Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2302755	02/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Baytown Med Center Lp Dba Independence Heights	510 W Tidwell, Houston, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and (re)certification is recommended. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's quality control records, and staff interview, the laboratory failed to follow its policy three of three times when verifying new quality control (QC) ranges from December 2024 to January 2025. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Program' revealed the following: "Procedure for Verification of New Lot Number of Assayed Controls Perform this verification before the current control lot number is depleted. Before putting a new lot of control in use, verify that the new control performs as expected by parallel testing with the current lot number. - Run new control lot numbers concurrently with samples of known values, e.g. current QC - Run all levels of controls a minimum of 5 times per level." 2. A review of the laboratory's quality control records from December 2024 to January 2025 revealed the laboratory started the following quality control lot numbers and failed to have documentation of following its policy of verifying the new ranges: - Sysmex XN-L Check hematology controls Lot numbers: 43491401, 43491402, 43491403 Started on: 1/4/25 - Bio-Rad Liquid Assayed Multiqual chemistry controls Lot numbers: 46021, 46023 Started on:

	12/19/24 - Triage Total 5 Controls Lot numbers: C4079AN, C4045AN Started on: 1/1 /25 3. In an interview on 2/18/25 at 10:45 a.m. in the office, after review of the records, the laboratory director confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on a review of laboratory's procedure manual and staff interview, the laboratory failed to have one of one written procedure for how new test systems will be verified (studies to include: accuracy, precision, reportable range, normal patient range) prior to patient testing. Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory failed to have a written procedure for how new test systems will be verified (studies to include: accuracy, precision, reportable range, normal patient range) prior to patient testing. 2. In an interview on 2/18/25 at 10:45 a.m. in the office, after review of the records, the laboratory director confirmed the above findings. II. Based on a review of the Sysmex SN-430 Basic Operation Manual, a review of the laboratory's policies, patient's test records, and staff interview, the laboratory failed to have one of one policy that defines the steps for laboratory personnel to follow for verifying [*] flags on CBC (complete blood count) results. Findings include: 1. A review of the Sysmex SN-430 Basic Operation Manual revealed the following: "When an analysis result is determined to be abnormal, a mark appears. [*] Meaning Low Reliability- Indicates that the reliability of the data is low" 2. A review of the laboratory's policies revealed the laboratory failed to have a policy that defines the steps for laboratory personnel to follow for verifying [*] on CBC results. 3. A review of the laboratory's test records revealed the following patient's CBCs were reported when the [*] flag was present: Patient ID: 564989 Tested on 12 /17/24 Flag present on White Blood Cell, Neutrophil, Lymphocyte, Monocyte, Basophil, Eosinophil, Immature Granulocyte Patient ID: 563624 Tested on 12/17/24 Flag present on White Blood Cell, Neutrophil, Lymphocyte, Monocyte, Basophil, Eosinophil, Immature Granulocyte Patient ID: 565069 Tested on 12/20/24 Flag present on White Blood Cell, Neutrophil, Lymphocyte, Monocyte, Basophil, Eosinophil, Immature Granulocyte Patient ID: 565113 Tested on 12/23/24 Flag

	present on White Blood Cell, Neutrophil, Lymphocyte, Monocyte, Basophil, Eosinophil, Immature Granulocyte Patient ID: 565120 Tested on 12/23/24 Flag present on White Blood Cell, Neutrophil, Lymphocyte, Monocyte, Basophil, Eosinophil, Immature Granulocyte Patient ID: 565289 Tested on 12/31/24 Flag present on Platelet 4. In an interview on 2/18/25 at 10:45 a.m. in the office, after review of the records, the laboratory director confirmed the above findings.
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 a review of the laboratory's records and staff interview, the laboratory failed to have documentation of verifying the patient normal ranges for the analytes tested on three of three analyzers from October 2024 to February 2025. Findings include: 1. A review of the laboratory's records revealed the laboratory started testing using the following analyzers in October 2024: - Sysmex XN-430 hematology analyzer (Serial number: 12050) - Vitros XT-3400 chemistry analyzer (Serial number: 34501284) - Triage meter (Serial number: 00099415WW) 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of verifying the patient normal ranges for the following analytes, tested on the analyzers listed above: - Sysmex XN-430 hematology analyzer White Blood Cell Red Blood Cell Hemoglobin (male and female) Hematocrit (male and female) Mean Corpuscular Volume (male and female) Mean Corpuscular Hemoglobin (male and female) Mean Corpuscular Hemoglobin Concentration (male and female) Red Cell Distribution Width- SD (male and female) Red Cell Distribution Width- CV (male and female) Platelet (male and female) Mean Platelet Volume Neutrophil Lymphocyte Monocyte Eosinophil Basophil Immature Granulocyte - Vitros XT-3400 chemistry analyzer Albumin Alkaline Phosphatase Alanine Transaminase Asparate Transferase Blood Urea Nitrogen Calcium Chloride Creatinine Glucose Potassium Sodium Total Bilirubin Carbon Dioxide Total Protein - Triage meter Troponin Creatine Kinase-MB D-Dimer 3. In an interview on 2/18/25 at 10:45 a.m. in the office, after review of the records, the laboratory director confirmed the above 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 a review of the laboratory's records, the quality control (QC) records for the Triage analzyer from November 2024 to February 2025, and staff interview, the laboratory failed to have documentation of establishing an IQCP (Individualized Quality Control Plan) to support the modification in quality control testing for three of three analytes tested on the Triage analyzer. Findings include: 1. A review of the laboratory's records revealed the laboratory tested Troponin, Creatine Kinase- MB, and D-Dimer on the Triage analyzer. 2. A review of the QC records for the Triage analzyer revealed the laboratory ran 2 levels of QC material each month on the Cardiac and D-Dimer cartridges: 11/19/24 Cardiac and D-Dimer cartridges 12/19/24 Cardiac and D-Dimer cartridges 1/20/25 Cardiac cartridge 1/23/25 D-Dimer cartridge 2/4/25 D-Dimer cartridge 3. Further review of the laboratory's records revealed the laboratory failed to have documentation of an IQCP for the Triage meter lessening the frequency of quality control testing. 4. In an interview on 2/18/25 at 10:45 a.m. in the office, after review of the records, the laboratory director confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient's test reports from December 2024, the laboratory's test records, and staff interview, the laboratory failed to include the correct address of the testing facility on seven of seven patient's test reports reviewed. Findings include: 1. A random review of patient's test reports from December 2024 revealed the following results (documented as being run by this laboratory): Patient ID: 564663 Tested on 12/2/24 Amylase, Urine Drug Screen Patient ID: 564736 Tested on 12/5/24 Alcohol Patient ID: 564894 Tested on 12/13/24 Magnesium Patient ID: 564979 Tested on 12/16/24 Lipase Patient ID: 565021 Tested on 12/18/24 Magnesium Patient ID: 565099 Tested on 12/23/24 Amylase, Lipase Patient ID: 564398 Tested on 12/31/24 Triglyceride, Cholesterol 2. A review of the laboratory's test records revealed the laboratory did not run the above tests, they were run by a reference laboratory. 3. In an interview on 2/18/25 at 10:25 a.m., the technical consultant revealed the testing personnel would take the results from the reference laboratory and enter them into the laboratory's LIS system so that all results would show up on one report, therefore only showing this laboratory's address as the testing facility. 4. In an interview on 2/18/25 at 10:25 a.m. in the office, after review of the records, the laboratory director confirmed the above findings.