Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 04D0872195	**(X3) Date Survey Completed** 08/14/2019
Name of Provider or Supplier Mcgehee Family Clinic	**Street Address, City, State** 1507 South 1st Street, Mcgehee, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: . Through a review of package instruction for Roche Coagucheck, laboratory patient logs, patient medical records, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to follow manufacturer's instructions when performing the Coaguchek test system for evaluating Prothrombin Test (PT) and International Ratio (INR) as evidenced by. A. A review of Roche Coagchek package insert revealed the purpose of the test system "The purpose of Coaguchek test system is intended for use by professional healthcare providers for quantitative Prothrombin Time (PT) Testing for monitoring Warfin therapy." B. A review of Coaguchek patient logs from May- August 2019 (4 of 4 months) revealed patient #0027054 (eleven years old) had a PT (12.1) /INR (1.0) performed on 5/3/2019. C. A review of fifteen patient medical records revealed patient #0027054 (1 of 15 patients) was not on Warfin Therapy. D. In an interview on 8/14/2019 at 1300, the laboratory director confirmed the PT/INR was performed on patient #0027054 and this patient was not on Warfin Therapy.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

	laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of laboratory's policy and procedure manual, Quality Control (QC) data and Levy-Jennings graphs for January-June of 2019, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to monitor the accuracy and precision of the QC process and test performance over time as evidenced by: A. A review of the policy and procedure manual revealed the laboratory did not have a policy for addressing shifts and trends in quality control data. B. A review of quality control data and Levy-Jennings graphs for January-June of 2019 (six of six months) for nine of eighteen analytes revealed shifts and trends in QC data, without corrective actions. C. A review of Levy-Jennings graphs for January 2019 revealed Calcium level 1 shifted below the mean all month (22 points); Calcium level 3 shifted below the mean (18 points); High-density lipoproteins (HDL) level 1 shifted below the mean all month (22 points) and HDL level 3 shifted below the mean all month (22 points). D. A review of Levy-Jennings graphs for March 2019 revealed Blood Urea Nitrogen (BUN) level 1 shifted above the mean (11 points); BUN level 3 shifted above the mean (16 points); Alkaline Phosphatase (ALP) level 1 shifted above the mean (15 points); ALP level 3 shifted above the mean (19 points) and in April of 2019 ALP level 1 shifted above the mean all month (22 points). E. A review of Levy-Jennings graphs for May 2019 revealed ALP level 1 shifted below the mean all month (22 points) and Sodium (NA) level 3 shifted below the mean (17 points). F. A review of Levy-Jennings graphs for June 2019 revealed Prostate- Specific Antigen (PSA) level 3 shifted below the mean (13 points); and NA level 1 shifted below the mean 13 points. G. In an interview on 08/14/2019 at 13:00 laboratory director confirmed the laboratory failed to have a written procedure to monitor shifts or trends and failed to document actions for shifts in data.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: . The McGehee Family Clinical Laboratory failed to fill the position of Clinical Consultant as cited at D6059.
D6059	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(a) The clinical consultant must be available to provide clinical consultation to the laboratory's clients.

	This STANDARD is not met as evidenced by: . Through a review of the CMS 209 Laboratory Personnel Report, lack of documentation, and interviews with staff, it was determined the laboratory failed to designate a clinical consultant to provide opinions to laboratory's clients concerning the diagnosis, treatment and management of patient care as evidenced by. A. A review of the CMS 209 revealed the listing of laboratory's personnel positions: 1) Laboratory Director; 2) Testing personnel. No listing for Clinical Consultant. B. The surveyor requested the name and credentials of Clinical Consultant for the Laboratory. None was provided. C. In an interview on 8/14/2019 at 0945, the Laboratory Director confirmed the facility had not designated a Clinical Consultant to render opinions concerning the diagnosis, treat and management of the Laboratory's Clients.