Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2096122	03/15/2019
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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative 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 NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 45 CFR 493.803 Successful Participation 493.1403 Moderate Complexity Laboratory Director 493.1421 Testing Personnel (moderate complexity) 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.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review laboratory policy, laboratory American Proficiency Institute (API) proficiency testing (PT) records from 2017, 2018 and 2019, and confirmed in interview of facility personnel, the laboratory failed to test PT samples the same as

	patient samples for 31 of 60 proficiency samples. Findings included: 1. The laboratory policy titled "Critical Values" (Signed by the laboratory director 11/04/2016) stated, "Critical values may be repeated if the values are not consistent with the patient's condition or there is a possible specimen integrity issues. Defined Critical values: WBC: less than or equal to 2.0 or greater than or equal to 3.0 Hgb: less than or equal to 8.0 or greater than or equal to 20 Hct: less than or equal to 20 or greater than or equal to 60 Plt: less than or equal to 50,000 or greater than or equal to 800,000 CK-MB: greater than or equal to 6 Troponin: greater than or equal to 0.06 D-Dimer: greater than or equal to 600 BUN: greater than or equal to 80 Ca: less than or equal to 6 or greater than or equal to 12 K: less than or equal to 3.0 or greater than or equal to 6.0 Na: less than or equal to 120 or greater than or equal to 150 CO2: less than or equal to 15 or greater than or equal to 50 Creat: greater than or equal to 4.0 Glucose: less than or equal to 50 or greater than or equal to 400 Lactic Acid: greater than or equal to 4.0" 2. The laboratory policy titled "Proficiency Testing" stated the following: " NOTE: Test the specimens the same number of times as done routinely for patient specimens." 3. Review of API Hematology PT records from 2017 (1st, 2nd, and 3rd Events) and 2018 (1st, 2nd, and 3rd Events) revealed the following 6 of 30 proficiency samples had critical values that were not repeated: 2017 1st Event; HSY-01; Hgb=6.3; Hct=16.8 2017 2nd Event; HSY-08; Hgb=6.1; Hct=16.5 2017 3rd Event; HSY-14; Hgb=6.2; Hct=16.7 2018 1st Event; HSY-03; Hgb=5.6; Hct=16.2; Plt=45 2018 2nd Event; HSY-06; Hgb=5.8; Hct=16.6 2018 3rd Event; HSY-14; Hgb=5.8; Hct=16.9 3. Review of the API Chemistry Core PT records from 2018 (1st and 3rd Events) and 2019 (1st Event) revealed the following 25 of 30 proficiency samples had critical values that were not repeated: 2018 1st Event: CM-01; D-Dimer=692 CM-02; CK-MB=17.9; D-Dimer=1360; Troponin=3.55 CM-03; CK-MB=10.7; D-Dimer=1160; Troponin=12.40 CM-04; CK-MB=6.4; D-Dimer=822; Troponin=0.24 CM-05; CK-MB=34.8; D-Dimer=2090; Troponin=8.57 CH-01; CO2=11 CH-02; CO2=10 CH-03; Ca=13.1; Creat=5.30; Lactic Acid=6.9; K=6.8; Na=163 CH-05; Lactic Acid=4.1 2018 3nd Event: CM-11; CK-MB=9.8; D-Dimer=999; Troponin=1.97 CM-12; D-Dimer=643 CM-13; CK-MB=19.0; D-Dimer=1320; Troponin=7.79 CM-14; D-Dimer=818; Troponin=0.63 CM-15; CK-MB=26.3; D-Dimer=2200; Troponin=12.90 CH-11; CO2=12 CH-13; Lactic Acid=5.4; Na=160 CH-15; Lactic Acid=4.3 2019 1st Event CM-01; CK-MB=8.9; D-Dimer=936 CM-03; CK-MB=28.7; D-Dimer=1100; Troponin=9.43 CM-04; CK-MB=19.5; Troponin=4.43 CM-05; D-Dimer=757; Troponin=0.38 CH-01; CO2=9; K=2.6 CH-02; Ca=12.2; Creat=4.80; Lactic Acid=6.6; K=6.9; Na=169 CH-03; Lactic Acid=4.2; K=6.9 CH-04; CO2=10; K=2.5
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy

	to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records obtained from the CMS (Center for Medicare Medicaid Services) national database and verified with American Proficiency Institute (API) proficiency testing records, it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of hematology for the analyte White Blood Cell Differential (WBC Diff). Refer to D2130
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review American Proficiency Institute (API) proficiency testing (PT) records, the laboratory failed to attain a score of at least 80 percent for the Chemistry analyte Troponin for 1 of 3 proficiency testing events 2018 (Chemistry Core-2nd and 3rd Events) and 2019 (Chemistry Core 1st Event). Findings included: 1. Review of the laboratory API proficiency testing documents for 2019 Chemistry Core - 1st Event revealed the following result entries for the Troponin I analyte: Sample CM-03; Result = 9.43; Expected Result= 1.29 -7.43; Performance-Unacceptable Sample CM-04; Result = 4.43; Expected Result= 4.81 - 15.72; Performance-Unacceptable The laboratory received an unacceptable score of 60% for the Troponin analyte 2. Review of laboratory's API PT "Performance Summary" records for 2018 and 2019 Chemistry Core revealed the following unsatisfactory scores: 2019 1st Event; The laboratory received an unsatisfactory score of 60% for Troponin I. The laboratory failed to attain a score of at least 80% for Troponin analyte.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: I. Based on review of CMS 155 reports and American Proficiency Institute (API) proficiency testing (PT) records, the laboratory failed to attain a score of at least 80 percent for the Hematology analyte White Blood Cell Differential (WBC Diff) for 3 of 6 proficiency testing events in 2017(Hematology-1st, 2nd, 3rd Events) and 2018 (Hematology -1st, 2nd, 3rd Events). Findings included: 1. Review of CMS 155 Complete Emergency Care Pantego (45D2096122) report for API 2017 (1st, 2nd, and 3rd events) and 2018 (1st, 2nd, and 3rd events) revealed the following unsatisfactory

	score: Cell I.D. or WBC Diff 2017 3rd Event 67% 2018 1st Event 67% 2018 3rd Event 67% 2. Review of laboratory's API PT "Performance Summary" records for 2017 and 2018 Hematology revealed the following unsatisfactory scores: 2017 3rd Event; The laboratory received an unsatisfactory score of 67% for WBC Diff. 2018 1st Event ; The laboratory received an unsatisfactory score of 67% for WBC Diff 2018 3rd Event ; The laboratory received an unsatisfactory score of 67% for WBC Diff The laboratory failed to attain a score of at least 80% for WBC Diff analyte.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: I. Based on review of CMS 155 reports and American Proficiency Institute (API) proficiency testing (PT) records, the laboratory failed to achieve satisfactory performance for the same analyte in two consecutive testing events. The laboratory failed to achieve satisfactory performance (80 % or greater) in the specialty of hematology for the analyte White Blood Cell Differential (WBC Diff) for 2 consecutive testing events (2017 3rd Event and 2018 1st Event). Findings included: 1. Review of CMS 155 Complete Emergency Care Pantego (45D2096122) report for API 2017 (1st, 2nd, and 3rd events) and 2018 (1st, 2nd, and 3rd events) revealed the following unsatisfactory score: Cell I.D. or WBC Diff 2017 3rd Event 67% 2018 1st Event 67% 2. Review of laboratory's API PT "Performance Summary" records for 2017 and 2018 Hematology revealed the following unsatisfactory scores: 2017 3rd Event; The laboratory received an unsatisfactory score of 67% for WBC Diff. 2018 1st Event ; The laboratory received an unsatisfactory score of 67% for WBC Diff II. Based on review of CMS 155 reports and American Proficiency Institute (API) proficiency testing (PT) records, the laboratory failed to achieve satisfactory performance for the same analyte in 2 of 3 consecutive testing events. The laboratory failed to achieve satisfactory performance (80 % or greater) in the specialty of hematology for the analyte White Blood Cell Differential (WBC Diff) for 2 of 3 consecutive testing events (2018 1st Event and 2018 3rd Event). Findings included: 1. Review of CMS 155 Complete Emergency Care Pantego (45D2096122) report for API 2017 (1st, 2nd, and 3rd events) and 2018 (1st, 2nd, and 3rd events) revealed the following unsatisfactory score: Cell I.D. or WBC Diff 2018 1st Event 67% 2018 2nd Event 100% 2018 3rd Event 67% 2. Review of laboratory's API PT "Performance Summary" records for 2017 and 2018 Hematology revealed the following unsatisfactory scores: 2018 1st Event ; The laboratory received an unsatisfactory score of 67% for WBC Diff 2018 2nd Event ; The laboratory received a satisfactory score of 100% for WBC Diff 2018 3rd Event ; The laboratory received an unsatisfactory score of 67% for WBC Diff
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of Sysmex XP-300 operator's manual, laboratory environmental records (02/2018, 11/2018, and 02/2019) and confirmed in interview, the laboratory failed to ensure humidity levels were within the operating specifications for the hematology analyzer for 8 of 28 days in 02/2018, 7 of 30 days in 11/2018, and 15 of 28 days in 02/2019. Findings included: 1. Review of the Sysmex XP-300 hematology analyzer operator's revealed the specified humidity range was 30% to 85%. 2. Review of the laboratory form titled "Temperature and Humidity Log" specified the humidity range of 23% - 80%. 3. Review of laboratory environmental records (02/2018, 11 /2018, and 02/2019) revealed the following days when the humidity levels were NOT within manufacturer's operating specifications: 02/02/2018; 29% 02/03/2018; 27% 02 /05/2018; 28% 02/06/2018; 29% 02/09/2018; 29% 02/11/2018; 29% 02/12/2018; 27% 02/13/2018; 29% 11/11/2018; 26% 11/13/2018; 27% 11/14/2018; 28% 11/17/2018; 29% 11/18/2018; 29% 11/19/2018; 23% 11/28/2018; 27% 02/08/2019; 25% 02/09 /2019; 24% 02/10/2019; 23% 02/13/2019; 27% 02/14/2019; 27% 02/16/2019; 24% 02 /17/2019; 26% 02/18/2019; 26% 02/19/2019; 25% 02/20/2019; 29% 02/21/2019; 24% 02/22/2019; 27% 02/24/2019; 27% 02/25/2019; 24% 02/26/2019; 28% The laboratory has an annual volume of 12,000 hematology tests. 4. In an interview on 03/14/2019 at 1015 hours, the above findings were confirmed by technical consultant #1.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, laboratory records, and laboratory proficiency testing, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D6016. 2. The Laboratory Director failed to ensure 8 of 26 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6029
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2130.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review CMS-209 from, testing personnel records and staff interview, the laboratory director failed to ensure 8 of 26 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6065
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: I. Based on review laboratory policy, laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on 6 of 26 testing personnel (TP) who performed hematology and chemistry moderate complexity testing. Findings included: 1. Review of the laboratory policy titled "Personnel Training and Competency" (Revision Date 11/22/2016) stated, "Each employee will be given an evaluation for competency at six months from hire and annually thereafter." 2. Review of laboratory personnel records revealed the laboratory failed to have competency assessment documentation for the following testing persons: a. Testing Person #2 Date of Hire 12 /2017; No documentation of 2018 annual competency. b. Testing Person #20 Date of Hire 09/01/2018; No documentation of semi-annual competency c. Testing Person #21 Date of Hire 11/1/2014; No documentation of semi-annual competency, 2015, 2016, 2017, and 2018 annual competency. d. Testing Person #22 Date of Hire 10/03 /2017; No documentation of semi-annual competency, and 2018 annual competency. e. Testing Person #25 Date of Hire 09/01/2018; No documentation of semi-annual competency. f. Testing Person #26 Date of Hire 08/22/2015; No documentation of semi-annual competency, 2016, 2017, and 2018 annual competency. The laboratory was asked to provide documentation of competency assessments. No documentation was provided. 2. The above findings were confirmed by technical consultant #1 on 03 /14/2019 at 1020 hours. II. Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the

	technical consultant performing competency assessments at this facility on 6 of 26 testing personnel (TP) who performed hematology and chemistry moderate complexity testing. Findings included: 1. Review of laboratory personnel records revealed the following testing persons whose competency assessment was performed at another facility location: a. Testing person #9 2017 Annual competency assessment performed at the Azle, Texas location. b. Testing person #9 2019 Annual competency assessment performed at the Azle, Texas location. c. Testing person #14 2018 Annual competency assessment performed at the Fort Worth, Texas location. d. Testing person #15 2018 Annual competency assessment performed at the Fort Worth Texas location. e. Testing person #19 2017 Annual competency assessment performed at the Azle, Texas location. f. Testing person #23 2018 Annual competency assessment performed at the Azle, Texas location. 2. In an interview on 03/14/2019 at 1020 hours, technical consultant #1 explained that the facility had 5 locations in Texas (2 locations in Fort Worth, 1 location in Azle, 1 location in Southlake, and 1 location in Pantego). She further stated that testing persons floated among those locations. Technical consultant #1 was asked to provide documentation of competency assessment performed at this location (Pantego). No documentation was provided. This confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation for 8 of 26 testing persons met the qualifications required to perform moderate complexity testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 8 of 26 testing persons met the qualifications required to perform moderate complexity testing. Finding included: 1. Review of the CMS-209 form submitted by the laboratory revealed 26 testing persons who performed

	moderate complexity testing. 2. Review of personnel records revealed the laboratory failed to have qualifying education documentation for the following testing persons: a. Testing person #1 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. b. Testing person #6 Records did not include an evaluation of education to determine equivalent foreign to United States education. c. Testing person #13 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. d. Testing person #20 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. e. Testing person #21 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. f. Testing person #22 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. g. Testing person #25 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. h. Testing person #26 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. 3. The above findings were confirmed by technical consultant #1 on 03/14/2019 at 1020 hours.