Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2017411	10/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Austin Health Partners, Pllc	13625 Ronald Reagan Blvd, Building 6, Cedar Park, 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	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
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 proficiency testing records and interview with facility personnel, the laboratory failed to enroll in an HHS approved proficiency testing program (three testing events per year) for the regulated analytes in the specialty of hematology for the first event of 2018. The findings included: 1. Based on review of the CMS-155D proficiency testing report, no scores had been sent from a proficiency testing agency for the first (1st) event of 2018. 2. Based on review of laboratory corrective action records and American Proficiency Institute (API) records, the laboratory failed to enroll in an HHS approved proficiency testing program (three testing events per year) for the regulated analytes in the specialty of hematology for the first event of 2018. 3. The laboratory's quality assessment corrective action, signed

	by the Technical Consultant on 6/12/2018, stated the following: "1. When the laboratory failed to receive the 2018 1st Event samples, API was contacted and the lab was informed that API had not received the 2018 Renewal Form or payment. 2. API indicated that it was too late to order and participate in the 1st Event. They recommended that the lab place an order for the remaining 2018 testing events and to additionally purchase a 1st event sample set for self-evaluation. 3. The laboratory received and tested the 1st event samples. results were self-graded. A score of 100 percent was obtained on all analytes with the exception of 80 percent for both percent lymphocytes and percent granulocytes. Self-grade results validated the acceptable performance." 4. In an interview at 11:03 hours on 10/03/2018 in the conference room, the Technical Consultant stated there was some confusion in the enrollment process which lead to the laboratory not being able to participate in the first event in time for scoring and a self-grade was necessary.
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: Based on review of the CMS-155D proficiency testing report, American Proficiency Institute records, and interview with facility personnel, the laboratory failed to attain a score of at least 80 percent for 6 of 6 regulated analytes in the second event of 2018. The findings included: 1. Based on the CMS-155D proficiency testing report and American Proficiency Institute records for the second event of 2018, the laboratory failed to attain a score of at least 80 percent on the following analytes: Cell I.D. or Diff - 73 percent Red Blood Count - 60 percent Hemoglobin - 60 percent Hematocrit - 60 percent White blood cell count - 60 percent Platelet count - 60 percent 2. Review of the laboratory's corrective action form stated the following: "Original instrument printouts were reviewed and it was confirmed that the samples had been correctly identified and tested, but the results for the 2 samples (HEM-06 and HEM-08) were reversed when values were entered on-line." 3. In an interview at 11:03 hours on 10/03 /2018 in the conference room, the Technical Consultant stated the error was clerical.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the CMS-155D proficiency testing report, American Proficiency Institute records, and interview with facility personnel, the laboratory failed to attain a score of at least 80 percent for overall event score for Hematology in the second event of 2018. The findings included: 1. Based on the CMS-155D proficiency testing report and American Proficiency Institute records for the second event of 2018, the laboratory failed to attain a score of at least 80 percent: 2018 - Second Event Hematology - 62 percent 2. Review of the laboratory's corrective action form stated the following: "Original instrument printouts were reviewed and it was confirmed that the samples had been correctly identified and tested, but the results for the 2 samples

	(HEM-06 and HEM-08) were reversed when values were entered on-line." 3. In an interview at 11:03 hours on 10/03/2018 in the conference room, the Technical Consultant stated the error was clerical.
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 a review of the laboratory's quality control records, facility procedures, record review and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory services. The findings included: The Laboratory Director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the first event of 2018. Refer to D6015.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing records and interview with facility personnel, the Laboratory Director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program (three testing events per year) for the regulated analytes in the specialty of hematology for the first event of 2018. Refer to D2000.