Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2096122	05/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Surepoint Emergency Center Pantego	1607 S Bowen Rd, Pantego, 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	Laboratory representatives were present at the entrance conference conducted 05/11 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 05/11 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of laboratory SARS-Co-V-2 patient testing records, review of laboratory SARS-Co-V-2 result reporting records, and staff interview, it was revealed that the laboratory failed to report SARS-Co-V-2 negative test results for 38 of 38 days reviewed from 02/11/2021 through 05/10/2021. Findings: 1. Review of SARS-Co-V-2 patient tests records (test performed using the Sofia 2 SARS Antigen FIA COVID-19 Test kit and instrumentation) from 02/11/2021 through 05/10/2021 revealed 47 patients tested for SARS-CoV-2. 2. Further review of the SARS-Co-V-2

	patient tests results revealed of the 47 patients tested for SARS-Co-V-2, 43 patients tested negative. 3. Review of the laboratory's SARS-Co-V-2 result reporting documentation revealed the laboratory faxed SARS-Co-V-2 positive patient results Sunday through Saturday from 02/11/2021 through 05/10/2021 to the County Health Department. Further review of the laboratory's SARS-Co-V-2 reporting documentation revealed the laboratory failed to report the 43 negative test results to the County Health Department or to the Department of State Health Services. 4. During an interview on 05/11/2021 at 12:40 pm, the Technical Consultant and Nurse Manager confirmed that only positive SARS-Co-V-2 results were reported.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(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. 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 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 11 of 11 days in 2021 (random sampling 02/2021-05/2021). 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 intergrety 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 IQCP failed to support its reduction in frequency to every 30 days for D-Dimer on the Alere Triage analyzer. 3. A random sampling of QC and patient records from February through May 2021, revealed the following dates QC was not performed each 8 hours of testing using two levels of control materials on each day of patient testing and patients were analyzed for the D-Dimer analyte on the Alere Triage meter: 03/03/2021 Patient ID: E35763 03 /07/2021 Patient ID: E15480 03/13/2021 Patient ID: E36463 03/15/2021 Patient ID: E36660 QC was last performed on 02/25/2021 at 11:06 am 04/05/2021 Patient ID: E38117 04/13/2021 Patient ID: E06857 04/14/2021 Patient ID: E02307 04/17/2021 Patient ID: E14959 QC was last performed on 03/26/2021 at 8:15 am 05/07/2021 Patient ID: E41236 05/10/2021 Patient ID: E41524 05/11/2021 Patient ID: E35799 QC was last performed on 04/24/2021 at 11:50 am The laboratory failed to include two levels of liquid QC material and electronic QC each 8 hours of operation for the D-Dimer analyte on the Alere Triage analyzer. 4. During an interview on 05/11/2021 at 1:30 pm, the technical consultant confirmed the above findings.