

**Requesting Laboratory Input to Evaluate Assay
Performance Following Implementation of
Standardization and Manufacture (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 confirm that they have received and successfully implemented the CDC Zika MAC-ELISA assay negative control and calibrators (phase 2) as well as the final standardized assay (phase 3) to ensure continued assay accuracy and precision. CDC will use this data to track data performance between phase 2 and 3 of the assay improvement process. 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 2 and following the roll-out of phase 3.

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

CDC has implemented a phased approach to improve the performance of the CDC Zika MAC-ELISA assays.

- Phase 1 of this plan includes the distribution of instructions for additional primary (plate) and secondary (clinical sample) acceptance criteria. These instructions are designed to enhance the precision and accuracy of the assay across all testing laboratories, supplemental to previously established good laboratory practices (i.e., proper training and competency of testing personnel, lab specific safety and quality metrics and workflow, maintenance and calibration of equipment according to manufacturer’s instructions, etc.). Updated QC recommendations were sent out to

labs performing MAC ELISA through the LRN on August 2, 2017, and more detailed guidance on performing QC calculations was distributed on August 29, 2017.

- Phase 2 (following OMB approval) will include the evaluation and distribution of a standardized Calibration Control Serum and independent negative control, as well as recommendations for reagent reconstitution and a fully updated set of EUA Instructions for Use (IFU).
- Phase 3 (anticipate completion will be September 2018) will include the manufacture of a complete MAC-ELISA kit and submission of a new EUA.

Two questionnaires will be conducted (following Phase 2 and Phase 3) via broadcast email asking respondents to send information via email to the Zika MAC ELISA Implementation Team.

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. Examples of personal identifiable information would include work phone number and address and birthday and birth month.

Information that is 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.