Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2082028	01/22/2024
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 the Commonwealth Extended Care on 01/22/24 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems.
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 policy and procedures (P&P), manufacturer package inserts (PI), daily quality control (QC) logs, lack of documentation, and interviews, the lab failed to: 1. Follow the established policy ensuring that the liquid external White Blood Cell (WBC) QC materials were within manufacturer acceptable ranges for 144 days in 24 months reviewed. Refer to D5403. 2. Ensure the correct standard deviation (SD) was used to calculate the acceptable ranges for the white blood cell (BC) QC materials for six of seven lot numbers reviewed. Refer to D5469 A. 3. Verify seven of seven new lot numbers of white blood cell (WBC) QC materials according to manufacturer's instructions. Refer to D5469 B. and 4. Ensure that the established quality assurance (QA) plan identified and addressed analytical issues in the subspecialty of hematology. Refer to D5791.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 the review of policy and procedures (P&P), quality control (QC) records, electronic medical records (EMR), and interview, the lab failed to follow the established policy ensuring that the liquid external White Blood Cell (WBC) QC materials were within manufacturer acceptable ranges for 144 days in 24 of 24 months reviewed. Cross Reference D5469. Findings include: 1. Review of the P&P revealed the following statement, "Hemocue WBC Procedure, VII. Quality Control. Frequency- External quality control should be performed once daily when patient specimens will be run." "If the results do not fall within the established range, specimen testing can not be performed until QC troubleshooting produces a valid result." 2. Review of R&D HC WBC QC records from 01/22/22 up to 01/22/24 revealed the lab performs three levels of QC materials each day of patient testing. In addition, the following dates and QC materials failed to meet the manufacturer's acceptable range(s): 01/24, 26, 29-31/22- Level 1 out of range, 02/15, 17, 22 and 28 /22- Level 2 out of range, 02/16/22- Level 1 out of range, 02/08, 20, 21, 23, 24 and 26 /22- Level 1 and 2 out of range, 03/05/22- Level 1, 2 and 3 out of range, 03/14, 15, 17 and 23/22- Level 1 out of range, 03/28/22- Level 2 out of range, 04/01, 12-14, and 23 /22- Level 1 out of range, 04/04-08/22- Level 1 and 2 out of range, 04/16 and 24/22- Level 3 out of range, 04/25/22- Level 2 and 3 out of range, 04/28 and 29/22- Level 2 out of range, 05/07/22- Level 1 out of range, 05/12/22- Level 2 out of range, 05/19, 20 and 22/22- Level 1 out of range, 06/18/22- Level 1 and 3 out of range, 06/25/22- Level 3 out of range, 07/04, 05, 07, 08, 20 and 21/22- Level 1 out of range, 07/14-16 and 22/22- Level 1 and 2 out of range, 08/23 and 30/22- Level 1 out of range, 08/27 /22- Level 1 and 2 out of range, 08/29/22- Level 3 out of range, 09/02, 04, 05, 7-9, 17, 29 and 30/22- Level 1 out of range, 09/14-16, and 18/22- Level 1 and 2 out of range, 10/01, 17 and 23/22- Level 3 out of range, 10/02/22- Level 1 and 3 out of range, 10/08 /22- Level 1 out of range, 01/14/23- Level 1 out of range, 01/28/23- Level 3 out of range, 02/25/23- Level 2 out of range, 03/11 and 19/23- Level 2 and 3 out of range, 04 /19-22, 24, 27, 28 and 29/23- Level 3 out of range, 05/1-5, 8-14, 17-19, 25 and 26/23- Level 3 out of range, 05/28/23- Level 2 out of range, 06/01, 03, 06, 07, 09, 12, 13 and 25/23- Level 3 out of range, 06/10 and 24/23- Level 2 and 3 out of range, 07/06, 07,

	11 and 28/23- Level 3 out of range, 07/08 and 23/23- Level 1, 2 and 3 out of range, 07 /22/23- Level 2 out of range, 09/11/23- Level 3 out of range, 10/03, 04, 10, 11, 16-20, 22, 24, 25, 30 and 31/23- Level 3 out of range and 11/01 and 02/23- Level 3 out of range. There was no documentation of troubleshooting procedures for the above-specified dates as defined by the policy. 3. Review of patient testing data for the WBC parameter in the eClinical EMR revealed 784 patients reported in 2022 and 932 patients in 2023. 4. An exit interview with the technical consultant on 01/22/24 at approximately 1500 confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on the review of manufacturer package inserts (PI), daily quality control (QC) logs, and interviews, the lab failed to ensure the correct standard deviation (SD) was used to calculate the acceptable ranges for the white blood cell (WBC) QC materials for six of seven lot numbers for 24 of 24 months reviewed. Findings include: 1. Review of the R&D HC WBC QC manufacturer PIs and an interview with the technical consultant on 01/22/24 at 1300 revealed the lab uses the manufacturers' published lot specific mean and two SD to manually calculate the ranges for all three levels (low, normal, and high) of QC materials. The staff manually transcribes the calculated ranges for all the three levels to the log sheets for daily assessment of acceptability. 2. The surveyor reviewed QC records from 01/22/22 up to the date of survey on 01/22/24. The surveyor observed that the hand-written range of acceptability for all three levels of QC materials was incorrect on the QC logs sheets (greater than two SD provided by the manufacturer) for lot numbers HC03221, HC06221, HC09221, HC12221, HC03231 and HC06231. The lot numbers were used from 01/22/22 up to 07/31/23. 3. In an interview with the technical consultant on 01/22 /24 at 1500, they stated, "we use the mean and two SD provided by the manufacturer for each lot number of QC materials. The testing personnel responsible for calculating and writing the WBC QC ranges on the daily log sheets used the wrong calculations and that that individual is no longer with the lab." 4. An exit interview with the technical consultant on 01/22/24 at 1500 confirmed the findings. B. Based on the review of manufacturer package inserts (PI), daily quality control (QC) logs, lack of documentation, and interviews, the lab failed to verify seven of seven new lot numbers of white blood cell (WBC) QC materials according to manufacturer's instructions for 24 of 24 months reviewed. Findings include: 1. Review of the R&D HC WBC QC manufacturer PI revealed the following statements, "Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test

	the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range." 2. Review of the WBC manufacturer PIs and QC logs from 01/22/22 up to the date of survey on 01/22/24 revealed the lab received seven lot numbers- HC03221, HC06221, HC09221, HC12221, HC03231, HC06231 and HC09231. In addition, the review revealed lack of documentation of the verification of the new lot numbers prior to use. 3. In an interview with the technical consultant on 01/22/24 at 14:00, the inspector requested to review the verification of the lot numbers as described by the manufacturer. They stated, "the staff is supposed to perform that verification and there should be documentation." They reviewed the QC logs with the inspector and confirmed that there was no documentation of verification of new lot numbers. 4. An exit interview with the technical consultant on 01/22/24 at 1500 confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), daily quality control (QC) logs, lack of documentation and interview, the lab failed to ensure that the established quality assurance (QA) plan identified and addressed analytical issues in the subspecialty of hematology for 24 of 24 months reviewed. Findings include: 1. The review of the P&P revealed the following, "Quality Assurance Program" "Phase and Elements to be evaluated- Analytical- records correcting laboratory errors, instrument: quality control effective actions and follow-up." "Frequency of QA reviews: There will be a routine, scheduled monthly review of a selected element(s) AND in response to identified problem or complaint needed immediate attention." "All QA review and activities should be documented completely on the appropriate logs. The documentation should include: date of the review, initial of person performing review, scope of the review, results of review and any corrective action taken and date and description of the effectiveness of corrective action." 2. Review of the Hemocue white blood cell (WBC) QC logs sheets revealed the technical consultant signed the logs each month and lack of documentation of corrective actions taken for the incorrect calculated QC ranges for the 24 of 24 months reviewed from 01/22/22 up to the date of survey on 01/22/24. 3. An exit interview with the technical consultant on 01/22/24 at approximately 1500 confirmed the findings.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), manufacturer package inserts (PI), daily quality control (QC) logs, lack of documentation, and interview, the lab director failed to ensure that the current QC procedures and quality assessment reviews identified and corrected analytic issues in the subspecialty of hematology for the Hemocue white blood cell (WBC) Procedure for 24 of 24 months reviewed. Refer to D5403, D5469 A & B, and D5791.