Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2118296	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Altus Waxahachie, Lp	1791 North Hwy 77, Waxahachie, 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	An entrance conference was held with the laboratory director. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory director was 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 NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 42 CFR 493.1409 Technical Consultant 493.1421 Testing Personnel (moderate complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 2 of 3 Technical Consultants (TC-2 and TC-3). Findings included: 1. The laboratory policy titled, "Laboratory Operating Procedures" (Approved/Reviewed by the laboratory director on 09/06/2021), stated

	the following: " ...Supervision of Testing: Under the direction of the Laboratory Director, supervisory duties for evaluation and evidence of documentation of training, education, and competency of staff performing laboratory testing have been delegated to the technical supervisor/consultant or office manager." The laboratory policy titled, "Quality Control Program" (Approved/Reviewed by the laboratory director on 09/06 /2021) stated the following: " ...Competency Assessment Program ...6. Competency assessment-Technical Consultant: a. The laboratory director will assess the competency of the technical consultant annually to ensure compliance with CLIA personnel qualifications and competency assessment requirements ....b. The laboratory director will complete a Technical Consultant competency evaluation form to ensure compliance and acceptable performance of those duties designated to the technical consultant ..." 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed three Technical Consultants (TC-1, TC-2 and TC-3) for moderate complexity testing. TC-1 also served as the laboratory director. 3. Review of laboratory personnel records from 2020 and 2021 revealed there was no documented competency assessment for the duties performed as a technical consultant for TC-2 and TC-3 4. During an interview on 09/21/2021 at 10:57 am in the conference room, the Laboratory Director was asked to provide documentation technical consultant competency assessment. No documentation was provided. This confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, laboratory maintenance logs, and confirmed in interview the laboratory failed to perform monthly maintenance for 2 of 12 months in 2020 (08/2020, 11/2020) as required by the manufacturer for the Medonic M-Series hematology analyzer. Findings: 1. Review of Medonic M-Series hematology analyzer maintenance guide revealed the following: "Medonic M-Series Maintenance ... Monthly Cleaning Procedure (~10 minutes) 1. Fill a cup with 10 mL 2% hypochlorite from Boule Cleaning Kit (White Cap). 2. Fill another cup with 18 mL diluent. The diluent can be obtained by using the dispense function of the M-Series. To dispense diluent: a. Press [Dispense] from Main Menu. b. Hold empty cup under Pre-Dilute probe (1:200 probe on right side). c. Press 1:200 Start plate behind probe. d. Discard first dispense. e. Repeat steps b-c four times to achieve 18 mL of diluent. f. Press [Cancel] to exit the dispense function. 3. Aspirate the hypochlorite (White Cap) as a Pre-dilute sample (1:200 probe) twice. *Note: Pre-dilute mode has intentional delay. Press and hold start plate to start cycle (keep probe submerged in hypochlorite solution until the screen displays "Now Analyzing"). 4. Aspirate the clean diluent obtained is [sic] step 2e as a Pre-dilute Sample. Repeat. Discard results. 5. Perform a background check in the Pre-dilute mode by aspirating the remaining clean diluent obtained in step 2e. Verify all values are within specifications. 6. Continue to the clot prevention procedure. Clot Prevention Procedure (~15 minutes) This procedure should be done once a month, or every 1000 samples processed by the Medonic M-Series. You will not be able to run samples for approximately 15 minutes once the clot prevention cycle has started. 1. Fill a cup with 5 ml of Enzymatic Cleaner (Blue Cap) from the Boule Cleaning Kit. 2. If you have

	the Cap Pierce or Autoloader option, fill a clean standard 4.0-5.0 ml tube half full with the Enzymatic Cleaner (Blue Cap) as well. 3. From the Main Menu press [Advanced], then [Maintenance] and then [Clot Prevention]. (Do NOT press [OK] yet) 4. If you have the Open Tube configuration of the M-Series proceed to Step 7. If you have the Cap Pierce proceed to step 5. If you have an Autoloader proceed to Step 6. 5. If you have the optional Cap Pierce place the filled cleaner tube into Cap Pierce (Cap Down - same as a normal sample analysis). Close the door to continue to step 7. 6. If you have the optional Autoloader configuration place the filled cleaner tube into position number one on the wheel, lock the wheel in place, and continue to step 7. 7. Hold the cup (with 5 ml cleaner) under the Open Tube probe, submerged in cleaner, press [OK] to begin clot prevention cycle. Do not remove container (with cleaner) for at least 5 seconds after the aspiration has stopped. 8. The system will then perform the cleaning process for all analysis modes simultaneously. This will take 15 minutes. 9. Once the clot prevention cycle is completed perform a background check. Verify all values are within specifications." 2. Review of the laboratory's policy titled, "Complete Blood Count Using the Medonic M-Series" (Approved/Reviewed by the Laboratory Director 09/06/2021), stated the following: " Maintenance: Maintenance Procedures ...C. Monthly Cleaning Procedure: To insure the correct function of the instrument on a monthly basis, the following cleaning is strongly recommended. (This procedure takes 10 minutes to complete) ..." 3. Review of Medonic M-Series hematology analyzer's maintenance log revealed the following months in 2020 monthly maintenance performance was not documented: August 2020 November 2020. The laboratory failed to perform monthly maintenance as required by the manufacturer. 4. During an interview on 09/22/2021 at 01:03 pm in the conference room, the Laboratory Director, after review of the maintenance logs, confirmed the above findings.
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 direct observation, review of laboratory policy, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to provide data in the risk assessment to support its reduction in QC frequency to every 30 days for the Alere Cardiac Panel (CKMB and Troponin) and for the Alere D-Dimer test on the Quidel Triage analyzer. Findings included: 1. During a tour of the laboratory area on 09/22/2021 at 01:33pm, a Quidel Triage analyzer (Serial Number 82038) was observed. The laboratory used the Quidel Triage to test patient specimens for CKMB, Troponin, and D-Dimer analytes. 2. Review of the laboratory's policy titled, "Quality Control Program" (Approved/Reviewed by the laboratory director 09/06/2021) stated the following: "Non-Waived Test IQCP (Individual Quality Control Plan) Quality Control Procedure: Prior to modifying the daily QC requirement for non-waived tests, a complete quality control study to include external control material for each analyte

	and each day of the quality control plan will be documented. External Quality controls will be run for 30 consecutive days. The quality control result must be acceptable each day of testing ...The daily QC requirement may not be modified if the quality control study results are not acceptable." 3. The laboratory's Individualized Quality Control Plan (IQCP) for the Alere D-Dimer test and the Alere Cardiac Panel for CKMB and Troponin analytes (signed by the laboratory director 12/30/2018) stated the following: "Two levels of external controls (low and high) will be run for every new lot of cartridges and every 30 days ..." Further review of the laboratory's Individualized Quality Control Plan (IQCP) risk assessment showed that two levels of external controls were performed once daily for CKMB, Troponin and D-Dimer on 12/03 /2018, 12/04/2018, 12/05/2018, 12/06/2018, 12/07/2018, 12/08/2018, 12/09/2018, 12 /10/2018, 12/11//2018, 12/12/2018. QC was then performed weekly for CKMB, Troponin and D-Dimer on 12/19/2018, 12/26/2018, and 01/03/2019. The laboratory failed to perform two levels of external controls for 30 consecutive days (per laboratory policy) for the CKMB and Troponin analytes on the Quidel Triage analyzer to support its reduction in QC frequency to every 30 days. The laboratory failed to perform two levels of external QC material every 8 hours of operation for 30 consecutive days for the D-Dimer analyte on the Quidel Triage analyzer to support its reduction in QC frequency to every 30 days. 4. Review of QC records from 04/01 /2021 through 09/22/2021 revealed the laboratory performed external quality control once on the following dates: CKMB/Troponin; External QC performed on 04/14 /2021; 05/15/2021; 06/07/2021; 07/04/2021; 07/23/2021; 08/03/2021 and 08/24/2021. D-Dimer; External QC performed on 04/26/2021; 05/15/2021; 06/17/2021; 07/04 /2021; 08/01/2021; 08/24/2021 and 09/06/2021. The laboratory failed to perform two levels of external controls for the CKMB and Troponin analytes on the Quidel Triage analyzer at least once on each day of patient testing. The laboratory failed to perform two levels of external QC material each 8 hours of patient testing for the D-Dimer analyte on the Quidel Triage analyzer. 5. A random review of patient test records from 09/20/2021 and 09/21/2021revealed the following 4 patients tested for CKMB and Troponin in which the laboratory failed to perform two levels of external quality control material on the day of patient testing: Date of test 09/20/2021; Patient 12300 Date of test 09/21/2021; Patient 17817 Date of test 09/21/2021; Patient 17819 Date of test 09/21/2021; Patient 17816 6. In an interview on 09/22/2021 at 12:15 pm in the conference room, the laboratory director stated that the laboratory did not perform two levels of external controls for 30 consecutive days (per laboratory policy) for the CKMB and Troponin analytes and did not perform two levels external quality control material every 8 hours for 30 days for the D-Dimer analyte to support its reduction in frequency to every 30 days for these analytes. This confirmed the above findings. Work Key: CKMB= Creatine Kinase Isoenzyme
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by:

	Based on review of laboratory policy, quality control (QC) records, corrective action logs, patient reports, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results 1 of 1 patient in 2021(April) on the Medonic M-Series hematology analyzer. Findings: 1. Review of the laboratory's policy titled, "Quality Control Program" (Approved/Reviewed by the laboratory director 09/06/2021) stated the following: " ...8. Quality Control Corrective Action-When control values are not within the posted limits: Make sure instrument and kit reagents and controls are within their expiration dates and replace any reagent or control that may be too old. Then repeat the controls. If the values are within limits, proceed with patient testing. If control values are not within limits, notify the laboratory supervisor and do not report patient results until problem is resolved." The policy did not include evaluation of patients when test systems adjustments were performed for QC failures since the last acceptable QC run. 2. Review of Medonic M-Series hematology quality control (QC) records revealed test system adjustments performed for the following sampling of QC test events in 2021: 04/11/2021 Low Control Lot number 2201201 09:31:41 QC passed 19:34:29 QC failed for Platelet; Comment on QC record stated, "Prime system and repeat." 19:39:35 QC was repeated and failed for Platelet: Comment on QC record stated, "Clean Orifice and repeat." 19: 41: 27 QC was repeated and passed 3. Review of patient records revealed the following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed on 04/11/2021. Patient 14880 tested at 14:21 and 14:46 Patient 14881 tested at 18:05 4. During an interview on 09/22/2021 at 01:03 pm, the Laboratory Director confirmed the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and in interview with staff, the laboratory failed to have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. The laboratory failed to ensure the individual employed met the minimum educational requirements to qualify as a technical consultant. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such

	certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) -209 form, laboratory personnel records, and staff interview, the laboratory failed to provide documentation that one of three individuals met the educational requirements to qualify as a technical consultant. Findings included: 1. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed three Technical Consultants (TC-1, TC-2 and TC-3) for moderate complexity testing. TC-1 also served as the laboratory director. 2. A review of technical consultant personnel records revealed the laboratory failed to have documentation to ensure the following 1 of 3 technical consultants were qualified to perform moderate complexity testing: a. Technical Consultant-2; United States equivalent education evaluation documents not provided. 3. During an interview on 09/22/2021 at 10:32 am in the conference room, The Laboratory Director was asked to provide documentation of United States educational equivalency evaluation for the technical consultant listed above. No documentation was provided. This confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory personnel records, and staff interview, it was revealed the laboratory failed

	to have documentation that two of seventeen testing persons met the qualifications required to perform moderate complexity testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, personnel records, and confirmed in staff interview, the laboratory failed to have documentation that two of seventeen testing persons met the educational qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person-1 through Testing Person-17 listed to perform moderate complexity testing on the Medonic M-Series hematology analyzer. 2. A review of testing persons' personnel records revealed the laboratory failed to have documentation to ensure the following 2 of 17 testing persons were qualified to perform moderate complexity testing: Testing person-8; United States equivalent education evaluation documents not provided Testing person-15; United States equivalent education evaluation documents not provided 3. During an interview on 09/22/2021 at 10:32 am in the conference room, The Laboratory Director was asked to provide documentation of United States educational equivalency evaluation for the testing persons listed above. No documentation was provided. This confirmed the above findings.