

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2125361	(X3) Date Survey Completed 07/19/2021
Name of Provider or Supplier Surepoint Emergency Center Azle	Street Address, City, State 611 Northwest Parkway, Azle, 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 representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plan of correction was discussed with the laboratory representatives at the exit conference. The laboratory representatives were 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.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in</p>

interview, the laboratory failed to support its reduction in frequency to every 30 days and failed to perform two levels of liquid QC material each 8 hours of operation for the D-Dimer analyte on the Alere Triage analyzer for 12 of 12 months in 2020 and 6 of 6 months in 2021. Findings: 1. Review of the Alere Triage user's manual stated: "TOTAL QUALITY ASSURANCE ... QUALITY CONTROL SAMPLES It is still valuable to apply the traditional approach to quality control by testing quality control samples. These controls will check the total integrity of the system. The interval for analyzing these controls, however, can be extended due to the many other Total Quality Assurance features inherent in the Alere Triage tests. The Alere Triage tests have been designed to maximize Total Quality Assurance in any testing environment. The combination of the QC features of the Alere Triage tests reduce the impact of procedural errors, ensure reagent integrity, and assurance that patient results are accurate each and every time a test is performed. Based on CLIA guidelines and other regulating bodies, Alere makes the following QC recommendations: Run two levels of POS and NEG external liquid control samples as appropriate with each new lot of reagents and once every thirty days with continued use of the reagent lot number. Run the QC Device daily." 2. Review of the laboratory's IQCP revealed: "IQCP LABORATORY RISK ASSESSMENT-TRIAGE ... The QCP Actions Required to Address Known Limitations ... Laboratory-implemented control processes: Analyze QC samples in triplicate for five days to monitor for calibration drift. This also allows the laboratory to collect sufficient data to establish confidence with measuring system stability over time ... IQCP PLAN The Individualized Quality Control Plan Developed from the Individual Components of the Quality Control Strategies described above. TRIAGE METER A. ELECTRONIC SIULATOR [sic] Run Electronic Simulator upon system arrival and every day of testing to check internal quality control. B. QC SAMPLES Analyze two levels of QC samples that were not in the same shipment as the reagents on receipt of new reagents; when a new lot number is opened; and every 30 days. Ensure QC sample acceptance criteria are appropriate for the clinical setting. Analyze two levels of QC samples before newly trained testing personnel start to run patient samples." The laboratories' IQCP failed to support its reduction in frequency to every 30 days for D-Dimer on the Alere Triage analyzer. 3. A review of patient records revealed the laboratory performed D-Dimer analysis, on the Alere Triage analyzer, on 200 patients in 12 of 12 months in 2020 and 6 of 6 months in 2021. 4. During an interview on 07/19/2021 at 11:30 AM, in the office, the technical consultant confirmed the above findings.