Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469039	09/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Johnson Regional Medical Center	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
D0000	This reflects findings of a recertification survey performed on 09/25/18 through 09/28 /18. Johnson County Regional Medical Center Laboratory is in compliance with the applicable Standards and conditions of 42 CFR Part 493, Laboratory Requirements. The following standard level deficiencies were cited on current survey: D5413: CFR 493.1252(b) - The laboratory failed to measure and record humidity levels in rooms in which instruments with an operating humidity requirement were in use, D5415: CFR 493.1252(c)- The laboratory failed to label coagulation controls with the date and time of preparation, D5503: CFR 493.1261(a)(2) - The laboratory failed to perform quality control for gram stains weekly, D5781: CFR.1282- The laboratory failed to document corrective action when quality control for partial thromboplastin times were not acceptable, D5783: CFR 492.1282(b)(2) - In the event that quality control samples failed to be within acceptable limits, the laboratory failed to evaluate patient results reported back until the last acceptable quality control run, D6046: CFR 493.1413(b)(8) - The laboratory failed to assure the competency of testing personnel using six required methods, D6107: CFR 493.1445(e)(15)- The authorization to test was not signed by the laboratory director for seven of twentry-three personnel on the CMS 209 report.
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 observation, review of manufacturer's operation manual, lack of documentation and interview it was determined that the laboratory failed to monitor ambient humidity in one of one rooms in which instruments with a required operational humidity range were used. Findings follow: 1. In an initial tour of the laboratory on 09/25/18 at approximately 09:00 AM two AU 480 chemistry analyzers were observed in operation. 2. Review of the manufacturer's operation manual for the AU 480 analyzer revealed an operational humidity requirement of 40% to 80%. 3. Upon request, the laboratory could not produce humidity measurement records for the room in which the AU 480 analyzers were located. 4. In an interview on 09/28/18 at approximately 09/15 AM, the technical consultant identified as number 7 on the CMS 209 form confirmed that the AU 480 analyzers were used to perform chemistry tests and humidity levels were not monitored and documented.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through review of package insert for Stago Coagulation Controls, observation, and interview it was determined that the laboratory did not label the control vials with the date and time, or an amended expiration date and time as required by the manufacturer. Findings follow: 1. Review of the manufacturer's package insert for Stago Coagulation controls state "once reconsitituted controls are stable in their original vials for 24 hours on the STA Compact instrument". 2. During a tour of the laboratory on 09/25/18 at approximately 2:30 PM two of two vials of Stago Coagulation controls lot # 253208 were observed on the Stago Compact coagulation analyzer which were not labeled with the date and time that the control was reconsituted and placed on the instrument. 3. In an interview on 09/25/18 at approximately 2:30 PM, the technical consultant identified as number 7 on the CMS 209 form confirmed that the vials of coagulation controls identified above had not been labeled with the date and time they were prepared and placed in the analyzer.
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: A) Through review of the laboratory policy and procedure for quality control (QC), laboratory quality control data review report for July 2018, patient result reports, lack

	of documentation and interview it was determined that the laboratory did not evaluate patient results for partial thromboplastin time results reported since the last acceptable quality control results on two of two patient results reported when quality control results for partial thromboplastin times failed to meet the laboratory's criteria for acceptability. Findings follow: 1. Review of the laboratory's quality control policy and procedure for coagulation revealed that "two levels of QC are to be run for each 8 hours of patient testing or after a change of reagents" and "unacceptable run: one or both levels outside 2 S.D." 2. Review of the laboratory quality control data review report for July 2018 revealed that an acceptable QC for Stago Coag Control ABN Plus lot # 251005 level 2 was performed on 07/17/18 at 1505 and QC results were unacceptable on 07/18/18 at 0512, 0518, 0545, before being acceptable at 0713. The report revealed that no acceptable QC was recorded between 07/17/18 at 1505 and 07 /18/18 at 0713. 3. In an interview on 09/25/18 at approximately 2:15 PM, the technical consultant identified as number 7 on the CMS 209 form stated that the level 2 coagulation control was "probably running high on 07/18/18 on the third shift and was unacceptable". 4. Review of patient result reports revealed that partial thromboplastin time results were reported on patient identified as number 1 on a separate patient identification list on 07/17/18 at 1554 and patient identified as number 2 on a separate patient identification list on 07/17/18 at 2246. 5. Upon request, the laboratory could not provide documentation of the evaluation of partial thromboplastin times reported on patients #1 and #2 identified above, 6. In an interview on 09/25/18 at approximately 2:15 PM the technical consultant identified as number 7 on the CMS 209 form confirmed that partial thromboplastin time results performed on the patients and occasions identified above were not evaluated. B) Through review of the laboratory policy and procedure for quality control (QC), laboratory quality control data review report for July 2018, lack of documentation, and interview it was determined that the laboratory did not document corrective action on one of one occasions when quality control results for partial thromboplastin times failed to meet the laboratory's criteria for acceptability. Findings follow: 1. Review of the laboratory's quality control policy and procedure for coagulation revealed that "two levels of QC are to be run for each 8 hours of patient testing or after a change of reagents" and "unacceptable run: one or both levels outside 2 S.D." 2. Review of the laboratory quality control data review report for July 2018 revealed that an acceptable QC for Stago Coag Control ABN Plus lot # 251005 level 2 was performed on 07/17 /18 at 1505 and QC results were unacceptable on 07/18/18 at 0512, 0518, 0545, before being acceptable at 0713. The report revealed that no acceptable QC was recorded between 07/17/18 at 1505 and 07/18/18 at 0713. 3. In an interview on 09/25 /18 at approximately 2:15 PM, the technical consultant identified as number 7 on the CMS 209 form stated that the level 2 coagulation control was "probably running high on 07/18/18 on the third shift and was unacceptable". 4. Upon request, the laboratory was unable to provide documentation of corrective action for when the level 2 coagulation was unacceptable on the third shift on 07/18/18. 5. In an interview on 09 /25/18 at approximately 2:15 PM, the technical consultant identified as number 7 on the CMS 209 form confirmed that level 2 quality control for partial thromboplastin times was unaaceptable on the third shift of 07/18/18 and there was no documentation of corrective action taken.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of the testing personnel records, a review of the procedure manual, and interviews with laboratory staff, it was determined the laboratory failed to evaluate the competency of testing personnel for 2017 through 2018 as shown by: 1. In review of personnel records for all testing personnel, it was determined the competency assessments documented in 2017 through 2018 did not address the following components required for evaluation of personnel at least annually as outlined in the CLIA regulations: a. Assessment of problem solving skills b. Direct observation of routine patient test performance, including patient preparation c. Monitoring the recording and reporting of test results. d. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. In an interview at 10:58 on 9/28/2018, laboratory director #1 (as listed on the form CMS 209) and employee #7 (as listed on the form CMS-209) confirmed the laboratory has no policy for, or any documentation of, performing competency assessment using: assessment of problem solving skills; direct observation; monitoring recording and reporting of test results; review of worksheets; quality control records; maintenance; and proficiency samples; or assessment through blind testing samples.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records for laboratory personnel, lack of documentation, and interviews with laboratory staff, it was determined the Laboratory Director failed to specify, in writing, the procedures seven of twenty-three testing personnel can perform, and whether supervision is required. Survey findings follow: A. Personnel records for blood gas laboratory employees #17, #18, #19, #20, #21, #22 and #23, as listed on the form CMS-209, failed to include written authorization to perform testing, signed by the laboratory director. B. In an interview at 11:45 AM on 9 /28/2018, laboratory director #1 (as identified on the CMS 209 form) and employee # 17 (as identified on the CMS 209 form) confirmed the authorizations for laboratory testing personnel were not signed by the laboratory director.