

Donald E. Williamson, MD State Health Officer

September 10, 2015

Roosevelt McCorvey, MD Reproductive Health Services 811 South Perry Street Montgomery, AL 36104

CLIA #01D0304393

Dear Dr. McCorvey:

Re: Revisit survey

We conducted an off-site revisit survey on September 10, 2015, regarding deficiencies cited on your on-site recertification survey on February 12, 2015. We have received documented verification that substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) has been achieved.

If you have any questions concerning this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Jeff Meank, BS, MT (ASCP) CLIA Laboratory Unit Director

Division of Health Care Facilities

Thomas M. Miller, M.D. State Health Officer

IMPORTANT NOTICE - ACTION NECESSARY

February 21, 2017

Roosevelt McCorvey, MD Reproductive Health Services 811 South Perry Street Montgomery, AL 36104

CLIA #01D0304393

Dear Dr. McCorvey:

Re: STANDARD-LEVEL DEFICIENCIES

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, conducted a routine recertification survey of your laboratory that was completed on February 14, 2017. Enclosed is form CMS-2567, Statement of Deficiencies, listing the deficiencies found during the survey. The deficiency statement references the CLIA regulations at 42 C.F.R. 493.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a Plan of Correction that is acceptable to the Centers for Medicare & Medicaid Services (CMS) in content and time frames. Further regulations at 42 C.F.R. 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.



Thomas M. Miller, M.D. State Health Officer March 8, 2017

Roosevelt McCorvey, MD Reproductive Health Services 811 South Perry Street Montgomery, AL 36104

CLIA ID #01D0304393

Dear Dr. McCorvey:

Re: Revisit survey

By letter dated February 21, 2017, we notified you that based on the onsite survey completed on February 14, 2017, your facility was not in compliance with standard-level CLIA requirements. In our letter we requested that you submit an acceptable plan of correction and acceptable evidence of correction. We received your response on March 2, 2017, and have determined that your plan of correction and evidence of correction are acceptable.

Based on the documentation submitted with your plan of correction, we conducted an off-site revisit survey on March 6, 2017, regarding deficiencies cited on your on-site recertification survey on February 14, 2017. The documentation verified that substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) has been achieved and maintained, effective March 6, 2017.

If you have any questions concerning this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

CLIA Laboratory Unit

Laye R. Ciller

Division of Health Care Facilities