

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0932920	(X3) Date Survey Completed 09/17/2026
Name of Provider or Supplier Vibra Hospital Of Clear Lake	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey completed on 09/17/2026 and recertification is recommended. Standard level deficiencies were cited.
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 review of the laboratory's quality control (QC) records from January to August 2026 and confirmed in an interview, the laboratory failed to have documentation of monitoring QC values over time for iSTAT system performing moderate complexity tests for eight of eight months reviewed. The findings were: 1. Review the laboratory's QC records revealed the laboratory had 1 iSTAT analyzer (SN: 430978) to perform moderate blood gas tests on the CG4+ Cartridges using iSTAT TriControl Level 1 and level 3 2. Further review of the laboratory's QC records from January to August 2026 revealed the laboratory failed to have documentation of monitoring QC values over time for iSTAT system performing

moderate complexity tests for eight of eight months reviewed. 3. An interview on 09/17/2026 at 11:50 am in the library, the RT director (as indicated on the sign in sheet) confirmed the above findings. Key: RT=Respiratory Therapist

D6046

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

(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on review of laboratory's policy, personnel competency records from January to August 2026, and confirmed in an interview, the laboratory's Technical Consultant failed to document performance of competency assessment for seven of eight personnel competency assessments performed in 2026. The findings were: 1. Review of the laboratory's policy titled S.19.52 Laboratory Personnel (PolicyStatID 16334958) under Technical Consultant/Supervisor responsibilities revealed "Evaluating the competency of all testing personnel and assuring that the staff maintain their competency ...All testing personnel must be listed on the CMS 209 and must undergo documented competency assessment. The technical consultant is responsible for assessing the competency of the testing personnel and the 6 competency assessment criteria." 2. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified eight testing personnel performing moderate complexity tests. 3. Further review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the testing personnel#1 is not qualified as a technical consultant. 4. Review of laboratory's personnel records from January to August 2026 revealed personnel competency assessments were performed by Testing Personnel#1 and not by the Technical Consultant (TC) indicated on the CMS 209 form for seven of eight testing personnel. TP#2 Hired Date: 01/01/2026 TP#3 Hired Date: 01/01/2026 TP#4 Hired Date: 01/01/2026 TP#5 Hired Date: 01/01/2026 TP#6 Hired Date: 01/01/2026 TP#7 Hired Date: 01/01/2026 TP#8 Hired Date: 01/01/2026 5. An interview on 09/17/2026 at 10:55 am in the library, the RT director (as indicated on the sign in sheet) confirmed the above findings. Key: TP=Testing personnel RT=Respiratory Therapist