Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0690020	05/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Family Practice Associates Llc	1704 South Forest Avenue, Luverne, AL	

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 a review of proficiency testing records, and interviews with the Technical Consultant and the Practice Manager, the surveyor determined the laboratory failed to enroll in proficiency testing (PT) with a CMS-approved PT provider for regulated tests for the 2021 calendar year until the day of the survey. This affected one of three PT events performed in 2021. The findings include: 1. A review of proficiency testing records revealed the laboratory had utilized Accutest PT for the regulated specialty of Hematology, and non-regulated Microscopy tests (Mycology, Parasitology and Urinalysis) in 2018-2020 (with the first event completed by late March to early April in previous years), however no proficiency testing had been performed by the laboratory in 2021. 2. A review of an email dated 4/26/2021 from "One World Support System" (providers of Accutest PT surveys) revealed, "Our records show you did not process your renewal subscription for 2021 ...". 3. During an interview on 5/6 /2021 at 11:46 AM, the surveyor asked if the laboratory had performed PT in 2021; the Technical Consultant stated she realized the PT survey was late, so she contacted Accutest, and was informed the renewal subscription was not received. The laboratory had already missed performing the first event. The Consultant then notified the Practice Manager, who paid for the renewal. The surveyor requested documentation

	verifying enrollment in 2021. 4. The interview continued at 11:48 AM, when the Technical Consultant returned with the Practice Manager, who stated she had not completed the 2021 PT renewal yet; the Manager completed the payment process by phone, and the order was received at 11:53 AM on the day of the survey (5/6/2021). The surveyor explained the laboratory must have a mechanism to ensure PT from a CMS-approved PT provider is ordered annually, to include three PT survey events for all regulated tests. .
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2018-2020 Accutest proficiency testing (PT) records and an interview with the Technical Consultant, the laboratory failed to implement and document corrective actions for proficiency testing results less than one-hundred percent (%). This affected two out of eight PT events reviewed. The findings include: 1. A review of the survey results revealed no documentation of investigation or corrective action for two surveys with results less than 100%, as follows: A) 2020-Event #2 Hematology with a failing score of 67% for the WBC (White Blood Cell Count) Differential (Individual scores, as follows: Granulocyte % and Monocyte %, each 60%, and Lymphocyte % was 80%). There was no documentation the cause of the failure had been investigated, with corrective action implemented. B) 2020-Event #3 Hematology with scores of 80% for Hematocrit, Platelets and the WBC Differential (with individual scores for Granulocyte %, Monocyte %, and Lymphocyte % of 80% each). The Technical Consultant had written "Reviewed log and CBC printout" on the page with the Granulocyte % score, however there was no documentation of review or corrective action for the other analytes. 2. During an interview at 11:40 AM on 5/6/2021, the Technical Consultant checked the Quality Assurance records, however no corrective actions were documented; the Technical Consultant then confirmed the above noted findings. .
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 a review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer, quality assurance records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to verify the manufacturer's performance specifications for precision before patient testing began on one of one Hematology analyzers. The findings include: 1. A review of the installation and validation records for the Horiba ABx Micros 60 Hematology

	analyzer revealed the Horiba technician calibrated the instrument on 7/20/2020. The manufacturer's instructions specified precision studies should be performed before the instrument calibration, however there was no documentation precision was verified. 2. A review of quality assurance records revealed patient testing on the Horiba ABx Micros 60 Hematology analyzer began on 7/20/2020. 3. During an interview and review of these records on 5/6/2021 at 12:30 PM, the surveyor asked if precision was verified during the installation; the Technical Consultant was unable to print precision studies from the Micros 60, and was unable to find any record precision was verified. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on reviews of the Horiba ABx Micros 60 Hematology analyzer records, the M60 Calibration Guide, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to perform calibrations as per manufacturer's instructions during July 2020 installation, and failed to follow the laboratory's procedure on calibration frequency in 2020-2021. This affected one of one Hematology analyzers. The findings include: 1. A review of the "M60 Calibration Guide when using LITE DM" revealed, "Clean First ... Precision Second:" "5. Precision is done using the "REPRO" QC file in the LITE DM computer. ..." 2. A review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer revealed the Horiba technician calibrated the instrument on 7/20/2020, however there was no documentation precision was verified as per manufacturer's instructions. [Refer to D5421.] 3. During an interview on 5/6/2021 at 12:35 PM, the surveyor asked if a calibration with precision had been performed since the installation; the Technical Consultant answered, "No', because she "had not gotten around to ordering a calibrator". The surveyor then asked how often a calibration should be performed; the Technical Consultant stated in the past, the usual policy was to perform a calibration every six months. .
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 reviews of the Hematology quality control (QC) records and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on two days in 2019-2020. The findings include: 1. A review of the Hematology records for revealed no documentation of QC on 6/10/2019 and 12/6/2020. 2. During interviews on 5/6/2021 at 1:50 and 2:10 PM, the Technical Consultant confirmed no QC was performed on the above dates. When asked if patient testing was performed, the Technical Consultant checked the patient records; ten patient CBC's (Complete Blood Counts) were run on 6/10/2019, and four CBC's on 12/6/2020. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of laboratory records, quality assurance documentation and interviews with the Technical Consultant, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems in the following areas: A. Proficiency Testing (PT) Enrollment--Failure to ensure PT from a CMS-approved PT provider was ordered in a timely manner, to include three PT survey events for all regulated tests. [Refer to D2000.] B. Proficiency Testing--Failure to investigate and implement corrective actions for analytes with results less than 100 percent [Refer to D5221.] C. Analyzer Validation--Failure to ensure all procedures verifying the manufacturer's performance specifications for the analyzer were performed and documented; and ensure the validation was reviewed and approved (as indicated by a signature and date), before patient testing began. [Refer to D5421 and D6040.] D. Hematology Calibrations--Failure to perform calibrations as per manufacturer's instructions, and with the frequency established by the laboratory [Refer to D5437.] E. Hematology Quality Control--Failure to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results [Refer to D5447.] 2. In the exit summation on 5/6/2021 at approximately 2:35 PM, the surveyor reviewed and confirmed the above concerns with the Technical Consultant. .
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by:

	Based on reviews of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer, quality assurance records, and an interview with the Technical Consultant, the surveyor determined the Technical Consultant failed to ensure the manufacturer's performance specifications for precision were verified, and failed to document review and approval of the validation before patient testing began. This affected one of one Hematology analyzers. The findings include: 1. A review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer revealed the Horiba technician calibrated the instrument on 7/20/2020, however there was no documentation precision was verified. [Refer to D5421.] 2. A further review of the validation records for the Horiba ABx Micros 60 revealed no documentation of the Technical Consultant's review and approval (as indicated by a signature and date). 3. A review of quality assurance records revealed patient testing on the Horiba ABx Micros 60 began on 7/20/2020. 4. During an interview on 5/6 /2021 from 12:25 to 12:35 PM, the Technical Consultant confirmed the above noted findings. SURVEYOR ID# 32558 Licensure and Certification Surveyor