

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2082028	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Commonwealth Extended Care	Street Address, City, State 1800 Glenside Drive - Suite 103, 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 Extended Care on November 5, 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:
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>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 personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments that included direct observation of routine White Blood Count (WBC) patient test performance for five (5) of six (6) testing personnel (TP) in 2018 and 2019. Findings include: 1. Review of the CMS 209 form revealed seventeen (17) testing personnel responsible for moderate complexity WBC patient testing: eleven (11) of 17 were identified as new TP in 2019 (initially trained in timeframe of February-October 2019) and six (6) of 17 identified as having performed moderate complexity WBC patient testing during the twenty-four (24) month review timeframe (November 2017 - 11/05/19). 2. Review of personnel files revealed the laboratory's 2018 and 2019 annual Hemocue WBC assessments lacked the required competency procedural element of direct observation of routine patient test performance (patient preparation, specimen handling, and analyzer testing) for: TP A, B, C, D, and E. (See Personnel Code Sheet.) The inspector requested to review additional competency documentation. The TC stated at approximately 2:00 PM: "I give an annual quiz that includes twenty (20) questions for all testing kits in the lab. I have not been able to</p>

document direct observation of the staff members performing WBC patient testing for their annual competency assessments." 3. In an exit interview with the TC at approximately 3:30 PM, the above findings were confirmed.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 competency assessment records, and interview, the technical consultant (TC) failed to perform the semi-annual competency assessment for one (1) new laboratory testing personnel (TP) in calendar year 2018. Findings include: 1. Review of the CMS 209 revealed seventeen (17) TP identified as responsible for moderate complexity White Blood Count (WBC) patient testing. TP F was identified as being a new TP in calendar year 2018. (See Personnel Code Sheet.) 2. Review of personnel records revealed that TP F was initially trained and started performing WBC patient testing in February 2018. The review of records revealed that no semi-annual competency assessment for TP F was documented in 2018. The inspector requested to view the semi-annual competency assessment documentation for the testing personnel listed above. The documentation could not be presented for review. 3. In an exit interview with the TC at approximately 3:30 PM, the above findings were confirmed.