Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470083	01/16/2025
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 01/13,14,15,16/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the director of nursing and laboratory manager during an exit conference performed at the conclusion of the survey.
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 the laboratory manager, the laboratory director failed to sign proficiency testing attestation statements for three of 20 proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 01/13/2025, a review of 2023 and 2024 proficiency testing events identified the following for three of 20 events: (a) Chemistry/Core 2024 Third Event - The attestation statement had not been signed by the laboratory director; (b) Chemistry/Core 2024 First Event - The attestation statement had not been signed by the laboratory director; (c) Microbiology 2024 Third Event - The attestation statement

	had not been signed by the laboratory director. (2) The findings were reviewed with the laboratory manager, who stated on 01/13/2025 at 02:25 pm, the attestation statements had not been signed by the laboratory director.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with the laboratory manager and nursing manager, the facility failed to ensure written policies were followed for preventing transfusion reactions for three of seven units of packed red-blood cells transfused. Findings include: (1) On 1/16/2024 at 09:00 am, the laboratory manager stated blood transfusions were performed by nursing staff; (2) A review of the nursing policy titled, "Blood Product Checkout and General Guidelines for Administration" stated: (a) "Obtain baseline vital signs then"; (b) "Every 15 minutes twice, then"; (c) "Every 30 minutes until the transfusion is complete." (3) A review of transfusion records for seven units transfused, identified the policy had not been followed for three of seven units as follows: (a) Unit #W091024438786 - The transfusion started on 01/14/2024 at 05:20 am and ended at an undocumented time. Vital signs had not been taken as follows; (i) Every 30 minutes until complete - Not taken between 06:35 am and 07:33 am; (ii) There was no completion time documented for this unit. (b) Unit #W091024423690 - The transfusion started on 01 /14/2024 at 01:56 am and ended at 04:32 am. Vital signs had not been taken as follows; (i) Every 15 minutes twice - Not taken between 02:13 am and 02:46 am. (c) Unit # W091024431175 - The transfusion started on 01/02/2025 at 11:34 am and ended at 01:45 pm. Vital signs had not been taken as follows; (i) Every 15 minutes twice - Not taken between 11:34 am and 12:00 pm. (4) The records were reviewed with the laboratory manager and nursing manager who confirmed on 01/16/2024 at 3: 30 pm, the vital signs had not been documented according to policy.
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 the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for two of five Chemistry proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 1/13/2025, a review of Chemistry proficiency testing records for 2023 (second and third events) and 2024 (first, second, and third events) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program) for two of five events: (a) Chemistry Core - Third Event 2023 (i) Alcohol - five of five results exhibited a positive bias (aa) Sample ALC-11 - SDI of 2.8 (bb) Sample ALC-12 - SDI of 2.7 (cc) Sample ALC-13 -

	SDI of 3.3 (dd) Sample ALC-14 - SDI of 1.7 (ee) Sample ALC-15 - SDI of 2.6 (ii) Acetaminophen - five of five results exhibited and negative bias (aa) Sample CH-11 - SDI of - 1.3 (bb) Sample CH-12 - SDI of - 1.5 (cc) Sample CH-13 - SDI of - 2.2 (dd) Sample CH-14 - SDI of - 2.2 (ee) Sample CH-15 - SDI of -2.3 (b) Chemistry Core - Third Event 2024 (i) Alcohol - five of five samples exhibited a positive bias (aa) Sample ALC-11 - SDI of 2.8 (bb) Sample ALC-12 - SDI of 3.9 (cc) Sample ALC-13 - SDI of 2.1 (dd) Sample ALC-14 - SDI of 2.5 (ee) Sample ALC-15 - SDI of 2.7 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager who stated on 11/13/2025 at 01:40 pm, 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 records, policy, and interview with the laboratory manager, the laboratory failed to follow their written policy for documentation on the transfusion service record for two of 16 days of patient testing during the review period of January 1, 2025 through the current date. Findings include: (1) A review of blood bank policies and procedures on 01/16/2025, identified a policy titled, "ABO-Rh Policy" which stated the following: (a) "The results of all blood bank testing must be documented in the Blood Bank log and in Epic. This log must be filled in completely for each test performed. Leaving out patient information or testing results can lead to unnecessary clerical errors when entering results into EPIC." (2) A review of the transfusion service record for patients tested from 01/01/2025 through the current date identified the following; (i) 01/02/2025 - The ABO and Rh interpretation had not been documented when unit #W091024436468 and unit #W091024431175 had been tested; (ii) 01/15/2025 - The ABO and Rh interpretation had not been documented when unit #W091024438786 had been tested. (3) The findings were reviewed with the laboratory manager who stated on 01/16/2025 at 10:00 am, the blood bank log had not been documented as required.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the laboratory manager, the laboratory failed to ensure five of five policies; and two of two procedure manuals had been approved, signed, and dated by the current laboratory director. Findings include: QUALITY CONTROL PLANS (1) On 01/14/2025 at 10: 00 am, the laboratory manager stated the laboratory performed the following testing and IQCP's (Individualized Quality Control Plans) had been developed for the test systems: (a) Urine drug screen testing using the Med Tox Profile II test system; (b)

	Blood Gas (pH, pCO2, pO2) using the iSTAT 1 analyzer and the EG6+ cartridge; (c) D-dimer testing using the BioSite Triage Meter test system; (d) Clostridium difficile testing using the Solana test system; (e) Campylobacter antigen testing using the Meridian Bioscience Immunocard STAT! test system. (2) A review of the IQCP's identified the QCP's (Quality Control Plans) for the above test systems had not been approved, signed, and dated by the current laboratory director; (3) The records were reviewed with the laboratory manager who stated on 01/14/2025 at 3:00 pm, the QCP's for the test systems had not been approved, signed, and dated by the current laboratory director. PROCEDURE MANUALS Based on a review of procedure manuals and interview with the laboratory manager, the laboratory failed to ensure two of two procedure manuals had been approved, signed, and dated by the current laboratory director. Findings include: (1) A review of two procedure manuals on 01/15 /2025 and 01/16/2025 identified no evidence they had been signed and dated as approved by the current laboratory director as follows: (a) The manual titled "Microbiology Procedure Manual". Examples of procedures contained in the manual were: (i) "Microbiology Quality Control" (ii) "Gram Stain" (iii) Urine Culture" (iv) Blood Culture Procedure" (b) The manual titled, "Chemistry and Special Chemistry". Examples of procedures contained in the manual were: (i) "Serum Beta HCG" (ii) "iSTAT Quality Control Policy and Procedure" (2) The manuals were reviewed with the laboratory manager who stated on 01/16/2025 at 02:00 pm, the manuals had not been signed and dated as approved by the current laboratory director. 48517 Based on a review of procedure manuals and interview with the laboratory manager, the laboratory failed to ensure two of two procedure manuals had been approved, signed, and dated by the current laboratory director. Findings include: (1) A review of two procedure manuals on 01/15/2025 and 01/16/2025 identified no evidence they had been signed and dated as approved by the current laboratory director as follows: (a) The manual titled "Lab Policy and Procedures". Examples of procedures contained in the manual were: (i) "Complete Blood Count" (ii) "Erythrocyte Sedimentation Rate" (iii) "Manual Diffs, NRBC Correction, and slide preparation and review" (iv) "PT and PTT" (v) "Saline replacement procedure for CBC" (b) The manual titled, "Blood bank procedures". Examples of procedures contained in the manual were: (i) "ABO/Rh" (ii) "Weak D Testing" (2) The manuals were reviewed with the laboratory manager who stated on 01/16/2025 at 02:00 pm, the manuals had not been signed and dated as approved by the current laboratory director.
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: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure corrective action had been taken for unacceptable humidity readings for two of 29 days reviewed. Findings include: (1) A review of the laboratory

	humidity records from 12/22/2024 through the current date identified the following: (a) The laboratory's acceptable humidity range was 30-85%; (b) Humidity readings were less than 30% for two of 29 days, with no corrective action documented. (2) The records were reviewed with the laboratory manager, who stated on 01/15/2025 at 10: 00 am, that corrective action had not been documented for the unacceptable humidity readings.
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 the laboratory manager, 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 for three of 20 proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 01/13/2025, a review of 2023 and 2024 proficiency testing events identified attestation statements had been signed up to eight months after the graded evaluation was completed by the proficiency testing program for three of 20 events reviewed: (a) Second Chemistry Core Event 2023 - The graded evaluation was completed on 07/14/2023 and the attestation statement had not been signed by the laboratory director until 07/14/2023; (b) First Hematology/Coagulation Event 2024 - The graded evaluation was completed on 04/18/2024 and the attestation statement had not been signed by the laboratory director until 12/23/2024; (c) Third Microbiology 2024 - The graded evaluation was completed on 11/21/2024 and the attestation statement had not been signed by the laboratory director until 12/23/2024; (2) The records were reviewed with the laboratory manager who stated on 01/13/2025 at 01: 10 pm the attestation statements had not been signed timely as stated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of five persons during the review period of January 2022 through the current date. Findings include: (1) On 01/13/2025 a review of personnel records for five persons performing moderate complexity testing from January 2022 through the current date identified no evidence an annual competency evaluation had been performed for one of five testing persons as follows: (a) Testing Person #1 - Between 01/05/2022 and 02/05/2024 (2) The records were reviewed with

	the laboratory manager who stated on 01/14/2025 at 01:20 pm the annual evaluation had not been performed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure personnel performing high complexity testing had been evaluated at least annually for one of five persons during the review period of January 2022 through the current date. Findings include: (1) On 01/13/2025 a review of personnel records for five persons performing high complexity testing from January 2022 through the current date identified no evidence an annual competency evaluation had been performed for one of five testing persons as follows: (a) Testing Person #1 - Between 01/05/2022 and 02/05/2024 (2) The records were reviewed with the laboratory manager who stated on 01/14/2025 at 01:20 pm the annual evaluation had not been performed.