Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2296675	12/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Qoros Clear Lake Surgery Center, Llc	1240 Clear Lake City Blvd, Ste 100, 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	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 on 12/15/2025 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: A. Based on the review of the laboratory's aqueous/liquid QC records from January 2025 to November 2025 and confirmed in an interview, the laboratory failed to have documentation of monitoring QC values over time for 4 of 4 quantitative analytes performed on iSTAT analyzer for 11 of 11 months reviewed: pH, pCO2, pO2, and lactate. The findings were: 1. Review of the iSTAT analyzer aqueous/liquid QC records from January 2025 to November 2025 revealed the laboratory performed 4 of 4 analytes on CG4+ cartridge on iSTAT instrument (SN: 433150) with quantitative values. CG4+ cartridge analytes pH pCO2 pO2 Lactate 2. Further review of the iSTAT analyzer aqueous/liquid QC records from January 2025 to November 2025 revealed no documentation of the laboratory monitoring the QC values over time for 4 of 4 quantitative analytes performed on iSTAT analyzer for 11 of 11 months

	reviewed. 3. An interview on 12/15/2025 at 2:15 pm in the break room, the testing personnel #5 (as indicated on CMS 209 form) confirmed the above findings. B. Based on the review of the laboratory's verification studies, annual test volume & proficiency testing programs worksheet, aqueous/liquid QC records from August 2025 to November 2025 and confirmed in an interview, the laboratory failed to have documentation of monitoring QC values over time for ACT quantitative analyte performed on 2 of 2 Hemochron signature Elite analyzers for 4 of 4 months reviewed. The findings were: 1. Review of the laboratory's verification studies on Hemochron Signature Elite analyers revealed the laboratory director signed in July 2025. Hemochron Signature Elite SN:SE27833 Hemochron Signature Elite SN:SE27834 2. Review of the laboratory's annual test volume & proficiency testing programs worksheet signed by the laboratory director on 12/05/2025 revealed the facility started performing ACT on Hemochron Signature Elite analyzers on 07/15/2025. 3. Review of the Hemochron analyzer aqueous/liquid QC records from August 2025 to November 2025 revealed no documentation of the laboratory monitoring the QC values over time for ACT quantitative analyte performed on Hemochron Signature Elite analyzers for 4 of 4 months reviewed. 4. An interview on 12/15/2025 at 2:15 pm in the break room, the testing personnel #5 (as indicated on CMS 209 form) confirmed the above findings. Key: QC=Quality Control ACT=Activated clotting time CMS=Center of Medicare and Medicaid Services