

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0932920	<b>(X3) Date Survey Completed</b> 01/17/2025
<b>Name of Provider or Supplier</b> Vibra Hospital Of Clear Lake	<b>Street Address, City, State</b> 709 Medical Center Blvd, Webster, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial onsite survey was completed on 01/17/2025. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the method verification records, and confirmed in an interview, the laboratory failed to document verification of the laboratory's reference ranges for 1 of 1 new chemistry instrument implemented in 2023: iSTAT instrument. The findings were: 1. Review of the laboratory's policy titled LABORATORY QUALITY ASSESSMENT PLAN, revised on 3/2023, under Verification of Performance Specifications revealed, "When new non-waived test tests /methods are introduced into the laboratory, the manufacturer's stated claims for the performance specifications of accuracy, precision, reportable range, and reference range are verified before testing patients." 2. Review of the laboratory's method verification records reveal no documentation of the laboratory's verification of reference ranges for 1 of 1 new chemistry instrument: iSTAT MN300 Analyzer (SN:</p>

430978) prior to patient testing. 3. An interview on 01/17/2025 at 4:49 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's aqueous/liquid QC records in 2024 and confirmed in an interview, the laboratory failed to have documentation of monitoring QC values over time for 3 of 3 quantitative analytes performed on iSTAT analyzer for 12 of 12 months reviewed: pH, pCO<sub>2</sub>, and pO<sub>2</sub>. The findings were: 1. Review of the iSTAT analyzer aqueous/liquid QC records in 2024 revealed the laboratory performed 3 of 3 analytes on CG4+ cartridge on iSTAT instrument (SN: 430978) with quantitative values. CG4+ cartridge analytes pH pCO<sub>2</sub> pO<sub>2</sub> 2. Further review of the iSTAT analyzer aqueous/liquid QC records in 2024 revealed no documentation of the laboratory monitoring the QC values over time for 3 of 3 quantitative analytes performed on iSTAT analyzer for 12 of 12 months reviewed. 3. An interview on 01/17/2025 on 3:45 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. Key: QC=Quality Control CMS=Center of Medicare and Medicaid Services

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

(d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's establishment verification records, the laboratory's policy, QCP records in IQCP plan, and confirmed in an interview, the laboratory failed to establish a QCP to support the modification in quality control testing to every 30 days for 1 of 1 iSTAT analyzer. The findings were: 1. Review of the laboratory's establishment verification records for iSTAT Analyzer (SN: 430978)

revealed the verification of performance of the iSTAT analyzer in use was in January, 2023. 2. Review of the laboratory's policy titled Risk Assessment revealed "Type of quality control: External Quality Control Normal Value Abnormal Value. Frequency: Two levels of liquid controls every 30 days or the first day of patient testing each month." 3. Surveyor requested for the laboratory's QCP to support the reduction in QC frequency from every day of patient testing to every 30 days, but none was provided. 4. Review the laboratory's CMS 116 application, provided by the laboratory on 01/17/2025, revealed the annual testing volume was 180. 5. An interview on 01/17/2025 at 2:00 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. The testing personnel #8 stated the laboratory performs two levels of external quality control with the new lot batch of reagents and when there is no patient testing in a month. Key: QCP=Quality Control Plan IQCP=Individualized quality control plan

**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 the surveyor's direct observation, the review of the laboratory's temperature records from October 2024 to December 2024, patient results, and confirmed in an interview, the laboratory failed to have documentation of corrective actions for 7 of 92 days reviewed when the temperature was documented outside the laboratory's acceptable ranges. The findings were: 1. Review of the laboratory's temperature acceptable ranges revealed, "Refrigerator temperature must be 2-8C (35-46F)." 2. Review of the laboratory's temperature documentation from October 2024 to December 2024 revealed 7 of 92 days reviewed the temperature was documented outside the laboratory's acceptable ranges. 11/10/2024 34F 11/11/2024 34F 11/13/2024 34F 11/18/2024 32F 11/26/2024 34F 12/01/2024 34F 12/03/2024 34F 3. The surveyor's direct observation on 01/17/2025 at 1:45pm in the lab revealed the refrigerator contained: iSTAT Control Level 1 iSTAT Control Level 3 iSTAT TriControls for calibration verification Level 1 to Level 5 3. Review of the laboratory's patient results for the above dates revealed 2 patients had iSTAT testing performed when the refrigerator temperature was out of acceptable ranges. 12/01/2024 MRN: 90934 12/03/2024 MRN:90180 4. An interview on 01/17/2025 at 2:00 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. Key: C=Celsius F=Fahrenheit MRN=Medical record number CMS=Center of Medicare and Medicaid Services

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

(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:

A. Based on the review of the laboratory's patient report and confirmed in an interview, the laboratory failed to include the address of the laboratory where the tests were performed for 5 of 5 patient final reports reviewed. The findings were: 1. Review of the laboratory's patient reports revealed the laboratory failed to include the address of the laboratory where the tests were performed for 5 of 5 patient final reports reviewed. 01/03/2025 Account#: 221070000539 01/10/2025 Account#: 221070000536 01/14/2025 Account#: 221070000540 01/15/2025 Account#: 221070000546 01/17/2025 Account#: 221070000547 2. In an interview on 01/17/2025 at 4:55 pm in the office, the testing personnel #8 (as indicated on the CMS 209 form) confirmed the above findings. B. Based on the review of the manufacturer's package insert, the laboratory's patient reports, and confirmed in an interview, the laboratory failed to include the specimen sources, and the units of measurement for 5 of 5 patient final reports reviewed. The findings were: 1. Review of the manufacturer's package insert titled iSTAT CG4+ Cartridge (Rev. Date 07-Sep-2020 7679355-00 Rev. B) Under EXPECTED VALUES revealed Analyte: iSTAT pH Unit of measurement: pH units Analyte: iSTAT PCO2 Unit of measurement: mmHg Analyte: iSTAT PO2 Unit of measurement: mmHg Analyte: iSTAT Total CO2 Unit of measurement: mmol/L Analyte: iSTAT HCO3 Unit of measurement: mmol/L Analyte: iSTAT Base excess Unit of measurement: mmol/L Analyte: iSTAT SO2 Unit of measurement: % 2. Random review of the laboratory's patient reports revealed the laboratory reported 7 of 7 blood gas analytes performed from iSTAT CH4+ cartridge. iSTAT pH iSTAT PCO2 iSTAT PO2 iSTAT Total CO2 iSTAT HCO3 iSTAT Base excess iSTAT SO2 3. Further random review of the laboratory's patient reports revealed the laboratory failed to include the specimen sources, and 6 of 7 the units of measurement for 5 of 5 patient final reports reviewed. Units of measurement not included: iSTAT PCO2 iSTAT PO2 iSTAT Total CO2 iSTAT HCO3 iSTAT Base excess iSTAT SO2 Patient reports reviewed: 01/03/2025 Account#: 221070000539 01/10/2025 Account#: 221070000536 01/14/2025 Account#: 221070000540 01/15/2025 Account#: 221070000546 01/17/2025 Account#: 221070000547 4. In an interview on 01/17/2025 at 4:55 pm in the office, the testing personnel #8 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's proficiency testing events in 2004, the laboratory's records, and confirmed in an interview, the laboratory director failed to

have documentation of delegating the responsibility of signing attestation sheets to qualified personnel for 2 of 3 events in 2024. The findings were: 1. Review the laboratory's API proficiency testing events in 2024 revealed the testing personnel #8 (as indicated on CMS 209 form) signed the attestation forms and performance evaluations for 2 of 3 testing events. 2024 Chemistry Core 2nd Event 2024 Chemistry Core 3rd Event 2. Review of the laboratory's records revealed no documentation of delegation for testing personnel to sign proficiency testing documents. 3. An interview on 01/17/2025 at 1:27 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. Key: API=American Proficiency Institute CMS=Center of Medicare and Medicaid Services

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iii)

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

This STANDARD is not met as evidenced by:  
Based on the review of the laboratory's policy, arterial blood gas competency form and confirmed in an interview, the technical consultant failed to include the review of test results, quality control, proficiency testing, and preventive maintenance for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer. The findings were: 1. Review of the laboratory's policy titled Risk Assessment under Competency Assessment revealed "Criteria for acceptability (Range of Accepted Values): All testing personnel must successfully meet all six CLIA elements for competency assessment." 2. Review of the laboratory's arterial blood gas competency form revealed the technical consultant failed to include the review of test results, quality control, proficiency testing, and preventive maintenance for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer (SN: 430978). Testing personnel#1 Testing personnel#2 Testing personnel#3 Testing personnel#4 Testing personnel#5 Testing personnel#8 Testing personnel#9 Testing personnel#10 3. An interview on 01/17/2025 on 12:55 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

**D6050**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:  
Based on the review of the laboratory's policy, arterial blood gas competency form and confirmed in an interview, the technical consultant failed to include the direct observation of instrument maintenance and function check performance for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer. The findings were: 1. Review of the laboratory's policy titled Risk Assessment under Competency Assessment revealed "Criteria for acceptability (Range of Accepted Values): All testing personnel must successfully meet all six CLIA elements for competency assessment." 2. Review of the laboratory's arterial blood gas competency form revealed the technical consultant failed to include the direct observation of

instrument maintenance and function check performance for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer (SN: 430978). Testing personnel#1 Testing personnel#2 Testing personnel#3 Testing personnel#4 Testing personnel#5 Testing personnel#8 Testing personnel#9 Testing personnel#10 3. An interview on 01/17/2025 on 12:55 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:  
Based on the review of the laboratory's policy, arterial blood gas competency form and confirmed in an interview, the technical consultant failed to include an assessment of previously analyzed specimens, blind samples or proficiency testing samples for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer. The findings were: 1. Review of the laboratory's policy titled Risk Assessment under Competency Assessment revealed "Criteria for acceptability (Range of Accepted Values): All testing personnel must successfully meet all six CLIA elements for competency assessment." 2. Review of the laboratory's arterial blood gas competency form revealed the technical consultant failed to include an assessment of previously analyzed specimens, blind samples or proficiency testing samples for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer (SN: 430978). Testing personnel#1 Testing personnel#2 Testing personnel#3 Testing personnel#4 Testing personnel#5 Testing personnel#8 Testing personnel#9 Testing personnel#10 3. An interview on 01/17/2025 on 12:55 pm in the office, the testing personnel #8 (as indicated on CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(vi)

(b)(8)(vi) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:  
Based on the review of the laboratory's policy, arterial blood gas competency form and confirmed in an interview, the technical consultant failed to include an assessment of problem solving skills for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer. The findings were: 1. Review of the laboratory's policy titled Risk Assessment under Competency Assessment revealed "Criteria for acceptability (Range of Accepted Values): All testing personnel must successfully meet all six CLIA elements for competency assessment." 2. Review of the laboratory's arterial blood gas competency form revealed the technical consultant failed to include an assessment of problem solving skills for 8 of 11 competency assessment performed arterial blood gas testing on iSTAT analyzer (SN: 430978). Testing personnel#1 Testing personnel#2 Testing personnel#3 Testing personnel#4 Testing personnel#5 Testing personnel#8 Testing personnel#9 Testing personnel#10 3. An interview on 01/17/2025 on 12:55 pm in the office, the testing personnel #8 (as indicated on CMS 209

form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

**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 the review of the laboratory's policy, the CMS 209 form, the personnel's competency assessment records, and confirmed in an interview, the technical consultant failed to evaluate and document at least twice of competency assessments during the first year for 3 of 11 TP performing moderate complexity testing. The findings were: 1. Review of the laboratory's policy titled Rick Assessment revealed, "Type of Quality Control: Competency Assessment Frequency: Six months and one year after initial training, annually thereafter. 2. Review of the laboratory's CMS 209 form, Laboratory Personnel Report (CLIA), provided by the laboratory on 01/17/2025, revealed the laboratory identified 11 TP performing moderate complexity testing. 3. Review of the laboratory's competency assessment revealed the technical consultant failed to evaluate and document at least twice of competency assessments during the first year for 3 of 11 TP performing moderate complexity testing. TP#6 Rehired date: June/July, 2022 Missing 6 month competency assessment and 1st annual competency assessment. TP#7 Hired date: August, 2024 Missing initial training TP#11 Hired date: 06/15/2023 Missing initial training, 6 month competency assessment and 1st annual competency assessment. 4. An interview on 01/27/2025 at 1:05 pm in the office, the TP#8 (as indicated on the CMS 209 form) confirmed the above findings. Key: TP=Testing personnel CMS=Center of Medicare and Medicaid Services

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy, the CMS 209 form, the personnel's competency assessment records in 2023 and 2024, and confirmed in an interview, the technical consultant failed to evaluate and document annual competency assessment in 2024 for 1 of 11 TP performing moderate complexity testing. The findings were: 1. Review of the laboratory's policy titled Rick Assessment revealed, "Type of Quality Control: Competency Assessment Frequency: Six months and one year after initial training, annually thereafter. 2. Review of the laboratory's CMS 209 form, Laboratory Personnel Report (CLIA), provided by the laboratory on 01/17/2025, revealed the laboratory identified 11 TP performing moderate complexity testing. 3. Review of the laboratory's competency assessment revealed the technical consultant failed to evaluate and document annual competency assessment in 2024 for 1 of 11 TP performing moderate complexity testing. TP#8 Hired date: December, 2022 Last annual competency assessment date: 03/01/2023 4. An interview on 01/27/2025 at 1:05 pm in the office, the TP#8 (as indicated on the CMS 209 form) confirmed the

above findings. Key: TP=Testing personnel CMS=Center of Medicare and Medicaid Services

**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 the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have qualifying documentation to qualify 1 of 11 testing personnel (TP) who performed moderate complexity testing. (Refer to 6065).

**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 the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have qualifying documentation to qualify 1 of 11 testing personnel (TP) who performed moderate complexity testing. The findings were: 1. Review of the laboratory's submitted CMS 209, the Laboratory Personnel Report, provided by the laboratory on 01/17/2025, revealed the laboratory identified 11 TP who performed moderate complexity testing. 2. Review of the laboratory's TP educational credential records revealed the laboratory failed to have qualifying documentation to qualify 1 of 11 TP who performed moderate complexity testing. TP#7 Hired Date: August, 2024 3. In an interview on 01/17/2025 at 1:05 pm in the office, the TP#8 (as indicated on CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel