Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2132143	08/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Surepoint Emergency Center Stephenville	2108 W Washington Street Suite 184, Stephenville, 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 representatives at the entrance and exit conferences. The facility 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 NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 45 CFR 493.801 Enrollment and Testing of Samples 493.1403 Laboratory Director, (moderate complexity). 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.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API)

	Proficiency Testing (PT) records, and laboratory records, the laboratory failed to meet the requirements of participating in PT for the specialty of hematology and chemistry, as evidenced by: 1. The laboratory failed to examine Hematology and Chemistry PT samples in the same manner as it tests patient specimens for PT testing event 1 of 2019. Refer to D2006 2. The laboratory failed to ensure PT samples were tested by trained personnel who routinely perform the testing in the laboratory. Refer to D2007. 3. The laboratory failed to test PT samples the same number of times that it routinely tests patient samples for 1 of 2 Hematology testing events in 2019 (2019 Hematology 1st Event). Refer to D2010.
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 of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, laboratory records, quality assurance records and interview with staff, the laboratory failed to test Hematology and Chemistry PT samples in the same manner as it tests patient specimens for 1st Proficiency testing events of 2019. Findings included: 1. Review of the laboratory policy titled "Laboratory Procedure for Proficiency Testing" (Effective date 12/07/2018 and signed by the laboratory director on 12/07/2018) stated the following: "Proficiency testing samples must be tested with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory using routine methods of the laboratory) the individual performing testing on the samples must attest to this policy by signing the Attestation Statement accompanying each testing event). Proficiency testing samples must be tested the same number of times as routine patient samples are tested ... ...Handle repeats as stipulated in procedure for each analyte and in the same manner as patient specimens." 2. Review of the API 2019 Hematology 1st Event proficiency testing records revealed the following samples were part of the event: HSY-01; HSY-02; HSY-03; HSY-04; HSY-05 Further review of the API Attestation Statement for the 2019 Hematology 1st Event revealed the following testing persons who performed testing and the corresponding PT sample tested: Testing person #9; HSY-01 Testing person #10; HSY-02 Testing person #14; HSY-04 Testing person #18; HSY-03 Testing person #2; HSY-05 Testing person #6; HSY-05 Testing person #1; HSY-01 Testing person #8; HSY-02 Testing person #5; HSY-03 Testing person #3; HSY-04 The laboratory performed duplicate testing of the PT sample by different testing persons. The laboratory failed to test Hematology PT samples and in the same manner as it tests patient specimens. 3. Review of the sample printout from the hematology analyzer revealed the following dates/times when PT samples were tested: a. Sample HSY-01 tested 03/22/2019 00:16 and 03/24/2019 17:15 No indications (critical or flagged results) for repeat testing. b. Sample HSY-02 tested 03 /24/2019 17:13 and 03/27/2019 11:32 No indications (critical or flagged results) for repeat testing. c. Sample HSY-03 tested 03/18/2019 14:56 and 03/27/2019 11:34 No

	indications (critical or flagged results) for repeat testing. d. Sample HSY-04 tested 03 /18/2019 14:54 and 03/27/2019 11:35 No indications (critical or flagged results) for repeat testing. e. Sample HSY-05 tested 03/18/2019 17:50 and 03/19/2019 16:16 No indications (critical or flagged results) for repeat testing. The laboratory failed to test Hematology PT samples and in the same manner as it tests patient specimens. 4. Review of the API 2019 Core Chemistry 1st Event proficiency testing records revealed the following samples were part of the event: CH-01; CH-02; CH-03; CH-04; CH-05; CM-01; CM-02; CM-03; CM-04; CM-05 Further review of the API Attestation Statement for 2019 Core Chemistry 1st Event revealed the following testing persons who performed testing and the corresponding PT sample tested: a. Testing person #6; No sample recorded on attestation statement b. Testing person #10; CH-01; CH-02; CH-03 c. Testing person #19; CH-01; CH-02; CH-03 d. Testing person #1; CH-04 e. Testing person #5; CM-05 f. Testing person #7; CM-04 The laboratory performed duplicate testing of the PT sample by different testing persons. The laboratory failed to test Chemistry PT samples and in the same manner as it tests patient specimens. 5. Review of the laboratory's quality assurance (QA) record for 06 /06/2019 in the section titled "Conclusion" stated, "Surepoint ER Stephenville QA study has revealed mishandling of Proficiency testing samples for the first two quarters of 2019 ... .The Laboratory has not been treating the Proficiency testing samples exactly like patients." 6. In an interview on 08/05/2019 at 1147 hours in the facility breakroom, the technical consultant confirmed that the laboratory had NOT been treating the Proficiency testing samples exactly like patients."
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records (2017 - 2019), laboratory personnel records and staff interview, the laboratory failed to ensure PT samples were tested by trained personnel who routinely perform the testing in the laboratory. Findings included: 1. Review of the laboratory policy titled "Laboratory Procedure Training for Technical Personnel" (Signed by the laboratory director on 12/07/2018) stated, "This policy ensures all new Technical Laboratory Personnel receive: Comprehensive training for all laboratory sections and test systems; This training that is administered is a planned and organized fashion; The training that is documented and signed to ensure accountability for both the trainer and the trainee ... ...Training documentation consists of completed training checklists, manufacturers' training certificates, quizzes, and other types of material such as videos, which all serve to prove adequate training has been provided for laboratory personnel according to the individuals' job descriptions." 2. Review of the laboratory policy titled "Laboratory Procedure for Proficiency Testing" (Effective date 12/07/2018 and signed by the laboratory director on 12/07/2018) stated the following: "Proficiency testing samples must be tested with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory using routine methods of the laboratory) the individual performing testing on the samples must attest to this policy by signing the Attestation Statement accompanying each testing event). 3. Review of the laboratory's API Proficiency testing records from 2017 through 2019 revealed the following persons signed the Attestation Statement

	indicating performance of the test and the corresponding sample that was tested: 2019 1st Event Hematology; Testing person #3; Sample HSY-04 2019 2ne Event Core Chemistry; Testing person #3; Sample CM-06; Sample CM-07 2019 1st Event Hematology; Testing person #14; Sample HSY-04 4. Review of laboratory personnel records revealed the following: a. Testing person #3; Date of hire 03/16/2019; No documentation of initial training. b. Testing person #14; Date of hire 01/07/2019; No documentation of initial training; No documentation of semi-annual competency assessment. The laboratory was asked to provide documentation of initial training and /or semi-annual competency. No documentation was provided. The laboratory failed to ensure proficiency testing samples were routinely performed by trained testing personnel. 5. The above findings were confirmed by the Chief Nursing Office in an interview on 08/05/2019 at 1150 in the breakroom.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, and staff interview, the laboratory failed to test PT samples the same number of times that it routinely tests patient samples for 1 of 2 Hematology testing events in 2019 (2019 Hematology 1st Event). Findings included: 1. Review of the laboratory policy titled "Laboratory Procedure for Proficiency Testing" (Effective date 12/07/2018 and signed by the laboratory director on 12/07 /2018) stated the following: "Proficiency testing samples must be tested with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory using routine methods of the laboratory) the individual performing testing on the samples must attest to this policy by signing the Attestation Statement accompanying each testing event). Proficiency testing samples must be tested the same number of times as routine patient samples are tested ... ...Handle repeats as stipulated in procedure for each analyte and in the same manner as patient specimens." 2. Review of the sample printouts from the hematology analyzer revealed the following dates/times when 2019 API Hematology 1st Event PT samples were tested: a. Sample HSY-01 tested 03/22/2019 00:16 and 03/24/2019 17:15 No indications (critical or flagged results) for repeat testing. b. Sample HSY-02 tested 03 /24/2019 17:13 and 03/27/2019 11:32 No indications (critical or flagged results) for repeat testing. c. Sample HSY-03 tested 03/18/2019 14:56 and 03/27/2019 11:34 No indications (critical or flagged results) for repeat testing. d. Sample HSY-04 tested 03 /18/2019 14:54 and 03/27/2019 11:35 No indications (critical or flagged results) for repeat testing. e. Sample HSY-05 tested 03/18/2019 17:50 and 03/19/2019 16:16 No indications (critical or flagged results) for repeat testing. The laboratory failed to test PT samples the same number of times that it routinely tests patient samples for the 2019 API Hematology 1st Event. 3. In an interview on 08/05/2019 at 1147 hours in the facility breakroom, the technical consultant confirmed that the PT samples had no indications for repeat testing but were tested twice. This confirmed the above findings.
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 of Centers for Medicare and Medicaid (CMS) form 155, American Proficiency Institute (API) proficiency testing records (Chemistry Core 2017 3rd Event, Chemistry Core 2018 1st, 2nd, and 3rd Event, Chemistry Core 2019 1st and 2nd Event) and staff interview, it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for each analyte for 2 of 6 testing events (2017 Chemistry API 3rd Event and 2018 Chemistry API 1st Event). Findings included: 1. Review of the CMS form 155 revealed the unsatisfactory scores for regulated analytes: 2017 Chemistry API - 3rd Event laboratory received an unsatisfactory score of 60 % for the Creatine Kinase (CK) analyte. 2018 Chemistry API - 1st Event laboratory received an unsatisfactory score of 40% for the Potassium (K) analyte and an unsatisfactory score of 40% for the Sodium (Na) analyte. 2. Review of the laboratory's API Chemistry Core proficiency testing records revealed the following: a. API 2017 Chemistry Core 3rd Event comparative evaluation report revealed the following: Analyte: Creatine Kinase Sample Cm-11; Reported result=42. 2; Expected Result=10.6 - 33.5; Performance=Unacceptable Sample CM-13; Reported result=5.9; Expected Result=0.0 - 5.8; Performance=Unacceptable Overall Score 60% Analyte: Troponin Sample CM-11; Reported result=13.70; Expected Result=1.26 - 8.32; Performance=Unacceptable Sample CM-13; Reported result=0.49; Expected Result=0.00 - 0.94; Performance=Unacceptable Overall Score 60% Analyte: Carbon Dioxide Sample CH-11 Reported result=17; Expected Result=23 - 31; Performance=Unacceptable Sample CH-12; Reported result=24; Expected Result=26 -35; Performance=Unacceptable Sample CH-14; Reported result=9; Expected Result=10 -18; Performance=Unacceptable Sample CH-15; Reported result=18 Expected Result=20 -28; Performance=Unacceptable Overall Score 20% The laboratory failed to attain an acceptable score of at least 80% for the Creatine Kinase, Troponin and Carbon Dioxide analytes. b. API 2018 Chemistry Core 1st Event comparative evaluation report revealed the following: Analyte: Potassium Sample CH-01; Reported result=3.0; Expected Result=1.8 - 2.9; Performance=Unacceptable Sample CH-02; Reported result=2.9; Expected Result=1.6 - 2.7; Performance=Unacceptable Sample CH-03; Reported result=7.2; Expected Result=6. 1 - 7.1; Performance=Unacceptable Overall Score 40% Analyte: Sodium Sample CH-03; Reported result=160; Expected Result=162 - 171; Performance=Unacceptable Sample CH-04; Reported result=130; Expected Result=133 - 142; Performance=Unacceptable Sample CH-05; Reported result=140; Expected Result=142 - 151; Performance=Unacceptable Overall Score 40% The laboratory failed to attain an acceptable score of at least 80% for the Potassium and Sodium analyte. 3. The above findings were confirmed in an interview with laboratory representatives on 08/05/2019 at 1100 hours in the facility breakroom.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory policy, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to ensure that 3 of 3 vials of Eightcheck 3WP X-TRA hematology quality control (QC) material were labeled with new expiration dates according to the manufacturer. Findings included: 1. Observed in the laboratory refrigerator on 08/05/2019 at 1616 hours were the following 3 vials of Eightcheck 3WP X-TRA hematology QC material in-use for the Sysmex XP 300 hematology analyzer: Lot number 91980710; Expiration date 2019-10-23 Lot number 91980711; Expiration date 2019-10-23 Lot number 91980712; Expiration date 2019-10-23 The vials were NOT labeled with the opened date or the new expiration date. 2. Review of the laboratory policy titled "Laboratory Procedure Good Laboratory Practices" (Signed by the laboratory director 12/07/2018) stated, "Always record the following information on all test kits and/or supplies received into the laboratory: ...Date PIU (put into use) ....Open expiration date." 3. Review of the manufacturer's instructions (06/2017, Rev.17) for Eightcheck 3WP X-TRA QC material stated, "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 C after being recapped." 4. The findings were confirmed by the Technical Consultant on 08/05/2019 at 1615 hours during a tour of the laboratory. II. Based on direct observation, review of laboratory policy, and staff interview, it was revealed the laboratory failed to ensure that in-use reagents for the Sysmex XP 300 hematology were labeled according to laboratory policy. Findings included: 1. During a tour of the laboratory on 08/05/2019 at 1615 hours, the following reagents were observed in-use on the Sysmex XP 300 hematology analyzer: Cell Pack; Lot number Y9004; Expiration date 2020-10-25 Stromatolyser; Lot number Y8009; Expiration date 2019-12-14 The reagents were NOT labeled with the open date or new expiration date. 2. Review of the laboratory policy titled "Laboratory Procedure Good Laboratory Practices" (Signed by the laboratory director 12/07/2018) stated, "Always record the following information on all test kits and/or supplies received into the laboratory: ....Date PIU (put into use) .... Open expiration date." 3. The Sysmex XP-300 Hematology analyzer manufacturer's instructions (Document number 1049-LSS, Rev. 01-July 2013) stated, "3. Record open date and revised expiration date (stability date) on container. a. Cellpack is good for 60 days after opening. b. Stromatolyser is good for 90 days after opening." The laboratory failed to ensure that in-use reagents on the Sysmex XP 300 hematology were labeled according to laboratory policy. 3. The findings were confirmed by the Technical Consultant on 08/05/2019 at 1615 hours during a tour of the laboratory.
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 laboratory policy and laboratory records, the Laboratory Director failed to provide overall management as evidenced by: 1. The laboratory director failed to ensure Hematology and Chemistry PT samples were tested in the same manner as it tests patient specimens. Refer to D2006 2. The laboratory director failed to ensure PT samples were tested by trained personnel who routinely perform the testing in the laboratory. Refer to D6016 3. The laboratory director failed to ensure PT samples were tested the same number of times that it routinely tests patient samples.

	Refer to D2010. 4. The laboratory director failed to ensure 5 of 22 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6065
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: The laboratory director failed to ensure Proficiency testing (PT) samples were tested by trained personnel who routinely perform the testing in the laboratory. Refer to D2007
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 form, testing personnel records and staff interview, the laboratory director failed to ensure 5 of 22 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6065
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 that 5 of 22 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 5 of 22 testing persons met the qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 through Testing Person #22 listed to perform moderate complexity testing. 2. Review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: a. Testing person #2; No education documents provided b. Testing person #3; No education documents provided c. Testing person #14; No education documents provided d. Testing person #12; No education documents provided e. Testing person #13; No education documents provided 3. The above findings were confirmed by the Technical Consultant in an interview on 08/05 /2019 at 1400 hours in the breakroom.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to ensure that 4 of 22 testing personnel had documentation of training prior to performing moderate complexity testing. Findings included: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of initial training for 4 of 22 testing personnel. They were (as listed on Form CMS 209): Testing personnel #3 Testing personnel #12 Testing personnel #13 Testing personnel #14 2. The above findings were confirmed by the Technical Consultant in an interview on 08/05/2019 at 1400 hours in the breakroom.