Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1083069	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Vibra Specialty Hospital	10300 Ne Hancock St, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the IL GEM 3500 blood gas analyzer operator manual, and interview with the laboratory lead testing personnel, the laboratory failed to maintain and store the IL GEM analyzer and cartridges per the manufacturers instructions. Findings include: 1. According to the manufacturers operation manual, the IL GEM 3500 is to be maintained at a humidity level between 15 to 85% and the IL GEM cartridges must be stored at 15 to 25 degrees centigrade. 2. There were no humidity and temperature records from January 1, 2022, to March 31, 2023. 3. The GEM cartridges are stored at the lead testing personnel office, the laboratory failed to have documentation of humidity and temperature records. 4. Interview with the lead testing personnel on 07/12//2023, at 4:00 PM, confirmed these findings. 5. The laboratory performed 871 arterial blood gas tests in 2022, and 217 arterial blood gas tests in 2023.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests

	and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the IL GEM 3500 procedure manual, patient results in the laboratory information system (LIS), and interview with the lead testing personnel, the laboratory failed to provide the reference ranges or normal values for the arterial blood gas analytes PO2 and PCO2 to the authorized persons responsible for the test results. Findings include: 1. Review of the laboratory's IL GEM 3500 blood gas analyzer procedure manual, the reference ranges for PO2 were 75 to 100 mmHg and PCO2 was 35 to 45 mmHg. 2. The reference ranges were missing in the LIS and the patient report on one of one patient test report was reviewed. 3. The laboratory provided no other sources for the test requester to access the normal reference ranges, other than the patient test report. 4. Interview with the lead testing personnel on July 12, 2023, at 4:00 PM, confirmed these findings. 5. The laboratory performed 871 arterial blood gas tests in 2022 and 217 arterial blood-gas tests in 2023.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on a review of patient test results and an interview with the lead testing personnel, the laboratory failed to document the date, time, test results, and the person to whom the critical test results were reported. Findings include: 1. Review of a patient's electronic medical record with a critical pH of 7.26, revealed there was a lack of documentation for the date, time, test results, and the name of the person to whom the results were given. 2. Interview with the lead testing personnel on July 12, 2023, at 4:00 PM, confirmed these findings. 3. The laboratory performed 871 arterial blood gas in 2022 and 217 arterial blood gas in 2023
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 a review of personnel records, training, competency records, proficiency testing (PT) records, and Quality Assurance (QA) records, the laboratory director (LD) failed to provide overall management and direction of the laboratory. Refer to D6019, D6021, D6029 and D6032.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the College of American Pathology (CAP) proficiency testing (PT) records and an interview with the lead testing personnel (TP), the laboratory director (LD) failed to provide documentation of corrective actions taken for PT testing results found to be unacceptable or unsatisfactory. Findings include: 1. CAP 3rd event 2021, Routine Chemistry =50%, PO2 = 0%. 2. The LD failed to provide documentation of corrective actions taken for failed PO2 results. 3. Interview with the lead testing personnel on 07/12/2023 at 4:00 PM, confirmed these findings. 4. The laboratory performs approximately 871 PO2 tests annually.
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 review of the quality assurance (QA) record and interview with the lead testing personnel, the laboratory director (LD) failed to ensure that quality assessments were performed and documented. Findings include: 1. The laboratory failed to provide documentation of QA performance, as outlined in their QA plan, for the years 2022 to the time of survey 2023. 2. Interview with the lead testing personnel on 07/12/2023 at 4:00 PM, confirmed these findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel training records and an interview with the lead testing personnel, the laboratory director (LD) failed to ensure that prior to patient testing, all testing personnel (TP) have the required documentation of education and experience

	required. Findings include. 1. Nine (9) out of fifteen (15) TP performing moderately complex arterial blood gas testing did not have copies of their diploma or transcript of records on file at the time of the survey. 2. Interview with the lead testing personnel on 07/12/2023 at 4:00 PM, confirmed these findings. 3. The laboratory performed 871 arterial blood gas in 2022 and 217 arterial blood gas in 2023 to the date of the survey.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and an interview with the lead testing personnel, the laboratory director (LD) failed to specify in writing, the responsibilities, and duties of each consultant and each person involved in all phases of the testing process. Findings include: 1. The laboratory director failed to provide documentation for the delegation of duties and responsibilities for the following laboratory personnel. a) Technical Consultant (TC) b) Testing Personnel (TP) 2. Interview with the lead testing personnel on 07/12/2023 at 4:00 PM, confirmed these findings.