Requesting Laboratory Input to Evaluate Assay Performance Following Implementation of Updated QC Recommendations (Phase 1) and Standardization (Phase 2, 3) of the CDC Zika MAC-ELISA

Request for OMB approval of a New Generic Information Collection Request
OMB Control No. 0920-0881

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Supporting Statement B

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The Laboratory Response Network's (LRN) mission is to maintain an integrated national and international network of laboratories that can respond to suspected acts of biological, chemical, or radiological terrorism and other public health emergencies. This collection of information does not employ statistical methods.

When federal, state, and local public health laboratories voluntarily join the LRN, they assume specific responsibilities and are required to provide information to the LRN Program Office at CDC. The Centers for Disease Control and Prevention (CDC) is submitting a request to survey LRN laboratories performing the CDC Zika MAC-ELISA to ensure implementation of new quality control recommendations. In that, we are requesting the mean and confidence intervals for the controls from each laboratory conducting the CDC Zika MAC-ELISA following the implementation of each of three phases of the standardization of the CDC Zika MAC-ELISA. Correlating this data to CDC established ranges will ensure assay accuracy and precision across all testing laboratories.

1. Respondent Universe and Sampling Methods

Respondents include the 110 members of the Laboratory Response Network. Expected response rate 100% of all labs who wish to continue to receive the Zika MAC-ELISA kits. Compliance with this request is required for laboratories using the assay. No statistical methods are used to determine the sampling group for respondents.

2. Procedures for the Collection of Information

Three questionnaires will be conducted via broadcast email asking respondents to send information via email to the Zika MAC ELISA Implementation Team.

CDC is requesting the mean, standard deviation, and 99% confidence interval for the controls from each laboratory conducting the CDC Zika MAC-ELISA following the implementation of each of three phases of the standardization of the CDC Zika MAC-ELISA. Correlating this data to CDC established ranges will ensure assay accuracy and precision across all testing laboratories. The questionnaire will be distributed after getting OMB approval for phase 1 and following the roll-out of phase 2 and 3.

Personal identifiable information is collected as a condition of membership in the LRN as a mechanism to maintain communication with members. The collection of personal identifiable information to

maintain communication with members was approved in OMB 0920-0850, The Laboratory Response Network.

Information collected from LRN members is restricted to program staff. Individuals outside of the program that request access to data must provide justification to see data and sign nondisclosure agreements. Data is contained electronically on program staff personal computers that are password protected.

3. Methods to maximize Response Rates and Deal with No Response

If limited responses to the questionnaires are received from LRN member laboratories, the LRN Program office at CDC will extend the deadline and send another announcement of the data call and the need for the information by broadcast email. If no responses are received after the second announcement, then a maximum of two personal phone calls to the Lab Director of the LRN member laboratory will be used to follow up.

4. Tests of Procedures or Methods to be undertaken

Data collected from each laboratory will be input into an Excel spreadsheet. No pre-test is necessary for this data input.

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

No individuals consulted are consulted on statistical aspects or the design of the data collection.