sites. These sites include HIV counseling and testing centers, mobile vans, community based organizations testing sites, entertainment sites frequented by high-risk individuals, street-corners, pharmacies, an expanded group of physician-office laboratories, and private testing centers. Thus, the performance of the test procedure, test reporting, and follow-up counseling are parts of the overall testing process for many non-traditional testing sites.

Using CLIA waived test kits allows for personnel not trained in traditional laboratory practices to perform HIV-RT. Even within traditional testing sites, such as hospitals, the tests are being used in expanded point-of-care settings such as emergency rooms, labor and delivery units, surgery units, and employee health clinics. These expanded testing capabilities may to lead to earlier detection of HIV-infection and to a greater proportion of HIV-infected individuals knowing their status.

However, CDC has concerns about this group of waived test kits; (1) the quality of HIV tests could be compromised due to less stringent quality assurance requirements; and (2) persons not trained in traditional laboratory practices are likely to be performing the tests as well as reporting results to patients. Further, in low-prevalence populations such as the U.S. population at large, the predictive value (i.e., whether a positive test result represents a true infection) of the HIV rapid tests may not be understood by persons performing the tests and advising patients of their result interpretation, including counseling on the possibility of a false-positive result, and therefore, the necessity for follow-up (confirmatory) testing.

CDC considers it an urgent and top priority to continue to address the gaps in quality assurance of performance and practices surrounding HIV rapid testing. Thus, CDC offers a model performance evaluation program (HIV-RT MPEP) specifically targeting HIV rapid testing and the unique aspects of laboratory practices presented by the flexibility of these tests. This voluntary program provides testing sites with the opportunity for self-assessment and improvement by comparing their testing results on challenge specimens with the composite results of all testing sites enrolled in HIV-RT MPEP. Every year testing sites are asked to voluntarily participate in a laboratory practices questionnaire to compare their testing practices with aggregate results from all HIV-RT MPEP participants. Data gathered provides valuable information that helps with the development of appropriate HIV rapid testing guidelines. In addition, CDC collects valuable demographic information that provides a better understanding of where and how these tests are being used, so that quality assurance efforts are targeted to those areas.

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

Privacy Impact Assessment

Information is filed and retrieved under the HIV-RT MPEP identification number which is linked to the name of the organization conducting testing. The Privacy Act is not applicable to this data collection. While names of persons completing the form are requested, no other personally identified information is collected other than their title. Individuals are responding in their roles as laboratory staff that perform the testing and are knowledgeable their laboratory's practices.

Overview of the Data Collection System

The HIV-RT challenge sample surveys are sent to participants in the form of six well-characterized samples for which the HIV status, i.e., either positive, negative, or sero-converter, is known. Responses are submitted online, using the online HIV Rapid Testing Form EZ. Participants are given advance notice, via a pre-shipment letter (Attachment 3b), of upcoming shipments and will have the opportunity at that time to notify the MPEP via an information

change form (ICF) of any changes in their program's contact information (Attachment 6a). These challenge surveys are administered twice per year, with results being submitted by participants via the MPEP website. A cover letter (Attachment 3c) is provided with each sample survey to provide instructions about the sample panel and result submission. Both general online instructions (Attachment 3d) and instructions specific to the HIV-RT sample survey questions (Attachment 3e) are available on the MPEP results entry website. Since the testing sites are considered non-traditional sites, CDC also includes as warning (Attachment 3f) concerning the possible infectivity of the challenge samples. Previously, results were also collected via hardcopy forms received by mail, but participants now are only asked to enter their results online and have the option, for their convenience, of using a hardcopy of the questions as a worksheet prior to entering their results online.

New participants are added to this program via the Enrollment Form (Attachment 5a) and are sent a Welcome letter/email (Attachment 5b).

Items of Information to be Collected

The results of the challenge sample surveys are collected electronically in an online format using the HIV Rapid Testing online Form EZ. The HIV Rapid Testing Form EZ includes information which is critical to measuring and evaluating laboratory testing practices. The actual values of the samples in the HIV-RT survey as determined by the MPEP, called the "Donor Report", as well as an explanation for the result values (the Donor Report cover letter) are provided to the participants via letter or email (Attachments 3g and 3h) after the deadline for result entry has passed. Results are processed and returned to participants within 60 - 75 days of the sample shipment and a summary report (Attachment 3l) is produced.

Brand names of commercial products are mentioned on the online survey form; however, these questions are for the sole purpose of data collection related to practices and procedures for performing and handling of laboratory results. The use of brand names and questions regarding products and test systems do not represent endorsement of these test kits by CDC.

The Laboratory Practices Questionnaire (LPQ) will now be administered once every other year. An email cover letter (Attachment 4b) will be provided to give instructions regarding the questionnaire and submission of results online. HIV rapid testing is still relatively new. Practices and methodologies have changed since the inception of the HIV-RT MPEP, particularly with regard to additional test kits coming to market. Conceivably, practices and methodologies are likely to continue to change rapidly during the next several years. Results from this questionnaire are returned to participants within 90 days of questionnaire administration. CDC also produces a summary of the LPQ (Attachment 4c).

No individually identifiable information is being collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Data is collected via the MPEP results website. No MPEP website content is directed at children under 13 years of age. To access the online results website an MPEP identification number and password must be used; these are only provided to testing sites enrolled in the MPEP. Password notification emails (Attachment 3i) are sent only to the email address of the site's contact on record. Cookies are not used. MPEP does not have a privacy policy specific to the program or a code of conduct specific to the MPEP on the MPEP website.

2. Purpose and Use of Information Collection

The information collected using the online HIV Rapid Testing Form EZ is used to relate factors directly involved with performing the tests to overall accuracy of results. Aggregate results will be collated, commented upon by CDC scientists in the form of national reports, which will be made available online to participant laboratories within 60 – 75 days. These results are used by laboratories/testing sites for self-evaluation. Laboratories/testing sites have the opportunity to compare the accuracy of their results with overall aggregate results, and may adjust their procedures to improve testing quality. Laboratories and testing sites are also given the opportunity to discuss testing quality issues directly related to the results with CDC scientists for help and guidance. The online HIV Rapid Testing Form EZ is administered twice per year.

The HIV-RT MPEP is free to participants, except for the cost of test kits and personnel time, therefore participating laboratories testing sites have a low cost advantage for self improvement that non-participants do not. CDC has seen improvement in individual testing site performance across shipment periods. CDC considers that the goal of the HIV-RT MPEP to improve testing accuracy has been met.

The online HIV-RT LPQ collects detailed information every other year on testing site demographics and laboratory practices associated with HIV rapid testing. The information is used to characterize laboratory practices associated with performing HIV rapid testing and develop and improve the HIV-RT MPEP. The surveys provides updated information that allows CDC to better target and customize the HIV-RT MPEP to meet the needs of the variety of testing sites using HIV rapid tests. Thus biennial surveys are warranted in order to detect changes in practices for improving HIV-RT MPEP, for detecting trends and for updating recommendations and guidelines which CDC may be issuing.

In addition to the demographics of test utilization, CDC requests information on quality control and quality assurance practices. This information helps CDC recommend appropriate and reasonable quality assurance practices. This is particularly challenging since many of the test kits likely to be used most often in the U.S. are waived under CLIA. CDC anticipates that providing an up-to-date, dynamic and interactive service will benefit testing sites and influence continuous improvement of testing practices.

None of this information is available for sites that do not participate in an external quality assessment (EQA) program, such as the MPEP. Testing sites performing waived tests are not required to participate in proficiency testing (PT), and although there is available fee-based HIV-rapid testing PT, no performance data exists for sites that cannot or will not pay for a PT program. Testing sites performing waived test are also not subject to CLIA inspections that would provide lab practice data. Literature review has not revealed any other program with cost-free EQA samples, such as the samples provided by the HIV-RT MPEP. Because the field is rapidly changing, and more tests are likely to be introduced in the U.S. soon, CDC needs to continue to collect this information.

CDC feels that systematic monitoring of testing practices will result in an optimal HIV-RT MPEP, making the program most useful to the new testing venues as well as to traditional clinical laboratories.

Privacy Impact Assessment Information

The information collected in both the HIV Rapid Testing Form EZ and the LPQ helps develop standards and guidelines for use of HIV rapid tests, emphasizing test accuracy and predictive value in low prevalence vs. high prevalence populations. CDC believes that providing this information to testing sites leads to improved testing practices and results in improved overall performance and accuracy. No Information in Identifiable Form (IIF) is being collected. The Privacy Act does not apply to this data collection.

3. Use of Improved Information Technology and Burden Reduction

The data collection now uses an online response format. One hundred percent of the MPEP results are received using the MPEP website. Hardcopy forms are still available to respondents for use as a worksheet.

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 at the March 2003 Association of Public Health Laboratories (APHL) Conference for the project well in advance of its initiation, thereby ensuring that duplicate efforts would not take place elsewhere within CDC.

CDC also conducts an internal CDC, cross-Center HIV Matrix meeting once per month. At these HIV Matrix meetings, a core group of representatives from the various operating units within CDC work on issues related to HIV/AIDS. These professionals have no report that any source of information similar to that to be collected by the HIV Rapid Testing MPEP exists within the CDC. Recently, the Rapid Testing Briefing (RTB) group was formed to discuss HIV rapid testing issues and specifically avoid duplication of programs and to make known and available information that has been collected regarding HIV rapid testing throughout CDC and elsewhere. No other cost-free voluntary HIV rapid testing program similar to the MPEP has been identified. In addition, literature searches conclude that there is no other information encompassing the same testing site sources to be found outside of the CDC.

Providers such as the College of American Pathologists, the American Association of Blood Banks, and the American Association of Bioanalysts 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.

5. Impact on Small Businesses or Other Small Entities

Some of the laboratories, clinician offices, and other facilities addressed by the HIV-RT MPEP LPQ and HIV Rapid Testing Form EZ can be classified as small business entities. To reduce the burden on these entities we have streamlined the data collection instruments (i.e., the online LPQ and the online HIV Rapid Testing Form EZ) to keep 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-RT MPEP imposes no additional record-keeping burden.

6. Consequences if Information Collected Less Frequently

The CDC intends to collect information through the Laboratory Practice Questionnaires (LPQ) every other year (biennially), and the HIV Rapid Testing Form EZ bi-annually. The biennial collection of the LPQ information is important to allow for the timely addition of participants, especially alternative (non-laboratory) testing sites, to the HIV Rapid Testing MPEP. It is necessary to collect the HIV Rapid Testing Form EZ information on a bi-annual basis in order to maintain an accurate and up-to-date database reflecting recent changes in HIV rapid testing issues, including new technologies, testing algorithms and quality control procedures.

Many participating facilities have limited experience with HIV rapid testing technology, therefore, it is important for the CDC to track, within the aforementioned time intervals, the effects new developments will have on HIV testing practices at laboratories and other alternative testing sites. If information collection in either the LPQ or HIV Rapid Testing Form EZ program components were to be performed less frequently, the CDC's database would present an inaccurate picture of the current activity at these facilities, adversely affecting the CDC's ability to properly interpret results and suggest effective guidelines. It is therefore necessary to continually monitor the quality of HIV rapid testing to ensure that the quality of testing is meeting public health needs. Laboratories and testing sites participating in the HIV-RT MPEP have the opportunity for self assessment and access to CDC personnel for consultation to assist in resolving test performance issues.

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. A 60-day Federal Register notice was published in the *Federal Register* on June 28, 2009, Volume 74, No. 116, pages 28938-28939 (Attachment 2). No public comments were received.

B. In revising the surveys and planning for this project, CDC solicited the advice and help of the following internal CDC experts in 2009:

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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 data collection procedures allow CDC to conduct primary analyses on secure data. Since CDC is offering consultation for testing sites, we maintain the capability reviewing identification information if an individual testing site seeks CDC's help to resolve testing problems. In addition, if results from the sample surveys which indicate that a laboratory is consistently providing incorrect interpretations, CDC may 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, CDC offers quick and expedient help to the testing sites.

Data will be treated in a secure manner, and will not be disclosed unless compelled by law. Individual participants are not identified in any way in the published national reports.

Privacy Impact Assessment Information

A. This information collection request has been reviewed by CDC's Information Collection Review Office (ICRO) that has determined that the Privacy Act does not apply to this data collection. Respondents are organizations that provide rapid 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 in 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-RT MPEP possess any information about the persons whose samples are used for the sample performance panels.

B. Response data is primarily filed and retrieved by the HIV-RT MPEP identification number. No personal identifying information (PII) and personal health information (PHI) are collected. All facility data are protected through access control and personnel and physical facility security policies and procedures. Security controls include detecting and defending against intrusive attacks, such as viruses, malware and denial of service; regular backups of data; and patch management and automatic upgrades of data systems. Specifically, the master copy of the database resides on a Microsoft SQL Server within the CDC network. Data is backed up nightly and archived off-site. The database server is in the CDC internal network, and not directly accessible via computers outside of the network. These backup procedures are in place to ensure that accidental or natural occurrences will not result in loss of project data. In addition, backups are made after major updates to the data base are performed.

CDC staff are responsible for processing MPEP registration forms and downloading the data collected online. All reports that require the use of the laboratory identifier are the responsibility of CDC.

C. No consent forms are used.

D. Participants are instructed at the time of enrollment that participation in the HIV-RT program is voluntary. They also receive a "Welcome" letter with MPEP contact information (Attachment 5b). No IIF is being collected.

11. Justification for Sensitive Questions

While testing sites may view their laboratory performance as sensitive, no individualized reports are generated and published. We encourage sites to compare data results to the aggregate results and to perform self-assessments. CDC does not consider any of the information collected to be sensitive.

12. Estimates of Annualized Burden Hours and Costs

A. Respondents receive two sample surveys per year consisting of 6 questions on the online HIV Rapid Testing Form EZ. The estimated annualized burden hours will be 10 minutes per respondent to complete the survey. Respondents will receive the LPQ every other year consisting of 22 questions. CDC estimates that respondents will need 30 minutes complete the survey. Participants will use the Information Change form to inform CDC of changes to their program's information. CDC has also developed an Enrollment Form for new participants.

Table A.12.A Estimated of Annualized Burden to Respondents

Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
HIV Rapid Testing EZ Form	660	2	10/60	220
Laboratory Practices Questionnaire (LPQ)	330	1	30/60	165
Enrollment Form	10	1	3/60	1
Information Change Form	20	1	3/60	1
Total	660			387

B. Actual cost to the respondent's organization will depend on the hourly wage of individual respondents. Many respondents may be Medical Technologists or Medical Technicians. Some of the respondents are likely to be volunteers in HIV counseling and testing centers, therefore, may be making near minimum wage or may not be paid staff. According to the U.S. Department of Labor, Bureau of Labor Statistics, the median income for Medical Technologists is $25.72 per hour and the median income for Medical Technicians is $17.01 per hour. Based on previous data collection, 50% of the respondents are Medical Technologists, 25% are Medical Technicians, and 25% are near minimum wage ($7.25/hour). Thus, CDC has averaged these hourly rates to calculate respondent cost, giving an average hourly rate of $18.93 per hour.

Table A.12.B Estimated Annualized Cost to Respondents

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Respondent Cost
Laboratorians	387	$18.93	$7,326

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

None

14. Annualized Cost to the 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, emailing, data collection, data input, data analysis, and overhead expenses. The estimated cost is based on the projected number of HIV Rapid Testing sites that will participate in the CDC HIV Rapid Testing Program. The annualized cost to the Federal Government is $397,490.

Table A.14 Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Costs (dollars)
Direct Cost to the Federal Government	CDC Project Officer (GS-13/14, step 5)	$103,497
	CDC Health Scientist (GS-13, step 5)	$ 94,877
Contractor and Other Expenses	Contractor Cost and Fees	$ 199,116
Total Cost		$ 397,490

15. Explanations for Program Changes or Adjustments

This information collection request is currently approved for 750 respondents and 625 burden hours. This submission requests approval for 660 respondents and 387 burden hours. The decrease in burden (-238 hours) is due to the elimination of foreign laboratories in this Model Performance Evaluation Program. This request also includes the addition of 2 new forms (total of 2 burden hours) and revisions to existing forms. The changes to the existing forms do not result in an increase in burden.

16. Plans for Tabulation and Publication and Project Time Schedule

Participants are surveyed using the online HIV Rapid Testing Form EZ twice per year. Participants are surveyed using the LPQ every other year. Survey questionnaire national reports are available for viewing through the CDC Internet Web Page. Descriptive statistics are used to analyze the generated data. For example, the relative frequencies of different types of testing sites responding to the questionnaire and performing the tests are determined. The proportions of different types of specimens used for the tests are 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 online HIV Rapid Testing Form EZ are made available online to respondents and made public through an online national report that contains CDC description and interpretation of results as well as graphic representations of frequency distributions. The data from the online LPQ is calculated using frequency distribution, proportions and regression analysis. The results are made public through an online national report and may be published in peer reviewed journals (such as the Journal of Clinical Microbiology) by project officers and scientists from CDC.

In general, the online HIV Rapid Testing Form EZ survey is conducted in March and September of each year. The LPQ is conducted every other year.

Table A.16 Project Time Schedule

Surveys made available	Completed Surveys Processed	Analysis of Data	National Reports Prepared/Published

online Form EZ (September & March)	Form EZ : 60 – 75 days after survey;	Form EZ : 75 – 90 days after survey;	Form EZ : 90 – 120 days after survey mailed;
LPQ (May)	LPQ: 60 – 75 days after survey	LPQ: 75 – 90 days after survey	LPQ: 90 – 120 days after survey mailed

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.

B. Collections of Information Employing Statistical Methods

This data collection does not use statistical methods.

CDC sponsors the Model Performance Evaluation Program for HIV Rapid Testing to address the gaps in quality assurance of performance and practices surrounding HIV rapid testing. This voluntary program provides testing sites with the opportunity for self-assessment and improvement by comparing their testing results on challenge specimens with the composite results of all testing sites enrolled in HIV-RT MPEP. Proficiency testing samples are sent to participants twice a year. Every year testing sites are asked to voluntarily participate in a laboratory practices questionnaire to compare their testing practices with aggregate results from all HIV-RT MPEP participants. All data is submitted electronically. Data gathered provides valuable information that helps with the development of appropriate HIV rapid testing guidelines. In addition, CDC uses the demographic information to better understand where and how the HIV rapid test kits are being used so that quality assurance efforts can be targeted to those areas.

List of Attachments

1. Authorizing Legislation
2. 60 day Federal Register Notice
3. HIVRT EZ documents
- **a. HIV RT EZ worksheet/online form**
- **b. HIV RT EZ pre-shipment letter**
- **c. HIV RT EZ cover letter**
- **d. MPEP General Information**
- **e. HIV RT General and specific online result entry instructions**
- **f. HIV RT Warning document**
- **g. Donor report (example)**
- **h. Donor report cover letter (example)**
- **i. Sample survey password notification email**
- **j. Reminder email**
- **k. Non-responder email**
- **l. HIV RT EZ Sample Report (example)**

4. Laboratory Practice Questionnaire (LPQ) documents
- **a. LPQ worksheet/online form**
- **b. LPQ cover letter/password email**
- **c. LPQ Sample Report (example)**

5. Enrollment Form documents
- **a. Enrollment Form**
- **b. Welcome letter**

6. Information Change Form documents
- **a. Information Change Form (ICF)**
- **b. ICF cover email**