Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2211147	12/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Vascular Labs Of The Rockies, Pllc	4105 E Florida Ave Suite 100, Denver, CO	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a record view and an inteview with the laboratory's technical consultant (TC), the lab failed to follow the written policy for the evaluation of testing personnel competency, as well as establish a policy for technical consultant competency. The laboratory employs two testing personnel, one of which is also designated as the TC. Findings include: 1. A review of the lab's policies revealed the lack of a written policy for competency evaluation for consultants. 2. An interview with the TC on 12.19.2023 at 9:30AM confirmed that no policy for evualation of TC competency was in place. 3. A review of the lab's testing personnel competency assessments showed that competency evaluations were not signed off by a competent trainer, such as the LD or a TC with approved competencies.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by:

	Based on a laboratory observation and an interview with the laboratory's technical consultant (TC), the lab failed to label control and calibration materials with preparation and expiration dates. The laboratory performs 430 chemistry and hematology tests annually. Findings include: 1. Observation during a laboratory tour revealed that no preparation or expiration dates were written on opened QC or calibration reagents. 2. An interview with the TC on 12.19.2023 at 12PM confirmed that these dates were not written on materials when opened.
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 record review and an interview with the laboratory's technical consultant (TC), the laboratory failed to regularly perform and document calibration verifications for the I-STAT instrument used for Blood Gas and Chemistry testing every six months, as required under CLIA regulations. The laboratory performs 230 chemistry and tests annually. Findings include: 1. A review of the lab's policies showed that there was no written policy for calibration verification. 2. A review of the lab's calibration verification logs revealed that since 2021 only one calibration verification was documented for Blood Gas (May 2023) and only two calibration verifications were documented for Chemistry (May 2023 and August 2022). 3. An interview with the TC on 12.19.2023 at 11AM confirmed that the lab had failed to perform calibration verifications every six months.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a record review and an interview with laboratoy's technical consultant (TC), the lab failed to list the address of the location where the test was performed. The laboratory performs 430 chemistry and hemotology tests annually. Findings include: 1. A record review of patient test reports showed that no address was listed. 2. An interview with the TC on 12.19.2023 at 12PM confirmed that the patient test report reviewed was all that would be sent to a patient upon request and did not list the address of the lab.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant (TC) showed that the laboratory director (LD) failed to review proficiency testing (PT) reports and implement corrective actions for failed PT events. PT events reviewed spanned 2021, 2022 and 2023. Findings include: 1. A review of the lab's PT records revealed that no PT evaluation forms had been reviewed and signed by the LD, nor by any delegated employee. 2. A review of the lab's PT records did not find any evidence of investigation or corrective action for failed PT events. 3. An interview with the lab's TC on 12.19.23 at 10AM confirmed that no action was taken with PT events after the results were submitted.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a record review and an interview with the lab's technical consultant (TC), the laboratory director failed to ensure that a quality assessment (QA) policy was established for and maintained by laboratory staff. The laboratory performs 430 chemistry and hematology tests annually. Findings include: 1. A record review of the

	lab's policies showed that the lab's QA policy was a section of CLIA regulations 493.1230 - 493.1299 and did not include actual policy specific to the laboratory. 2. An interview with the lab's TC on 12.19.23 at 1130AM confirmed that the lab did not have any other QA policy and that QA activities were not established to ensure the quality of lab services.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based a record review and an interview with the lab's technical consultant (TC), the laboratory director failed to approve the laboratory's policies and procedures. The laboratory performs 430 chemistry and hematology tests annually. Findings include: 1. A record review revealed that the policies available in the lab were not approved and signed by the lab director. 2. An interview with the TC on 12.19.2023 at 1130AM confirmed that the available policies were not approved and signed by the LD.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a record review and an interview with laboratory's technical consultant (TC), the lab failed to establish a competency assessment policy that evaluated testing personnels' problem solving skills. The laboratory employs two testing personnel, one of which is also designated as the TC. Findings include: 1. A review of the lab's policy for evaluating testing personnel competency revealed that the policies used for competency testing did not evaluate testing personnels' problem solving skills. 2. An interview with the TC on 12.19.2023 at 930AM confirmed that competency evaluations did not address problem solving skills.