Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470083	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Weatherford Regional Hospital	3701 E Main, Weatherford, OK	

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 recertification survey was performed on 02/11/19 through 02/14/2019. The findings were reviewed with technical consultant #2/general supervisor #1 at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
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 a review of records and interview with technical consultant #2/general supervisor #1, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following was identified for 1 of 28 testing events: (a) Second 2018 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with technical consultant #2 /general supervisor #1 who stated the attestation had not been signed as indicated above.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy and interview with technical consultant #2/general supervisor #1, the laboratory failed to have a written technical consultant and general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence competencies had been performed for the technical consultant and general supervisor, based on their job responsibilities; (2) The surveyor asked technical consultant #2/general supervisor #1 if a written policy to evaluate the technical consultant and general supervisor based on job responsibilities was available. Technical consultant #2/general supervisor #1 stated a policy to evaluate the technical consultant and general supervisor based on job responsibilities had not been written; and competencies had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2/general supervisor #1, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2017 Chemistry Core Event (i) Lipase - 3 of 5 results exhibited a positive bias (aa) Sample CH-01 - SDI of 2.8 (bb) Sample CH-04 - SDI of 2.0 (cc) Sample CH-05 - SDI of 2.2 (ii) Phenytoin - 3 of 5 results exhibited a positive bias (aa) Sample CH-02 - SDI of 2.4 (bb) Sample CH-04 - SDI of 2.9 (cc) Sample CH-05 - SDI of 2.3 (b) Second 2017 Chemistry Core Event (i) Total Protein - 3 of 5 results exhibited a positive bias (aa) Sample CH-07 - SDI of 2.4 (bb) Sample CH-08 - SDI of 2.6 (cc) Sample CH-09 - SDI of 4.0 (ii) Cholesterol HDL (High Density Lipoprotein) - 4 of 5 results exhibited a positive bias (aa) Sample CH-07 - SDI of 2.5 (bb) Sample CH-08 - SDI of 3.0 (cc) Sample CH-09 - SDI of 3.7 (dd) Sample CH-10 - SDI of 2.1 (iii) Creatinine - 4 of 5 results exhibited a positive bias (aa) Sample CH-07 - SDI of 3.0 (bb) Sample CH-08 - SDI of 2.7 (cc) Sample CH-09 - SDI of 4.4 (dd) Sample CH-10 - SDI of 2.3 (c) Third 2017 Chemistry Core Event (i) Cholesterol HDL - 5 of 5 results exhibited a positive bias (aa) Sample CH-11 - SDI of 2.4 (bb) Sample CH-12 - SDI of 2.8 (cc) Sample CH-13 - SDI of 2.1 (dd) Sample CH-14 - SDI of 2.8 (ee) Sample CH-15 - SDI of 2.6 (ii) Potassium - 3 of 5 results exhibited a negative bias (aa) Sample CH-12 - SDI of -2.7 (bb) Sample CH-14 - SDI of -2.0 (cc) Sample CH-15 - SDI of -2.4 (iii) Phenobarbital- 3 of 5 results exhibited a negative bias (aa) Sample CH-11 - SDI of -2.3 (bb) Sample CH-13 - SDI of -2.2 (cc) Sample CH-14 -

	SDI of -2.1 (d) First 2018 Chemistry Core Event (i) Albumin - 4 of 5 results exhibited a positive bias (aa) Sample CH-02 - SDI of 2.2 (bb) Sample CH-03 - SDI of 2.0 (cc) Sample CH-04 - SDI of 2.1 (dd) Sample CH-05 - SDI of 2.4 (ii) Cholesterol HDL - 3 of 5 results exhibited a negative bias (aa) Sample CH-01 - SDI of -2.3 (bb) Sample CH-02 - SDI of -2.8 (cc) Sample CH-03 - SDI of -2.0 (iii) Creatinine - 3 of 5 results exhibited a positive bias (aa) Sample CH-01 - SDI of 2.5 (bb) Sample CH-03 - SDI of 2.6 (cc) Sample CH-05 - SDI of 3.2 (e) Second 2018 Chemistry Core Event (i) Albumin - 3 of 5 results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.6 (bb) Sample CH-08 - SDI of 2.6 (cc) Sample CH-09 - SDI of 2.5 (ii) Cholesterol Total - 4 of 5 results exhibited a positive bias (aa) Sample CH-07 - SDI of 2.3 (bb) Sample CH-08 - SDI of 2.0 (cc) Sample CH-09 - SDI of 2.1 (dd) Sample CH-10 - SDI of 2.1 (iii) Uric Acid - 4 of 5 results exhibited a negative bias (aa) Sample CH-06 - SDI of -4.0 (bb) Sample CH-07 - SDI of -2.2 (cc) Sample CH-08 - SDI of -2.3 (dd) Sample CH-10 - SDI of -2.6 (f) Third 2018 Chemistry Core Event (i) Total Iron - 5 of 5 results exhibited a positive bias (aa) Sample CH-11 - SDI of 5.5 (bb) Sample CH-12 - SDI of 2.9 (cc) Sample CH-13 - SDI of 3.0 (dd) Sample CH-14 - SDI of 3.3 (ee) Sample CH-15 - SDI of 2.7 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with technical consultant #2/general supervisor #1 who stated the biases had not been addressed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with technical consultant #2/general supervisor #1, the laboratory failed to follow written procedures for performing manual differentials. Findings include: (1) On the first day of the survey, technical consultant #2/general supervisor #1 stated to the surveyor manual differential testing was performed in the laboratory; (2) On the third day of the survey, the surveyor requested the manual differential procedure from technical consultant #2 /general supervisor #2; (3) The surveyor reviewed the "Criteria for a manual differential reflex & further review of smears, Correct WBC for nRBCs" which stated, (i) "Manual differential counts or review of slide, will be done on a reflex basis if the automated results, meet any one or more of the following criteria: (ii) "3. Platelet counts of less than 60 or greater than 500 uL/fL" (3) The surveyor reviewed 44 patient records. For 1 of 44 patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient #1 tested 12/21/18 at 11:17 am - Platelet result: 514 uL/fL (3) The surveyor reviewed the findings with technical consultant #2/general supervisor #2 who stated that the procedure had not been followed as indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2/general supervisor #1, the laboratory failed to follow the manufacturer's instructions for Hematology and Coagulation. Findings include: HEMATOLOGY (1) On the first day of the survey, technical consultant #2/general supervisor #1 stated that CBC (Complete Blood Count) testing was performed on the Sysmex XT 4000i analyzer; (2) On third day of the survey, the surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer: (a) "Iron Deficiency?" - " 1. Scan the peripheral smear for the presence of microcytic and hypochromic RBCs." (3) The surveyor randomly reviewed 2 patient records which contained "Iron Deficiency?" flags from CBC testing performed during 12/01 /18 and 12/29/18. For 2 of 2 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the 2 records were: (a) Patient #2 - Testing was performed on 12/26/18 at 07:15 am (b) Patient #3 - Testing was performed on 12/29/18 at 12:14 pm (4) The surveyor reviewed the records with technical consultant #2/general supervisor #1, who stated that the flags obtained for the above 2 patients had not been documented as verified. COAGULATION (1) On the third day of the survey, technical consultant #2/general supervisor #1 stated the following to the surveyor: (a) The IL ACL Elite analyzer was used to perform PTT (Partial Thromboplastin Time) testing; (b) Hemosil PTT Reagent Lot#0587978 was put into use 08/31/18. (2) The surveyor reviewed the manufacturer's Hemostasis Performance Verification Manual instructions for "Changing of Lot Numbers of Reagents", which stated: (a) "2. Perform 'Changing Lot Number of Control' procedure for each test using the new lot numbers of reagent and all related levels of controls." (3) The surveyor reviewed the "Changing Lot Number of Control" procedure which required the following: (a) "1. Ensure all maintenance is current."; (b) "2. Perform at least 20 runs (once per day for 20 days) of each test for each level of control. A greater number of runs may improve the statistics of the assay range. The attached worksheet has space for up to 40 values."; (c) "3. It is good lab practice to run the new lot of material in parallel with the current lot."; (d) "4. Test the control values over several days, using controls and reagents over the time period and conditions under which they would normally be used for patient testing. It is inadvisable to perform testing on all fresh reagents or from the same bottle of control since these conditions will not be representative of how the material will be used, and will result in very tight assay ranges. "; (e) "5. Record the data on the Controls Assay worksheet (attached)."; (f) "6. Calculate the mean and +2 sd range as the target once the materials are put into routine use.". (3) The surveyor reviewed Changing of Lot Numbers of Reagents records and was not able to locate evidence that control assays ranges had been established as required by the manufacturer; (4) The surveyor review the manufacturer's instructions with technical consultant #2/general supervisor #1 who stated the Changing Lot Number of Control procedure had not been performed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with technical consultant #2/general supervisor #1, the laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process. Findings include: BIASES (1) On the third day of the survey, technical consultant #2/general supervisor #1 stated the following to the surveyor: (a) Vitamin B12 and Folate testing were performed using the Beckman Coulter Access II analyzer; (b) Three levels (Level 1, Level 2, and Level 3) of Bio Rad control materials were performed each day of patient testing. (2) The surveyor reviewed quality control records for testing performed between 11/01/18 through 01/31/19. The following biases were identified for level 3 control (Lot# 40963): (a) Vitamin B12 - 32 out of 43 control results were consistently above the established mean; (b) Folate - 39 out of 44 control results were consistently below the established mean. (3) There was no evidence in the records the control biases had been identified and addressed; (4) The surveyor reviewed the records with technical consultant #2/general supervisor #1 and asked if there was documentation to prove the biases had been identified and addressed. The technical consultant #2/general supervisor #1 stated the biases had not been addressed; (5) Since the above biases had not been identified and addressed, the surveyor determined the laboratory failed to have control procedures that monitored the accuracy of testing for the above analytes. CONTROL LIMITS (1) On the first day of the survey, technical consultant #2/general supervisor #1 stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XT 4000i analyzer; (b) Three levels (low, normal, and high) of Sysmex e-check XS quality control materials were tested each day that patient testing was performed; (c) The laboratory utilized the Sysmex Evidence Based Control Limits, which were provided by the manufacturer. (2) On the second day of the survey, technical consultant #2/general supervisor #1 assisted the surveyor in reviewing the Sysmex Evidence Based Control Limits that had been entered into the analyzer's Limit Range (%). The surveyor identified the values provided by the manufacturer had not been entered into the analyzer as follows: (a) Low Control (i) RBC (Red Blood Cell) - The manufacturer's Limit Range (%) value was 4.3 and a value of 4.5 had been entered by the laboratory. (ii) Hemoglobin - The manufacturer's Limit Range (%) value was 4.5 and a value of 5.26 had been entered by the laboratory. (iii) Hematocrit - The manufacturer's Limit Range (%) value was 5.2 and a value of 5.95 had been entered by the laboratory. (iv) Platelet - The manufacturer's Limit Range (%) value was 20.9 and a value of 18.97 had been entered by the laboratory. (b) Normal Control (i) RBC (Red Blood Cell) - The manufacturer's Limit Range (%) value was 3.8 and a value of 4.31 had been entered by the laboratory. (ii) Hemoglobin - The manufacturer's Limit Range (%) value was 3.2 and a value of 3.97 had been entered by the laboratory. (iii) Hematocrit - The manufacturer's Limit Range (%) value was 4.6 and a value of 5.88 had been entered by the laboratory. (iv) Platelet - The manufacturer's Limit Range (%) value was 10.6 and a value of 11.37 had been entered by the laboratory. (c) High Control (i) RBC (Red Blood Cell) - The manufacturer's Limit Range (%) value was 3.6 and a value of 4.3 had been entered by the laboratory. (ii) Hemoglobin - The manufacturer's Limit Range (%) value was 2.8 and a value of 4.32 had been entered by the laboratory. (iii)

	Hematocrit - The manufacturer's Limit Range (%) value was 4.5 and a value of 5.88 had been entered by the laboratory. (iv) Platelet - The manufacturer's Limit Range (%) value was 8.1 and a value of 10.83 had been entered by the laboratory. (3) The records were reviewed with technical consultant #2/general supervisor #1. Technical consultant #2/general supervisor #1 did not know where the above ranges came from, but stated they were not ranges that would not detect immediate error.
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: Based on a review of records, written policies, and interview with technical consultant #2/general supervisor #1, the laboratory failed to follow written quality control policies. Findings include: (1) At the beginning of the survey, technical consultant #2 /general supervisor #1 stated the following to the surveyor: (a) The ImmunoCard STAT! EHEC Rapid test for Shiga toxins 1 and 2 in human stool was performed in the laboratory; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP that had been developed for the test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested with each new lot or shipment or every 6 months (whichever is first); (3) The surveyor then reviewed quality control records from January 2017 through July 2018 and identified the laboratory failed to follow the written QCP of performing quality control testing every 6 months. Quality control testing had not been performed between: (a) 11/19/17 and 06/18/18 (4) The findings were reviewed with technical consultant #2/general supervisor #1 who stated the laboratory had not performed quality control testing as required by the QCP.
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: Based on a review of records and interview with technical consultant #2/general supervisor #1, the laboratory failed to ensure units of FFP (Fresh Frozen Plasma) were stored under appropriate conditions. Findings include: (1) On the second day of the

	survey, technical consultant #2/general supervisor #1 stated to the surveyor units of FFP were stored in the Sanyo Biomedical Freezer. The units were to be used for patient transfusions; (2) The surveyor observed the thermograph temperature recorder for the blood bank freezer. The freezer had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of FFP must be stored at -20 degrees Centigrade or colder). Each chart monitored the temperature for a 7 day period; (3) The surveyor reviewed 19 freezer charts dated from 10/02/17 through 02 /05/18. The review indicated that 1 of 18 charts had not been changed by the 7th day of as follows: (a) Chart #8 - The chart was put into use on 11/20/17 and removed on 12 /04/17 (13 days). (4) The surveyor reviewed the charts with technical consultant #2 /general supervisor #1 who stated the 1 chart had not been changed by the 7th day, as indicated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2/general supervisor #1, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 5 of 28 events, the attestation statements had been signed approximately 2 - 4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Second 2017 Chemistry Core Event - The samples had been tested on 05/26/17 and the attestation statement had not been signed by the laboratory director until 07/07 /17; (b) Second 2017 Chemistry Miscellaneous Event - The samples had been tested on 10/20/17 and the attestation statement had not been signed by the laboratory director until 01/03/18; (c) First 2017 Microbiology Event - The samples had been tested on 03/06/17 and the attestation statement had not been signed by the laboratory director until 05/08/17; (d) First 2018 Chemistry Core Event - The samples had been tested on 11/29/18 and the attestation statement had not been signed by the laboratory director until 03/06/18; (e) First 2018 Chemistry Miscellaneous Event - The samples had been tested on 04/27/18 and the attestation statement had not been signed by the laboratory director until 06/08/18. (2) The surveyor reviewed the findings with technical consultant #2/general supervisor #1 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.