

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227910	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Family Practice Associates Of Chesterfield	Street Address, City, State 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 November 29, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2004	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on a review of 2017 proficiency testing (PT) records and interview, the laboratory failed to participate in one (1) approved PT program for the year before designating a change in programs. Findings include: 1. Review of the laboratory's 2017 PT records, a total of three (3) events, for hematology and chemistry revealed the laboratory enrolled and was scored by the following PT providers: 2017 1st Event- College of American Pathologists (CAP) for General Chemistry, Endocrinology, and Hematology Auto Differentials; 2017 2nd Event - American Proficiency Institute (API) for Routine Chemistry, Chemistry Endocrinology, and Hematology; 2017 3rd Event - American Proficiency Institute (API) for Routine Chemistry, Chemistry Endocrinology, and Hematology. The inspector inquired regarding the change from CAP to API for PT in 2017. The lead tech stated: "we were not satisfied with API in calendar year 2016 and wanted to try CAP. CAP's format was hard to use so we decided to switch back to API in 2017 after the first event". 2. In an interview with the practice manager and lead tech at approximately 4:00 PM, it was confirmed that the</p>

	<p>laboratory failed, in 2017, to participate in one approved PT program for chemistry and hematology testing for a year before designating a change in programs as outlined above.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for Albumin in one (1) out of six (6) routine chemistry testing events reviewed. Findings include: 1. Review of the laboratory's 2017 and 2018 PT records, a total of 6 events, revealed Albumin scores of less than 80 % for the following routine chemistry event: 2017 College of American Pathologists C-A General Chemistry 1st Event : score 40% (samples CHM-03, CHM-04, CHM-05 were scored as unacceptable). 2. In an interview with the practice manager and lead tech at approximately 4:00 PM, it was confirmed that the laboratory received an unsatisfactory performance score for Albumin on the chemistry PT event listed above.</p>
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, and an interview, the laboratory failed to document corrective action for unsatisfactory Albumin scores received in one (1) of six (6) routine chemistry events in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's 2017 and 2018 PT documentation, a total of 6 events, revealed that the laboratory failed to document corrective or remedial action for: 2017 College of American Pathologists (CAP) C-A General Chemistry 1st Event : Albumin score reported as 40% (samples CHM-03, CHM-04, CHM-05 were scored as unacceptable). The inspector requested to review documentation of remedial action for the unacceptable analyte scores. No records were available. 2. In an interview with the practice manager and lead tech at approximately 4:00 PM, it was confirmed that the laboratory failed to document corrective action for the unsatisfactory Albumin scores listed above in 2017.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and an interview, the laboratory failed to verify the accuracy of directly measured Low Density Lipoprotein Cholesterol (LDL-C) chemistry testing performed on the Olympus AU 400 analyzer twice annually in calendar year 2017. Findings include: 1. Review of the laboratory's 2017 PT documentation, a total of three (3) events, revealed the laboratory utilized PT enrollment to verify the AU 400 analyzer's LDL-C test accuracy. A review of the PT reports revealed the laboratory failed the accuracy verification twice in calendar year 2017 by receiving the following scores: 2017 1st Event with College of American Pathologists (CAP) C-A General Chemistry: 60% Unsatisfactory Score, 2017 2nd Event with American Proficiency Institute (API) Routine Chemistry: 0% Unsatisfactory Score. 2. In an interview with the practice manager and lead tech at approximately 4:00 PM, it was confirmed that the laboratory, by receiving the unsatisfactory scores outlined above, failed to successfully verify twice annually the accuracy of directly measured LDL-C testing in 2017.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on a tour, review of policies and procedures, manufacturer's package inserts, daily temperature logs, and interviews, the laboratory did not establish a policy or follow manufacturer's instructions for storage of patient samples when testing was delayed for seven (7) analytes assayed on the Olympus AU 400 analyzer and three (3) analytes assayed on the TOSOH A1A analyzer in the twenty-three (23) months reviewed. Findings include: 1. During a tour of the laboratory at approximately 12:00 PM, the inspector noted one (1) Gibson refrigerator/freezer unit in use for storing reagents and patient samples. The inspector noted the freezer compartment was filled to capacity with patient samples and inquired regarding the storage protocols. The lead tech stated: "we store all of our patient samples in the freezer for a month to allow time for the doctors to add on testing as needed". During the tour, the inspector reviewed the Olympus AU 400, TOSOH G8 and A1A analyzers' November 2018 maintenance log-sheets and noted the lead tech's signature and initials on all entries. The inspector inquired how many testing personnel (TP) were responsible for patient testing on the analyzers. The lead tech stated: "I am the only person that runs the chemistry analyzers. Our other staff run hematology and kit tests but I am the only one who runs the three chemistry machines". The lead tech stated: "On the weekend and days that I am not here, the other staff will leave samples in the refrigerator until I am able to run them". 2. Review of the laboratory's policies revealed no procedure for patient sample storage when processing delays occur or protocols for adding test orders to frozen samples. The laboratory's temperature policy stated: "record temperatures on a daily basis on the Temperature Log". The Temperature Log sheet

indicated the freezer parameters acceptable range as "zero (0) to minus fifteen (-15) degrees Celsius (C)" and refrigerator as "two (2) to eight (8) degrees C". 3. Review of the AU 400 reagent package inserts revealed manufacturer's specimen storage and stability requirements that stated: Alanine Aminotransferase (ALT) - "is stable for seven days refrigerated (2-8 C), and thirty days frozen at - 20 C; Alkaline Phosphatase (ALP) - "serum samples should be stored at 2 - 8 C and run within two days; Aspartate Aminotransferase (AST) - "is stable ten days refrigerated (2-8 C) or two weeks frozen at - 20 C; Creatinine - "serum is stable for twenty-four hours at 2-8 C and three months when frozen at - 20 C; Glucose - "stable for up to three days stored at 4 C; Total Bilirubin - "samples should be analyzed within twelve hours if stored refrigerated (2-8 C) and stable for three months when stored frozen at - 20 C; Triglyceride - "serum may be stored for one week at 2-8 C or three months at - 20 C". Review of the TOSOH reagent package inserts revealed a manufacturer's specimen storage and stability requirement that stated: Prostate Specific Antigen (PSA) - "is stable for seven days refrigerated (2-8 C), and sixty days frozen (- 20 C or colder); Thyroid Stimulating Hormone (TSH) - "is stable for seven days refrigerated (2-8 C), and sixty days frozen (- 20 C or colder); Thyroxine (FT4) - "is stable for seven days refrigerated (2-8 C), and sixty days frozen (- 20 C or colder). 4. Review of the daily Gibson freezer temperature logs for calendar year 2017 and up to the date of survey on 11/29/18 revealed that the storage temperature recorded was outside of the manufacturer's stability requirements of -20 C or colder for the nine (9) analytes ALP, ALT, AST, Creatinine, Total Bilirubin, Triglyceride, PSA, TSH, and FT4 for each recording in the twenty-three (23) months reviewed. 5. In an interview with the practice manager and lead tech at approximately 4:00 PM, it was confirmed that the laboratory did not establish protocols or document that they followed the Olympus AU 400 and TOSOH A1A reagent storage requirements for patient samples when testing was delayed beyond the date of collection for the chemistry analytes outlined above in the 23 months reviewed.

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 tour, a review of procedures, manufacturer's instruction manual, equipment calibration records, and an interview, the laboratory failed to document maintenance calibration protocols, from November 2016 to the date of the survey on 11/29/18, for the Diamond pipette utilized for patient glycated hemoglobin testing according to the manufacturer's instructions. Findings include: 1. During a tour of the laboratory at approximately 12:00 PM, the inspector noted a Diamond pipette in the chemistry testing area. The inspector was informed by the lead tech that the 10 L-100 L Diamond pipette (Serial Number 323203) was utilized for preparing controls and calibrators for glycated hemoglobin testing on the TOSOH G8 analyzer. 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 to: "calibrate the pipette at least once a year". 4. Review of the laboratory's equipment calibration records from November 2016 to 11/29/18 revealed one (1) calibration record for the Diamond Pipette (Serial

Number 323203) dated 4/4/2009. The inspector requested additional pipette calibration documentation. No records were available for review. 5. In an interview with the practice manager and lead tech at approximately 4:00 PM, it was confirmed that the laboratory failed to document the Diamond pipette calibration, according to the manufacturer's guidelines as outlined above, during the twenty-four (24) months reviewed.

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, review of procedures, equipment maintenance logs, and interviews, the laboratory failed to establish maintenance protocols for the chemistry Eppendorf variable volume pipetter during the twenty-four (24) months reviewed. Findings include: 1. During a lab tour, at approximately 12:00 PM, the inspector noted an Eppendorf pipette controller located in the chemistry testing area. The inspector inquired regarding the use and the lead tech stated: "we use the Eppendorf to make up reagents, controls, and calibrators for the Olympus AU 400 and TOSOH analyzer". 2. Review of the laboratory's procedures revealed no policy or manufacturer's instructions for the maintenance, cleaning, or calibration of the Eppendorf Pipette Controller (Serial Number 4423010). The inspector requested to review written maintenance protocols for the pipetter. No documentation was available for review. No manufacturer's guide or package insert was available for review. 3. Review of the laboratory's equipment maintenance records from November 2016 to 11/29/18 revealed no documentation for the Eppendorf Pipette device. 4. The inspector called the technical support division for Eppendorf, at approximately 3:00 PM, to inquire about the operating manual for the pipetter Serial Number 4423010. The technical support team member stated: "the units do come with an operating manual that lists safety, operation instructions, troubleshooting, and maintenance instructions. We recommend that all operators read the manual completely before using the device and to observe the maintenance and cleaning instructions". 5. In an interview with the practice manager and lead tech at approximately 4:00 PM, it was confirmed that the laboratory failed to establish maintenance protocols for the Eppendorf variable volume pipetter, listed above, located in the chemistry testing area.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to

identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and an interview, the laboratory director (LD) failed to document evaluation and corrective action plan for unsatisfactory Albumin scores received in one (1) of six (6) chemistry events in the twenty-four (24) months reviewed (Cross Reference D 2094) and failed to evaluate /verify the accuracy of directly measured Low Density Lipoprotein Cholesterol (LDL-C) chemistry testing performed on the Olympus AU 400 analyzer twice annually in calendar year 2017 (Cross Reference D 5217).

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), available personnel records, and an interview with the practice manager and lead tech at approximately 4:00 PM on 11/29/18, it was confirmed that the laboratory director failed to maintain documentation of personnel qualifications for one (1) of seven (7) new testing personnel in the twenty-four (24) months reviewed. Cross Reference D 6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

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), available personnel records, and an interview, the laboratory failed to maintain documentation of personnel qualifications for one (1) of seven (7) new testing personnel (TP) trained to assay and report complete blood count (CBC) results in the twenty-four (24) months reviewed. Findings include: 1. Review of the CMS 209 form with the lead tech, at approximately 11:45 AM, revealed seven (7) TP of the twenty-one (21) TP listed were considered new hires in 2017 and 2018. 2. Review of the laboratory's personnel records for the 7 new TP revealed initial CBC

testing training and education signed by the laboratory director (LD) for the following personnel on the following dates: TP A on 9/25/17; TP B on 12/12/17; TP C on 12/27/17; TP D on 1/25/18; TP F on 8/22/18; TP G on 10/18/18. The inspector noted no documentation of education for TP E whose initial training was recorded on 4/30/18. The inspector requested to review education documentation for TP E. No records were available for review. (See attached Personnel Code Sheet.) 3. In an interview with the office manager and lead tech at approximately 4:00 PM, it was confirmed that the laboratory failed to maintain documentation of education qualifications for TP E as outlined above.