

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0670586	<b>(X3) Date Survey Completed</b> 01/23/2020
<b>Name of Provider or Supplier</b> Fairfax County Health Dept Laboratory	<b>Street Address, City, State</b> 10310 Layton Hall Drive, Fairfax, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Fairfax County Health Department Laboratory on January 22 and 23, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
<b>D2089</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, lack of documentation and interview, the laboratory failed to submit PT results for Alanine Transaminase (ALT), Albumin, Alkaline Phosphotase, Aspartate Aminotranferase (AST), Total Bilirubin, Calcium, Chloride, Cholesterol, Cholesterol-High Density Lipoprotein (HDL), Creatinine, Glucose, Iron, Lactate Dehydrogenase (LDH), Potassium, Sodium, Total Protein, Triglycerides, Blood Urea Nitrogen (BUN), Uric Acid within the specified time frame for one (1) of six (6) Chemistry testing events reviewed in 2018 and 2019. Findings include: 1. Review of the laboratory's CAP 2018 and 2019 C-General Chemistry/Therapeutic Drugs PT records, a total of 6 events, revealed a lack of documentation of the submitted records for 2018 CAP Event B analytes: Alanine Transaminase (ALT),</p>

Albumin, Alkaline Phosphotase, Aspartate Aminotranferase (AST), Total Bilirubin, Calcium, Chloride, Cholesterol, Cholesterol-High Density Lipoprotein (HDL), Creatinine, Glucose, Iron, Lactate Dehydrogenase (LDH), Potassium, Sodium, Total Protein, Triglycerides, Blood Urea Nitrogen (BUN), Uric Acid. 2. At approximately 10:30 AM on January 22, 2020, the surveyor requested documentation of the submission of CAP 2018 General Chemistry/Therapeutic Drugs Event B. The laboratory provided no documentation to review. Technical Supervisor #1 stated "We analyzed the PT specimens but failed to submit the results in time. We did complete a self-grading of the event." 3. In an exit interview with the technical supervisors on January 23, 2020 at approximately 12:45 PM, the above findings were confirmed.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory policies, testing personnel records, lack of documentation, and interviews, the technical supervisors (TS) or general supervisors (GS) failed to perform annual competency assessment evaluations in calendar year 2019 for one (1) of the fifteen (15) testing personnel (TP) reviewed. Findings include: 1. Review of the CMS 209 form revealed three (3) personnel performed the duties of TS, 3 personnel perform the duties of GS and 15 TP who perform high-complexity testing. 2. Review of the laboratory's Standard Operating Procedure Manual revealed a "FCHDL Quality Manual" that stated: "Testing Personnel competency is reviewed, assessed, and signed off initially at 6 months and annually thereafter by the PHLS II (CLIA GS) or PHLS III (CLIA TS) following all regulatory guidelines." 3. Review of 15 TP records revealed TP I lacked a 2019 annual competency assessment. (See Personnel Code Sheet.) The surveyor requested to review TP I's 2019 competency assessment. The laboratory provided no records to review. 4. In an exit interview with the technical supervisors on January 23, 2020 at approximately 12:45 PM, the 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 two (2) of

fifteen (15) testing personnel responsible for reporting high complexity Chemistry, Microbiology, and Diagnostic Immunology patient test results during the twenty-one (21) 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 two (2) of fifteen (15) testing personnel (TP) responsible for high complexity Chemistry, Microbiology and Diagnostic Immunology test results during the twenty-one (21) months reviewed . Findings include: 1. Review of the CMS 209 form revealed 15 TP identified as responsible for reporting high complexity patient test results during the twenty-one (21) months reviewed. 2. Review of the laboratory's personnel records revealed job descriptions for the 15 TP to include performance of high complexity Chemistry, Microbiology and Diagnostic Immunology testing. Review of the education records in the personnel files revealed a lack of documentation of the educational qualifications for TP I and TP L. The surveyor requested the education qualification records for TP I and TP L. The laboratory provided no documentation of the education qualification records for TP I and TP L to review. (See Personnel Code Sheet) 3. In an exit interview with the technical supervisors on January 23, 2020 at approximately 12:45 PM, the findings were confirmed.