Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2062209	**(X3) Date Survey Completed** 07/24/2025
Name of Provider or Supplier Altus Baytown Hospital Er	**Street Address, City, State** 1404 W Baker Rd, Baytown, 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 announced survey of the laboratory was conducted on 07/24/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation, review of manufacturer instructions for use and staff interview, the laboratory failed to document amended expiration date for three of three Medonic hematology analyzer's control vials in use. Findings included: 1. Surveyor's observations on 07/24/2025 at 1255 hours in the laboratory revealed three Boule hematology control vials in use stored in the refrigerator: Abnormal low control lot number: 22504-31 Normal control lot number: 22504-32 Abnormal high control lot number: 22504-33 None of the vials had an open/in-use date or amended expiration date to verify control stability. 2. Review of the "CDS Boule Con-Diff Multi-Parameter Assayed Hematology Control" (document PN201078H R07.30.21) manufacturer's instructions revealed: "Open vial stability 14 days" 3. In an interview on 07/24/2025 at 1255 hours in the laboratory, facility's laboratory director (as indicated on submitted Form CMS 209) confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 laboratory's Medonic hematology analyzer's instrument maintenance records, patient test volumes and staff interview the laboratory failed to document the required Monthly Maintenance for six of twelve months reviewed from 2024 and 2025. Findings included: 1. Review of the Medonic hematology analyzer maintenance records revealed the following required Monthly Maintenance documentation: "MONTHLY MAINTENANCE (User Manual, Section 8.2) Boule Cleaning Kit Reagents Monthly Cleaning (Hypochlorite) Clot Prevention (Enzymatic)" 2. Review of random Medonic hematology analyzer maintenance records for 2024 and 2025 revealed the following six of twelve months reviewed did not have documentation of the required Monthly Maintenance: January 2024 February 2024 July 2024 January 2025 March 2025 April 2025 3. Review of laboratory's submitted patient test volumes revealed the laboratory performed approximately 14,500 hematology tests annually. 4. In an interview on 07/24/2025 at 1245 hours in the office, facility's laboratory director (as indicated on submitted Form CMS 209), after review of the records, confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of laboratory's Individualized Quality Control Plans (IQCP), quality control (QC) records, patient test records and staff interview, the laboratory failed to follow its own IQCP for documentation of QC every thirty days for two of two test panels used in 2024 and 2025, the Abaxis Piccolo Metlac 12 Panel, and the Alere D-Dimer panels. Findings included: 1. Review of laboratory's IQCP "Quality Control Plan - Abaxis Piccolo Metlac 12 Panel" (last reviewed 07/14/2025) revealed: "Two levels of external controls (low and high) will be run for every new lot number of reagent disc, every new shipment of reagent disc and every 30 days." 2. Review of laboratory's IQCP "Quality Control Plan - Alere Cardiac Panel (CK-MB, Troponin I, Myoglobin)" (last reviewed 07/14/2025) revealed: "Two levels of external controls (low and high) will be run for every new lot number of cartridges and every 30 days." The IQCP document included a handwritten amendment by laboratory director "Also to include D-Dimer in IQCP." 3. Review of laboratory's 2025 (January to June) QC records for the Metlac 12 and D-Dimer panels revealed the laboratory documented QC exceeding the IQCP required thirty days as follows: Metlac 12 Panel QC: QC documented: 02/06/2025 Next QC documented: 03/25/2025 Time elapsed: 47 days QC documented: 05/01/2025 Next QC documented: 06/24/2025 Time elapsed: 54 days D-Dimer: QC documented: 04/30/2025 Next QC documented: 06/24/2025 Time

	elapsed: 55 days 4. Review of laboratory's patient test records revealed the following patients were tested beyond the required thirty days QC: Metlac 12 tested 03/08/2025 to 03/24/2025: Patient's MRN: Tested: M1NO7BBM4714 03/08/2025 M1NO7BBM4713 03/08/2025 M1NO7BBM4712 03/08/2025 M1NO7BBM4763 03/12/2025 M1NO7BBM4837 03/16/2025 M1NO7BBM4834 03/16/2025 M1NO7BBM4844 03/16/2025 M1NO7BBM4872 03/18/2025 M1NO7BBM4953 03/22/2025 M1NO7BBM4956 03/22/2025 M1NO7BBM4954 03/22/2025 M1NO7BBM4966 03/23/2025 M1NO7BBM4982 03/24/2025 Metlac 12 tested 06/01/2025 to 06/23/2025: Patient's MRN: Tested: M1NO7BBM6294 06/01/2025 M1NO7BBM6311 06/01/2025 M1NO7BBM6337 06/03/2025 M1NO7BBM6339 06/03/2025 M1NO7BBM6361 06/04/2025 M1NO7BBM6357 06/04/2025 M1NO7BBM6389 06/06/2025 M1NO7BBM6392 06/07/2025 M1NO7BBM6428 06/08/2025 M1NO7BBM6464 06/11/2025 M1NO7BBM6331 06/11/2025 M1NO7BBM6511 06/15/2025 M1NO7BBM6569 06/20/2025 M1NO7BBM6589 06/21/2025 M1NO7BBM6588 06/21/2025 M1NO7BBM6597 06/22/2025 D-Dimer tested 05/31/2025 to 06/23/2025: Patient's MRN: Tested: M1NO7BBM6283 05/31/2025 M1NO7BBM6356 06/04/2025 M1NO7BBM6375 06/05/2025 M1NO7BBM6368 06/05/2025 M1NO7BBM6434 06/09/2025 M1NO7BBM6432 06/09/2025 M1NO7BBM6449 06/10/2025 M1NO7BBM6451 06/10/2025 M1NO7BBM6446 06/10/2025 M1NO7BBM6481 06/13/2025 5. In an interview on 07/24/2025 at 1150 hours in the office, facility's laboratory director (as indicated on submitted Form CMS 209), after review of the records, confirmed the findings.
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 review of laboratory's quality control (QC) records, instrument to instrument comparison records, policies/procedures and staff interview, the laboratory failed to document comparison of instrument results for two of two Piccolo analyzers in use in 2024 and 2025. Findings included: 1. Review of laboratory's QC records revealed the laboratory had two Piccolo Xpress analyzers in use, Piccolo 1 and Piccolo 2 on which Metlac 12 panels were tested. 2. The laboratory was asked to provide Piccolo 1 to Piccolo 2 test result comparison records for Metlac 12 panel testing, and no such records were available for review prior to survey exit. 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place for instrument-to-instrument test result comparison every 6 months. 4. In an interview on 07/24/2025 at 1135 hours in the office, facility's laboratory director (as indicated on submitted Form CMS 209), after review of the records, confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

	This STANDARD is not met as evidenced by: Based on review of laboratory's temperature records, corrective action records and staff interview, the laboratory failed to have documentation of corrective action for five of five instances recorded temperature in 2024 and 2025 was out of laboratory defined range. Findings included: 1. Review of laboratory's temperature records revealed the laboratory's acceptable temperature ranges were as follows: Refrigerator: 2-8C (Degrees Celsius) Room: 68-75F (Degrees Fahrenheit) 2. Further review of laboratory's temperature records revealed the following temperatures were documented outside of laboratory's required temperature range: Refrigerator: Date: Temperature(C): 02/01/2024 8.3 02/07/2024 8.3 03/09/2025 8.2 Room: Date: Temperature (F): 01/09/2024 64 01/10/2024 66 3. Review of laboratory's corrective action records revealed the laboratory did not document corrective action for the above out-of-range temperatures. 4. In an interview on 07/24/2025 at 1250 hours in the office, facility's laboratory director (as indicated on submitted Form CMS 209), after review of the records, confirmed the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and staff interview, the laboratory's Technical Consultant failed to document performance of competency assessment for twenty-four of twenty-four personnel competency assessments reviewed from 2024 and 2025. Findings included: 1. Review of laboratory's personnel records revealed personnel competency assessments were performed by Testing Personnel (TP) and not by the Technical Consultant (TC) as follows: 10/06/2024 Competency Assessment for TP number 16 (as indicated on submitted Form CMS 209) was documented by TP number 4. 10/15/2024 Competency Assessment for TP number 6 was documented by TP number 4. 11/01/2024 Competency Assessment for TP number 9 was documented by TP number 4. 11/01/2024 Competency Assessment for TP number 12 was documented by TP number 4. 11/12/2024 Competency Assessment for TP number 2 was documented by TP number 4. 12/02/2024 Competency Assessment for TP number 6 was documented by TP number 4. 12/04/2024 Competency Assessment for TP number 4 was documented by TP number 1. 12/04/2024 Competency Assessment for TP number 8 was documented by TP number 4. 12/04/2024 Competency Assessment for TP number 11 was documented by TP number 4. 12/04/2024 Competency Assessment for TP number 13 was documented by TP number 4. 12/05 /2024 Competency Assessment for TP number 1 was documented by TP number 4. 12 /05/2024 Competency Assessment for TP number 5 was documented by TP number 4. 12/05/2024 Competency Assessment for TP number 14 was documented by TP number 4. 02/16/2025 Competency Assessment for TP number 7 was documented by TP number 4. 03/01/2025 Competency Assessment for TP number 16 was documented by TP number 4. 04/12/2025 Competency Assessment for TP number 6 was documented by TP number 4. 05/01/2025 Competency Assessment for TP number 2 was documented by TP number 4. 05/01/2025 Competency Assessment for TP number 9 was documented by TP number 4. 05/01/2025 Competency Assessment for TP number 11 was documented by TP number 4. 05/01/2025 Competency

	Assessment for TP number 12 was documented by TP number 4. 06/01/2025 Competency Assessment for TP number 8 was documented by TP number 4. 06/14 /2025 Competency Assessment for TP number 3 was documented by TP number 4. 2. In an interview on 07/24/2025 at 1040 hours in the office, Laboratory's Testing Person number 4 (as indicated on submitted Form CMS 209) confirmed the findings.