B. Collections of Information Employing Statistical Methods

The CDC Model Performance Evaluation Program (MPEP) evaluates the performance of laboratories that conduct testing for antibody (Ab) to human immunodeficiency virus type 1 (HIV-1). Since the MPEP has no regulatory authority and participation in the MPEP does not serve to satisfy the regulatory requirement for enrollment in a CLIA-approved PT program, MPEP participants have enrolled voluntarily for the sole purpose of evaluating/improving the performance of their laboratory.

The laboratories periodically receive express shipped performance evaluation (PE) samples/specimens consisting of plasma or whole blood, report their testing results to CDC, and receive aggregate reports of testing results. The PE results are used by the laboratories for self-evaluation (quality assurance), by state and federal agencies to shape policy decisions, and by international agencies to support international quality assurance efforts.

In addition to testing PE samples, the MPEP laboratories are periodically asked to complete survey questionnaires describing the demographics of their laboratory and their testing practices. The results of these surveys complement the retroviral and AIDS-related testing data that is obtained through the MPEP. The survey data is used to develop a profile of the characteristics which distinguish a laboratory testing process that performs consistently well from one that performs poorly, and will be essential for targeting strategies for improving the quality of laboratory testing.

The current request for OMB approval includes the enrollment forms (attachment 3) for laboratories to participate in the MPEP. The request also includes the PE Results Forms for HIV-1 Ab testing (attachment 10) and cover letter (attachment 9). The aggregate result report returned to the laboratories for the HIV-1 Ab testing and does not employ the use of any statistical methods. The reporting of the frequency of response for a particular testing parameter (e.g., laboratory type, test kit used, etc.) is determined by percentages.

1. Respondent Universe and Sampling Methods

Statistical methods are not and will not be used to select participants in the MPEP for the shipped PE samples/specimens. Respondents are voluntarily enrolled laboratories performing testing, both in the United States and in countries outside the United States. Race ethnicity questions do not apply to this survey.

2. Procedures for the Collection of Information

Advance letters are sent to participants prior to each PE survey event notifying the laboratory the date of shipping of the PE surveys (attachment 10). A laboratory information change form (ICF) is included with the letters preceding the PE surveys (attachment 8). These ICF's are used only by the laboratories to verify/correct the shipping address the MPEP has on file for the laboratory. A Password Notification letter is sent to advise laboratories of their new passwords for online data entry (attachment 7). All

letters and their associated forms are returned directly to the CDC contractor responsible for maintaining the MPEP enrollment data base.

Results booklet for the PE sample/specimen survey (attachment 10) are sent by the laboratories directly to the CDC. CDC personnel forward the result booklets, in batches, to the CDC contractor responsible for keypunching the result booklet data. The contractor provides SAS data files containing the results to CDC. CDC personnel are then responsible for creating the aggregate result reports which are sent to the participant laboratories.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Methods used to maximize the response rate for the Result From are letters sent to the laboratories prior to the survey event (attachment 6) verifying the mailing address help to maximize the response rate by reducing the risk of the survey not reaching the intended recipient.

The only method used to maximize the response rate for the sample/specimen surveys is the letter sent to the laboratories prior to the survey event informing the laboratories of the date of shipment and requesting verification of the shipping address (attachment 6). By notifying the laboratories prior to the survey event, the laboratories are able to better schedule the additional workload created by the shipped samples/specimens and therefore are more likely to return testing results in a timely fashion. The ICF included with the

preshipment letter helps to maximize the response rate by reducing the risk of misdirected shipments.

Based on previous data, we anticipate a response rate for the Performance Evaluation Result Form to be greater than 90%. Shown below is a table with the most recently obtained response rate for the HIV-1 Antibody PE Result Form:

Previous Performance Evaluation Form Response Rates		
Form Name	**Date**	**Response Rate**
HIV-1 Ab PE Result Form	January 2007	650/724 (89.8%)

4. Test of Procedures or Methods to be Undertaken

The HIV Testing were originally developed with help from scientists at CDC, recognized experts located outside CDC, and the Questionnaire Design Research Laboratory, Office of Research and Methodology, National Center for Health Statistics. The results booklets for the PE surveys were developed by CDC personnel in the Division of Laboratory Systems (DLS), National Center for Preparedness, Detection, and Control of Infectious Diseases, CCID, with assistance from personnel in the National Center for Infectious Diseases.

The PE survey results booklets have been used successfully in the MPEP for more than fourteen years (see response rates listed above in B.3). The data collection procedures have not significantly changed from previous MPEP HIV Testing Performance Evaluation Program Laboratory Survey, expiration date 08/2004; OMB No. 0920-0274).

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

Statistical consultation for the questionnaire surveys was performed by James H. Handsfield, Division of Laboratory Systems, Centers for Disease Control and Prevention. For both surveys, Mr. Wayne Myers, Courtney Rodi, and Daline Derival of Constella Group, Inc. (404) 325-2660 assisted in both the collection and processing of data. Project Officer, Mr. David Cross, has extensive experience in testing practice, survey design and analysis for HIV-related testing.

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