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

Expiration Date: 03/31/2020

Supporting Statement A

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- **Goal of the study:** The goal of this study is to ensure LRN laboratories performing the CDC Zika MAC-ELISA have received and successfully implemented the additional primary (plate) and secondary (clinical sample) acceptance criteria using the CDC quality control recommendations following phase 1 of the CDC Zika MAC-ELISA standardization. The objective of continued data collection following the implementation of phases 2 and 3 of assay standardization is to ensure continued assay accuracy and precision across LRN laboratories performing the CDC MAC-ELISA.
- **Intended use of the resulting data:** The resulting data collected will confirm precision and accuracy of the CDC Zika MAC-ELISA across all testing laboratories when the additional recommendations (phase 1), standardized negative calibrator and independent negative control (phase 2) and standardized CDC Zika MAC-ELISA (phase 3) are implemented.
- **Methods to be used to collect:** After phase 1, data will be collected using a questionnaire sent electronically to LRN labs performing the Zika MAC-ELISA that requests mean, standard deviation, and 99% confidence interval for positive and negative controls. The same questionnaire will be sent after implementation of phase 2 and phase 3, requesting mean, standard deviations, and 99% confidence intervals for the laboratory's positive and CDC-provided negative calibrator and independent negative controls.
- **The subpopulation to be studied:** LRN laboratories performing the CDC Zika MAC-ELISA.
- **How data will be analyzed:** Data will be submitted to the Zika MAC ELISA Implementation Team (referencereagents@cdc.gov**)** and will be analyzed to determine if the control data from each laboratory falls within CDC established ranges to ensure assay accuracy and precision across all testing laboratories.
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1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is submitting a new request under generic package 0920-0881, "Data Calls for the Laboratory Response Network," to survey LRN laboratories performing the CDC Zika MAC-ELISA to ensure implementation of additional quality control (QC) recommendations and measures as part of a three-phase plan to standardize the CDC Zika MAC-ELISA and submit a new Emergency Use Authorization (EUA).

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services (HHS), in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to Federal Departments and agencies. The LRN's 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.

- 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 (anticipated completion: November, 2017) 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 (anticipated completion: end of 2017) will include the manufacture of a complete MAC-ELISA kit and submission of a new EUA.

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.

Federal, state, and local public health laboratories join the LRN voluntarily. When laboratories join, they assume specific responsibilities and are required to provide facility information to the LRN Program Office at CDC as well as test results for real samples or proficiency tests. LRN laboratories participate in Proficiency Testing Challenges, Exercises and Validation Studies each year. This special data call will be conducted via broadcast email/questionnaire (Attachment 1) asking respondents to send information via email to the Zika MAC ELISA Implementation Team after each of the three phases.

Data collection for this project is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241).

2. Purpose and Use of Information Collection

The Zika MAC ELISA Implementation Team is requesting electronic submission of:

A. The mean, standard deviation and 99% confidence interval for each laboratory's positive and negative calibrator control using the new guidelines following implementation of phase 1;
B. The mean, standard deviation and 99% confidence interval for each laboratory's positive and CDC-provided negative calibrator and independent negative controls following implementation of phase 2 and 3.

All of this information will be correlated with CDC-established ranges to ensure assay accuracy and precision across all testing laboratories as each phase of the three-phase plan to further standardize the CDC Zika MAC-ELISA is implemented.

3. Use of Improved Information Technology and Burden Reduction

This data call will be conducted using a questionnaire sent to all LRN laboratories conducting the CDC Zika MAC-ELISA. All information is reported electronically. Thus, 100% of information is collected electronically. CDC will collect the minimum information necessary for this assay accuracy and precision analysis.

4. Efforts to Identify Duplication and Use of Similar Information

There is no similar data collection conducted either within the Federal government or privately. There is no overlap or duplication of specific projects. CDC is not aware of the availability of any similar information.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses. Respondents are other federal, state, or local governmental laboratories. The data requested has been held to the absolute minimum required for its intended use.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden. This is a one-time information collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice for the generic package (0920-0881) was published in the *Federal Register* on November 17, 2016, vol. 81, No. 222, pp. 81146-81147. One public comment was received. However, because there was no return mailing address, no response was sent.

B. FDA was consulted on this data collection effort and they are supportive.

9. Explanation of Any Payment or Gift to Respondents

There will be no remuneration for participants.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This information collection request has been reviewed by NCEZID who has determined that the Privacy Act does not apply. Individuals responding to this request are doing so as part of their job. Although participation in the Laboratory Response Network is voluntary, member laboratories are requested to provide information to improve program activities at CDC. Personal identifiable information will be collected for this data call.

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. Personal identifiable information includes, name, email address, phone number, and lab address.

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.

Respondent consent is not needed for special data calls. LRN member laboratories have the option to respond or decline response.

Questionnaires will be sent via broadcast email that asks respondents to send information via email to the Zika MAC ELISA Implementation Team (referencereagents@cdc.gov).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board

The questionnaire associated with this Gen-IC has been reviewed by NCEZID's human subjects advisor and was determined to be non-research (Attachment 2).

Justification for Sensitive Questions

This data call does not have questions of sensitive nature (e.g. individual identifiers such as race, medical history or patient information related to laboratory samples).

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The annualized response burden for data collections under this generic clearance is estimated at 28 hours. A participant responding to each questionnaire is estimated to take 5 minutes.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Public Health Laboratorians	Special Data Call - Questionnaire	110	3	5/60	28
Total					28

B. Estimated Annualized Burden Costs

The estimated annualized costs were determined by using the 2017 General Schedule Pay Tables for a GS-11, Step 5 scientist.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Public Health Laboratorians	Special Data Call - Questionnaire	28	$30.89	$850.92
Total				$850.92

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

Estimated annualized costs were determined by using the 2017 General Schedule Pay Tables of a GS-12, Step 4 scientist. Approximately 9 hours will be needed for collecting and analyzing the results. No other expense will be incurred for this collection.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Direct Cost to the Federal Government	$359.10

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for publication of this data.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Special Data Call - Questionnaire
2. Non-research determination