Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465276	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson Regional Medical Center	1600 West 40th Street, Pine Bluff, 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	The State Agency conducted a validation survey on August 14, 2018 through August 16, 2018. At the time of the survey, the laboratory was not in compliance with the following condition: CFR 42 493.1250 - Analytic Systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through review of the laboratory's policy and procedure manual, the laboratory's Individualized Quality Control Plans (IQCP), quality control data reports, patient test logs, personnel records, observation, lack of documentation, and interview it was determined that the laboratory failed to meet analytic system requirements or monitor and correct problems in the analytic systems as evidenced by: D5413- the laboratory failed to monitor the temperature in storage areas in which supplies with a storage temperature requirement were stored, D5417- the laboratory had supplies available for use after their expiration date, D5449- the laboratory failed to perform positive and negative controls for QuickVue Mono tests on each day of patient testing, D5451- The laboratory failed to include a control material with titred reactivity on days when patient specimens were assayed for syphilis serology, D5469- the laboratory failed to document all quality control procedures performed, D5481- the laboratory failed to ensure quality control results were acceptable before reporting patient results, D5545 - the laboratory failed to document quality control results on each day when activiated clotting time tests are performed and reported, D5781- the laboratory failed to

	document corrective action when quality control results for partial thromboplastin times failed to meet criteria for acceptability, D5783- the laboratory failed to evaluate patient results back to the last acceptable quality control results when quality control results failed to meet criteria for acceptability, and, D6032- the laboratory director failed to authorize testing personnel to perform testing.
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, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature in two of three rooms in which supplies with storage temperature requirements were stored in the Outpatient Surgery Satellite Laboratory. Findings follow: A. A tour of the Outpatient Surgery Laboratory revealed that in addition to the laboratory room there were two additional storage rooms (storage room #1 and storage room #2) separated from the laboratory room by closable doors. B. In a tour of the Outpatient Surgery Satellite Laboratory on 8/16/18 at approximately 01:30 PM, one box of Stromatolyzer reagent lot # G91-128 with a temperature requirement of 2 degrees to 30 degrees C. and one bottle of cleaning solution lot # 202408 with a storage temperature requirement of 2 degrees to 25 degrees C. were observed in a storage room #1 separated from the laboratory by a closable door. C. In a tour of the Outpatient Surgery Satellite Laboratory on 8/16/18 at approximately 01:30 PM, 1350 4.5 ml Na Heparin blood collection tubes lot # B1805136R with a storage temperature requirement of 4 degrees to 25 degrees C, 1250 4.5 ml. EDTA blood collection tubes lot # B180339H with a storage temperature requirement of 4 degrees to 25 degrees C. and 25 2.7 ml. a Citrate blood collection tubes lot # 8074676 with a storage temperature requirement of 4 degrees to 25 degrees, were observed in storage room #2 separated from the laboratory room by a closable door which was in the closed position at the time of the tour. D. Upon request, the laboratory was unable to provide documentation of temperature records for the storage rooms identified above. E. In an interview on 8/16/18 at approximately 01:30 PM, the testing personnel identified as number 42 on the CMS 209 form confirmed that the temperature had not been monitored in the two storage rooms identified above.
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 and interviews with laboratory staff, it was determined laboratory supplies were available for use when they had exceeded their expiration. Survey findings follow: A. During a tour of the laboratory, at 10:12 on 8/14/2018, the surveyor observed the following expired Vaccuette blood collection tubes available for use: 10 each Vaccuette 4 ml Clot Activator tubes (lot #B1701394) which expired 7/5/2018 on phlebotomy trays used for collection of patient blood samples; 6 each Vaccuette 9 ml Clot Activator tubes (lot #B17013HJ) which expired 7/12/2018 on phlebotomy trays used for collection of patient blood samples; 2 each Vaccuette 9 ml Clot Activator tubes (lot #B160936T) which expired 3/1/2018 on phlebotomy trays used for collection of patient blood samples; and 36 each Vaccuette 4 ml Clot Activator tubes (lot #B1701394) which expired 7/5/2018 on the shelf above the phlebotomy trays. B. In an interview, at 10:27 on 8/14/2018, general supervisor #2 (as listed on the form CMS-209) confirmed the tubes were available for use beyond their expiration date.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of the Individualized Quality Control Plan (IQCP) for Abbott i-stat, quality control (QC) data, patient testing logs, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to document QC when patients were tested. As evidenced by: A. A review of the IQCP for Abbot i-stat revealed " two levels of external quality control for ACT testing will be performed weekly." B. A review of the Activated Clotting Time QC data for January, March and July 2018 revealed no QC was documented the week of 7/3/18 thru 7/6/18. For the week of 7/23/18 thru 7/27/18, the laboratory documented one level (Level 1) of quality control. C. A review of Activated Clotting Time patient testing logs for July 2018 (2 of 31 days) revealed two patients were tested and resulted on 7/3/18: patient #7101875 and patient #7102332; and one patient #5009778 on 7/23/2018 with only one level of QC documentation. D. In an interview on 8/15/2018 at 13:00, laboratory personnel #42 (as listed on form CMS 209) confirmed patients were analyzed without performing quality controls.
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 Annual test volume worksheet, quality control data for the Quickvue Mono Test, patient testing logs, lack of documentation, as well as interview with staff, it was determined the laboratory failed to perform a positive and negative controls on days when patients were analyzed. As evidence by: A. The laboratory utilizes the Quidel Quick-Vue test system to screen for serum Mononucleosis (MONO). A review of the Annual test volume worksheet revealed the laboratory performs 147 MONO test annually. B. A review of the laboratory quality control policy for Quickvue Mono test revealed "positive and negative controls should be run weekly and with each new lot number." C. In an interview on 8/15/2018 at 1430, laboratory personnel #44 (as listed on form CMS 209) stated the laboratory did not develop an Individualized Quality Control Plan (IQCP) for Quickvue Mono test. D. A review of quality control data for January, March and July of 2018 revealed on five of thirty-one days in July of 2018, the laboratory had no documentation of quality control. E. A review of the Quickvue Mono patient log revealed the following patients had Mono testing performed and resulted on days with no quality control: on 7/7/18 patient #12025286; 7/8/18 patient #1202529; 7/22/18 patient #3413016; 7/23/18 patient #3414111 and on 7/25/18 patient #12025534. F. In an interview on 8/15/2018 at 1430, laboratory personnel #44 (as listed on form CMS 209) confirmed patients were test without documentation of quality controls.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of the Annual test volume worksheet, laboratory's policy and procedure manual, patient and Quality Control (QC) documentation for Syphilis Serology, lack of documentation as well as interviews with staff, it was determined the laboratory failed to include a control material with titered reactivity on days when patient specimens were assayed. As evidenced by: A. The laboratory utilizes the Fisher Scientific Sure-Vue Rapid Plasma Regain (RPR) test to screen for Syphilis. A review of the Annual test volume worksheet revealed 2,397 as the annual volume of RPR test performed by the laboratory. B. A review of the laboratory's policy for Syphilis Serology revealed "An RPR titer is to be performed on the control serum reactive along with the titer of any positive reactive patients." C. A review of RPR patient logs for January thru August of 2018 (6 of 8 months) revealed the following patients had titered results reported: patient #12023407 on 2/7/18 RPR positive 1:4; patient #4481956 on 3/16/18 RPR positive 1:256; patient #7069682 on 5/23/18 RPR positive 1:4; patient #7076921 on 6/1/18 RPR positive 1:4; patient #7078780 on 6/5 /18 RPR positive 1:2; patient #7095030 on 6/23/18 RPR positive 1:4; patient #7113372 on 7/18/2018 RPR positive 1:32 and patient #7128156 on 8/7/18 RPR positive 1:2. D. A review of RPR patient logs for January thru December of 2017 (8 of 12 months) revealed the following patients had titered results reported: patient #4294075 on 1/3/17 RPR positive 1:8; patient # 40062708 on 1/24/17 RPR positive 1:

	8; patient #4310108 on 2/10/17 RPR positive 1:8; patient #4329490 on 3/26/17 RPR positive 1:8; patient #4341742 on 4/20/17 RPR positive 1:4; patient # 4343667 on 4/26 /17 RPR positive 1:8; patient #4343472 on 4/28/17 RPR positive 1:2; patient #4341612 on 5/4/17 RPR positive 1:1; patient #4352567 on 5/16/17 RPR positive 1:1; patient #4421464 on 10/20/17 RPR positive 1:1; patient #4423423 on 10/25/17 RPR positive 1:2; patient #4427109 on 11/3/17 RPR positive 1:4; patient #12022605 on 12 /3/17 RPR positive 1:32 and patient #12022689 on 12/10/2017 RPR positive 1:8. E. There was no documentation that a control material with titered reactivity was included on the days when patient specimens produce a titered result. The Quality Control results were recorded as reactive (R), weakly reactive (WR) and non-reactive (NR). F. In an interview on 8/15/2018 at 1400, laboratory personnel #44 (as listed on CMS form 209) confirmed the control material was not titered on days when patients' specimens produce a titered result.
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 quality control results through the Unity quality control software, lack of documentation, a review of the Daily Journal Report of patients tested, and interviews with laboratory staff, it was determined the lab failed to ensure control material results were acceptable before reporting patients. Survey findings follow: A. Through a review of the Unity quality control software data for ten different chemistry tests (Albumin, ALT, Alkaline Phosphatase, Calcium, Creatine Kinase, Cholesterol, Glucose, Potassium, Total Bilirubin, and Triglyceride) performed in the JML laboratory it was determined that results were not acceptable before reporting patient results on one of eight failures observed. Quality control results reviewed in the Unity quality control software included a failure of the Level 3 control for ALT (Alanine Aminotransferase) on 5/25/2018. The result documented for Level 3 ALT was 182 (flagged as -3.8 Standard Deviations away from the target mean). The two standard deviation acceptable range for ALT was 187.24 to 204.96. A note in the comments column states, "repeated Level 1 repeated Level 3". There was no repeated run in the Unity quality control report and no acceptable result on 5/25/2018 for ALT on Level 3 control. The next acceptable result (193) was documented at 6:15 a.m. on 5 /29/2018. B. In an interview at 12:55 on 8/16/2018, laboratory employee #42 stated that although he had put a note in the Unity system that he repeated the control, he was so busy with patients that he forgot to repeat it. C. The Daily Journal Report listed 10 patients who had ALT reported on 5/25/2018. Patients with ALT reported on 5/25/2018 were Patient Accession # 3355320 (ALT - 18), #3354890 (ALT - 21), #3354927 (ALT - 27), #3354983 (ALT - 26), #3354991 (ALT - 26), #3355012 (ALT - 29), #3355396 (ALT - 42), #3355072 (ALT - 21), #3355190 (ALT - 19), and #3355304 (ALT - 23).
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's

	verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: 1. Through a review of quality control results through the Unity quality control software, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document all control procedures performed. Survey findings follow: A. During a review of quality control results for January through August on the Vitros 5600 (Rex) it was determined that on 1/2/2018 Glucose on the Multiqual Level 3 Control (lot #45770 acceptable range 345 +/- 16) was flagged as unacceptable and was tested four times before the result was accepted. Results that were flagged as unacceptable were 356, 361, and 357. The quality control result was acceptable on the fourth run (362). B. In an interview at 10:00 on 8/15 /2018, laboratory personnel #44 (as listed on the form CMS-209) stated the reason that the fourth run was acceptable was that the mean and acceptable range had been changed between runs. When asked for the documentation of the calculations used for the new mean and range she stated that there was no documentation of the data used for the change. 35659 2. Through review of the laboratory's policy and procedure for "Quality Control and Proficiency Testing" (policy number 500.20 dated 7/15/10), quality control summary reports for July 2018, lack of documentation and interview it was determined that the laboratory failed to document corrective action on one of two occasions in July 2018 when quality control results for partial thromboplastin time (PTT) test quality control results failed to meet criteria for acceptability. Findings follow: A. Review of the laboratory's policy and procedure for "Quality Control and Proficiency Testing" revealed that paragraph number four stated "the cause of the controls being out of range and corrective action taken must be documented and initialed by the technologist". B. Review of the quality control summary for PTT testing on 31 of 31 days in July 2018 revealed that on 7/26/18, the level 2 quality control material lot # 145636 with an acceptable range of 81.3 to 85.3 was resulted: * 128.4 at 12:26 PM with a comment "Patient testing ceased until corrective action taken", * 126.9 at 12:26 PM with a comment "Patient testing ceased until corrective action taken", * 91.7 at 12:49 PM with a comment "Patient testing ceased until corrective action taken", and * 83.6 at 02:50 PM with no comment appended. C. Upon request, the laboratory was unable to provide documentation of the corrective action taken to bring level 2 quality control within acceptable range. D. In an interview on 8 /15/18 the general supervisor, identified as number 44 on the CMS 209 form stated that in the instance cited above the corrective action should have been documented on the quality control summary report and that the comments relative to" patient testing ceased until corrective action taken" did not define the corrective action taken.
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 a review the laboratory's policy and procedure for "Quality Control and Proficiency Testing", of January through August 2018 quality control results through the Unity quality control software, lack of documentation, and interviews with laboratory staff, it was determined that the laboratory failed to document that patient results were evaluated since the last acceptable run of quality control action on two of two occasions when quality control results for partial thromboplastin time (PTT) test quality control results failed to meet criteria for acceptability and one of one occasion when Creatine Kinase (CK) failed to meet criteria for acceptability . Findings follow: A. Review of the laboratory's policy and procedure for "Quality Control and Proficiency Testing" (policy number 500.20 dated 7/15/10), revealed that paragraph number five stated "if the cause of the errant control results is determined to be inaccuracy of the analyzer or test assay then all patient results released after the previous successful control run should be evaluated to determine if the difference in the previous result and the corrected one is clinically significant". B. Review of the quality control summary for PTT testing revealed that on 7/26/18, the level 2 quality control material lot # 145636 with an acceptable range of 81.3 to 85.3 was resulted: * 81.5 at 05:56 AM and both level 1 and level 2 controls were acceptable at that time, * 128.4 at 12:26 PM with a comment "Patient testing ceased until corrective action taken", * 126.9 at 12:26 PM with a comment "Patient testing ceased until corrective action taken", * 91.7 at 12:49 PM with a comment "Patient testing ceased until corrective action taken", and * 83.6 at 02:50 PM with no comment appended. C. Review of patient result reports revealed that patients identified as numbers 1 through 30 on a separate "Patient Identification List #1" had PTT test results between 05:56 AM on 7/26/18 and 02:50 PM on 7/26/18. D. Review of the quality control summary for PTT testing revealed that from 05:45 PM 7/27/18 until 01:37 AM on 7/28/18, the level 2 quality control material lot # 145636 with an acceptable range of 81.3 to 85.3 was resulted: * 81.5 at 05:45 PM and both level 1 and level 2 controls were acceptable at that time, *79.2 at 11:54 AM with a comment "No patient testing until successful controls" * 78.9 at 00:13 AM with a comment "control repeated" * 79.4 at 00:22 AM with a comment "control repeated", * 79.2 at 00:32 AM with a comment "new control reconstituted, reagent made, control repeated". E. Review of patient result reports revealed that patients identified as numbers 31 through 35 on a separate "Patient Identification List #1" had PTT test results between 05:45 AM on 7/27/18 and 01:37 AM on 7/28/18. F. Upon request, the laboratory could not provide documentation that the results for the patients and testing instances identified above had been evaluated. G. In an interview on 8/15/18 said that the two instances of quality control results identified above failed the laboratory's policy for acceptable quality control and the patient results reported back to the last acceptable quality control results should have been evaluated but no documentation of the evaluation was made. H. During a review of June 2018 chemistry quality control results for Albumin, Alkaline Phosphatase, AST, Cholesterol, Glucose, Potassium, Calcium, Creatine Kinase, Acetaminophen, CEA, Folate, TSH, hCG, Amphetamine, Cannabinoid, and Cocaine performed on the Vitros 5600 labeled "Rex" it was determined on 6/15/2018, Creatine Kinase (CK) on Multiqual Level 3 (lot 45770 acceptable range 387.54 to 431.50) was documented as being tested 10 times on 6/15/2018 before an acceptable result was reported. The failed results of the Multiqual Level 3 were 369, 357, 464, 464, 465, 443, 442, 444, 433, and 443. During the 10 runs on 6/15/2018, which were flagged as unacceptable,

	the laboratory documented performing calibration three times. Although the calibrations were acceptable, the quality control was not within acceptable range until 10:33 p.m. on 6/15/2018 after the initial run of unacceptable quality control at 9:49 a. m. on 10/15/2018. There was no documentation that patient results had been reviewed back to the last acceptable quality control at 10:10 on 8/14/2018. I. In an interview at 10:19 on 8/15/2018 laboratory employee #44 (as listed on the form CMS-209) stated the laboratory did not document a review of patients back to the last successful quality control on 6/15/2018 when the CK failed and calibration was performed. 35659
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 review of personnel records of a sample of 14 personnel included on the CMS 209 form, lack of documentation, and interview it was determined that the laboratory director did not authorize 8 of 14 personnel to perform testing. Findings follow: A. Review of personnel records of a sample of 14 testing personnel included on the CMS 209 form revealed that no authorization to perform testing was present in the personnel records of the testing personnel identified as numbers 4,8,16,21, and 42 through 45 inclusive on the CMS 209 form. B. Upon request, the laboratory was unable to produce authorization to perform testing issued by the laboratory director for the testing personnel identified as numbers 4,8,16,21 and 42 through 45 on the CMS 209 form C. In an interview on 8/15/18 at approximately 09:10 AM, the general supervisor identified as number 2 on the CMS 209 form confirmed that the laboratory director had not signed an authorization to perform testing for the personnel identified above.