

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0682350	<b>(X3) Date Survey Completed</b> 04/20/2023
<b>Name of Provider or Supplier</b> Share Medical Center	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 04/18,19,20/2023 The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and technical consultant #2 at the conclusion of the survey.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory manager and technical consultant #2, the laboratory failed to have a written policy to assess the competency of the general supervisors, based on the position responsibilities as listed in Subpart M, for six of six persons serving as general supervisor. Findings include: (1) On 04/18/2023 a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the general supervisors, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of June 2021 through the current date identified competencies, based on job responsibilities, had not been performed for six of six persons listed as general supervisor on Form CMS-209; (3) The findings were reviewed with the laboratory manager and technical consultant #2. Both stated on 04/18/2023 at 02:49 pm a policy had not been written and competencies had not been performed for the general supervisors.</p>
<b>D5311</b>	<b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:  
Based on observation, review of written policies, and interview with the laboratory manager, the laboratory failed to have policies to ensure positive identification of one of one peripheral blood smear slide for manual differential testing. Findings include: (1) On 04/18/2023 at 11:35 am, the laboratory manager stated manual differential testing was performed in the laboratory; (2) On 4/20/2023 at 09:20 am, observation of the Hematology area of the laboratory identified an unlabeled slide of a peripheral blood smear for manual differential testing on the counter waiting to be stained with Wright's stain; (3) A review of policies identified the following: (a) The policy titled, "Manual Differential Policy" did not provide guidance on labeling slides; (b) The policy titled, "Specimen Labeling" stated, "After specimens have been drawn they must be properly labeled" but did not specifically address labeling slides. (4) Interview with the laboratory manager on 04/18/2023 at 09:30 am confirmed the peripheral blood slide had not been labeled with the patient identification and the laboratory polices did not address labeling slides.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate 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 and technical consultant #2, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test method introduced into the laboratory in June 2022. Findings include: (1) On 04/11/2023 at 11:40 am, the laboratory manager stated the laboratory began using the ACL Elite analyzer to perform PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing on 06 /27/2022; (2) A review of the performance specification records for the analyzer identified the laboratory had demonstrated the following reportable ranges: (a) PT - 9.8-124.0 (b) PTT - 18.9-165.0 (3) Interview with the laboratory manager and technical consultant #2 on 04/18/2023 at 04:00 pm confirmed the laboratory was not using the lower limit of the reportable ranges that had been demonstrated as follows: (a) PT - The laboratory was using the manufacturer's reportable range of 8.0-115; (a) PTT - The laboratory was using the manufacturer's reportable range of 5.5-113.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to perform calibration verification procedures at least once every six months for one of three test systems (D-dimer testing) reviewed from January 2022 through the current date; and failed to ensure identical materials were not utilized to perform calibration verification and QC (quality control) procedures for one of three test systems (Troponin I testing) reviewed from 09/14/2021 through 03/29/2023. Findings include: D-DIMER (1) On 04/18/2023 at 11:20 am, the laboratory manager stated the laboratory performed D-dimer testing using the Biosite Triage Meter Pro analyzer; (2) On 04/19/2023 a review of records from January 2022 through the current date identified no evidence calibration verification had been performed during the review period; (3) The records were reviewed with the laboratory manager and technical consultant #2. Both stated on 04/19/2023 at 12:08 pm, calibration verification procedures had not been performed at least once every six months. TROPONIN I (1) On 04/18/2023 at 11:25 am, the laboratory manager stated the laboratory performed Troponin I testing using the iSTAT 1 analyzer and the cTnI cartridge; (2) On 04/19/2023 a review of records from 09/14/2021 through 03/29/2023 identified the following: (a) 09/14/2021 (i) Calibration verification had been performed using cTnI Calibration Verification Control Set (level 1 lot #471129, level 2 lot #481129, and level 3 lot #491129); (ii) QC testing had been performed using cTnI Calibration Verification Control Set level 1 lot #471129, level 2 lot #481129, and level 3 lot #491129). (b) 03/19/2022 (i) Calibration verification had been performed using cTnI Calibration Verification Control Set (level 1 lot #471137, level 2 lot #481137, and level 3 lot #491137); (ii) QC testing had been performed using cTnI Calibration Verification Control Set (level 1 lot #471137, level 2 lot #481137, and level 3 lot #491137). (c) 09/19/2022 (i) Calibration verification had been performed using cTnI Calibration Verification Control Set (level 1 lot #471155, level 2 lot #481155, and level 3 lot #491155); (ii) QC testing had been performed using cTnI Calibration Verification Control Set (level 1 lot #471155, level 2 lot #481155, and level 3 lot #491155). (d) 03/29/2023 (i) Calibration verification had been

performed using cTnI Calibration Verification Control Set (level 1 lot #471155, level 2 lot #481155, and level 3 lot #491155); (ii) QC testing had been performed using cTnI Calibration Verification Control Set (level 1 lot #471155, level 2 lot #481155, and level 3 lot #491155). (3) The records were reviewed with the laboratory manager and technical consultant #2. Both stated on 04/19/2023 at 12:10 pm, the laboratory routinely used the calibration verification materials to perform calibration verification and QC testing for Troponin I at the same time.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to make appropriate reference ranges available for two of two reagent lot numbers implemented for PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing. Findings include: (1) On 04/11/2023 at 11:40 am, the laboratory manager stated the following: (a) PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the ACL Elite analyzer; (b) The following lot numbers were put into use when the new analyzer was implemented on 06/27/2022: (i) PT Reagent - Hemosil Recombiplastin 2G lot #N1017425 (ii) PTT Reagent - HemoSIL Synthasil lot #N1117768 (3) A review of the implementation records identified the following: (a) PT - The normal reference interval had been verified as 9.6-12.9 (b) PTT - The normal reference interval had been verified as 24.0-31.0 (4) A review of a patient report with PT and PTT testing performed on 04/14/2023 showed the following normal ranges: (a) PT - 10.0-12.6 (b) PTT - 25.0-34.5 (5) The reports and implementation records were reviewed with the laboratory manager and technical consultant #2. Both stated on 04/19/2023 at 01:42 pm, the laboratory had not updated the normal reference ranges into the laboratory's computer information system.

**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 and technical consultant #2, the technical consultant failed to definitively ensure personnel performing moderate complexity testing had been evaluated at least annually for one of six persons. Findings include: (1) On 04/18/2023 a review of personnel records for six persons performing moderate complexity testing during June 2021 through the current date identified the following: (a) Although an annual competency had been documented as completed on 04/27/2022, the competency form had not been signed and dated by the evaluator to definitively determine who performed the assessment. (2) The record was reviewed with the laboratory manager and technical consultant #2.

Both confirmed on 04/18/2023 at 02:49 pm, technical consultant #2 performed the competency assessment and failed to sign and date as the evaluator.