

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227910	(X3) Date Survey Completed 04/28/2021
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	<p>An announced CLIA recertification survey was conducted for Family Practice Associates of Chesterfield on April 27-28, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance interview and initial record review conducted remotely on 04/26/21. 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 Regulations. Specific deficiencies cited are as follows:</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>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 interviews, the laboratory failed to rotate PT among testing personnel (TP) performing patient chemistry tests utilizing the Olympus and TOSOH analyzers during the twenty-seven (27) months reviewed. Findings include: 1. During an entrance interview on 4/26/21 at approximately 11:00 AM, the inspector reviewed the laboratory's CMS 209 form with the primary laboratory tech. The review revealed Testing Personnel (TP) #1 and TP #2 were identified as responsible for performing non waived patient chemistry testing (General, Immunochemistry, Endocrinology, Glycohemoglobin) during the 27 months reviewed (January 2019 to 4/26/21). See Personnel Code Sheet. 2. Review of the CMS 116 form revealed the laboratory utilized analyzers Olympus AU400 (Serial</p>

Number 9060461), TOSOH G8 (SN 11219006), and TOSOH A1A 360 (SN 11878301) for non waived chemistry testing during the review timeframe. 3. Review of the laboratory's American Proficiency Institute (API) PT and twice annual Olympus AU400 Low Density Lipoprotein (LDL) spilt sample proficiency records, a total of twelve (12) testing modules, revealed that TP #1 signed attestations as performed the following testing events reviewed: 2019 API Events 1-3 for Modules Core Chemistry, Immunochemistry, Endocrinology, Glycohemoglobin; 2019 Olympus AU400 Low Density Lipoprotein (LDL) spilt sample events 1 and 2; 2020 API Events 1-3 for Modules Core Chemistry, Immunochemistry, Endocrinology, Glycohemoglobin; 2020 Olympus AU400 Low Density Lipoprotein (LDL) spilt sample events 1 and 2. TP #1 performed twelve (12) of the 12 chemistry PT modules in the ten events for the 27 months reviewed. 4. In an interview with the primary testing personnel on 4/28/21 at approximately 1:30 PM, the above findings were confirmed.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of procedures, manufacturer package inserts, chemistry analyzer calibration verification records, patient test logs, lack of documentation, and interviews, the laboratory failed to follow their procedure to document TOSOH analyzer Prostate Specific Antigen (PSA) calibration verification twice annually in calendar year 2020. Findings include: 1. Review of the laboratory's procedures for the TOSOH analyzer and manufacturer's PSA package insert revealed instructions to "perform calibration verification at least once every six months for the PSA". 2. Review of the laboratory's TOSOH A1A calibration verification records for calendar year 2020 revealed one PSA calibration verification was performed (dated 07/01/20). The inspector requested to review additional documentation of PSA calibration verification performed in calendar year 2020. The documentation was not available for review. The lead testing personnel stated: "I did PSA verification again on 3/3/21. Our policy is to perform it every six months but there was a delay in getting it

completed." 3. Review of the patient test logs revealed that one hundred ninety (190) patient PSA specimens were resulted during the three month lapse in calibration verification. 4. In an interview with the primary testing personnel on 4/28/21 at approximately 1:30 PM, the above findings were confirmed.