Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0668555	11/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Commonwealth Primary Care Laboratory	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 Commonwealth Primary Care Laboratory on November 13-14, 2025 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 and include the Conditions under 42 CFR part 493 CLIA Regulation: D5200 -42 CFR. 493.1230 General Laboratory Systems D5400 -42 CFR. 493.1250 Analytic Systems *Repeat Deficiency
D2025	BACTERIOLOGY CFR(s): 493.823(c) (c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the Centers of Medicaid and Medicare Services CLIA Survey Summary Report (CMS 0096D), proficiency testing (PT) records, and interviews, the laboratory failed to submit Microbiology PT results receiving unsatisfactory scores for one (1) of six (6) events reviewed (timeframe: January 2024 through November 13-14, 2025). Findings include: 1. A pre-survey review of the CMS 0096D revealed zero percent (0%) scores were reported on 2024 Event 2 for speciality code 0005 Bacteriology. 2. Review of the laboratory's American Proficiency Institute (API) Microbiology PT module event results (2024 Events 1-3, 2025 Events 1-3), a total of 6 events, revealed the following unsatisfactory scores for the API 2024 Event 2: Bacteriology 0%, Susceptibility Testing 0%, Urine Colony Count 0%, Urine Identification 0%. The inspector noted that API reported "Failure to Participate". 3. The inspector inquired regarding the failure to submit for the event outlined above. The Technical Supervisor (TS) stated on 11/13/25 at 4 PM, "We ran the samples but failed to get them submitted by the deadline". The inspector requested to review self

	grading for the event. The documentation presented for review had no corrective action for responses that were outside of the API peer reviewed report. 4. An exit interview with the technical and general supervisor on 11/14/25 at 12:00 confirmed the above findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 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. This CONDITION is not met as evidenced by: Based on a review of the Centers of Medicaid and Medicare Services CLIA Survey Summary Report (CMS CASPER Report 0096D), proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to evaluate and document corrective action for: 1. twelve non-graded Chemistry analyte challenges reported on four of 6 events (timeframe outlined above) Cross Reference D5215; 2. seven Chemistry/Immunology PT challenges scored as unacceptable on three of 6 events (timeframe outlined above) Cross Reference D5221.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to evaluate twelve (12) non-graded chemistry analyte challenges resulted on four (4) of six (6) events in the twenty-two (22) months reviewed (timeframe: January 2024 to November 13-14, 2025). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2024 Events 1-3, 2025 Events 1-3), a total of 6 events, revealed that API released non-graded analyte responses for Total Bilirubin (T Bili), Iron, and Folate due to result variance on the following 4 events: API 2024 Core Chemistry Event 1 - T Bili challenges CH-02, CH-03, CH-05; API 2024 Core Chemistry Event 2 - Iron challenges CH-08, CH-10; API 2025 Core Chemistry Event 2 - T Bili challenges CH-07, CH-09, CH-10, Folate challenge samples IA-07, IA-09; API 2025 Core Chemistry Event 3 - T Bili challenges CH-12, CH-15; a total of 12 non graded chemistry challenge samples were reported by API. 2. Review of the laboratory's PT review documentation revealed no evaluation/verification of accuracy recorded for the non-graded challenge samples listed above. 3. An exit interview with the technical and general supervisor on 11/14/25 at 12:00 confirmed the above findings.

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to document an evaluation for seven (7) unacceptable Chemistry/Immunology scored Aspartate Aminotransferase (AST), Creatine Kinase (CK), Unsaturated Iron Binding Capacity (UIBC), Parathyroid Hormone (PTH), H Pylori Antibody (HPY Ab), and Hepatitis B Core Antigen IgM Antibody PT challenges reported on three (3) of six (6) events reviewed (timeframe: January 2024 to November 13-14, 2025). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2024 Events 1-3, 2025 Events 1-3), a total of 6 events, revealed no evidence that the laboratory evaluated the following unacceptable scores: 2024 Core Chemistry/Immunology Event 1 - AST challenge #CH-04 resulted as 13 acceptable range (25-39), CK #CH-01 resulted as 8 acceptable range (10-21), UIBC #CH-04 resulted as 421 acceptable range (369-418), PTH #IAS-03 resulted as 1445.2 acceptable range (1449.3-2136.7); 2024 Core Chemistry/Immunology Event 2 - PTH #IAS-07 reported as 18.3 acceptable range (20.0-30.0), HPY Ab #HPY-03 reported as Negative expected result Positive; 2025 Core Chemistry/Immunology Event 1 - Anti HBc IgM #VM-05 reported as Negative expected result Positive; a total of 7 challenge samples were scored by API as unacceptable. 2. The inspector requested to review documentation that the laboratory evaluated the 7 unacceptable challenge scores outlined above. Documentation was not available for review. 3. An exit interview with the technical and general supervisor on 11/14/25 at 12:00 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 procedures, equipment calibration records, laboratory tour, instrument maintenance logs, chemistry analyzer calibration verification records, lack of documentation, and interviews, the laboratory failed to document: 1. pipette maintenance calibration according to their policy in two (2) of 2 calendar years (review timeframe: January 2024 to November 13-14, 2025) Cross Reference D5403 -REPEAT DEFICIENCY; 2. Tosoh G8 Hemoglobin A1C analyzer's 6 month preventative maintenance procedure for one (1) of two (2) years reviewed (review timeframe outlined above) Cross Reference D5429; 3. calibration verification for eight (8) of thirty-three (33) analytes every six (6) months per their procedure (review timeframe outlined above) Cross Reference 5439 -REPEAT DEFICIENCY.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of the laboratory's procedures, equipment calibration records, laboratory tour, and interview, the laboratory failed to document performance of pipette calibration protocols according to protocol in two (2) of 2 calendar years reviewed (timeframe: January 2024 to November 13-14, 2025). *REPEAT DEFICIENCY Findings include: 1. A review of the laboratory's procedures revealed a procedure (Pipette Calibration) that stated, "Bi-annual calibration of the laboratory pipettes are used to ensure the accuracy of the solutions and reagents being measured. The pipettes are used to reconstitute controls and reagents and to dilute patient specimens as necessary. Appropriate documentation will be contained within the QA manual". 2. Review of the laboratory's 2024 equipment calibration records revealed documentation for the following pipettes: MLA D-Tipper Pipette Serial Number (SN) 936301: one calibration in May 2024; MLA D-Tipper Pipette SN 936510: one calibration in May 2024; MLA D-Tipper Pipette SN 927037: one calibration in June 2024; MLA D-Tipper Pipette SN 972577: one calibration in June 2024; MLA D-Tipper Pipette SN 915630: one calibration in May 2024; CPC200A 200L: one calibration in June 2024; CPC500A 500L: one calibration in July 2024; MLA D-Tipper Pipette SN 975994: one calibration in August 2024; CPC 3A 3000L: one calibration in June 2024; CPC 4A 4000L: one calibration in June 2024; CPC 5A 5000L: one calibration in June 2024. The inspector requested additional pipette calibration documentation for the pipettes listed above completed in calendar year 2024. No additional calibration records were available for review. The Technical Supervisor (TS) stated on 11/13/25 at 4 PM, "It was realized in May 2025 that we had skipped the second semiannual pipette calibrations in 2024." 3. Review of the laboratory's 2025 equipment calibration records revealed no calibration record year to date for the following pipette: MLA D-Tipper Pipette SN 970300. The inspector requested to review pipette calibration for SN 970300 completed in 2025. No calibration record was available for review. 4. An exit interview with the technical and general supervisor on 11/14/25 at 12:00 confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(a)(1) (a)(1) 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 review of the laboratory's instrument maintenance logs, lack of documentation, and interview, the laboratory failed to perform and document every six month preventative maintenance procedures for the Tosoh G8 Hemoglobin A1C analyzer in one (1) of two (2) years reviewed (survey timeframe January 2024 to November 13-14, 2025). Findings include: 1. Review of the laboratory's Tosoh G8 maintenance logs revealed preventative maintenance procedure to replace fluid supply line filters at the frequency of every six (6) months. 2. Review of the Tosoh G8 maintenance logs from January 2024 to the dates of the inspection, November 13-14, 2025, revealed that the laboratory recorded the procedure as completed in June and December 2024. The inspector noted no entry for the required 6 month maintenance year to date in calendar year 2025. The inspector requested to review documentation that the six month maintenance was completed in or near June 2025. The documentation was not available for review. 3. An exit interview with the technical and general supervisor on 11/14/25 at 12:00 confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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, chemistry analyzer calibration verification records, lack of documentation, and interview, the laboratory failed to document calibration verification for eight (8) of thirty-three (33) analytes every six (6) months per protocol during the twenty-two months of review. (Timeframe: January 2024 to November 13-14, 2025.) *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's procedures revealed: Quality Assurance guide (titled: Calibration Verification Chart) that outlined calibration verification to be completed at least once every six months for Alinity c-and i-Series analytes and Tosoh HbA1c. Procedure (titled: Calibration Verification) that stated, "Calibration verification will be completed every six months

	for analytes that have less than 3 calibration levels. It is also recommended to run calibration verification when a complete change of reagents for a procedure is introduced or major preventative maintenance or replacement of critical parts. The following tests must undergo calibration verification every six months: Alinity c: ICT (Na, K, Cl), Albumin, ALP, ALT, Amylase, AST, Total and Direct bilirubin, CPK, CO2, BUN, Creatinine, Glucose, Calcium, Total Protein, Lipase, GGT, Phosphorus, Magnesium, Uric Acid, Cholesterol, Triglyceride, Iron, UIBC, HDL, LDL. Alinity i: TSH, PSA, FSH, Ferritin, and Tosoh: Hemoglobin A1c." 2. Review of the laboratory's Alinity calibration verification worksheets during the review timeframe of January 2024 to the date of the inspection on 11/14/25 revealed the following two analytes lacked calibration verification every six months in calendar year 2024: D Bili - calibration verification completed June 2024, June 2025, August 2025; T Bili - calibration verification completed June 2024, June 2025, August 2025. The inspector requested to review additional calibration verification documentation for D. Bili and T. Bili completed in 2024. The records were not available for review. 3. Review of the Alinity calibration verification worksheets during the review timeframe of January 2024 to 11/14/25 revealed the following five (5) analytes that lacked calibration verification every six months in calendar year 2024 and year to date 2025: UBIC, Ferritin, FSH, PSA, TSH - calibration verification completed June 2024, September 2025. The inspector requested to review additional calibration verification documentation completed at or near the six month interval of December 2024 and June 2025 for the 5 analytes above. The records were not available for review. 4. Review of the laboratory's Tosoh HbA1c calibration verification worksheets for the review timeframe of January 2024 to 11/14/25 revealed calibration verification completed in June 2024 and November 2024. The inspector requested to review HbA1c calibration verification documentation completed in 2025. No records were available for review. 5. An exit interview with the technical and general supervisor on 11/14/25 at 12:00 confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of analyzer validation records, procedures, quality assessment (QA) records, lack of documentation, and interview, the laboratory failed to verify the accuracy of test results/data transmission prior to reporting patient results on one (1) of 1 newly installed chemistry/immunoassay analyzer in June 2024 and failed to follow protocol to document laboratory information system (LIS) verification semi-annually for two (2) of 2 years reviewed. Findings include: 1. Review of analyzer validation records revealed that a new Abbott Alinity ci Series chemistry/immunology instrument (Serial Number ACO6558) was installed in April 2024. The inspector noted a "go-live" date of 6/24/24 and requested to review the analyzer to LabDaq LIS interface verification records. The documentation was not available for review. 2.

	Review of the laboratory's procedures revealed a QA Policy (titled: Laboratory Information System Verification) that stated, "Post analytical monitoring is an important step in ensuring test results are correctly transmitted. The laboratory is responsible for monitoring and evaluating the overall quality of the postanalytical systems and identifying problems that may occur. Commonwealth Primary Care Laboratory will complete a LIS verification process twice yearly. All documentation will be stored appropriately." The inspector noted that the above policy included a QA documentation form (titled: LIS Verification Form) to be completed semi-annually. 3. Review of the laboratory's QA documentation revealed no evidence that the laboratory completed the semi-annual LIS verification procedures in calendar year 2024 and year to date 2025. The inspector requested to review the LIS Verification Form for calendar years 2024 and 2025. No records were available for review. 4. An exit interview with the technical and general supervisor on 11/14/25 at 12:00 confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) competency assessment records, and interview, the technical supervisor (TS) failed to perform semi-annual competency assessment for one (1) of 1 new TP after initial training was documented in calendar year 2024. Findings include: 1. Review of the CMS 209 revealed four (4) TP identified as responsible for high complexity patient laboratory testing during the review timeframe of January 2024 to the date of the inspection, November 13-14, 2025. TP A was identified as a new laboratory technician responsible for moderate and high complexity chemistry, immunology, microbiology, and hematology patient testing in 2024. (See Personnel Code Sheet.) 2. Review of personnel records revealed that TP A was initially trained and started performing Chemistry/Immunology and Hematology patient testing in July 2024 and Microbiology in November 2024. The inspector requested to review the semi-annual competency assessment documentation for TP A. Documentation was not available for review. 3. An exit interview with the TS and general supervisor on 11/14/25 at 12:00 confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) competency assessment records, and interview, the technical supervisor (TS) failed to perform annual

	competency assessment for TP B for one of two years reviewed (timeframe: January 2024 to November 13-14, 2025). Findings include: 1. Review of the CMS 209 revealed four (4) TP identified as responsible for high complexity patient laboratory testing during the review timeframe of January 2024 to the date of the inspection on November 13-14, 2025. 2. Review of personnel records revealed that TP B lacked an annual competency assessment during calendar year 2024. The inspector requested to review the competency assessment documentation for TP B. The documentation was not available for review. (See Personnel Code Sheet.) 3. An exit interview with the TS and general supervisor on 11/14/25 at 12:00 confirmed the above findings.