

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0668555	(X3) Date Survey Completed 03/01/2022
Name of Provider or Supplier Commonwealth Primary Care Laboratory	Street Address, City, State 1800 Glenside Drive - Suite 101-A, Richmond, 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 the Commonwealth Primary Care Laboratory on 03/01/22 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5200- 42 C.F.R. 493.1230 Condition: General Laboratory Systems. D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems. The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation and interview with the technical supervisor, the lab failed to verify the accuracy of the urine microalbumin, urine creatinine and C-reactive protein (quantitative) twice a year in 2020. Refer to D5217. **REPEAT DEFICIENCY**</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 procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
****REPEAT DEFICIENCY**** Based on the review of proficiency testing (PT) records, lack of documentation and interview with the technical supervisor, the lab failed to verify the accuracy of the urine microalbumin, urine creatinine and C-reactive protein (quantitative) twice a year in 2020. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed the lab utilizes API PT samples for verification of accuracy twice a year for the urine microalbumin, urine creatinine and C-reactive protein (quantitative), categorized as non-regulated analytes. 2. API provides two events per calendar year for the urine microalbumin and urine creatinine analytes and provides three events for C-reactive protein (quantitative) analyte. Review of API PT results revealed the laboratory received the following scores: 2020 Routine Chemistry Event 1- 33% for urine microalbumin and urine creatinine, 2020 Routine Chemistry Event 2- 100% for both analytes. 2020 Immunology Event 1- 100% for C-reactive protein (quantitative), 2020 Immunology Event 2- 50% for C-reactive protein (quantitative) and 2020 Immunology Event 3- 50% for C-reactive protein (quantitative). On 03/01/22 at approximately 11:15 AM, the surveyor requested the technical supervisor provide documentation of an alternative method(s) for verification of accuracy twice a year for the above-specified analytes in 2020. The documentation was not available for review. 3. An exit interview with the technical supervisor on 03/01/22 at approximately 1715 confirmed the 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 review of policy and procedures (P&P), calibration records, lack of documentation, daily patient test log and interview, the lab failed to follow the established P&P for calibration of the Human Chorionic Gonadotropin (HCG) and Follicle Stimulating Hormone (FSH) every 90 days in 2020 and 2021 (Refer to D5437) ****REPEAT DEFICIENCY****.

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:

****REPEAT DEFICIENCY**** Based on review of policy and procedures (P&P), calibration records, lack of documentation, daily patient test log, plan of correction submitted on 10/30/19, and interview, the lab failed to follow the established P&P for calibration of the Human Chorionic Gonadotropin (HCG) and Follicle Stimulating Hormone (FSH) every 90 days in 2020 and 2021, reporting three patients. Findings include: 1. Review of the P&P revealed the following statements, "Tosoh AIA 360-IV Calibration" "B. Calibration Frequency- Every 90 Days. All assays have a 90 day calibration frequency." "iv. Calibration prior to 90 days is acceptable, by if calibration is greater than 90 days, then patients may not be released until calibration is completed." 2. Review of calibration records for the HCG analyte revealed a calibration on 09/22/20 and on 01/05/21. According to the established P&P, a calibration of the HCG analyte was required on 12/21/20. The lab lacked documentation of the calibration prior to 01/05/21. Review of the daily patient test log revealed one patient reported on expired calibration on 12/31/20. 3. Review of the calibration records for the FSH analyte revealed a calibration on 02/05/21 and on 05/14/21. According to the established P&P, a calibration of the FSH analyte was required on 05/06/21. The lab lacked documentation of the calibration prior to 05/14/21. Review of the daily patient test log revealed two patients reported on expired calibration on 05/11/21. 4. An exit interview with the technical supervisor on 03/01/22 at approximately 1715 confirmed the findings.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records, policy and procedures (P&P), calibration records, daily patient test log, lack of documentation and interview with the technical supervisor, the technical supervisor failed to 1) ensure the verification of accuracy of the urine microalbumin, urine creatinine and C-reactive protein (quantitative) twice a year (Refer to D5217); and 2) to ensure testing personnel followed the established P&P for calibration of the Human Chorionic Gonadotropin (HCG) and Follicle Stimulating Hormone (FSH) every 90 days (Refer to D5437).