Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470083	05/21/2021
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 05/19,20,21/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager at the conclusion of the survey.
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: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager and general supervisor #2, the laboratory failed to ensure control materials were stored as required for 34 of 51 days; and failed to ensure the humidity was acceptable for the Microscan Walkaway for 4 of 4 months. Findings include: STORAGE OF CONTROL MATERIALS (1) On 05/21/2021 at 08:40 am, the surveyor observed the contents of the white Whirlpool freezer in the laboratory. The following control materials were being stored in the freezer, with the manufacturer's storage requirements: (a) Bio-Rad Liquichek Unassayed Chemistry controls - 1 box of 12 bottles each of level 1 lot #56951 and level 2 lot #56952; the storage requirement was -20 to -70 degrees C (Centrigrade). (2) The surveyor reviewed temperature records from 04/01/2021 through 05/21/2021. The documented temperatures were warmer than -20 degrees C (the warmest temperature allowed for the materials for 34 of 51 days as follows: (a) April 2021 - 22 of 30 documented temperatures were warmer than -20 degrees C (b) May 2021 - 12 of 21 documented

	temperatures were warmer than -20 degrees C (3) The surveyor reviewed the records with the laboratory manager, who stated on 05/21/2021 at 09:00 am, the freezer temperatures were unacceptable as shown above. HUMIDITY FOR MICROSCAN WALKAWAY (1) On 05/20/021 at 01:00 pm, general supervisor #2 stated to the surveyor the Microscan Walkaway analyzer was used to perform identification and susceptibility testing procedures on culture isolates; (2) The surveyor reviewed the operator's manual contained in the analyzers memory, with the assistance of general supervisor #2. The manufacturer required the humidity be maintained at 30-80%; (3) The surveyor reviewed humidity records for 4 months (January through April 2021). It was identified the documented humidity readings were less than 30% for 4 of 4 months reviewed as follows: (a) January 2021 - 31 of 31 days (b) February 2021 - 28 of 28 days (c) March 2021 - 18 of 31 days (d) April 2021 - 25 of 30 days (4) The surveyor reviewed the records with general supervisor #2 who stated on 05/20/2021 at 01:20, the humidity was not acceptable for the Microscan Walkaway as listed above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to follow the function check protocol to ensure the urine centrifuge was functioning properly for 1 of 2 function checks performed. Findings include: (1) On 05/19/2021 at 09:40 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed microscopic urine sediment examinations; (b) The laboratory used the Drucker Horizon 642 VES centrifuge to process urines at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) On 05/20/2021 the surveyor reviewed the function check policy titled, "Centrifuge RPM Verification/Calibration, and Timer Verification" which stated, "Centrifuges timer and RPM nominal setting will be verified yearly"; (3) The surveyor reviewed the centrifuge maintenance records for 2019 and 2020. The following was identified for 1 of 2 checks performed: (a) 08/28/2020 - The speed had been checked at 3190 rpm an the timer had been checked at 10 minutes, which were not the speed and time settings that urine specimens were processed. (4) The surveyor reviewed the findings with the laboratory manager who stated on 05/20/2021 at 09:29 am, the laboratory did not ensure the urine centrifuge was functioning properly as indicated above.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (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 the laboratory manager, the laboratory failed to use control materials of a similar matrix to that of patient specimens 7 of 30 days of patient testing. Findings include: (1) On 05/19/2021 at 09: 30 am, the laboratory manager stated the following to the surveyor: (a) Serum Ketone testing was performed using the Germaine Laboratories Aim Tab ketone tablets; (b) When quality control (QC) testing was performed on the tablets, a negative and a positive urine control was performed instead of blood based (serum/plasma) controls; (c) The QC materials used by the laboratory were Bio-Rad Liquichek Urinalysis control materials Levels 1 & 2. (2) The surveyor reviewed QC and patient Serum Ketone records from 10/13/2020 through 03/23/2021, which showed that patient testing had been performed on 14 days using negative and positive urine controls specimens. The specific days were 10/13,20,23,24,30/2020; 11/03/2020; 12/11/2020; 01/08,15,21,29/2021; 02/09,19/2021, and 03/23/2021; (3) The surveyor reviewed the records with the laboratory manager who stated on 05/19/2021 at 04:00 pm, the laboratory had performed QC using urine controls instead of serum based controls. NOTE: The interpretive guidelines at D5465 (493.1256) state "Control materials of a similar matrix to that of patient specimens should be utilized, if available, and the control materials must be treated in the same manner as patient specimens and go through all analytic test phases."
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers. Findings include: (1) On 05 /19/2021 at 09:44, the laboratory manager stated to the surveyor Sodium, Potassium, Chloride, CO2, Glucose BUN, and Creatinine testing were performed using two methods: (a) Beckman Coulter DXC AU 700 analyzer as the primary method; (b) iSTAT 1 analyzer and the Chem 8+ cartridge as the back-up method. (2) On 05/20 /2021 the surveyor asked the laboratory manager if the relationship between the test results using the two different analyzers had been evaluated at least twice annually during 2020 and to date in 2021. The laboratory manager stated on 05/20/2021 at 09: 40 am the relationship between the analyzers had not been evaluated.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP; and failed to perform reviews to ensure the accuracy of Prothrombin Time calculations. Findings include: IQCP (1) On 05/19/2021 at 09:30 am, the laboratory manager stated the following to the surveyor: (a) Urine drug screen testing was performed using the MedTox Profile II ER test; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 05/12/2019), which stated, "This QC Plan will be reviewed for effectiveness at least annually"; (3) The surveyor reviewed records for 2020 and to date in 2021 and could not locate annual QA reviews since the IQCP had been approved on 05/12/2019; (4) ON 05/20/2021, the surveyor reviewed the records with the laboratory manager and asked if there was documentation of QA reviews to evaluate the QCP annually. The laboratory manager stated to the surveyor on 05/20 /2021 at 04:30 pm the QA reviews had not been performed annually as stated in the policy. PROTHROMBIN TIME CALCULATIONS (1) On 05/19/2021 at 10:15 am, the laboratory manager/technical consultant #1 stated the following to surveyor #1: (a) The ACL Elite analyzer was used to perform PT/INR (Prothrombin Time /International Normalized Ratio) testing (the INR was calculated using the PT reference interval mean); (b) The PT reagent, HemoSil RecombiplasTIN 2G reagent, lot #N0696619 was put into use on 01/30/2020. (2) On 05/21/2021, the surveyor reviewed the Normal Patient Mean (PT reference interval mean) that had been programmed into the analyzer, with the assistance of the laboratory manager and reviewed the records for the PT reagent lot change. The surveyor identified that, although the laboratory had followed the manufacturer's instructions for calculating a normal patient geometric mean, they did not ensure the calculated mean had been programmed into the analyzer as required to ensure the accurate calculation of the INR. The following was identified: (a) The geometric mean that had been programmed into the analyzer was 11.3; (b) The geometric mean that had been calculated by the laboratory was 11.03. (3) The surveyor asked the laboratory manager if the laboratory performed QA reviews to check the accuracy of PT calculations, to include ensuring the correct values were programmed into the analyzer. The laboratory manager stated on 05/21/2021 at 10:20 am, the laboratory had not accurately entered the normal patient mean into the analyzer and had not performed QA reviews to verify the values.