Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469039	(X3) Date Survey Completed 03/16/2023
Name of Provider or Supplier Johnson Regional Medical Center	**Street Address, City, State** 1100 East Poplar, Clarksville, 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: Through observations made during a tour of the laboratory, review of manufacturer's package inserts, review of the laboratory's temperature and humidity records and interviews with staff, it was determined the laboratory criteria for storage of quality control materials was not consistent with the manufacturer's instructions and the acceptable range for humidity levels in the laboratory were outside the manufacturer's requirement for operating humidity levels for the laboratory's routine chemistry analyzers. Survey findings include: 1) Storage temperature requirement for chemistry controls: A) During a tour of the laboratory at 9:45 a.m. on 3/15/23 the surveyor observed BioRad Cardiac Controls (lots 67641, 67642, and 67643) and BioRad Multiqual Controls (lot 45911, 45912, and 45913) stored in the laboratory freezer . The manufacturers storage instructions on the packages states that the controls are to be stored at -70 to -20 degrees Celsius in a non-defrosting freezer. B) In an interview, at 9:45 am on 3/15/23, the laboratory personnel (#2 on the CMS 209 form) ,when asked if the freezer was automatic self-defrosting (frost free), replied "yes sir" and confirmed that the manufacturer's instructions require storage of Biorad quality control materials in a non-defrosting freezer. 2) Room humidity requirement for chemistry analyzers. A) During a tour of the laboratory on 3/14/23 at 10:45 am, two Beckman Coulter AU 480 chemistry anayzers were observed in the main laboratory.

	B) In an interview on 2/14/23 at 10:45 am the laboratory staff member (# 2 on the CMS 209 form) stated that the Beckman Coulter AU 480 analyzers were the only analyzers in use for routine chemistry testing and the instruments were used interchangeably. C) Review of the manufacturer's user manual for the Beckman Coulter AU 480 analyzers revealed an operating humidity requirement of 40% to 85% non-condensing humidity. D) Review of the laboratory's room humidity documentation for 2022 revealed a defined acceptable range of 20% to 80% and humidity levels were less than 40% for 29 of 31 days in January 2022, 28 of 28 days in February 2022 and 30 of 31 days in March 2022. E) In an interview on 3/16/23 at 08:45 am the laboratory staff member (# 2 on the CMS 209 form) confimed that the minimum humidity requirement for the Beckman Coulter AU 480 analyzers was 40%, that the acceptable range defined on the laboratory's humidity records did not meet the manufacturer's requirement and that humidity records in January, February and March 2022 were below the manufacturer's requirement.
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 observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During an inital tour of the laboratory on 3/14/.23 at 10:45 am, two phlebotomy rooms were observed in the laboratory; one to the right side and one to the left side of the laboratory entrance. B) During a tour of the laboratory on 3/16/23 at 10:30 am six of seventeen Vacuette Na Citrate blood collection tubes (lot 8220233N expiration date 2023-02-01) were observed in bins in the right-side phlebotomy room and five of eighteen Vacuette Na Citrate blood collection tubes (lot 8220233N expiration date 2023-02-01) were observed in bins in the left-side phlebotomy room and eleven of twenty-three Vacuette Na Citrate blood collection tubes (lot 8220233N expiration date 2023-02-01) were observed in a phlebotomy tray in the left-side phlebotomy room. C) In an interview on 3/16/23 at 10:45 am the laboratory staff member (number 2 on the CMS 209 form) confirmed that the items, identified above, had exceeded their expiration dates and were available for use.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through observation, lack of documentation and interview it was determined that the laboratory failed to conduct temperature alarm checks for the freezer in which fresh

	frozen plasma (FFP) and cryoprecipitate (cryo) were stored. Findings follow: A) During a tour of the laboratory on 2/16/23 at 10:30 am eight units of FFP and three units of cryo were observed in the Blood Bank freezer. B) No record of quarterly alarm checks for the Blood Bank freezer were found during review of the Blood Bank refrigerator and freezer quarterly alarm checks. C) In an interview on 2/16/23 at 10:30 am the laboratory staff member (# 2 on the CMS 209 form) confirmed that the laboratory had not performed quarterly alarm checks of the freezer in which FFP and cryo were stored.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Through a review of proficiency testing events of 2022 and interviews with laboratory staff, it was determined the corrective actions performed failed to prevent the recurrence of deficient performance. As evidence by: A) Review of American Proficiency Insttitute reports for 2022 Chemistry Core 1st event revealed that specimen CM-01 for NT pro-BNP was resulted as 997 with an acceptable result of 832-995 and a comment of "unacceptable" and specimum IA-01 for PSA was resulted as 55.78 with an acceptable range of (35.94-50.78) and a comment of "unacceptable". B) Review of American Proficiency Insttitute reports for 2022 Chemistry Core 2nd event revealed that specimen CM-06 for NT pro-BNP was resulted as 76 with an acceptable result of 49-70 and a comment of "unacceptable", specimen CM-07 for NT pro-BNP was resulted as 724 with an acceptable range of 536-617 and specimen IA-06 for PSA was resulted as 0.10 with an acceptable range of (9.91 - 14.93 and a comment of "unacceptable". C) Review of the American Proficiency Institute 'Performance Summary" report revealed for NT pro-BNP 1st event 2022 was scored as 50% and 2nd event 2022 was scored as 0% with an overall assessment of "unsuccessful". D) Review of the American Proficiency Institute 'Performance Summary" report revealed for PSA 1st event 2022 was scored as 50% and 2nd event 2022 was scored as 50% with an overall assessment of "unsuccessful". E) In an interview on 3/16/23 at 11:45 am , laboratory personnel (#'s 1 and 2 on the CMS 209 form) confirmed that corrective actions failed to correct performance issues with NT-pro BNP and PSA analyses.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Through a review of ten final result patient reports, microbiology work logs and interview with laboratory staff it was determined that five of ten results reviewed did not have the date the test was completed. Findings follow: A) Review of ten laboratory final reports revealed that ten of ten of the reports stated "date/time of collection" and the "date/time received " but no date/time of test completion and verification. B) Review of the microbiology work logs revealed that five of five of the microbiology final reports reviewed were completed two days after "date/time of collection" and "date/time received" documented on the final report and the final report did not document the date/time of test completion and verification C) In an interview on 2/16/23 at 10:00 am, the laboraatory staff member (# 2 on the CMS 209 form) confirmed that the date and time that testing is completed is not contained on the final result report.