Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0682350	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Share Medical Center	800 Share Drive, Alva, 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 03/19/19-03/21/19. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory supervisor and general supervisor #2 during an exit conference performed at the conclusion of the survey.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to sign the proficiency testing attestation form to attest the proficiency testing samples were tested as patient testing using the laboratory's routine methods. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory performed Clostridium difficile testing on stool samples using the Alere C. diff Quik Chek test kit; (2) The surveyor reviewed Microbiology proficiency testing records for the Second and Third 2017 Events, and the First, Second, and Third 2018 Events. From the review, the surveyor identified the laboratory director failed to sign the attestation statement for 1 of the 5 testing events reviewed (First 2018 event); (3) The surveyor reviewed the findings with the laboratory supervisor, who stated to the surveyor, the laboratory director failed to sign the attestation statement listed above.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without

	analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to verify the accuracy of proficiency testing results which had not been graded by the proficiency testing program. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory performed urine drug screen testing using the BioRad Tox/See Rapid Urine Drug Screen test device; (2) The surveyor then reviewed the Chemistry Miscellaneous proficiency testing records from the Second and Third 2017 Events, and the First, Second, and Third 2018 Events. The surveyor identified in the First event of 2018, the proficiency testing program had not graded the laboratory's result for the analyte Opiates on Sample UDS-02: (a) The laboratory reported "Positive." The proficiency testing program had not graded the result due to "No Consensus" among the participants; (b) In addition, the proficiency testing program's expected response was "See Data Summary." (3) The surveyor reviewed the proficiency testing program's, "Performance Review and Corrective Action Sheet," included in the proficiency testing program's documentation. It stated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures, or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective actions for failures and must perform a self-evaluation using statistics presented in the 'Participant Data' for samples not graded."; (4) The surveyor reviewed the records again but could not locate documentation that the laboratory: (a) Identified the ungraded response (b) Obtained the Participant Summary Data (c) Evaluated their response against the proficiency testing program's expected response (5) The findings were reviewed with the laboratory supervisor, who stated to the surveyor, the laboratory did not perform a self-evaluation of the non-graded response listed above to verify accuracy of the testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: VITROS 5600 (1) On the first day of the survey, the laboratory supervisor stated to the surveyor routine chemistry testing was performed using the Vitros 5600 analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance logs and identified the following procedures were required: (a) Weekly maintenance: (i) Clean Microwell Incubator (ii) Clean Primary Tip Sealer (iii) Clean Secondary Tip Sealer (iv) Clean Sample Supply (v) Clean Tip Locator (vi) Clean DISPENSE BLADE and SENSORS (vii) Clean Leak Pads (viii) Clean Touchscreen Monitor and Keyboard (ix) Perform Subsystem Cleaning Note: Not Manually Selectable (x) Process VITROS MicroSensor Check Fluids I & II (b) Monthly maintenance: (i) Clean Cuvette Arm (ii)

	Clean Cuvette Incubator (iii) Clean PM Discard Chute (iv) Clean/Replace PM Evaporation Caps (v) Clean PM Incubator Slot and Insert Blade Channels (vi) Clean Microsensor Cover and Reagent Area (vii) Inspect/Clean u1A Reagent Supply Top Cover (viii) Inspect/CleanSupply 3 Pack Opener (ix) Clean VersaTip Supply (x) Inspect/Clean Reagent Cooler Filter (xi) Perform System Backup (3) The surveyor then reviewed maintenance records from 14 months (January 2018 through February 2019) and identified the following: (a) The weekly maintenance had not been documented as performed during the review period between: (i) 03/16/18 and 03/28 /18 (ii) 03/28/18 and 04/10/18 (iii) 06/09/18 and 06/19/18 (iv) 10/05/18 and 10/15/18 (v) 10/15/18 and 10/25/18 (vi) 12/22/18 and 12/31/18 (b) The monthly maintenance had not been documented as performed during 2 of the 14 months reviewed: (i) Between 03/01/18 and 03/31/18 (ii) Between 05/01/18 and 05/31/18 (4) The surveyor reviewed the records with the laboratory supervisor, who stated there was no documentation in the records, the manufacturer's maintenance procedures listed above had been performed as required. ACL ELITE (1) On the first day of the survey, the laboratory supervisor stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing was performed using the ACL Elite analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance log and identified the manufacturer required the following procedures be performed on a weekly basis: (a) Clean Exterior Surfaces (b) Rinse Waste Reservoir (c) Probe Align (d) Bleach Waste Line (3) The surveyor then reviewed maintenance records from 5 months (June and November 2017, February 2018 and October 2018, and January 2019) and identified the weekly maintenance had not been documented as performed between 11/16/17 and 12/01/17; (4) The surveyor reviewed the records with the laboratory supervisor, who stated there was no documentation in the records, the manufacturer's maintenance procedures listed above had been performed as required.
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 the laboratory supervisor, the laboratory failed to ensure that blood products were stored under appropriate conditions. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor units of packed red blood cells to be used for patient transfusions were stored in the blood bank refrigerator; (2) The surveyor reviewed the blood bank alarm check policy and procedure. The policy stated the high temperature of activation should be no higher than 6 degrees C. (Note: units of packed cells must be stored between 1-6 degrees Centigrade, therefore, the low temperature of activation should be no lower than 1 degree Centigrade and the high temperature of activation should be no higher than 6 degrees Centigrade): (3) The surveyor then reviewed alarm check records from January 2018 through January 2019. The surveyor identified that, although the alarm checks had been performed quarterly, 2 of the 5 high temperature activation alarm checks performed during the time period reviewed were

	unacceptable: (a) 07/17/18: The high temperature alarm sounded at 7.9 C, which is warmer than the acceptable limit; (b) 01/25/19: The high temperature alarm sounded at 6.5 C, which is warmer than the acceptable limit. (4) The surveyor reviewed the records with the laboratory supervisor and explained the high temperature of activation must be 6.0 C or less to ensure units of packed red blood cells were stored at the appropriate temperature; (5) The laboratory supervisor stated to the surveyor the records showed the laboratory did not ensure the blood bank refrigerator alarm sounded before the refrigerator reached an unacceptable temperature for storage of units of packed red blood cells. NOTE: D5555 was cited at the previous recertification survey performed 04/04/17-04/06/17.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for urine drug screen testing. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor, the laboratory performed urine drug screen testing using the BIORAD Tox/See Rapid Urine Drug Screen test kit to screen for the following drugs: Amphetamines, Barbiturates, Benzodiazepine, Cocaine, MDMA (3-4 Methylenedioxymeth amphetamine), THC (Tetrahydrocannabinol), PCP (Phencyclidine), Opiates, Oxycodone, Methadone, Methamphetamine and TCA (Tricyclic Antidepressants); (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions (package insert) for the testing, which stated, "This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be performed in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used."; (3) The surveyor then reviewed 2 patient test reports and identified the laboratory failed to include the manufacturer's statement that urine drug screen results are "preliminary" and must be confirmed by another method (i.e., GC/MS) to obtain a confirmed analytical result; (4) The surveyor reviewed the findings with the laboratory supervisor who stated the laboratory did not include the manufacturer's statement that results are preliminary and testing must be confirmed by another method for final results; (5) Examples of patient urine drug screen testing performed and reported without the manufacturer's statement about confirmatory testing included: (a) Patient #1: Testing performed 03/17/19 (b) Patient #2: Testing performed 03/20/19 NOTE: D5805 was cited at the previous recertification survey performed 04/04/17-04/06/17.