Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 38D0623604	**(X3) Date Survey Completed** 01/20/2022
Name of Provider or Supplier Vancouver Clinic - Lovejoy	**Street Address, City, State** 2222 Nw Lovejoy Suite #505, Portland, OR	
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**
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records and interview with the staff the laboratory showed zero results in Hematology for the 3rd event of 2021. Findings include: 1. API 3rd event 2021. a) Cell ID or WBC Diff = 0% b) Red Blood Cell = 0% c) Hematocrit = 0% d) Hemoglobin = 0% e) White Blood Cell = 0% f) Platelets = 0% 2. There were no corrective actions documentation for failed proficiency testing (PT) results. 3. Interview with the laboratory staff revealed that the laboratory failed to submit the PT results on time. The laboratory staff confirmed these findings on 01/20/2022 @ 15:30 PM.
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 review of calibration records and discussion with the staff the laboratory failed to perform calibration verification every six months for the Architect 1000i and the Beckman Coulter AU480 Chemistry Analyzers. Findings include: 1. Calibration verification for the Architect 1000i for Thyroid Stimulating Hormone, Free Thyroxine, Prostate Specific Antigen and Ferritin were last performed 04/30/2019. Calibration verifications were not perform for the year 2020 and 2021 . 2. Calibration verification for analytes run using Beckman Coulter AU480 Chemistry Analyzer was last performed 03/06/2019. Calibration verifications were not perform for the year 2020 and 2021. 3. Discussion with the laboratory staff confirmed these findings 01/20 /2022 @ 15:30 PM.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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. This STANDARD is not met as evidenced by: Review of Personnel records and discussion with the staff the laboratory's Technical Consultant (TC) failed to perform competency assessment of one testing personnel (TP). Findings include: 1. One of two testing personnel performing moderate complexity testing do not have record of competency assessment for the year 2020 and 2021. 2. Discussion with the staff confirmed these findings 01/20/2022 @ 15:30 PM.