Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2082028	02/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Commonwealth Extended Care	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 February 3, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Commonwealth Extended Care was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the following Conditions under 42 CFR part 493 CLIA Regulation: D5400- 42 C.F.R. 493.1250 Condition: Analytic systems; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; and D6063- 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
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 the review of laboratory policy and procedures, maintenance and quality control (QC) logs, and interview, the lab failed to: 1. ensure that four (4) lots of White Blood Cell (WBC) QC were not utilized beyond the listed open stability requirements (see D5417); 2. follow the established policy to perform external liquid QC materials each day of WBC patient testing for 162 days and 502 patients (see D5447).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of laboratory policy and procedures, maintenance and quality control logs, and an interview, the laboratory failed to ensure that four (4) of twenty-one (21) R&D Systems HC WBC quality control (QC) lots were not utilized beyond the listed open stability requirements. Findings include: 1. Review of the lab's Hemocue WBC Procedure revealed that the R&D Systems HC WBC control material is good for 30 days after opening. 2. Review of the 2024 and 2025 HemoCue WBC Maintenance & Quality Control logs revealed the following 4 lots were utilized beyond their 30 day open stability: Lot HC06241, 6242, 6243, opened 7/2/24, ran after the 30 d expiration (exp) date of 8/2/24 with QC documented August 5, 6, 7, 8, 9, 10, 11, 12, 13 (9 days); HC06251, 6252, 6253, opened 8/8/25, Exp 9/8/25, QC ran September 9, 10, 11, 12, 15 ,16 (6 days); HC09251, 9251, 9253, opened 10/20/25, exp 11/20/25, QC ran November 21, 22, 23 (3 days); and HC12251, 9252, 9253, opened 11/24/25, exp 12/24/25, QC ran December 28, 29, 30 (3 days). 3. In an exit interview with the technical consultant at noon on 2/3/26, the above findings were confirmed
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on the review of laboratory policy and procedures, quality control (QC) records, and interviews, the lab failed to follow the established policy to perform liquid external QC materials each day of Hemocue White Blood Cell (WBC) patient testing for 162 days out of two years (2024 & 2025) reviewed while reporting 502 patient results. Findings include: 1. Review of the lab's Hemocue WBC Procedure revealed "External quality control should be performed once daily when patient specimens will be run." 2. Review of the WBC QC records from 01/01/24 through 01 /01/26 revealed the lab failed to perform liquid QC testing on the following dates and patients tested: 3/02/24 -3 patients, 3/03/24 -1, 3/09/24 -1, 3/11/24 -2, 3/14/24 -6, 3/16 /2024 -3, 4/05/24 -5, 4/13/24 -2, 4/25/24 -7, 5/13/24 -2, 5/23/24 -5, 5/24/24 -4, 5/27 /24 -2 6/15/24 -1, 6/18/24 -3, 6/20/24 -3, 6/21/24 -3, 6/22/24 -2, 6/23/24 -2, 6/27/24 -2, 7/01/24 -2, 7/04/24 -2, 7/05/24 -3, 7/07/24 -3, 7/13/24 -4, 7/15/24 -2, 7/22/24 -9, 7 /23/24 -3, 7/24/24 -4, 7/27/24 -4, 8/16/24 -9, 8/23024 -3, 9/22/24 -4, 9/28/24 -1, 9/29 /24 -3, 9/30/24 -1, 10/06/24 -3, 10/22/24 -7, 10/23/24 -7, 10/24/24 -4, 10/26/24 -3, 10 /27/24 -2, 10/28/24 -1, 10/29/24 -6, 10/30/24 -7, 11/01/24 -3, 11/02/24 -4, 11/10/24 -4, 11/11/24 -5, 11/12/24 -6, 11/22/24 -6, 11/23/24 -1, 11/24/24 -3, 12/01/24 -2, 12/02 /24 -3, 12/06/24 -5, 12/07/24 -1, 12/08/24 -2, 12/10/24 -4, 12/11/24 -1, 12/14/24 -2, 12 /15/24 -4, 12/20/24 -3, 12/22/24 -2, 12/23/24 -5, 12/27/24 -6, 12/28/24 -1, 12/29/24 -4, 1/03/25 -3, 1/04/25 -2, 1/10/25 -8, 1/11/25 -2, 1/13/25 -4, 1/14/25 -6, 1/15/25 -5, 1 /16/25 -3, 1/18/25 -5, 1/20/25 -6, 1/21/25 -6, 1/22/25 -2, 1/23/25 -6, 1/24/25 -4, 1/25 /25 -1, 1/27/25 -3, 1/28/25 -2, 1/29/25 -2, 1/30/25 -2, 2/01/25 -1, 2/02/25 -3, 2/03/25 -3, 2/04/25 -3, 2/05/25 -3, 2/06/25 -3, 2/09/25 -2, 2/10/25 -2, 2/11/25 -2, 2/16/25 -2, 2 /22/25 -2, 2/28/25 -3, 3/01/25 -2, 3/02/25 -1, 3/09/25 -2, 3/15/25 -3, 3/16/25 -4, 3/17

	/25 -6, 3/22/25 -3, 3/28/25 -2, 3/30/25 -2, 4/05/25 -1, 4/06/25 -1, 4/18/25 -3, 4/25/25 -6, 4/26/25 -7, 5/02/25 -3, 5/04/25 -2, 5/09/25 -2, 5/10/25 -2, 5/11/25 -2, 5/17/25 -2, 5 /18/25 -2, 5/19/25 -3, 5/21/25 -2, 5/26/25 -1, 6/07/25 -2, 6/08/25 -4, 6/14/25 -2, 6/15 /25 -2, 6/21/25 -2, 6/22/25 -3, 6/28/25 -1, 6/29/25 -2, 7/05/25 -3, 7/06/25 -5, 7/12/25 -1, 7/13/25 -6, 7/18/25 -4, 7/20/25 -1, 7/24/25 -5, 7/26/25 -2, 7/27/25 -1, 8/02/25 -2, 8 /03/25 -1, 8/16/25 -1, 8/17/25 -1, 8/23/25 -1, 9/06/25 -2, 9/07/25 -1, 9/14/25 -1, 9/26 /25 -5, 10/04/25 -2, 10/05/25 -3, 10/11/25 -5, 10/19/25 -2, 10/23/25 -6, 10/24/25 -2, 10 /26/25 -1, 10/28/25 -3, 10/29/25 -1, 10/30/25 -9, 10/31/25 -3, 12/12/25 -5, and 12/21 /25 -1, 3. When asked at 11:25 AM on 2/3/26 how the lab ensures QC is run each day of patient testing, the technical consultant stated that they rely on the testing personnel to follow procedure. 4. In an exit interview with the technical consultant at noon on 2/3 /26, the findings above were confirmed.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of laboratory policy and procedures, daily temperature logs, Quality Control and Quality Assurance (QA) logs, lack of documentation, and interviews, the laboratory failed to document corrective action when recorded room temperatures (RT) were outside of acceptable limits on twelve (12) of 702 days during the twenty three month review timeframe (March 2024 through January 2026). Findings include: 1. Review of the lab's HemoCue WBC (White Blood Cell) Procedure revealed that the HemoCue microcuvettes are to be stored at RT. 2. Review of the lab's temperature logs revealed an acceptable room temperature lower limit of 68 degrees Fahrenheit. Laboratory temperature logs for March 2024 through January 2026 lacked corrective action documentation when the recorded RT was below the established lower limit on the following 12 days: 12/15/24, 12/16/24, 1/10/25, 1/16 /25, 1/20/25, 1/21/25, 1/24/25, 1/27/25, 1/28/25, 1/29/25, 1/30/25, and 1/31/25. 3. Review of the lab's Quality Control & Quality Assurance logs revealed periodic quality monitors that included review of temperature logs. The 2024 and 2025 QA logs revealed no notation or record of corrective action for the dates when recorded room temperatures were below the established lower limit. 4. In an interview with the technical consultant (TC) on 2/3/26 at 11:25 AM, the surveyor inquired about how corrective actions were documented and communicated to testing personnel. The TC stated that they verbally discuss issues with the office manager and that there were no notes or emails to provide for review. 5. In an exit interview with the TC at noon on 2 /3/26, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratory policy and procedures, daily temperature logs,

	Quality Control (QC) and Quality Assurance (QA) logs, lack of documentation, and interview, the laboratory director failed to provide overall laboratory management by failing to ensure that the current QC procedures and QA reviews identified and corrected quality issues in the subspecialty of Hematology. See D6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the review of laboratory policy and procedures, daily temperature logs, Quality Control (QC) and Quality Assurance (QA) logs, lack of documentation, and interview, the laboratory director failed to ensure that the current QC procedures and QA reviews identified and corrected quality issues in the subspecialty of Hematology for the 23 month timeframe reviewed. Refer to D5417, D5447, and D5785. **REPEAT DEFICIENCY
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, laboratory policy and procedures, Hematology quality control (QC) records and interviews, the technical consultant (TC) failed to: - ensure testing personnel followed the established QC policy when testing patient White Blood Cell (WBC) counts on the HemoCue for 162 days out of two years (2024 & 2025) reviewed (see D6042); - assess annual Hematology HemoCue WBC System competency for two (2) of fifteen (15) testing personnel (TP) (See 6046); and - perform the semi-annual competency assessment for five (5) laboratory TP (See D6053).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the review of laboratory policy and procedures, Hematology quality control (QC) records, and interviews, the technical consultant failed to ensure testing

	personnel followed the established QC policy when testing patient White Blood Cell (WBC) counts on the HemoCue for 162 days out of two years reviewed while reporting 502 patient results. (Review dates 01/01/2024 - 01/01/2026.) Refer to D5447.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, and an interview, the technical consultant (TC) failed to assess annual Hematology HemoCue WBC System competency for two (2) of fifteen (15) testing personnel (TP). Findings include: 1. Review of the CMS 209 revealed 15 TP identified as responsible for moderate complexity White Blood Count (WBC) patient testing. 2. Review of personnel records revealed no annual HemoCue WBC System competency assessments for: Testing Personnel E in 2024 (previous competency 12/21/23), and Testing Personnel F in 2025 (initial training documented 1/12/23). See testing personnel code sheet. 3. In an exit interview with the technical consultant at noon on 2/3/26, the above findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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), personnel records, and interview, the technical consultant (TC) failed to perform the semi-annual competency assessment for five (5) of 15 laboratory testing personnel (TP). Findings include: 1. Review of the CMS 209 revealed fifteen (15) TP identified as responsible for moderate complexity White Blood Count (WBC) patient testing. 2. Review of personnel records revealed no semi-annual competency assessment documented for the following 5 trained TP: Testing Personnel F - trained 1/12/23, Testing Personnel H - trained 12/20/23, Testing Personnel L - trained 7/7/24, Testing Personnel M - trained 3/1/24, and Testing Personnel O - trained 10/7/24. (See Personnel Code Sheet.) 3. In an exit interview with the TC at noon on 2/3/26, the above findings were confirmed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.

	1425 for the volume and complexity of tests 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), laboratory personnel files, and an interview, the laboratory failed to maintain documentation of personnel qualifications for five (3) of fifteen (15) moderate complexity testing personnel. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and 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), available laboratory personnel records, and an interview, the laboratory failed to maintain documentation of personnel qualifications for five (5) of fifteen (15) testing personnel. Findings include: 1. Review of the CMS 209: Laboratory Personnel Report revealed 15 moderate complexity testing personnel. 2. Review of the laboratory personnel records revealed no education documentation for: Testing Personnel B, Testing Personnel C, Testing Personnel J Testing Personnel M, and Testing Personnel O. (See Personnel Code Sheet) 3. In an exit interview with the technical consultant at noon on 2/3/26, the above findings were confirmed.