Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2022504	04/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Elite Care 24 Hr Emergency Center	2530 Gulf Freeway South, League City, 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	A validation survey was completed on 04/25/2025. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the review of the laboratory's test menu, proficiency testing records from 2024 3rd event to 2025 1st event, FDA categories of tests website, the laboratory's policies, and confirmed in an interview, the laboratory failed to establish a written policy to monitor and/or correct problems in proficiency testing programs. The findings were: 1. Review of the laboratory's test menu revealed the analyte, uric acid, was performed on BioChemistry Panel Plus on the Piccolo Xpress Chemistry Analyzers. 2. Review of the laboratory's proficiency testing records from 2024 Chemistry Core 3rd event to 2025 Chemistry 1st event revealed the laboratory reported Uric Acid was performed by Abaxis Piccolo/Abaxis Piccolo Reagent as a waived test. 3. Review of the FDA categories of tests for CLIA revealed the analyte, uric acid, performed on Abaxis Piccolo Xpress Chemistry Analyzer was categorized a moderate complexity test. 4. Review of the laboratory's policies revealed the laboratory failed to establish a written policy to monitor and/or correct problems in proficiency testing programs. 5. An interview on 04/24/2025 at 2:00 pm in a station across the lab, the TC (as indicated on the CMS 209 form) confirmed the above findings. Key: API=American Proficiency Institute CLIA=Clinical Laboratory

	Improvement Amendments TC=Technical Consultant CMS=Center for Medicare and Medicaid Services
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of the laboratory's test menu, the manufacturer's package insert, the laboratory's policies, and confirmed in an interview, the laboratory failed to establish an acceptable test timing for "immediately" for 1 of 1 test of lactic acid performed on i-STAT chemistry analyzer CG4+ cartridge. The findings were: 1. Review of the laboratory's test menu revealed the laboratory performed CG4+ cartridge on 1 of 1 i-STAT MN-300 Analyzer (SN:357415). 2. An interview on 04/24 /2025 at 2:00 pm in a station across the lab, the TC (as indicated on the CMS 209 form) confirmed the laboratory used Lithium Heparin whole blood tube for i-STAT CG4+ cartridge testing. 3. . Review of the manufacturer's package insert (767935-00 Rev. B. Rev. Date: 07-Sep-2020) for i-STAT CG4+ cartridge under SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS in Blood collection Options and Test Timing (time from collection to cartridge fill) revealed "Evacuated Tubes: With lithium heparin anticoagulant ... Test timing: Immediately." 4. Review of the laboratory's policies revealed the laboratory failed to establish an acceptable test timing for "immediately" for the test of lactic acid performed on i-STAT chemistry analyzer CG4+ cartridge. 5. An interview on 04/25/2025 at 11:10 am in a station across the lab, the TC (as indicated on the CMS 209 form) confirmed the above findings. Key: TC: Technical Consultant CMS=Center for Medicare and Medicaid Services
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the laboratory's test menu, the manufacturer's package inserts, and confirmed in an interview, the laboratory failed to document open dates and revised expiration dates on thawed opened QC vials for 5 of 5 lot numbers in use for Pathfast cardiac Biomarker analyzer. The findings were: 1. Review of the laboratory's test menu revealed the tests of Troponin I, NT-proBNP, and D-dimer was performed on Pathfast cardiac Biomarker analyzer (SN: 1902D5380). 2. Review of the manufacturer's package insert titled Liquichek Cardiac

	Marker Plus Control LT Level 1, 2, 3, 1A, 1B and 1C (English. 2023-05. 16000202-00) under STORAGE and STABILITY revealed, "Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: -All Analytes: 20 days -N-terminal pro-Brain Natriuretic Peptide (NT-proBNP), B-type Natriuretic Peptide (BNP) and Troponin I: 5 days." 3. Review of the manufacturer's package insert titled Liquichek D-dimer Control Levels Low, 1, 2, and 3 (English. 2024-04. 5872-00) under STORAGE and STABILITY revealed, "Once opened and stored tightly capped at 2 to 8C, this product will be stable for 15 days." 4. Surveyor's direct observation on 04/25/2025 at 10:07 am from the laboratory refrigerator revealed no opened dates nor revised expiration dates documented on the thawed opened QC vials for 5 of 5 lot numbers in use. BioRad Liquichek Cardiac Markers Plus Control Level 1 Lot#: 67711 Original Exp. 2026-06-30 Level 3 Lot#: 1003113 Original Exp. 2027-03-31 Level 1B Lot#: 67705 Original Exp. 2026-02-28 BioRad Liquichek D-dimer Control Level Low Lot#: 74424 Original Exp. 2025-07-31 Level 1 Lot#: 74441 Original Exp. 2027-06-30 8. An interview on 04/25/2024 at 10:29 am in a station across the lab, the TC (as indicated on the CMS 209 form) confirmed the above findings. Key: QC=Quality Control NT-proBNP=N-terminal pro-B-type natriuretic peptide C=Celcius
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (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. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the laboratory's the QC records, validation records, and confirmed in an interview, the laboratory failed to have documentation of establishment studies for 3 of 3 Piccolo Chemistry Analyzers prior to put in use for patient testing. The findings were: 1. The surveyor's direct observation on 04/24/2025 at 1:45 pm revealed the laboratory had 3 Piccolo Chemistry Analyzers. SN: P06688 SN: P31427 SN: P1080 2. Review of the laboratory's QC records revealed the 3 Piccolo Chemistry Analyzers dates in service as follows: SN: P06688 Date in service: 03/02/2023 SN: P31427 Date in service: 12/20/2023 SN: P1080 Date in service: 02/04/2024 3. Review of the laboratory's validation records for the above SN analyzers reveal no documentation of establishment studies prior to date in service for patient testing for 3 of 3 Piccolo Chemistry Analyzers. 8. An interview on 04/25/2024 at 11:25 am in a station across the lab, the TC (as indicated on the CMS 209 form) confirmed the above findings. Key: QC=Quality Control SN=Serial Number
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's test menu, the manufacturer's reagent package inserts, the laboratory's records, and confirmed in an interview, the laboratory failed to perform comparison studies for 1 of 1 analyte lactate between i-STAT chemistry analyzer and Piccolo chemistry analyzers in 2023 and 2024. The findings were: 1. Review of the laboratory's test menu revealed the laboratory performed lactate on CG4+ cartridge on i-STAT chemistry analyzer and lactate on MetLac 12 Panel on Piccolo chemistry analyzers. 2. Review of the manufacturer's package insert titled i-STAT CG4+ Caartridge (767935-00 Rev. B. Rev. Date: 07-Sep-2020) under INTENDED USE revealed " ...i-STAT 1 System is intended for use in the in vitro quantification of pH, PO2, PCO2, and lactate ..." 3. Review of the manufacturer's package insert titled Piccolo MetLac 12 Panel (July 2022 PN: 400-7192-1 Rev K.) under Summary and Explanation of Tests revealed "Lactate: ...". 4. Review of the laboratory's records revealed no comparison study documentation twice-per-year for 1 of 1 common analyte, Lactate, for i-STAT chemistry analyzer (SN: 357415) and Piccolo chemistry analyzers (SN: P06688, P31427, and P1080) in 2023 and 2024. 5. An interview on 04/24/2025 at 2:00 pm in a station across the lab, the TC (as indicated on the CMS 209 form) confirmed the above findings.