

This broadcast is being provided to laboratories performing the CDC Zika MAC-ELISA assay. All questions/comments regarding this message should be sent to referencereagents@cdc.gov .

Over the past year we have learned a lot about the Zika MAC-ELISA including the identification of quality control approaches that, when implemented, improve standardization of ELISA assay performance. The CDC, in consultation with FDA, established a three phase plan to further standardize the Zika MAC-ELISA.

- Phase 1 of this plan included 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.).
- Phase 2 includes 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 will include the manufacture of a complete MAC-ELISA kit and submission of a new EUA.

Phase 1, rolled out in July 2017, included the requirement for acknowledgement of the receipt of the CDC Quality Control Recommendations for the Zika MAC-ELISA along with completion of the Zika MAC-ELISA QC Data Collection Form, a template that included a summary of the laboratory's quality control data.

As per our previous communications, CDC has completed Phase 2 and is now ready to distribute the standardized Negative Control and Negative Calibrator Set. Upon receipt of this reagents set, CDC requests that each lab provide within 30 days:

- A second Zika MAC ELISA QC Data Collection form. Data reported on the form for Phase II must be generated using the new Negative Control and Calibrator Set.
- A complete MAC ELISA Verification Panel Results Information spreadsheet.