

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2010863	(X3) Date Survey Completed 02/02/2023
Name of Provider or Supplier Swiftstar Emergency River Oaks, Llc	Street Address, City, State 2320 S Shepherd, Houston, TX	
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	An entrance conference was held with the laboratory technical consultant. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the technical consultant at the exit conference. The facility was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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</p>

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 direct observation, laboratory policy, manufacturer's instructions, review of laboratory records, and confirmed in interview, the laboratory failed to have documentation of performing calibration verification for 1 of 1 cartridge tested on the Alere Triage analyzer (cardiac panel) every 6 months as required in 2022. Findings included: 1. During a tour of the facility on 02/02/2023 at 09:20 a.m. an Alere Triage (Serial Number: 29908761) was observed in the laboratory for cardiac panel patient sample analyses. 2. Review of the laboratory's policy "Alere Cardio Profiler with EDTA Whole Blood" (Reviewed by the Laboratory Director on 02/22/2022) revealed the following: "This procedure utilizes the Alere Triage Cardio Profiler, a fluorescent immunoassay for the simultaneous, quantitative, determination of the cardiac proteins, Creatinine Kinase (CK) ...Troponin.. in EDTA whole blood and plasma specimens." Further review revealed the following: "Instructions for running Calibration Verification Samples with the Triage Cardiac System: 1. Calibration Verification Samples are run every new meter and every six months." 2. Review of the Alere Triage Cardiac Panel Quick Reference Guide (02/2018) revealed the following: "QC Panel.. Cal Ver Controls (5) - Run every 6 months" 3. Review of laboratory records revealed no six-month calibration verification records for 1 of 1 cartridge tested on the Alere Triage (cardiac panel) in 2022. Note: The laboratory only reported CK and Troponin in the cardiac panel. 4. During an interview on 02/02/2023 at 10:00 a.m., Technical Consultant-1 stated six-month calibrations were not performed on the Alere Triage in 2022, confirming the above findings.