Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642072	10/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mcgehee Hospital Inc	900 S 3rd, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Through a review of the Proficiency Testing records for 2020 and 2021, Survey Exception Reports, lack of documentation, and interviews with staff, it was determined the laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. Survey findings follow: A. A review of the Chemistry Core Proficiency testing records for the third event of 2020 and the first event of 2021 (two of two testing events) revealed the laboratory received a score of 60% for the analyte Lipase in each proficiency testing event. B. A review of the Survey Exception Report for the 3rd Chemistry Core proficiency testing event of 2020 revealed: "Lipase was calibrated on 9/30 and 10/02/2020, API was ran on 8/28/20. Pulled samples and reran. QC good rerun better; samples still on the positive bias but closer to the mean and within range. Testing personnel suggested to used new reagent well since Lipase is ran so infrequent." C. A review of the Survey Exception report for the first Chemistry Core proficiency testing event of 2021 revealed: "Lipase: repeated samples and still same result." D. The corrective actions taken by the laboratory in the third Chemistry Core proficiency testing event of 2020 failed to prevent the recurrence of problems identified in the first Chemistry Core proficiency testing event of 2021. E. In an interview on 10/20/2021 at 1300, laboratory personnel #4 (as listed on form CMS 209) confirmed the action taken failed to prevent the recurrence of failures in two of two proficiency testing events. .
D5449	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of policy and procedure manual, Quality Control documentation, patient testing logs, lack of documentation and interview with staff, it was determined the laboratory failed to perform a positive and negative controls for Serum Human Chorionic Gonadotropic (HCG) and Serum Acetone test on days when patients were analyzed. Survey Findings Follow: A. A review of the laboratory quality control policy for Serum HCG and Serum Acetone revealed "A positive and negative Quality Controls will be ran with each patient or if an issue arises." B. A review of patient logs revealed on 7/29/2021 patient #10117517 had a Serum HCG performed with no documentation of quality controls. C. A review of the patient logs revealed on 8/27 /2021 patient #10117963 had a Serum Acetone performed with no documentation of quality controls. D. In an interview on 10/21/2021 at 1300, laboratory personnel #4 (as listed on form CMS 209) confirmed the laboratory performed and resulted patients without documentation of quality controls.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Through a review of the policy and procedure, temperature records for 2021, lack of documentation, and interviews with staff, it was determined the laboratory failed to document corrective actions taken when room temperatures and humidity were outside of the laboratory's acceptable criteria. Survey findings follow: A. A review of policy for documenting temperatures revealed "if the temperature is out on any piece of equipment please adjust and retake. If is is still out call maintenance and the Laboratory Manager." B. A review of temperature logs for 2021 revealed the laboratory Phlebotomy room temperature acceptable range was listed as 17 to 30 degrees Celsius, Humidity acceptable range as 30% to 80% and Microbiology room temperature acceptable range was listed as 15 to 30 degrees Celsius. C. A review of the temperature logs for ten of ten months in 2021 revealed the Phlebotomy room temperature was documented outside the acceptable criteria and no corrective actions were performed on eight of thirty-one days in January 2021: ten of twenty-eight days in February 2021: two of thirty days in June of 2021 and the Microbiology room temperature was documented outside the acceptable criteria two of thirty days in April 2021 and nine of twenty days in October 2021. D. A review of the Humidity logs for ten of ten months in 2021 revealed the Humidity was documented outside the acceptable criteria and no corrective actions were performed on seven of thirty-one days in January 2021 and twelve of twenty-eight days in February 2021. E. In an interview at 10:30 on 10/21/2021, laboratory personnel #4 (as listed on CMS form

	209) confirmed the lack of documented corrective actions for the room temperatures and humidity conditions documented outside the laboratory's acceptable criteria.