Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2069850	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Altus Lake Jackson, Lp	200 Oak Drive South, Lake Jackson, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2121	HEMATOLOGY CFR(s): 493.851(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 review of the 2017 - 2019 American Proficiency Institute (API) proficiency testing (PT) results and confirmed in interview, the laboratory failed to attain at least 80% for the analyte Monocytes for 1 of 6 Hematology events. Findings were: 1. Review of the 2017 - 2019 API Hematology PT results revealed the laboratory received the following scores for Monocytes. 2019 2nd event (40% Monocytes) Hem-08: lab result 8.3 (acceptable range 4.4 - 8.0) Hem-09: lab result 8.8 (acceptable range 6.5 - 8.7) Hem-10: lab result 8.9 (acceptable range 6.3 - 8.7) 2. An interview with the technical consultant #1 on 9/25/19 at 1010 hours in the admin office confirmed the above findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a

	proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing records, PT corrective actions, and confirmed in interview, the laboratory failed to document the remedial action for 1 of 1 hematology testing events with PT failures. findings were: 1. Review of the laboratory policy Quality Control Program under Proficiency Testing Corrective Action Plan revealed "the lab personnel performing the survey must review survey results and document the findings. The review will include result printouts, quality control, maintenance and calibration records. The review should include data during the time the survey was analyzed as well as those days before and after the survey. " 2. Review of the 2017 -2018 API proficiency testing records revealed 1 of 6 Hematology events with PT failures for the Monocytes. Cross refer to D2121 3. Review of the 2019 2nd event Proficiency Testing records revealed no documentation of the patient remedial action for the test event. 4. An interview with the technical consultant #1 on 09/25/19 at 1010 hours in the admin office confirmed the above findings.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's quality control records from January to September 2019, and confirmed in interview, the laboratory failed to have documentation of monitoring quality control values over time for CKMB, Troponin, Myoglobin, and D-dimer on the Alere Triage analyzer. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed the following tests on the Triage analyzer: CKMB Troponin Myoglobin D-dimer 2. A review of the laboratory's quality control records from January to September 2019 revealed no documentation to monitor over time the quality control for CKMB, Troponin, Myoglobin and D-dimer. Triage Controls Cardiac lot C3535AN level 1, exp 2/24/20 Cardiac lot C3560AN level 2, exp 2/29/20 DDimer Controls lot C3535AN level 1, exp 2/24/20 lot C3560AN level 2, exp 2/29/20 3. An interview with the technical consultant #1 on 09/25/19 at 1100 hours in the admin office confirmed the laboratory did not monitor quality control values over time. Key CKMB: creatine kinase: muscle brain

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 review of the manufacturer's instructions, laboratory policy, laboratory quality control records, patient test records, and confirmed in interview, the laboratory IQCP failed to have documentation of a complete quality control study to include external quality control material for each analyte and each day of the quality control plan prior to modifying the frequency of quality control testing for the Triage CKMB (Creatinine Kinase-MB), Myoglobin, Troponin, and DDimer to every 30 days. Findings were: 1. Review of the laboratory quality control study of the IQCP revealed no documentation of the quality control study that included at least two levels of external quality control material for the Triage CKMB, Myoglobin, Troponin, and DDimer for a minimum of 30 days. 2. Review of laboratory records revealed the laboratory performed 1000 Triage testing annually. 3. An interview with the technical consultant #1 on 9/25/19 at 1030 hours in the admin office confirmed the above findings. key: IQCP - Individualized Quality Control Plan
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: A review of proficiency testing records and confirmed in interview revealed that the laboratory director failed to ensure the laboratory performed remedial action for proficiency testing failures. (refer to D2128)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and confirmed in interview, the laboratory director failed to ensure the laboratory maintained a quality control program. Refer to D5441, D5445