

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0668555	(X3) Date Survey Completed 01/11/2024
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 January 10 & 11, 2024 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: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems. **Repeat Deficiency** D6168 - 42 C.F.R. 493-1487 Condition: Testing Personnel.
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the review of policy and procedures (P&P), pipette records, chemistry records, microbiology media plate records, inventory shipment documents, lack of documentation and interview, the lab failed to 1. Perform the pipette calibrations every six months as defined in the policy for eight of eight pipettes reviewed. Refer to D5403. 2. Perform calibration verification procedures every six months as defined in the P&P for four of four analytes in 2022 and 30 of 30 analytes in 2023. Refer to D5439. and 3. Perform and document the sterility, ability to support or inhibit growth, physical characteristics for a total of eight shipments of microbiology media plates received by the lab from 05/01/23 up to 10/30/23. Refer to D5477.</p>
D5403	PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on the review of policy and procedures (P&P), pipette records, lack of documentation and interview, the lab failed to perform the pipette calibrations every six months as defined in the policy for eight of eight pipettes reviewed in 2022 and 2023. Findings include: 1. Review of the P&P revealed the following statement, "Quality Assurance, Pipette Calibration- Bi-annual calibration and calibration verification of the laboratory pipettes are used to ensure the accuracy of the solutions and reagents being measured." 2. Review of pipette records revealed the following: MLA Pipette SN 936301 and 936510, 972037- calibration performed on 11/14/23, previously calibrated on 10/04/22. MLA Pipette SN 972577 and 915630- calibration performed on 09/20/23, previously calibrated on 11/14/22. MLA Pipette SN 915630- calibration performed on 11/14/23, previously calibrated on 11/14/22. MLA Pipette SN 505497- calibration performed on 11/28/23, previously calibrated on 10/12/22. MLA Pipette SN 06916- calibration performed on 11/18/23, previously calibrated on 06/13/22. 3. The inspector requested to review additional calibration documentation for the identified pipettes as defined by the policy. The documentation was not available for review. 4. An exit interview with the technical supervisor on 01/11/2024 at 1400 confirmed the findings.

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 the review of policy and procedures (P&P), chemistry records, and interview, the lab failed to perform calibration verification procedures every six months as defined in the P&P for four of four analytes in 2022 and 30 of 30 analytes in 2023. Findings include: 1. Review of the P&P, revealed the following statements, "calibration verification will be completed at least every 6 months for those analytes that have less than 3 calibration levels. The following tests must undergo calibration verification: AU680- ISE (Na, K, Cl), Urine creatinine, Urine protein, HDL, LDL, CPK, CO2, BUN, creatinine, glucose, calcium, total protein, albumin, ALP, ALT, AST, total and direct bilirubin, amylase, lipase, GGT, phosphorus, magnesium, uric acid, cholesterol, triglycerides, iron and UIBC. Architect- TSH, PSA, FSH and Ferritin." 2. Review of chemistry records for the Abbott Architect i2000 analyzer revealed lack of documentation of calibration verification procedures every six months in the calendar year 2022 as defined in the above-specified policy. Calibration verification procedures performed on 06/22/22 and 05/23/23. The inspector requested to review additional calibration verification documentation for the above-specified analytes in 2022. The documentation was not available for review. 3. Review of the chemistry records for the Beckman Coulter AU680 analyzer revealed lack of documentation of calibration verification procedures every six months in the calendar year 2023 as defined in the above-specified policy. Calibration verification procedures performed on 12/19/22 and 08/07/23. The inspector requested to review additional calibration verification documentation for the above-specified analytes in 2023. The documentation was not available for review. 4. An exit interview with the technical supervisor on 01/11/2024 at 1400 confirmed the findings.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the review of policy and procedures (P&P), microbiology quality control media plate records, inventory shipment documents, and interview, the lab failed to perform and document the sterility, ability to support or inhibit growth, physical characteristics for eight of eight shipments of microbiology media plates received by

the lab from 05/01/23 up to 10/30/23. Findings include: 1. Review of the P&P revealed the following statements, "Urine Culture Procedure with Beckman Microscan, VI. Commercially Prepared media should be checks for proper color, consistency, depth, smoothness, hemolysis, excessive bubbles, and contamination. Each shipment or batch of media must be tested." 2. Review of the microbiology media plate quality control records revealed lack of documentation of the media checks for the 5% blood agar and blood/MacConkey media plates from 05/01/24 up to 10/30/24. The inspector requested to review documentation media checks for the specified media plates during timeframe. The documentation was not available for review. 3. Review of the inventory shipment documents revealed that the lab received four shipments of the 5% blood agar media and four shipments of the blood /MacConkey bi-plate agar media during the specified timeframe. 4. An exit interview with the technical supervisor on 01/11/2024 at 1400 confirmed the findings.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on the review Laboratory Personnel Report Form (CLIA) (CMS-209 Form), proficiency testing (PT) and instrument maintenance records, testing personnel (TP) records, lack of documentation and interview, the lab failed to retain documentation of education qualifications for one of one new TP personnel at the date of survey on 01/10/24. Refer to D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on the review Laboratory Personnel Report Form (CLIA) (CMS-209 Form), proficiency testing (PT) and instrument maintenance records, testing personnel (TP) records, lack of documentation and interview, the lab failed to retain documentation of education qualifications for one of one new TP personnel at the date of survey on 01/10/24. Finding include: 1. Review of the CMS 209 form, PT, and instrument records revealed TP #1 as a new employee and performing patient testing in the subspecialty of hematology, chemistry, and microbiology in the calendar year 2023. 2. Review of TP records revealed lack of documentation of education qualifications for TP #1. The inspector requested to review the required education documentation for TP #1 at the date of survey on 01/10/24. The documentation was not available for review. 3. An exit interview with the technical supervisor on 01/11/2024 at 1400 confirmed the findings.