CDC Model Performance Evaluation Program (MPEP)

OMB Revision Request Title Page
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Title of Project:

Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program (MPEP)
HIV Rapid Testing Form EZ and Laboratory
Practices Questionnaire Surveys

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Type of Review:

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HIV Rapid Testing Performance Evaluation Sample Results and Laboratory Practices Questionnaire Surveys

A. Justification

This request is an extension with a revision of a previously approved project, 0920-0595, of a human immunodeficiency virus (HIV) rapid testing form EZ (RTF EZ ; Attachment 3) and a HIV rapid testing laboratory practices questionnaire (LPQ; Attachment 4) to be submitted to facilities and testing sites that perform HIV rapid testing. Participation is on a voluntary basis and is expected to include approximately 750 HIV testing sites.

1. Circumstances Making the Collection of Information Necessary

CDC's stated mission is: **"To promote health and quality of life by preventing and controlling disease, injury, and disability."** One aspect of this mission is to prevent infections and to reduce associated morbidity and mortality. The infectious agent responsible for Acquired Immune Deficiency Syndrome (AIDS) is HIV. Prevention and control of HIV infection is a top priority public health issue for CDC.

Public health providers rely on the accuracy of HIV testing results in diagnosing HIV infection and in determining 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. Further, accurate and reliable information regarding application and testing practices among sites performing HIV testing is crucial to recommending meaningful and effective quality assurance practices. It is the mission of the Centers for Disease Control and Prevention (CDC), Division of Laboratory Systems (DLS) to continuously improve public health through improvement of the quality of laboratory testing.

Recently, rapid HIV test (HIV-R) kits have been approved by the U.S. Food and Drug Administration, and marketed in the U.S. These tests offer testing sites the capability of providing preliminary positive (reactive) test results to clients and patients within 1 hour. One of these tests, the OraQuick Rapid HIV-1 Antibody Test (OraSure Technologies, Inc.) is waived (i.e. doesn't 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-R tests 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 being used in a variety of non-traditional testing sites. These include HIV counseling and testing centers, mobile vans, community based organizations, 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 will be parts of the overall testing process for many non-traditional testing sites. The CLIA waiver allows for untrained personnel to perform HIV-R tests. 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. There are many other possibilities and wide-spread use is anticipated. These expanded testing capabilities are likely to lead to earlier detection of HIV-infection and to a greater proportion of HIV-infected individuals knowing their status. This should enhance HIV prevention efforts over time.

The concerns of CDC are that (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.

In view of CDC's mission, we consider it an urgent and top priority to address quality assurance of performance and practices surrounding HIV rapid testing. In support of

this we offer a model performance evaluation program (HIV-R 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 through comparing their testing results on challenge specimens with the composite results of all testing sites enrolled in HIV-R MPEP. Annually, testing sites are also encouraged to participate, on a volunteer basis, in a laboratory practices questionnaire to compare their testing practices with aggregate results from all HIV-R MPEP participants. Data gathered provides valuable information leading to the development of appropriate HIV rapid testing guidelines. In addition, valuable demographic information collected provides a better understanding of where and how these tests are being used, so that quality assurance efforts are targeted.

The HIV-R challenge sample surveys presented to participants are in the form of 6 well-characterized samples for which the HIV status, i.e., either positive, negative, or sero-converter, is known. These surveys are administered twice per year. The results of the samples surveys are collected, both electronically or in hard-copy format using the HIV Rapid Testing Form EZ for which the revision of OMB clearance is being requested. The burden for filling out the forms is the same regardless of the format. The HIV Rapid Testing Form EZ includes information which is critical to measuring and evaluating laboratory testing practices. Results are processed and returned to participants within 60 - 75 days post-sample shipment.

Brand names of commercial products are mentioned on the 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. Questions regarding products and test systems do not represent endorsement by CDC.

The laboratory practices questionnaire (LPQ), for which revision of OMB clearance is also being requested, is administered once per year. HIV rapid testing is still relatively new. Practices and methodologies have changed since the inception of the HIV-R 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.

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

The information collected using the HIV Rapid Testing Form EZ will be 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, and sent 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 HIV Rapid Testing Form EZ is administered twice per year.

Since the HIV-R MPEP is provided at no charge to participants, except for the cost of test kits and personnel time, laboratories testing sites participating have a low cost advantage for self improvement that non participants do not. The goal of the HIV-R MPEP, to improve testing accuracy, has shown to have been met by improvement in individual testing sites performance tracked across shipment periods.

The HIV-R LPQ collects detailed information on testing site demographics and laboratory practices associated with HIV rapid testing. The information is used to characterize laboratory practices associated with performance of HIV rapid testing. The CDC uses results generated in several different types of testing sites to further develop and improve the HIV-R MPEP. The survey is expected to provide baseline information that allows CDC to better target and customize the HIV-R MPEP to meet the needs of the variety of testing sites using HIV rapid tests. Thus annual surveys are warranted in order to detect changes in practices for improving our quality assurance program, for detecting trends and for updating recommendations and guidelines which CDC may be issuing.

In addition to the demographics of test utilization, quality control and quality assurance practices will be elucidated. This information will help CDC to recommend appropriate and reasonable quality assurance practices. This is particularly challenging since the test likely to be used most often in the U.S., the OraQuick test, is CLIA-waived. We anticipate that by providing an up-to-date, dynamic and interactive service, we will be able to benefit testing sites and influence continuous improvement of testing practices.

None of this information is available elsewhere. Testing sites performing waived tests are not required to participate in proficiency testing, therefore, no performance data exists. Testing sites performing waived test are not subject to CLIA inspections, and therefore, lab practice data does not exist. Literature review has not revealed any other program similar to the free of cost HIV-R MPEP. Because the field is rapidly changing, and more tests are likely to be introduced in the U.S. soon, we need to continue to collect this information on an annual basis.

The information collected in both the HIV Rapid Testing Form EZ and the LPQ facilitates the development of standards and guidelines for use of HIV rapid tests, emphasizing test accuracy and predictive value in low prevalence vs. high prevalence populations. We anticipate that the provision of this information to testing sites will lead to improvement in practices and will result in improvement in overall performance and accuracy.

We envision that, through systematic monitoring of testing practices, we will be able to optimize the HIV-R MPEP to make it most useful to the new testing venues as well as to traditional clinical laboratories.

3. Use of Improved Information Technology and Burden Reduction

Data Collection forms are available in hard copy format. Alternatively the CDC MPEP has developed a response format for the Rapid HIV Testing MPEP using the survey questionnaire and performance evaluation result forms uploaded to the web page to allow on-line response. This represents a convenience for the respondent that may not reduce the burden.

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 a cross-CIO 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. In addition, literature searches conclude that there is no other information 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. No information collections are currently conducted to provide specific information on HIV rapid testing performance and practices.

5. Impact on Small Businesses or Other Small Entities

Some of the laboratories, clinician offices, and other facilities addressed by the HIV-R MPEP LPQ and HIV Rapid Testing Form EZ can be classified as small business entities. To reduce the burden on these entities, we offer a choice of response methods, we have streamlined the data collection instruments (i.e., the LPQ and the 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-R 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) annually, and the HIV Rapid Testing Form EZ bi-annually. The annual 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 sties participating in the HIV-R 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 Wednesday, April 5, 2006, Volume 71, No. 65, pages 17103-17104 (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 experts and external consultants:

Internal experts:

Tim Granade, M.S., Laboratory Supervisor
National Center for Infectious Diseases
Division of Aids and Sexually Transmitted Diseases Laboratory Research
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External Consultants:

Mr. Wayne Meyers, Project Manager
Ms. Courtney Rodi, Research Programmer
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Dr. Greg Chiklis, Vice-President of Product Development
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508-520-0588

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 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 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-R MPEP possess any information about the persons whose samples are used for the sample performance panels.

A contractor, Constella LLC, is responsible for collecting the data collection instruments, and sending de-identified data to CDC. The contractor assigns a unique identification number to each respondent organization 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. The

name and address of the participating testing sites appear on a cover page for both HIV Rapid Testing Form EZ and Laboratory Practice Questionnaires (LPQ). The cover page is removed by the contractor prior to forwarding any result forms to the CDC.

Response data is primarily filed and retrieved by the HIV-R 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. The facilities of the TOP SECRET mainframe security package will be used to restrict access to the data to designated CDC personnel and the contractor. The contractor is responsible for ensuring that adequate backup and recovery procedures are in place.

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 SRQ 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. Because HIV rapid testing is so new, is untested in the field, and has tremendous potential public health impact, we acknowledge that these situations could occur. 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 survey.

Hard copies of the HIV Rapid Testing Form EZ and LPQs 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 will not be disclosed unless compelled by law.

Respondent organizations 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 Costs**

A. 750 respondents will receive two HIV Rapid Testing Form EZ surveys per year consisting of 6 questions. The estimated annualized burden hours will be 10 minutes per respondent to complete the survey. 750 respondents will receive the LPQ once per year consisting of 22 questions. The estimated annualized burden hours will be 30 minutes per respondent to complete the survey. Pilot tests were performed on the LPQ with the additional questions and the average additional time was 15 minutes. Based on field testing, the burden for the electronic form and the paper from are the same.

Estimated of Annualized Burden to Respondents

Form Name	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
HIV Rapid LPQ	750	1	30/60	375
HIV Rapid testing Form EZ	750	2	10/60	250
Total				625

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, the median income for Medical

Technologists is $20.31/hour and the median income for Medical Technicians is $13.85/hour. Based on previous data collection, 50% of the respondents are Medical Technologists, 25% are Medical Technicians, and 25% are near minimum wage ($5.50/hour), the average hourly rate is $15 per hour, and the maximum cost per respondent would be approximately $10.00 per year, assuming all three surveys are completed. There are no direct costs other than the time required to complete the survey.

Estimated Annualized Cost to Respondents

Type of Respondents	No. of Respondents	Number of Responses per Respondent	Hourly Wage Rate	Respondent Cost
HIV Rapid Testing Questionnaire (LPQ)	750	1	$15.00/hour	$5,625
HIV Rapid Testing Form EZ	750	2	$15.00/hour	$3,750
Total				$9,375.00

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

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

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, 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.

Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Costs (dollars)
Direct Cost to the Federal Government	CDC Project Officer (2% effort)	$ 2,000
	CDC Health Scientist (25% effort)	$ 15,000
Contractor and Other Expenses	Contractor Cost and Fees	$ 20,500
	TOTAL COST TO THE GOVERNMENT	$ 37,500

15. Explanations for Program Changes or Adjustments

This is a revision of a previous data collection (0920-0595). Revision of data collection instruments was necessitated by additional test kit manufacturers coming to market and the employment of new testing procedures by participants. The burden estimate for the LPQ is changing from 15 to 30 minutes due to the additional questions. The burden of the HIV Rapid testing Form EZ remains the same in spite of the fact that additional test kits choices have been added.

16. Plans for Tabulation and Publication and Project Time Schedule

Participants are surveyed using the HIV Rapid Testing Form EZ twice per year for five years. Participants are surveyed using the LPQ once per year for five years. Survey questionnaire national reports are available for viewing through the CDC Internet Web Page, http://www.phppo.cdc.gov/mpep/default.aspx. Descriptive statistics, done by the contractor, 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 will be determined. 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 Rapid Testing Form EZ 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, http://www.phppo.cdc.gov/mpep/default.aspx.

The data from the LPQ is calculated using frequency distribution, proportions and regression analysis. The results may be published in peer reviewed journals (such as the Journal of Clinical Microbiology) by project officers and scientists from CDC.

Project Time Schedule

In general, the HIV Rapid Testing Form EZ survey will be conducted in June and December of each year. The LPQ will be conducted in December of each year.

Surveys mailed	Completed Surveys Processed	Analysis of Data	National Reports Prepared/Published
EZ Form (June & December) LPQ (December)	EZ Form: 60 – 75 days after survey; LPQ: 60 – 75 days after survey	EZ Form: 75 – 90 days after survey; LPQ: 75 – 90 days after survey	EZ Form: 90 – 120 days after survey mailed; 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

1. Respondent Universe and Sampling Methods

The group of respondents in the HIV-R MPEP is the universe for these surveys. This includes 750 testing sites that were recruited using CDC databases of sites currently performing HIV testing, reagent manufacturers' customer lists, and respondents recruited from announcements made at national meetings. Because HIV rapid tests are new in the U.S., and because there is no other substantial proficiency testing program currently available that target these tests, we believe our recruitment efforts have covered, as closely as possible, the universe of U.S. testing sites. Foreign testing

sites are generally those involved in other CDC collaborations or are national reference laboratories. There is no claim that these are representative of all foreign testing sites.

Since the most common test used in the U.S. is waived under CLIA, it is uncertain which types of testing sites will tend to enroll in HIV-R MPEP. For this reason it is uncertain whether or not the HIV-R participants will be a truly representative sample of all testing sites. However, we are currently offering the HIV-R MPEP service to all types of testing sites in an effort to obtain a sample of the universe of potential respondents.

We anticipate a 95% response rate from all active HIV-R participants. The surveys are designed in such a way that the information gained will benefit all HIV-R testing sites. The information gained from the surveys is available to all HIV testing sites and associated organizations through public domain.

2. Procedures for the Collection of Information

Data is collected from respondents who return either the hard copy of the HIV Rapid Testing Form EZ (mailed in June and December) and LPQ surveys (mailed In December) or respondents who answer the surveys via electronic web site. Hard copy surveys are returned to the contractor through mail in a postage-paid envelope to Constella Group, LLC, Contract # 200-2003-F-01325. Hard copies of the HIV Rapid Testing Form EZ and LPQs are secured in locked, fire-proof file and storage cabinets whose access is strictly limited to approved personnel. The contractor will download

the online data from the electronic website and combine it with the data resulting from keypunch of the hard copy data. All data is treated in a secure manner and will not be released in identifiable form, unless compelled by law.

Non-respondents receive one follow-up call from Constella three weeks after the initial surveys are mailed, as a reminder. During this call they ask the participant to respond by submitting their forms. Since this program is the only aggregate quality assurance information specifically directed to HIV rapid testing, we expect a 95% response rate, and sufficient interest from participants to complete these surveys.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Because all of the respondents are voluntary participants in the HIV-R MPEP and are keenly interested in further information about the performance of the tests and testing practice procedures, we anticipate a 95% response rate. Through outside and CDC consultation with organizations involved in HIV counseling and testing centers, the language used in the surveys has been adjusted so as to be broadly understood by all types of testing sites and personnel. The HIV Rapid Testing Form EZ has been designed as a 2-page collection instrument with the first page being of foremost importance. The LPQ has been designed to collect the minimum amount of information needed for improving CDC prevention and control efforts regarding HIV-R testing. Adequate choices of categorical answers have been provided to minimize uncertainty in answering questions. Numerical variables have been linearized for simplification in

answering. All answers are voluntary. There should be a minimal number of answers that need to be “looked up.”

This approach is analogous to other unique and successful CDC project surveys. Participants who have not responded within 3 weeks of receipt of the survey will be called by the contractor (Constella) as a reminder. In an effort to minimize public burden, we assume that if participants decline to respond after the follow-up phone call, they are unable to respond, and we therefore drop them from the participant cohort. We expect this to be rare, and fully expect adequate participation to constitute a valid project survey.

4. Tests of Procedures or Methods to be Undertaken

These surveys were developed by public health scientists, statisticians, epidemiologists, and program managers from the Division of Laboratory Systems, CDC. The survey design was directed by Project Officers who are public health scientists and epidemiologists with experience in HIV testing and in survey design and analysis. In addition, microbiologists, physicians and public health scientists from the National Center of HIV, STD, and TB Prevention (NCHSTP) and from the National Center for Infectious Diseases (NCID) were consulted. The comments and advice from these experts were incorporated into the survey designs.

The survey was sent to the director of a community-based HIV counseling and testing center for advice as to its practicality for use by non-scientist, non-laboratory based personnel. The surveys were also reviewed by an experienced HIV counselor. Based upon this collective advice, the wording of questions was modified so as to be broadly understood by volunteers or other persons with limited technical qualifications. Feedback from all consultants was incorporated into the survey designs.

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

Statistical consultation for the surveys was provided by Dr. Harvey Lipman, Senior Statistician, CDC/DLS. The comments of Dr. Lipman were assessed and incorporated into the survey design by the Project Officers. Project Officer, Dr. Laurina Williams has extensive training and experience in public health, epidemiology, survey design, and statistical analysis. Project Officer, Mr. David Cross, has extensive experience in testing practice, survey design and analysis for HIV-related testing.

The surveys were designed by:

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The Contractor for the HIV-R MPEP program is:

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The Statistical Consultant is:

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LIST OF ATTACHMENTS

Attachment #3

HIV Rapid testing Form EZ

OMB Approval # 0920-0595

List of Proposed Changes

Changes in HIV Rapid Testing EZ form

Question	Change
Front Cover	Type of testing facility added.
1	Test kit choices reordered. New test kits added
2a	Choice for "Oral fluid" further described "Oral fluid (from swabbing gums)
2b	New question added to determine the purpose of using HIV rapid testing
4	Question reformatted for ease of response
5	Term QC defined within question. Additional choices given for sources of QC material. One additional choice given for frequency of use – "With each Run/Set/Batch of patient tests"

Attachment # 4

HIV Rapid testing laboratory practices questionnaire (LPQ; Attachment 4)

OMB Approval # 0920-0595

List of Proposed Changes

Question	Change/Justification
1a.	Choices reordered. Additional choices added: Drug use treatment center, HIV counseling/testing field site, oral health
1b	New question to determine location of testing
1d	New question added to eliminate submission of survey by testing sites not performing HIV Rapid testing.
1e	Question reformatted for ease of response
2b,c,d,e	New questions added to collect demographic information on patient population
3d,e,f	New questions added to gain information on utility of using rapid testing in various patient populations. This data is necessary to collect to determine the ratio of preliminary positive (rapid test) results to true positive results (confirmed positive)
5	New test kits added
6	Choice for “Oral fluid” further described “Oral fluid (from swabbing gums)
7a	Question reformatted for ease of response
7b,c,e	New questions added to further refine data collected in questions 7a and 7d
9	New question added to determine if rapid testing is replacing traditional HIV testing methods.
11c,d	New questions to further refine data collected in question 11b regarding HIV rapid test training.
12b,c	Questions reformatted for ease of response

12e,f,g,h	New questions added to further define HIV Rapid testing algorithms
13a, b	Previous question related to reporting time split into two questions to determine if there is a difference in reporting time based on testing result.
14a-e	New questions added to collect data regarding how preliminary positive results are reported.
15a-e	New questions added to collect data regarding how preliminary negative results are reported.
16	Question reformatted for ease of response
19b	New question to obtain the source of quality control materials
20b,c	New questions added to further refine responses from questions 20a regarding proficiency testing/performance evaluation programs.
21b	New question added to further refine reason for no cost given in question 21a
22a-c	New questions added to determine opinions regarding the advantages and disadvantages of HIV rapid testing