Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2112647	04/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Beaumont Family Practice Associates	8525 9th Ave, Port Arthur, 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
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 documentation, confirmed by staff interview, the laboratory failed to enroll in an HHS approved proficiency testing program for hematology. Findings: 1. Proficiency testing results for hematology were requested. None were available or could be offered. 2. In an interview at the site on 04-10-2018, testing person 1 (CMS form 209) stated that proficiency testing had been initiated with American Proficiency Institute (API) in December 2017, and that samples for the first event 2018 had been submitted, but results not yet received. 3. Review of laboratory documentation revealed that hematology testing on patient specimens began on 10-12-2016, with the most recent test performed on 02-14-2018. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on review of performance verification documentation for the Sysmex XP-300 hematology instrument, confirmed by staff interview, the laboratory failed to verify that the manufacturer's reference intervals were appropriate for the laboratory's patient population before initiating patient testing. Findings: 1. Performance verification documentation for the Sysmex XP-300 was reviewed. Studies performed prior to the date patient testing began did not include a reference range study for the patient population served by the laboratory. 2. In an interview at the site on 04-10-2018, testing person 1 stated that to her knowledge no such study had been performed. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of quality control documentation for the Sysmex XP-300 hematology instrument from 2016, 2017 and 2018, confirmed by staff interview, the laboratory failed to perform quality controls as required each day of patient testing. Findings: 1. Hematology quality control documentation and patient results were reviewed. Patient results were found for tests performed on days when no quality control documentation could be offered. In an interview at the site on 04-10-2018, testing person 1 (CMS form 209) stated she had been told by the Sysmex field service technician that, due to the low volume of testing to be performed, hematology controls should be necessary no more than once a week. 2. Laboratory documentation showed that, between the start of hematology testing on 10-12-2016 and the most recent test on 02-14-2018, 99 patients were tested using the Sysmex XP-300 on days when no quality controls were performed. In an interview at the site on the day of the survey, testing person 1 verified this finding. .
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: . I. Based on review of patient test reports for 2016, 2017 and 2018, verified by staff interview, the laboratory failed to utilize two forms of patient identification on patient hematology reports. Findings: 1. Patient test reports were reviewed. Hematology reports from the Sysmex XP-300 analyzer were available as instrument printouts scanned into the patient chart. These reports were identified only by patient name; some by first and last name, others by last name only. No other unique identifier was used. In an interview at the site on 04-10-2018, testing person 1 stated that all hematology reports produced at the site were scanned to the patient chart in this way. II. Based on review of patient test reports for 2016, 2017 and 2018, the laboratory failed to indicate the address of the laboratory on patient hematology reports. Findings: 1. Patient test reports scanned into patient charts showed the laboratory location as Southeast Texas Occupational Med, Port Arthur, TX. No street address was included. In an interview at the site on 04-10-2018, testing person 1 stated that all hematology reports produced at the site were scanned to the patient chart in this way. .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on review of patient reports for 2017 and 2018, confirmed by staff interview, the laboratory failed to provide reference intervals for hematology reports. Findings: 1. Patient test reports were reviewed. Hematology reports from the Sysmex XP-300 analyzer were available as instrument printouts scanned into the patient chart. These reports did not include reference intervals. No other information on reference intervals or normal values was provided in patient reports. In an interview at the site on 04-10-2018, testing person 1 stated that all hematology reports produced at the site were scanned to the patient chart in this way. .
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 deficiencies found in the following areas, the laboratory director failed to provide overall management and direction of the laboratory. 1. Proficiency testing. Refer to D6015,D6017. 2. Quality controls. Refer to D6020. 3. Patient result reporting. Refer to D6026. .
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 documentation for 2016, 2017 and 2018, confirmed by staff interview, the laboratory director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program for hematology. Findings: 1. Documentation available for review at the time of the survey did not include proficiency testing results for 2016, 2017 or 2018. When requested, testing person 1 offered a purchase order dated 12-30-2017 and submission documentation for the first event of 2018 for the American Proficiency Institute. 2. In an interview at the site on 04-10-2018, testing person 1 stated that prior to the current testing event, no proficiency testing had been ordered or performed since hematology testing had begun in October 2016. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: . Based on review of API proficiency testing documentation for the first event of 2018, confirmed by staff interview, the laboratory director failed to ensure that proficiency testing results were returned according to the testing program timeframe. Findings: 1. Proficiency testing documentation was requested. A packing slip and submission documentation for the first testing event of 2018 were offered. Examination of the attestation statement for the first event showed the testing was performed on 04-09-2018. The API PT schedule for 2018 showed a due date for the first event of 03-30-2018. 2. In an interview at the site on 04-10-2018, testing person 1 (CMS form 209) stated that proficiency testing results for hematology had not been submitted before the first event 2018 deadline. .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	. Based on review of quality control documentation for hematology for 2016, 2017 and 2018, the laboratory director failed to ensure the quality control program was established and maintained to assure the quality of laboratory services provided. Refer to D 5447. .
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: . Based on review of patient test reports, the laboratory director failed to ensure that hematology reports included pertinent information required for interpretation. Refer to 5807. .