Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 04D0642072	**(X3) Date Survey Completed** 10/05/2023
Name of Provider or Supplier Mcgehee Hospital Inc	**Street Address, City, State** 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency test documentation and interviews with laboratory staff, the laboratory director failed to sign proficiency testing attestation statements for one of five CAP arterial blood gas proficiency events reviewed from 2022 and 2023. Survey findings include: A. A review of proficiency testing documentation from 2022 and 2023 revealed the laboratory director or designee and the analysts failed to sign the attestation statement on the first (CAP AQA 2023)Testing Event of 2023. B. In an interview, at 12:07 p.m. on 10/3/23, laboratory employee #3 (as listed on the form CMS-209) confirmed the attestation statement identified above had not been signed by the laboratory director/designee or analysts.
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

	This STANDARD is not met as evidenced by: Through review of the laboratory policy and procedure "Blood and Blood Components - Sign Out Protocol", nursing service policy and procedure "Blood and Blood Components - Transfusion of Whole Blood or Packed Cells", and interview with hospital staff it was determined that documentation of patient identity was not required when blood for transfusion is obtained from the laboratory blood bank. Findings follow: A) Review of the laboratory policy and procedure "Blood and Blood Components - Sign Out Protocol", and nursing service policy and procedure "Blood and Blood Components - Transfusion of Whole Blood or Packed Cells", revealed that no requirement of documentation of the patient identity is specified when obtaining blood or blood components for transfusion from the laboratory blood bank. B) In an interview on 10/4/23 at 2:36 p.m., laboratory staff member (# 4 on the CMS 209 form) and hospital staff member (# 1 on a separate personnel identification list) confirmed that when nursing personnel retrieves blood and blood components for transfusion from the laboratory blood bank, they do not bring documentation of the patient/recipient identification.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, it was determined the laboratory had reagents available for use when they had exceeded their expiration date. Survey findings follow: A) During a tour of the laboratory at 10:02 a.m.on 10/5/23 22 of 22 Blod/Mac biplates microbiology media lot # 3159064 expiration date 2023-09-25 were observed available for use when they had exceeded their expiration date. B) In an interview on 10/5/23 at 10:10 a.m., the laboratory staff member (# 4 on the CMS 209 form) confirmed that the media identified above had exceeded the expirration date and was available for use.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of chemistry quality control results for January, May and September 2023, and interviews with laboratory staff, it was determined that patients were reported when results of control material failed to meet the criteria for acceptability on one of thirty days in September 2023. Survey findings follow: A) Through a review of chemistry quality control results for September 2023, it was revealed that on 9/17/23 the Biorad Multiqual Level 3 lot # 45953 Aspartate Transferase (AST) was reported as 242 with an acceptable range of 248 to 270 and

	flagged as >3.0 SDI. There was no documentation that the control was ever in acceptable range on that date. B) Two patients (10129580, 10129587) had AST results reported on 9/17/23. C. In an interview at 15:32 on 10/4/23, laboratory employee #4 (as listed on the form CMS-209) confirmed the two patients were reported when the quality control results were outside of acceptable range and the results had not been evaluated.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of the laboratory's "Quality Control Out of Control Policy", partial thromboplastin time (PTT), Prothrombin time (PT), Creatine Phosphokinase (CPK) quality control (QC) summary reports for January, March and July July 2023, corrective action documentation, patient result reports and interview with laboratory staff it was determined that the laboratory failed to evaluate patient results since the last successful QC performance in three of three occasions when corrective action to correct QC failures required a change in the testing system. Findings follow: A) Review of the laboratory's "Quality Control Out of Control Policy" revealed that if QC failure is determined to be a failure in the test system; i.e. not the fault of QC material, "all patient results in current analytical run are suspect and may require repeat analysis. Analytical run is defined as the time interval since the last acceptable scheduled QC run". B) Review of QC results for PTT testing on 3/3/23 revealed that the level 1 coagulation control lot # 564866 was out of acceptable range (+ 2 standard deviations (SD)) on two successive attempts at 04:32 a.m., 04:49 a.m. until being acceptable at 05:05 a.m.. C) Review of the corrective action documentation revealed the statement "reran, reran with fresh control and actin". The change to fresh reagent represented a change in the test system. D) Review of the QC summary for PTT testing revealed that the last acceptable QC for PTT testing prior to 3/3/23 05:05 a.m. was performed on 3/2/23 at 01:59 p.m.. E) Review of patient results for PTT testing revealed that 2 patients (10126644, C0091987) had PTT test results performed since the last successful QC on 3/2/23. F) Review of QC results for PT testing in July 2023 revealed that Citrol Level 3 lot # 556570 was out of acceptable range (+ 2 SD) on three succesive attempts at 11:29 p.m on 7/3/23., at 00:31 and 00:27 a.m. on 7/4/23 until acceptable at 01:07 a.m on 7/4/23.. G) Review of the corrective action documentation revealed the statement "make fresh control and reagent rerun". The making of fresh reagent represented a change in the test system. H) Review of the QC summary for PT testing revealed that the last acceptable QC for PT testing prior to 7/4 /23 at 01:07 a.m. was performed on 7/3/23 at 01:55 p.m. I) Review of patient results for PT testing revealed that one patient (C0096533) had a PT test performed between 7/3/23 01:55 p.m. and 7/4/23 at 01:07 a.m. J) Review of QC results for CPK testing on January 27, 2023 revealed that the Biorad Chemistry Control lot # 45953 was out of acceptable range (>+ 2 SD) on three successive occasions at 08:50, a.m, 08:55 a. m. and 09:13 a.m.until acceptable at 10:36 a.m.. K) Review of the corrective action

	documentation revealed the statement "replaced reagents". The fresh reagent represented a change in the test system. L) Review of the QC summary for CPK testing revealed that the last acceptable QC for CPK testing prior to 1/27/23 at 10:36 a.m. was performed on 1/26/23 at 04:46 a.m M) Review of patient results for CPK testing revealed that 2 patients (10126159, 10126161) had CPK tests performed between 1/26/23 at 04:46 a.m. and 1/27/23 at 10:36 a.m. N) In an interview on 10/4/23 at 10:40 a..m., the laboratory staff member (# 4 on the CMS 209 form) confirmed the patient results on the occasions identified above had not been evaluated and should have been in accordance with laboratory policy.