Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0668555	10/09/2019
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 October 8 - October 9, 2019 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:
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 and an interview, the laboratory failed to evaluate non-graded endocrinology Parathyroid Hormone (PTH) PT results for one (1) of four (4) events in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results for PTH (2018 Events 1 and 2, 2019 Events 1 and 2), a total of four (4) events, revealed that the PT program reported non-graded responses for the 2018 Event 1 samples IAT 01, IAT 02, and IAT 03 due to result variance. The laboratory's 2018 Event 1 documentation revealed no evaluation/verification of accuracy for the non-graded responses listed above. The inspector requested to review additional accuracy records. No additional documentation was available for review. 2. In an interview with the general supervisor, at approximately 2:30 PM on 10/9/19, the above findings were confirmed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	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. This STANDARD is not met as evidenced by: A. Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to perform twice annual accuracy verification for C-Reactive Protein (CRP) immunology testing in calendar year 2018 and up the date of the inspection on October 9, 2019. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2018 Events 1-3, 2019 Events 1-2), a total of five (5) events, revealed that the laboratory received unsatisfactory CRP scores of fifty percent (50%) on the following four (4) Diagnostic Immunology modules: 2018 2nd Event, 2018 3rd Event, 2019 1st Event, and 2019 2nd Event. The laboratory's CRP scores resulted in an Unsuccessful Long-Term Performance rating from API in calendar year 2018 and year to date 2019. The inspector requested to review documentation of accuracy verification during the timeframe of the events outlined above. No records were available for review. The general supervisor stated, on 10/8 /19 at approximately 5:00 PM, "We did attempt to repeat the missed challenges but do not have the instrument print outs for three of the four events that we received unsatisfactory scores". 2. In an interview with the general supervisor, at approximately 2:30 PM on 10/9/19, the above findings were confirmed. B. Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to perform twice annual accuracy verification for Parathyroid Hormone (PTH) endocrinology testing in calendar year 2018. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) endocrinology PTH results (2018 Events 1-2, 2019 Events 1-2), a total of four (4) events, revealed that the laboratory received an unsatisfactory PTH score of sixty-seven percent (67%) on 2018 Event 1. The laboratory's PTH scores on 2018 Event 2 were not graded by API due to sample variance. The inspector requested to review documentation of PTH accuracy verification during the timeframe of the events outlined above. No records were available for review. The general supervisor stated, on 10/8/19 at approximately 5:00 PM, "I looked back at my records and noted that I printed the peer group for Event 2 but do not have a record of assessing our performance". 2. In an interview with the general supervisor, at approximately 2:30 PM on 10/9/19, the above findings were confirmed.
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:

	Based on review of procedures, calibration records, and an interview, the laboratory failed to document calibration procedures for Human Chorionic Gonadotropin (hCG) and Follicle Stimulating Hormone (FSH) according to the every ninety (90) day frequency required by the manufacturer in calendar years 2018 and 2019. Findings include: 1. Review of the laboratory's procedure manual revealed a Tosoh A1A 360 manufacturer's calibration guideline for hCG and FSH that stated: "The calibration curve is stable for up to 90 days. Calibrate at a frequency of every 90 days. Calibration may be necessary more frequently if controls are out of the established ranges". 2. Review of the laboratory's 2018 and 2019 Tosoh A1A 360 instrument's calibration worksheet records revealed the following calibration dates: hCG: 03/30/18, 07/20/18, 05/24/19, 09/18/19; FSH: 02/12/19, 04/12/19, 08/13/19. The lab inspector requested to review hCG calibration records for the time periods of: 06/30/18 to 07/19 /18; 10/20/18 to 05/23/19; 08/24/19 to 09/17/19; The lab inspector requested to review FSH calibration records for the time periods of: 07/12/19 to 08/12/19; 3. In an interview with the general supervisor, at approximately 2:30 PM on 10/9/19, 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, chemistry analyzer calibration verification records, and an interview, the laboratory failed to follow their procedure to document Total and Free Triodothyronine (TT3 and FT3) calibration verification twice annually in calendar year 2018. Findings include: 1. Review of the procedure manual revealed a quality assurance policy (titled: Calibration Verification) that stated "perform calibration verification at least once every six months for the Architect i2000 analytes: TSH, PSA, TT3, FT3 and Ferritin". 2. Review of the laboratory's Architect calibration verification worksheets from November 2017 to the date of the inspection, on 10//9 /19, revealed the following verification dates for TT3 and FT3: 12/28/17, 06/26/18, 02 /13/19, 06/07/19. The inspector requested to review additional documentation of TT3 and FT3 calibration verification performed in calendar year 2018. The documentation

	was not available for review. 3. In an interview with the general supervisor, at approximately 2:30 PM on 10/9/19, the above findings were confirmed.
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel records, and interviews, the laboratory failed to retain documentation of education qualifications for one (1) of four (4) testing personnel responsible for reporting high complexity hematology and microbiology patient test results during the twenty-four (24) months reviewed. See 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel records, and interviews, the laboratory director failed to obtain/retain documentation of education qualifications for one (1) of four (4) testing personnel (TP) responsible for high complexity hematology and microbiology test results during the twenty-four (24) months reviewed. Findings include: 1. Review of the CMS 209 form revealed 4 TP identified as responsible for reporting high complexity patient test results during the twenty-four (24) months reviewed. 2. Review of the laboratory's personnel records revealed job descriptions for the 4 TP to include performance of high complexity hematology and microbiology identification testing. Review of the education records in the personnel files revealed a foreign institution education document for TP A. The inspector requested an evaluation of United States credentials equivalency for TP A. No documentation was available for review. The general supervisor stated, at approximately 11:00 AM on 10/8/19, "he recently enrolled to complete a Medical Laboratory Technician Associate's degree. We have not requested an equivalency for his Bangladesh studies yet." (See Personnel Code Sheet) 3. In an interview with the general supervisor, at approximately 2:30 PM on 10/9/19, the above findings were confirmed.