Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1020113	**(X3) Date Survey Completed** 03/22/2024
Name of Provider or Supplier Vibra Hospital Of Houston	**Street Address, City, State** 1300 Binz, Houston, TX	
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 validation survey was performed on March 20, 2024. 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
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 the review of the manufacturer's instructions, the laboratory's policy, the

	laboratory's records in 2023, CMS 116 application, and confirmed in an interview, the laboratory failed to have documentation for 2 of 2 calibration verification records in 2023 for i-STAT chemistry analyzer for analytes pH, pCO2, and pO2. The findings were: 1. Review of the manufacturer's instructions titled i-STAT 1 System Manual (Art: 714377-00U. Rev Date: 18-OCT-2021) Under Chapter 15, page 15-1 revealed "Overview: ... It is the responsibility of the laboratory to determine when and how this procedure should be performed." 2. Review of the laboratory's policy titled VIBRA Healthcare Individualized Quality Control Plan revealed the following, "Type of Quality Controls: Calibration Verification. Frequency: Once every 6 months". 3. Review of the laboratory's records in 2023 revealed the laboratory failed to have documentation for 2 of 2 calibration verification records in 2023 for i-STAT chemistry analyzer for analytes pH, pCO2, and pO2. 4. Review of the laboratory's CMS 116 application, signed by the laboratory director on 03/20/2024, revealed the annual routine chemistry volume was 392. 5. In an interview on 03/20/2024 at 4:30 pm outside the lab, the Market Respiratory Director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services pH=Potential of hydrogen pCO2= Partial pressure of carbon dioxide pO2=Partial pressure of oxygen
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the laboratory's IQCP policy, the laboratory's liquid QC records in 2023, patient results, and confirmed in an interview, the laboratory failed to perform two levels of liquid QC at the frequency specified by the laboratory (every 30 days) for 3 of 12 months in 2023 on i-STAT Analyzer. The findings were: 1. Review of the laboratory's policy titled VIBRA Healthcare Individualized Quality Control Plan revealed the following, "Type of Quality Controls: 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." 2. Review of the laboratory's liquid QC records in 2023 revealed the following, 2 levels liquid QC performed on 08/25/2023 Next 2 levels liquid QC due on 09/24/2023 2 levels liquid QC performed on 10/02 /2023 QC overdue: 09/24/2023-10/01/23 (9 days overdue) 2 levels liquid QC performed on 10/02/2023 Next 2 levels liquid QC due on 11/01/2023 No documentation of next 2 levels liquid QC records QC overdue: 11/01/2023-2/15/2024 (107 days overdue) 3. Review of the laboratory's patient results from 09/24/2023 to 10 /01/2023 and 11/01/2023 to 12/31/2023 revealed total of 36 patients had testing performed on i-STAT analyzer and reported to the ordering physicians. 09/26/2023 Patient MR#: 68941 09/29/2023 Patient MR#: 68941 11/01/2023 Patient MR#: 67924 11/02/2023 Patient MR#: 67924 11/03/2023 Patient MR#: 72078 11/11/2023 Patient MR#: 74005 11/12/2023 Patient MR#: 73801 11/12/2023 Patient MR#: 74098 11/13 /2023 Patient MR#: 74005 11/13/2023 Patient MR#: 73343 11/13/2023 Patient MR#: 74098 11/16/2023 Patient MR#: 73511 11/16/2023 Patient MR#: 74004 11/21/2023

	Patient MR#: 72078 11/22/2023 Patient MR#: 74673 11/22/2023 Patient MR#: 74004 11/23/2023 Patient MR#: 74004 11/29/2023 Patient MR#: 74204 11/29/2023 Patient MR#: 74958 11/29/2023 Patient MR#: 74671 12/01/2023 Patient MR#: 74671 12/01 /2023 Patient MR#: 73836 12/07/2023 Patient MR#: 74428 12/07/2023 Patient MR#: 75263 12/10/2023 Patient MR#: 70458 12/11/2023 Patient MR#: 75263 12/12/2023 Patient MR#: 75644 12/16/2023 Patient MR#: 75433 12/23/2023 Patient MR#: 76374 12/24/2023 Patient MR#: 76218 12/28/2023 Patient MR#: 76374 12/29/2023 Patient MR#: 76573 12/29/2023 Patient MR#: 76531 12/30/2023 Patient MR#: 76522 12/31 /2023 Patient MR#: 76522 12/31/2023 Patient MR#: 76531 4. In an interview on 03/20 /2024 at 2:00 pm outside the lab, the Market Respiratory Director confirmed the above findings. Key: IQCP=Individual Quality Control Plan QC=Quality Control MR=Medical Record
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 documentation of education to qualify 6 of 19 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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(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 documentation of education to qualify 6 of 19 TP who performed moderate complexity testing. The findings were: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report, signed by the laboratory director on 03/06/24 and on 03/20/24, revealed the laboratory identified 19 TP who performed moderate complexity testing. 2. Review of the laboratory's TP educational credential records revealed the laboratory failed to have documentation of education to qualify 6 of 19 TP who performed moderate complexity testing. TP#4 Hired Date: 2/16/2020 No

	education documentation provided TP#7 Hired Date: 5/16/2023 No education documentation provided TP#9 Hired Date: 1/17/2023 No documentation of high school diploma TP#10 Hired Date: 2/21/2023 No education documentation provided TP#14 Hired Date: 8/6/2018 No education documentation provided TP#16 Hired Date: 3/10/2020 No education documentation provided 3. In an interview on 03/20 /2024 at 4:00 pm outside the lab, the Market Respiratory Director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel