Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2065842	10/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Altus Lumberton Hospital, Llc	137 North Lhs Drive, Lumberton, 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	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 of Participation in the CLIA program, and recertification is recommended. .
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the review of API chemistry Core test events in 2021, and confirmed in an interview found the laboratory failed to attain a score of at least 80% in one of three 2021 Chemistry Core test Events (2021 Chemistry Core 3rd event) for i-STAT blood analyzer using CG4+ cartridges for one of four analytes: pH. The findings were: 1. Review of the API chemistry test events in 2021 revealed the laboratory performed chemistry with CG4+ cartridges for the analytes of Lactate, pCO2, pH, and pO2 on i-STAT blood analyzer. 2. Further review of the API chemistry test events in 2021 revealed the laboratory scored unsatisfactory score of 40% for one of four analytes of pH in one of three chemistry test events: 2021 Chemistry Core 3rd event. 3. Review of 2021 Chemistry Core 3rd event revealed the analyte of pH attained three of five unacceptable responses. IB13 Reported result 2.41 Expected result 7.34-7.43 IB14 Reported result 8.69 Expected result 6.95-7.04 IB15 Reported result 6.70 Expected result 7.09-7.18 4. An interview with the technical consultant on 10/12/22 at 10:45 am in the conference room confirmed the above findings. Key: API=American Proficiency Institute
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 direct observation of the surveyor, the review of the manufacturer's insert, the laboratory records, patient results, and confirmed in interview found he laboratory failed to perform one of two calibration verification for four of four analytes on the Abbott i-STAT blood analyzers in 2021. The findings were: 1. Direct observation of the surveyor on 10/12/22 at 10:00 am in the lab revealed the laboratory used two i-STAT blood analyzers: SN: 364466 and SN: 365791. 2. Direct observation of the surveyor on 10/12/22 at 10:00 am in the lab revealed the laboratory used CG4+ cartridges on i-STAT blood analyzers. 3. Review of the manufacturer's insert titled i-STAT CG4+ Cartridge (Art: 765788-00 Rev. A Rev. Date: 20-Feb-2020) under p.6 Calibration Verification revealed "Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test... However, it may be required by regulatory or accreditation bodies." 4. Review the laboratory's calibration verification records for CG4+ revealed the laboratory had documentation of calibration verification performed on 11/27/2020, and then on 12/24/2021 for i-STAT blood analyzers SN: 364466 and SN: 365791. The laboratory had no documentation of calibration verification for CG4+ of both i-STAT blood analyzers between 5/28/2021 to 12/23/2021. 5. Random review of the laboratory's patient records from 9/2/2021 to 12/15/2021 revealed 51 patient had testing performed with CG4+ cartridges on i-STAT blood analyzers. 9/2/2021 Patient MRN#: 46310 9/4 /2021 Patient MRN#: 46348 9/6/2021 Patient MRN#: 46427 9/7/2021 Patient MRN#: 46338 9/7/2021 Patient MRN#: 46427 9/8/2021 Patient MRN#: 46356 9/8/2021 Patient MRN#: 46485 9/9/2021 Patient MRN#: 46427 9/10/2021 Patient MRN#: 46427 9/11/2021 Patient MRN#: 46554 9/13/2021 Patient MRN#: 46554 9/14/2021 Patient MRN#: 46554 9/15/2021 Patient MRN#: 46642 9/18/2021 Patient MRN#: 46699 9/18/2021 Patient MRN#: 40649 9/20/2021 Patient MRN#: 46714 9/23/2021 Patient MRN#: 45736 9/25/2021 Patient MRN#: 46831 9/26/2021 Patient MRN#: 46858 9/27/2021 Patient MRN#: 46827 9/27/2021 Patient MRN#: 46874 9/28/2021 Patient MRN#: 37137 10/2/2021 Patient MRN#: 46969 10/4/2021 Patient MRN#: 46985 10/4/2021 Patient MRN#: 38160 10/10/2021 Patient MRN#: 46469 10/11/2021 Patient MRN#: 37518 10/11/2021 Patient MRN#: 47126 10/18/2021 Patient MRN#:

	45681 10/18/2021 Patient MRN#: 44279 10/19/2021 Patient MRN#: 44279 10/21 /2021 Patient MRN#: 47306 10/23/2021 Patient MRN#: 47344 11/20/2021 Patient MRN#: 47828 11/26/2021 Patient MRN#: 47942 12/1/2021 Patient MRN#: 48025 12 /6/2021 Patient MRN#: 48129 12/7/2021 Patient MRN#: 40602 12/7/2021 Patient MRN#: 48138 12/9/2021 Patient MRN#: 33832 12/15/2021 Patient MRN#: 43358 6. An interview with the technical consultant on 10/13/22 at 11:35 am in the conference room confirmed the above findings.