Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0698063	11/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baylor St Luke's Medical Group	310 Gaslight Boulevard, Lufkin, 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	Based on the recertification survey, the laboratory is not in compliance with the following conditions of participation required for certification in the CLIA program: D 2016 Successful Particpation-493.803 .
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2017 and 2018 confirmed by staff interview, the laboratory failed to participate successfully in chemistry testing using the Alfa-Wasserman Ace Axcel analyzer during the second and third events of 2018. Findings: 1. API PT documentation was reviewed. Scores for general chemistry included the following

	results: 2nd event 2018 Creatinine (mg/dL) Specimen Reported Expected Grade CH-06 2.27 2.41-3.27 Unacceptable CH-07 1.28 1.23-1.84 Acceptable CH-08 3.24 3.45-4.68 Unacceptable CH-09 0.88 0.80-1.40 Acceptable CH-10 2.93 3.17-4.30 Unacceptable Event score: 40% Sodium (mmol/L) Specimen Reported Expected Grade CH-06 145 143-152 Acceptable CH-07 127 126-135 Acceptable CH-08 155 159-168 Unacceptable CH-09 123 122-130 Acceptable CH-10 151 155-163 Unacceptable Event score: 60% 3rd event 2018 Creatinine (mg/dL) Specimen Reported Expected Grade CH-11 1.05 0.91-1.52 Acceptable CH-12 2.44 2.46-3.34 Unacceptable CH-13 3.18 3.27-4.44 Unacceptable CH-14 1.82 1.78-2.42 Acceptable CH-15 2.77 2.83-3.84 Unacceptable Event score: 40% Sodium (mmol/L) Specimen Reported Expected Grade CH-11 118 111-119 Acceptable CH-12 133 133-142 Acceptable CH-13 145 149-158 Unacceptable CH-14 125 122-131 Acceptable CH-15 138 140-149 Unacceptable Event score: 60% 2. Scores below 80% in two consecutive testing events for the analytes creatinine and sodium resulted in long term unsuccessful performance. In an interview at the site during the survey, testing person 1 (CMS form 209) confirmed the results. .
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for 2017 and 2018, confirmed by staff interview, the laboratory failed to achieve satisfactory performance for chemistry testing of the analytes creatinine and sodium using the Alfa-Wasserman Ace Alera analyzer in the second and third events of 2018. Refer to D 2016. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of quality control (QC) documentation for 2017 and 2018, surveyor observation and staff interview, the laboratory failed to employ control procedures to monitor the accuracy of test performance over time in chemistry testing using the Alfa-Wasserman ACE Axcel analyzer. Findings: 1. During the survey, it was observed that QC documentation for chemistry testing consisted of individual printouts of daily QC testing. A Levey-Jennings plot of the current control lot was requested. Testing person

	1 stated that she did not know whether the instrument could produce such a report. 2. Review of the manufacturer's introductory documentation revealed that the analyzer could display and print such plots in three different formats and referenced instructions for their generation in the operator's manual. (Alfa-Wasserman Diagnostic Technologies, LLC; ACE Axcel Clinical Chemistry System, Introduction to Quality Control Practices in the Clinical Laboratory, P/N 701419, Rev. A-10/13, page 9) .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: . Based on review of validation documentation for the Sysmex XP-300 hematology analyzer and staff interview, the laboratory director (CMS form 209) failed to ensure that adequate procedures were employed to verify the performance characteristics of the instrument prior to patient testing. 1. Documentation for the Sysmex XP-300 was reviewed. Validation and correlation studies, dated 03-13-2018 and 03-14-2018, were included. The provided documentation showed no evidence of review by the laboratory director. All spaces provided for signatures of persons performing testing and review were left blank. 2. In an interview at the site on 11-29-2018, testing person 1 stated that the validation data was provided to the manufacturer's service representative for analysis and to her knowledge had not been reviewed by the laboratory director. .
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Based on review of the laboratory procedure manual and staff interview, the laboratory director failed to specify in writing the responsibilities and duties of the laboratory technical consultant or testing personnel 1 and 2. Findings: 1. The laboratory procedure manual was reviewed. No document specifyiing the duties or

	responsibilities delegated to the laboratory technical consultant (CMS forrm 209) was found or could be offered during the survey. 2. No document specifying the responsibilities or duties of testing personnel 1 or 2 (CMS form 209) was found or could be offered during the survey. 3. In an interview at the site on 11-29-2018, testing person 1 stated that to her knowledge no such document was available. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: . Based on surveyor observation, review of 2018 quality control documentation for the Alfa-Wasserman Ace Accel chemistry analyzer and staff interview, the technical consultant failed to identify training needs for testing personnel in collecting control performance data. Refer to D 5441. .