Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2112898	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Star Er,Llc	7007 Indiana Ave, Lubbock, 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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Observations, review of manufacturer's instructions, patient final reports, personnel records and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the Sofia SARS Antigen FIA test kits and the BD Veritor System for SARS-CoV-2 test for testing patients as defined by the manufacturer under the Emergency Use Authorization (EUA). The findings included: 1. Observations made during the tour of the laboratory found the laboratory was using the following rapid test kits for detecting SARS-CoV-2 testing: a. Sofia SARS Antigen FIA lot 706424 expiration 2022-11-02 b. BD Veritor System for SARS-CoV-2 lot 1011225402 expiration 2021-12-10 2. Review of the Sofia SARS Antigen FIA test kits manufacturer's instructions for use found under the heading CONDITIONS OF AUTHORIZATION FOR THE LABORATORY: "Authorized laboratories using your product must include with the test result reports, all authorized Fact Sheets." Review of the BD Veritor SystemSARS-CoV-2 instructions for use found on page 11 under the heading CONDITIONS OF AUTHORIZATION FOR THE LABORATORY (APPLICABLE IN THE US): "Authorized laboratories using your product will include witht he test result reports, all authorized Fact Sheets." 2. Review of patient test records found the laboratory tested 1441 patients for SARS- CoV-2 using the following test kits: a. Sofia SARS Antigen FIA - 1336 patients tested

	between September 13, 2021 and October 21, 2021. b. BD Veritor System for SARS-CoV-2 - 105 patients were tested between September 5, 2020 and October 21, 2021. 3. Interview of the Technical Consultant conducted October 21, 2021 at 12:07 PM confirmed that the laboratory did not disseminate the Authorized Fact Sheets with SARS CoV-2 test results as required under the Emergency Use Authorization.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that the laboratory failed to perform and document corrective actions when proficiency testing failures occurred in one of three testing events for Routine Chemistry proficiency testing events in 2021. Failure to achieve a score of at least 80 percent is unsatisfactory performance. Findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2021 found that laboratory failed to undertake additional training or employ technical assistance to correct problems with proficiency testing failures for the analyte Sodium in the 2021 Chemistry Core 3rd testing event, when the lab obtained a score of 60%. The laboratory submitted unacceptable responses for CH-12 and CH-14. Review of the performance evaluation found the laboratory documented repeat testing on 12 Oct 2021 with no other documentation of corrective actions or training. 2. Interview of the Technical Consultant conducted October 21, 2021 at 10:25 AM confirmed that no additional training or remedial actions were taken for the proficiency testing failure for Sodium.
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 the laboratory's test menu Individualized Quality Control Plan (IQCP) for chemistry testing performed on the Abbott Piccolo analyzer, patient test records and staff interview, it was revealed the laboratory failed to have an acceptable IQCP to support its modification of the frequency of quality control testing. The

	findings included: 1. A review of the laboratory's test menu revealed the laboratory used the moderately complex Met Lac 12 Panel to test patients on the Abbott Piccolo. The analytes included in the Met Lac 12 Panel are: Albumin, Calcium, Chloride, Creatinine, Glucose, Lactate, Magnesium, Phosphorus, Potassium, Sodium, Total Carbon Dioxide and Blood Urea Nitrogen. 2. A review of the laboratory's IQCP performed between November 11, 2020 through December 12, 2020 revealed the laboratory modified the frequency of quality control testing from each day of patient testing to once every 30 days, with each new shipment, or each new lot, without results being evaluated for acceptability. Further review found the 30 day Quality control study was evaluated on October 20, 2021, with errors identified by the Technical Consultant. 3. Review of patient test records found the laboratory tested 512 patients using the Met Lac 12 Panel without an acceptable IQCP between November 17, 2021 and October 19, 2021. 4. Interview of the Technical Consultant revealed the laboratory had quality control failures during the verification process without restarting the study. She stated she discontinued use of the Met Lac 12 Panel until the IQCP could be redone to include a successful 30 day study to reduce the frequency of quality control testing. Based on review of the laboratory's IQCP (Individualized Quality Control Plan) for the Triage Cardiac/D Dimer Tests, manufacturer's instructions, and staff interview, the laboratory's IQCP (used to decrease the frequency of quality control testing) was unsuccessful in supporting the reduction in frequency of testing to once each 30 days, new shipment and new lot for the Triage Cardiac Marker and the Triage D dimer. Findings included: 1. A review of the laboratory's IQCP studies for the Triage Cardiac and D Dimer test found: a. Triage meter 77516 in use September 2016 with a 10 day Quality control regimen. b. Triage meter 77864 in use February 9, 2021 Review of the Laboratory Quality Incident report (signed by the TC on 10/20/2021) found the IQCP either was not performed or failed, with documentation that the IQCP would be completed for Cardiac marker and D dimer to reduce the frequency of quality control performance to once each lot, shipment of every 30 days. 2. A review of the Triage Cardiac and D dimer test manufacturer's instructions found under the section "Quality Control Considerations" stated "users should follow government guidelines (for example, federal, state or local) and/or accreditation requirements for quality control." 3. Interview of the Technical consultant conducted October 21, 2021 at 2:34 PM confirmed that the IQCP studies for both D dimer and Cardiac Marker were not completed to support reducing the frequency of Quality control testing to once each 30 days or each new lot or shipment.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Review of policies and procedures quality control records and interview of facility personnel found the laboratory failed to follow their own procedure for establishing acceptable limits for the Cell Dyn Emerald quality control material for five of five lots reviewed. The findings included: 1. Review of policies and procedures found: a. In the policy titled Quantitative Quality Control (SOP QAP. 23) on page 57: "1. Perform Crossover Studies Whenever a new lot of QC material is received, new control ranges should be established by performing crossover studies PRIOR to putting the lot number into use. This is important so the "new" lot number results can be compared with those of the "old" lot number and also initial or provisional ranges can be established for the "new" lot number. To successfully accomplish the Crossover studies, perform the steps that follow: a. Before the old lot expires, run each level of new lot of QC material (Low, Normal and High) a number of times. b. Compare the results of the new lot to those of the current lot in use. c. Compare the results of the new lot to the ranges published by the manufacturer for this new lot. d. Ideally, run the new lot number levels again, at least once daily, for several days. Attempt to gather 10 data points for each level of the new lot prior to PIU (putting in use). 2. Review Data There are a few ways to set the new acceptable QC range limits for the new lot number. After at least 10 data points for each each QC level have been accumulated, print a QC summary for the performance of each level. This is normally done performed at the end of each month. The summary prints the SD and CV for each parameter. This data should be compared to past QC performance and to the manufacturer's recommendations for use as the acceptable QC range for the new lot of QC material." b. Review of the Policy titled Cell Dyn Emerald (approved September 1, 2016) found on page 2 under the heading Quality Control: " Run parallel testing on New Control Lot # alongside of current lot#. Run each level of the new control a minimum of 10 times over a minimum of two days. Determine the new established mean for the new lot#. (add all result values and divide by the total number of runs = new established mean) Enter the new established mean into the analyzer." 3. Review of Quality control records found CBC QC RANGE EVALUATION forms completed for the following lots of quality control material with comments as follows: a. lot 0349 expiration date 04/02/2021 - "True Ranges not set. New lot did perform well. (signed by TC 10/12/21)" b. lot 1039 expiration date 5/28/2021 - "I did not locate the actual crossover runs. Lot did perform well over time. Problem with auto ship confirmed (signed by TC 10/12/21)" c. lot 1095 expiration date 7/23/2021 - "crossovers complete Inhouse Range was not set. My review of LJ's showed good performance". (signed by TC on 10/12/2021) d. lot 1179 Expiration 10/15/2021 - " no crossover study found. "(signed by TC 10/20/2021) e. lot 1263 Expiration 01/07/2022 - " Inhouse ranges not set at this time. The analyzer seemed to have a clog, which caused the PLT CV's to increase. Run another week prior to setting ranges." (signed by TC 10/20/21) 4. Interview of Testing person 9 conducted on October 21, 2021 at 2: 11 PM found the laboratory entered the data for acceptable limits directly from the assay sheets and used the manufacturer's ranges as their own for acceptability of quality control.
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 laboratory's submitted Form CMS 209, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to ensure all testing personnel met the minimum education requirements to perform moderate complexity testing in Hematology. (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 laboratory's submitted Form CMS 209, personnel files, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify two of 18 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director October 21, 02021) found the laboratory identified 18 testing personnel. 2. A review of the laboratory's personnel records found two of 18 testing personnel failed to have documentation of education to qualify them to perform moderate complexity testing: a. Testing person 13 (hire date November 5, 2020) was educated outside the United States. The laboratory did not have a foreign credential evaluation report available for review. b. Testing person 14 (hire date November 5, 2020)- Review of transcripts did not have documentation of degree awarded. 3. Interview with the Technical consultant conducted on October 21, 2021 at 10:12 AM confirmed that the laboratory failed to have documentation of minimum education requirements being met for testing person 13 and 14. She went on to say she had removed testing person 13 from moderate complexity testing on October 21, 2021.