Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0690020	03/03/2023
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
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 a review of the Accutest proficiency testing (PT) records, a review of the personnel files, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. The previous Technical Consultant (who was also a testing personnel) performed all testing on five of five PT surveys reviewed from 2021 - 2022. The finding include: 1. A review of the 2021 - 2022 Accutest PT records revealed the Technical Consultant (who left in October 2022) had signed all attestation statements as the testing personnel on the 2021- Cycle #2 and #3, and 2022-Cycle #1, #2, and #3 surveys. 2. A review of the personnel files revealed Testing Personnel #1 was a full time employee and had been trained to perform moderate complexity patient testing since the previous CLIA survey on 5/6/2021. Testing Personnel #2 was trained to perform moderate complexity patient testing on 3/10 /2022. However, the Technical Consultant had failed to rotate PT testing between all testing personnel who routinely performed patient testing. 3. In an interview on 3/3 /2023 at 11:10 AM the surveyor reviewed the requirement for rotation of proficiency testing with Testing Personnel #1, who confirmed the Technical Consultant had performed all the proficiency testing. .
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable

	requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a review of the test menu during the entrance tour, a review of the manufacturer's assay sheet for the Quidel QuickVue SARS [Severe Acute Respiratory Syndrome] Antigen Test, and an interview and email from Testing Personnel #1, the laboratory failed to implement a mechanism to report 53 positive COVID-19 (Coronavirus disease 2019) results, as required to the Alabama Department of Public Health (ADPH) after testing began on 11/8/2022 through the date of the survey on 3/3/2023. The findings include: 1. During the entrance tour on 3/3/2023 at 9:10 AM, the surveyor reviewed the laboratory test menu and confirmed the laboratory performed COVID-19 testing using the Quidel QuickVue SARS Antigen Test kit. When asked if the laboratory reported COVID-19 results to ADPH, Testing Personnel #1 stated she needed to check. 2. A review of the manufacturer's assay sheet for the Quidel QuickVue SARS Antigen Test, under "Conditions of Authorization for the Laboratory and Patient Care Settings" revealed "...Authorized laboratories using your product must have a process in place for reporting test results to ... relevant public health authorities, as appropriate." 3. During an interview on 3/3/2023 at 9:55 AM, Testing Personnel #1 confirmed the facility had no mechanism to report positive COVID-19 results to ADPH. 4. In a 3/16/2023 email, Testing Personnel #1 confirmed the laboratory had started testing on 11/8/2022, and 53 patients had positive COVID-19 results. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of temperature logs, a review of the manufacturer's storage requirements for Horiba Minotrol Quality Controls (QC), and an interview with Testing Personnel #1, the laboratory failed to ensure the refrigerator maintained temperatures required for the storage of items therein, as per manufacturer's specifications for 19 days from July through December 2021. The findings include: 1. A review of the refrigerator temperature logs revealed acceptable ranges of 2-8 degrees Celsius (C), however, temperatures were below this range for 19 days from July through December 2021. 2. During the exit summation on 3/3/2023 at 2:05 PM, the surveyor reviewed and confirmed the above noted findings with Testing Personnel

	#1. Contents of the refrigerator included the Horiba Minotrol Hematology QC, with storage requirements of 2-8 degrees Celsius. Testing Personnel #1 confirmed the QC was stored at temperatures below the manufacturer's requirements in 2021. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Horiba ABx Micros 60 Hematology records, and an interview with Testing Personnel #1, the laboratory failed to ensure weekly maintenance was performed and documented, as per the manufacturer's instructions six out of seven months reviewed in 2021. The findings include: 1. A review of the Horiba ABx Micros 60 records revealed the laboratory failed to perform and document the weekly maintenance each week in June, July, August September October and December 2021. 2. A review of the "M60 Daily User Guide When Using Lite DM" revealed, "... Concentrated Cleaning should be done weekly or more often as needed ...". 3. During an interview on 3/3/2023 at 12:55 PM, Testing Personnel #1 confirmed the above noted findings. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the Form CMS-209 (Laboratory Personnel Report) and interviews with Testing Personnel #1 and the Laboratory Director, the Laboratory Director failed to ensure the position of Technical Consultant was filled with a person having appropriate educational credentials or experience after the previous Technical Consultant left in October 2022 until the date of the survey on 3/3/2023. The findings include: 1. Refer to D6035. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of the Form CMS-209 (Laboratory Personnel Report) and interviews with Testing Personnel #1 and the Laboratory Director, the laboratory failed to fill the position of Technical Consultant with a qualified individual after the previous Technical Consultant left in October 2022 until the date of the survey on 3/3 /2023. The findings include: 1. Refer to D6035. .
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of the Form CMS-209 (Laboratory Personnel Report) and interviews with Testing Personnel #1 and the Laboratory Director, the laboratory failed to fill the position of Technical Consultant with a person having appropriate educational credentials or experience after the previous Technical Consultant left in October 2022 until the date of the survey on 3/3/2023. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed the laboratory failed to list an individual in the Technical Consultant position. 2. During an interview on 3/3/2023 at 9:35 AM, the surveyor asked if the laboratory had a Technical

	Consultant (TC). Testing Personnel #1 stated she had assumed the responsibilities as Technical Consultant after the previous TC left in October 2022. When the surveyor asked about her educational credentials, Testing Personnel #1 stated she has an Associates in Science degree as an LPN (Licensed Practical Nurse); the surveyor then reviewed the requirement to have at least a Bachelor of Science degree in a chemical, physical or biological science or medical technology, and explained Testing Personnel #1 could not qualify as the Technical Consultant. 3. During an interview on 3/3/2023 at 10:20 AM, the surveyor then asked the Laboratory Director if he had "hands-on, in the laboratory" experience; the Director confirmed he did not. The surveyor then explained she was unable to qualify the Laboratory Director or Testing Personnel #1 as the Technical Consultant. .
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 a review of personnel files and an interview with Testing Personnel #1, the previous Technical Consultant failed to ensure one of one new testing personnel provided educational credentials before performing patient CBC (Complete Blood Count) testing. The findings include: 1. A review of employee files of testing personnel listed on the Form CMS-209 (Laboratory Personnel Report) revealed Testing Personnel #2 was trained to perform CBC's on 3/10/2022, however, the file had no documentation of the employee's educational credentials. 2. During a review of the file and an interview on 3/3/2023 at 10:00 AM, Testing Personnel #1 confirmed the above noted findings. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel files and an interview with Testing Personnel #1, the laboratory failed to ensure a qualified Technical Consultant performed/approved the semi-annual competency assessment for one of one new testing personnel. The findings include: 1. A review of employee files of testing personnel listed on the Form CMS-209 (Laboratory Personnel Report) revealed the 10/10/2022 semi-annual competency assessment for Testing Personnel #2 was performed and signed by Testing Personnel #1. 2. During an interview on 3/3/2023 at 9:35 AM, Testing Personnel #1 stated she had assumed the responsibilities as Technical Consultant (TC) after the previous TC left in October 2022. When the surveyor asked about her educational credentials, Testing Personnel #1 stated she has an Associates in Science degree as an LPN (Licensed Practical Nurse); the surveyor then reviewed the requirement to have at least a Bachelor of Science degree in a chemical, physical or

	biological science or medical technology, and explained Testing Personnel #1 could not qualify as the Technical Consultant. 3. During an interview on 3/3/2023 at 10:00 AM, Testing Personnel #1 confirmed her signature was on the semi-annual competency assessment for Testing Personnel #2. SURVEYOR ID#32558 Licensure and Certification Surveyor