Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642072	04/11/2019
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . 1. Through a review of manufacturer's instructions for Vacuette and BD Vacutainer blood collection tubes, temperature records for 2018, lack of documentation, as well as interviews with staff it was determined the laboratory fail to define temperature criteria that was not consistent with manufacturer's instructions. As evidenced by: A. A review of the manufacturer's instruction for Vacuette and BD Vacutainer blood collection tubes revealed " the recommended storage temperature is 4-25 degrees Celsius. Exceeding the recommended storage temperature may lead to impairment of collection tube quality." B. A review of the laboratory's temperature records for 2018 revealed the room temperature for the phlebotomy room as 17-30 degrees Celsius. C. A review of phlebotomy room temperature for twelve of twelve months in 2018 revealed the room temperature exceeded 25.0 degrees Celsius on one of thirty days in June 2018; four of thirty-one days in July 2018 and two of thirty-one days in October 2018. D. In an interview on 4/09/2019 at 1030, laboratory personnel #4 (as listed on form CMS 209) confirmed the phlebotomy room temperature range was not consistent with manufacturer's storage requirements. 2. Through a review of temperature records for 2018, lack of documentation, as well as interview with staff it was determined the laboratory failed to monitor the temperature in one of one phlebotomy room. As evidenced by: A. A review of temperature records for twelve of

	twelve months in 2018 revealed the laboratory failed to document phlebotomy room temperature on three of thirty days in April 2018; one of thirty-one days in May 2018; one of thirty days in June 2018; four of thirty-one days in July 2018; four of thirty-one days in August 2018; two of thirty days in September 2018 and four of thirty-one days in December 2018. B. Upon request the laboratory could not provide documentation of corrective actions taken for the days the temperatures were not monitored. C. In an interview on 04/09/2018 at 1030, laboratory personnel #4 (as listed on form CMS 209) confirmed the lack of documented corrective actions for days the temperature were not monitored.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through a review of Respiratory personnel records, lack of documentation, as well as interview with staff, it was determined the laboratory director failed to specify, in writing, which examinations and procedures each individual is authorized to perform and whether supervision is required. As evidence by: A. A review of personnel records for eight of eight Respiratory personnel revealed the authorization to perform Arterial Blood Gas testing for eight of eight Respiratory testing personnel (as listed on form CMS-209) were signed by the technical consultant. B. Upon request the Respiratory laboratory could not provide an authorization to perform Arterial Blood Gas testing signed by the laboratory director. C. In an interview at 1330 on 4/9/2019, the Respiratory general supervisor (as listed on form CMS 209) confirmed that the Respiratory laboratory failed to have a signed authorization for eight of eight personnel to perform Arterial Blood Gas testing.