Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0973962	**(X3) Date Survey Completed** 08/16/2018
Name of Provider or Supplier Baylor Scott & White Primary Care Associates	**Street Address, City, State** 4400 I-30 West, Ste 130, Greenville, 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**
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 American Proficiency Institute (API) proficiency testing (PT) documentation for 2016, 2017 and 2018, confirmed by staff interview, the laboratory failed to test PT samples using the personnel who routinely perform patient testing. Findings: 1. API attestation forms for 2016, 2017 and 2018 were reviewed. a. For 2016 Chemistry Group 2 2nd event, 2017 Chemistry Core 1st event, 2017 Chemistry Miscellaneous 1st event, 2017 Cemistry Core 2nd event, 2017 Chemistry Miscellaneous 2nd event, 2018 Chemistry Core 1st event, 2018 Chemistry Miscellaneous 1st event and 2018 Chemistry Core 2nd event, all testing was performed by testing person 1. (CMS form 209) b. For 2017 Hematology/Coagulation 1st event, 2017 Hematology/Coagulation 2nd event, 2017 Hematology/Coagulation 3rd event, 2018 Hematology/Coagulation 1st event and 2018 Hematology /Coagulation 2nd event, all testing was performed by testing person 2. (CMS form 209) c. In an interview at the site on 08-16-2018, testing persons 1 and 2 stated it had been their practice to divide proficiency testing between themselves, testing person 1 performing all chemistry and testing person 2 performing all hematology. The CMS form 209 lists 4 other testing personnel for the facility. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on review of patient results for 2018 in the laboratory information system (LIS), confirmed by staff interview, the laboratory failed to correctly identify the address at which testing was performed. Findings: 1. A copy of a patient report from the LIS was requested for review. The address listed was not correct for the site. In an interview at the site on 08-16-2018, testing person 1 stated that the laboratory had relocated to the current facility effective 08-14-2017, and that the address displayed was that of the former location. She further stated that the error had not been caught after the move and would affect all reports for the previous year. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: . Based on review of laboratory quality assurance (QA) documentation, confirmed by staff interview, the laboratory failed to employ a mechanism to verify the accuracy of calculated results in the LIS. Findings: 1. Laboratory QA documentation was reviewed. No policy or procedure for periodic verification of the accuracy of results calculated in the LIS was found or could be offered. 2. In an interview at the site on 08-16-2018, testing person 1 stated that calculated results were verified for accuracy when the information system was validated in May 2017, but that the laboratory had not instituted an ongoing policy for monitoring or evaluating the accuracy of these results.