Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227910	02/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Family Practice Associates Of Chesterfield	13911 St Francis Boulevard - Suite 101, Midlothian, VA	

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	An announced CLIA recertification survey was conducted at Family Practice Associates of Chesterfield on February 2, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
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 Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, and interview, the laboratory failed to rotate five (5) of 5 PT among testing personnel (TP) performing patient chemistry tests utilizing the Olympus and TOSOH analyzers during the twenty-two (22) months reviewed. *REPEAT DEFICIENCY Findings include: 1. During an entrance interview on 02/02/23 at approximately 10:00 AM, the inspector reviewed the laboratory's CMS 209 and CMS 116 forms with the laboratory manager. During the review, TP #1 and TP #2 were identified as responsible for performing non waived patient chemistry testing (General, Immunochemistry, Endocrinology, Glycohemoglobin) utilizing analyzers Olympus AU400, TOSOH G8, and TOSOH A1A 360 during the 22 months reviewed (April 2021 to the date of the inspection, 02

	/02/23). See Personnel Code Sheet. 2. Review of the laboratory's American Proficiency Institute (API) PT records, a total of five (5) testing modules, revealed that TP #1 signed attestations as having performed the following Core Chemistry, Immunochemistry, Endocrinology, and Glycohemoglobin testing events: 2021 API Event 3; 2022 API Event 1; 2022 API Event 2; 2022 API Event 3; 2023 API Event 1. TP #1 performed 5 of 5 PT modules for the 22 months reviewed. 3. An interview with the laboratory manager on 02/02/23 at approximately 3:30 PM confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's 2021 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), CMS Laboratory Personnel Report form (CMS 209), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, manufacturer's operations manual, procedures/quality assurance (QA) policies, analyzer/equipment maintenance records, tour, lack of documentation, and interviews, the laboratory failed to: 1. follow an established laboratory director approved corrective action procedure to ensure that PT samples be rotated for testing by personnel who perform non-waived testing, using the laboratory's routine methods (review timeframe of April 2021 to February 2, 2023) See D5401; 2. document performance of required every six month and annual Tosoh G8 analyzer preventative maintenance during the twenty-two (22) months reviewed (review timeframe: April 2021 - 02/02/23) See D5429 (A and B); 3. document maintenance calibration checks for four (4) of 4 pipettes utilized for patient chemistry testing during the 22 months reviewed (April 2021 to 02/02/23) See D5433.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 2021 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), CMS Laboratory Personnel Report form (CMS 209), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to follow an established laboratory director (LD) approved corrective action procedure to ensure that PT samples be rotated for testing by personnel who

	performed non-waived chemistry testing in the laboratory, using the laboratory's routine methods for the review timeframe of April 2021 to February 2, 2023. Cross Reference D2007. Findings include: 1. Review of the laboratory's CMS-2567 POC (LD signed/approved 05/18/21) revealed a corrective action plan for PT rotation that stated, "Effective 05/03/2021 or upon receipt of next proficiency testing - testing personnel who perform all non-waived chemistry testing to include General, Immunochemistry, Endocrinology, HbA1c, and LDL will both participate in testing of proficiency samples. This will be overseen by the lab director when review and signature of the attestations for PT are recorded." 2. Review of the laboratory's CMS 209 and CMS 116 forms revealed that the LD identified TP #1 and TP #2 as responsible for performing non waived patient chemistry testing (General, Immunochemistry, Endocrinology, Glycohemoglobin) utilizing analyzers Olympus AU400, TOSOH G8, and TOSOH A1A 360 during the 22 months reviewed (April 2021 to the date of the inspection, 02/02/23). See Personnel Code Sheet. 3. Review of the laboratory's American Proficiency Institute (API) PT records, a total of five (5) testing modules, revealed that TP #1 signed attestations as having performed 2021 API Event 3, 2022 API Events 1-3, and 2023 API Event 1 for Modules Core Chemistry, Immunochemistry, Endocrinology, Glycohemoglobin. The inspector requested to review chemistry PT performance documentation by TP #2. No records were available. TP #1 performed 5 of the 5 PT modules for the 22 months reviewed. 4. An interview with the laboratory manager on 02/02/23 at approximately 3:30 PM confirmed the above findings.
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: A. Based on a review of manufacturer's operations manual, procedures/quality assurance (QA) policies, endocrinology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required every six month preventative maintenance during the twenty-two (22) months reviewed (review timeframe: April 2021 - February 2, 2023). Findings include: 1. Review of the Tosoh Bioscience G8 Operations Manual revealed manufacturer's instructions to "Perform fluid line suction filter replacement on the inlet end of the elution buffer tube in order to remove foreign particles every 6 months. If the suction filter becomes clogged, the pump will not operate normally and reliable results may not be obtained. Make sure to periodically replace the filter. Replace all three filters at the same time. Foreign particles inside the filter cannot be removed by cleaning. Replace with new every 6 months." 2. Review of the laboratory procedure manual revealed a QA Policy (titled: Quality Control and Instrumentation) that stated, "The laboratory will follow manufacturer's recommendations for instrument maintenance." 3. During a review of the laboratory's Tosoh G8 endocrinology maintenance logs, the inspector noted that a required procedure denoted as "Every 6 Months: Replace Fluid Supply Line Filters" was outlined on each monthly log. Review of the logs from April 2021 to the date of the inspection on 02/02/23 revealed no documentation of the required supply line filter maintenance as outlined above. The inspector requested to review documentation for the every six month maintenance for the 22 months of review. No records were available. 4. An

	interview with the laboratory manager on 02/02/23 at approximately 3:30 PM confirmed the above findings. B. Based on a review of manufacturer's operations manual, endocrinology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required annual preventative maintenance (PM) in calendar year 2022 (timeframe reviewed January 2022 - February 2, 2023). Findings include: 1. Review of the Tosoh Bioscience G8 Operations Manual revealed manufacturer's instructions for the following required maintenance to be performed annually by field service personnel: Needle O-Ring - replaced annually; Check/Verify Bar Code Reader, End Marker Sensor, Sample Sensor, Needle Descent Positioning; Clean Dilution Port and Wash Assembly; Check screws of sampling unit, column oven temperature, solenoid valve (3 action locations), vacuum pump action; Replace the rotor seal of injection valve, rotor seal of AS valve, sample loop, plunger seal, Teflon tip of syringe; Lubricate pump drive unit. 2. Review of the laboratory procedure manual revealed a QA Policy (titled: Quality Control and Instrumentation) that stated, "The laboratory will follow manufacturer's recommendations for instrument maintenance." 3. Review of the available G8 maintenance records revealed no documentation of the annual required PM protocols as outlined above. The inspector requested to review a field service PM record for the G8 analyzer during calendar year 2022 to the date of the inspection on 02/02/23. No record was available for review. 4. An interview with the laboratory manager on 02/02 /23 at approximately 3:30 PM confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a tour, a review of procedures, manufacturer's instruction manual, equipment calibration records, and an interview, the laboratory failed to document maintenance calibration checks for four (4) of 4 Diamond pipettes utilized for patient chemistry testing during the twenty-two months reviewed (April 2021 to February 2, 2023). Findings include: 1. During a tour of the laboratory at approximately 11:00 AM, the inspector noted the following 4 Diamond pipettes in the chemistry testing area - listed by serial number (SN): SN999427 (10 -100 ul), SN1036409 (1000 ul), SN1046410 (2000 ul), and SN1028809 (5000 ul). The inspector inquired regarding the use for the pipettes and was informed by the lead tech that the 10 L-100 L Diamond pipette was utilized for preparing controls and calibrators for glycated hemoglobin testing on the TOSOH G8 analyzer, and that the other three were used to prepare controls, calibrators, and dilutions for processing samples on the Olympus AU400 and Tosoh A1A analyzers. 2. A review of the laboratory's procedure manual revealed a quality assurance (QA) policy that stated "all manufacturer's maintenance requirements will be followed and documented". 3. Review of the Diamond Instruction Manual (located in the procedure manual), revealed manufacturer's instructions for pipette calibration frequency "at least once a year". 4. Review of the laboratory's equipment calibration records from April 2021 to 02/02/23 revealed no

	annual pipette checks or verifications. The inspector requested pipette calibration documentation for the 4 pipettes outlined above. No records were available for review. The laboratory manager stated on 02/02/23 at approximately 2:00 PM, "I have asked our equipment maintenance company if they would check the pipettes when they are here for all the other annual checks. They do not do pipette calibrations." 5. An interview with the laboratory manager on 02/02/23 at approximately 3:30 PM confirmed the above findings.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: A. Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual hematology competency assessments that included review of test results/worksheets, proficiency testing, or trouble shooting/preventative maintenance for Complete Blood Count (CBC) patient testing for fifteen (15) of sixteen (16) testing personnel (TP) in the twenty-two (22) months reviewed. Findings include: 1. During an entrance interview with the laboratory manager on 02/02/23 at approximately 10 AM, a review of the CMS 209 form revealed that the laboratory director (LD) performed duties of the TC and identified 16 TP responsible for moderate complexity CBC patient testing during the review timeframe of April 2021 through 02/02/23. 2. During a review of the available Medonic hematology competency assessment documentation, the inspector noted that the competency assessments for TP #2 - TP #16 consisted of a check mark on a column header labeled "Performance Controls, Order CBC, Upload to EMR" with no additional evaluation. Review of the assessments revealed the criteria recorded lacked required competency procedural elements of review of test results/worksheets, proficiency testing, trouble shooting/preventative maintenance monitoring for the Medonic analyzer operation. (See Personnel Code Sheet.) 3. An interview with the laboratory manager on 02/02/23 at approximately 3:30 PM confirmed the above findings. B. Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual chemistry competency assessments that included review of test results/worksheets, proficiency testing, or trouble shooting/preventative maintenance for Tosoh G8, Tosoh A1A, Olympus AU400 patient testing for one (1) of two (2) testing personnel (TP) in the twenty-two (22) months reviewed. Findings include: 1. During an entrance interview with the laboratory manager on 02/02/23 at approximately 10 AM, a review of the CMS 209 form revealed that the laboratory director (LD) performed duties of the TC and identified 2 TP responsible for moderate complexity General Chemistry, Immunochemistry, Endocrinology, and Glycohemoglobin patient testing during the review timeframe of April 2021 through 02/02/23. 2. Review of the available chemistry competency assessment documentation for TP #2 revealed the criteria recorded lacked required competency procedural elements of review of test results /worksheets, proficiency testing, trouble shooting/preventative maintenance

	monitoring for the Tosoh G8, Tosoh A1A, Olympus AU400 chemistry analyzers' operation. (See Personnel Code Sheet) 3. An interview with the laboratory manager on 02/02/23 at approximately 3:30 PM confirmed the above findings.