Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0054765	07/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Texas State University	298 Student Center Drive, San Marcos, 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 deficiencies and plans of correction were 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.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, laboratory policy, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for specified staining time for the Quicklink I Wright-Giemsa blood cell differential stain. Findings Included: 1. Review of the manufacturer's instructions for the Quicklink I Wright-Giemsa Stain revealed the following: "Technique: 1. Transfer Stain Solution into copulin jar or staining dish and keep covered when not in use. 2. Prepare slides. 3.

	Immerse each slide to be processed for 15 to 30 seconds into the Stain Solution. Briefly, allow excess stain to drain or blot slide. 4. Repeat this process using DI water for 30 to 60 seconds. 5. Rinse slides with deionized water and allow to dry. Examine using immersion oil." 2. Review of the laboratory's policy, "Quick Stain Procedure: Blood Smears" (reviewed by the laboratory director on 07/20/2021), revealed the following: "Staining Procedure for Blood Smears 1. Prepare blood smear on slide. 2. Dip slide in stain for 10 seconds. (Manufacturer's instructions stated a dip time of 15-30 seconds. The laboratory failed to follow manufacturer's instructions.) 3. Dip slide in distilled water (pH 6-7) for 20 seconds or more for darker staining. (Manufacturer's instructions stated a dip time of 30 to 60 seconds. The laboratory failed to follow manufacturer's instructions.) 4. Air Dry. Staining times are approximate and should be varied as needed." 3. In an interview with the general supervisor at 10:30 AM on 07/28/2021, in the conference room, the general supervisor, after review of the documentation, confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure Aptima penetrable caps were not used passed their expiration dates. Findings Included: 1. A tour of the laboratory on 07/27/2021 at 09:30 AM, revealed the following package of Aptima penetrable caps that were being used passed their expiration date: Aptima penetrable caps Lot Number: 262553H Expiration Date: 09/15/2020 2. In an interview with the general supervisor at 10:30 AM on 07/28/2021, in the conference room, the general supervisor confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's QA (Quality Assurance) policy, CBC (complete blood count) test records, laboratory CBC audits, and confirmed in staff interview, the laboratory failed to ensure an effective QA (quality assessment) program was in place to identify and correct problems for the analytic phase of testing in hematology. Findings Included: 1. Review of the laboratory's QA policy (Approved by the laboratory director on 07/2019) revealed the following: " ...3. Outline of Quality Assurance Quality Assurance includes all the systems and procedures required to ensure accurate patient results. Accuracy and Precision: Methods of analysis are demonstrated to be precise and accurate according to approved (CLIA) standards. Analysis of specimens is performed with care and dedication of quality personnel. 4.

	Testing Phase- Assuring Quality in the Total Testing Process ..Analytic Procedure: Testing the specimen Potential Errors: Test procedure not followed, test not 'in control',of tests put in incorrect sequence, reagents/kits expired or contaminated." 2. Review of the laboratory's quarterly "In-House CBC Audit" reports revealed 21 CBC's were performed by the laboratory and reviewed by the laboratory director in 2021 (01/2021-06/2021): January 2021 In-House CBC's: 2 February 2021 In-House CBC's: 5 March 2021 In-House CBC's: 4 April 2021 In-House CBC's: 4 May 2021 In-House CBC's: 3 June 2021 In-House CBC's: 3 3. The following 3 of 21 CBC's had differences in the patient chart ID number and the number entered into the Beckman Coulter ActDiff hematology analyzer: a. Patient ID programmed into AcTDiff : 04952772 Date: 03/01/2021 Time: 16:29 CORRECT PATIENT ID Patient ID in patient chart: 04952771 b. Patient ID programmed into AcTDiff: 048814480 Date: 05 /25/2021 Time: 16:43 CORRECT PATIENT ID Patient ID in patient chart: 04881480 c. Patient ID programmed into AcTDiff: 004850608 Date: 06/01/2021 Time: 15:51 CORRECT PATIENT ID Patient ID in patient chart: 004850607 4. The laboratory failed to ensure patient identification (ID) numbers from the patient chart were transcribed correctly into the Beckman Coulter AcTDiff hematology analyzer for 3 of 21 patients in 2021 (01/01/2021-06/30/2021). Refer to D5801. 5. In an interview with the general supervisor at 10:30 AM on 07/28/2021, in the conference room, the general supervisor, confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on direct observation, CBC (complete blood count) test records, and confirmed in staff interview, the laboratory failed to ensure patient identification (ID) numbers from the patient chart were transcribed correctly into the Beckman Coulter AcTDiff hematology analyzer for 3 of 21 patients in 2021 (01/01/2021-06/30/2021). Findings Included: 1. During a tour of the laboratory on 07/27/2021, at 9:28 AM, the surveyor observed a Beckman Coulter AcTDiff hematology analyzer (Serial Number: 2090002686) currently in use for patient testing. 2. Review of CBC test records revealed the following 3 of 21 patients tested on the Beckman Coulter AcTDiff in 2021 (01/01/2021-06/30/2021) with the incorrect patient identification (ID) number: a. Patient ID programmed into AcTDiff : 04952772 Date: 03/01/2021 Time: 16:29 CORRECT PATIENT ID Patient ID in patient chart: 04952771 b. Patient ID programmed into AcTDiff: 048814480 Date: 05/25/2021 Time: 16:43 CORRECT PATIENT ID Patient ID in patient chart: 04881480 c. Patient ID programmed into AcTDiff: 004850608 Date: 06/01/2021 Time: 15:51 CORRECT PATIENT ID Patient ID in patient chart: 004850607 The laboratory failed to ensure patient identification (ID) numbers from the patient chart were transcribed correctly into the Beckman

	Coulter AcTDiff hematology analyzer for 3 of 21 patients in 2021 (01/01/2021-06/30 /2021). 3. In an interview with the general supervisor at 10:30 AM on 07/28/2021, in the conference room, the general supervisor confirmed the above findings.