Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2071757	08/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
America's Er Site 001, Llc	32784 Fm 2978, Magnolia, 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 validation survey was performed on 08/04/2023. The laboratory was found to be in compliance with CLIA regulations found at 42 CFR 493.1 through 493.1780.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) profiency testing records for 2022 and 2023 and confirmed interview, the laboratory failed to establish a mechanism to document patient remedial action for any unacceptable analyte proficiency testing (PT) score for one of five PT events reviewed. Findings included: 1. A review of the laboratory's American Proficiecncy Institute (API) proficiency testing for 2023 indicated the facility failed to attain a satisfactory score for proBNP (B-type natriuretic peptide) for the 2023 Chemistry 1st event. Four out of five samples received an unsatisfactory score, which resulted in a score of 20% (percent) on the first event of 2023. The failure to attain an individual score of at least 80% is unsatisfactory performance. CM-01 Lab result 126 pg/mL (API acceptable range 127-195 pg/mL) CM-02 Lab result 6863 pg/mL (API acceptable range 7043-9155 pg/mL) CM-03 Lab result 1608 pg/mL (API acceptable range 1674 - 2612 pg /mL) CM-05 Lab result 120 pg/mL (API acceptable range 126-194 pg/mL) 2. Review of the corrective action for the above PT failure did not include patient remedial action for the unsatisfactory score. 3. An interview with the Director of Clinical Operations on 08/04/2023 at 0950 hours in the conference room confirmed the above findings.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, American Proficiency Institute (API) proficiency testing (PT) results from 2022 to 2023, and confirmed in interview, the laboratory failed to establish a laboratory policy to resolve CBC (complete blood count) flags on the Medonic M-series hematology analyzer for one of five PT test events reviewed. The findings were: 1. Review of the laboratory policy Proficiency Testing Program stated "specimens are tested in the same manner as patient specimens and the results are reported back to the PT agency." 2. Review of the laboratory policy Medonic (PN203129B R03.1414) under Interpretation of Results stated "the following flags cover abnormalities in the WBC differential and indicate a possible problem with the accuracy of the results: BD, NM, OM, TM. Refer to the Medonic M-Series User's Manual for detailed information regarding the messages, their descriptions, and suggested actions for resolving them" 3. Review of the manufacturer's instructions for the Medonic M-series hematology analyzer under section 9: Parameter and System Information Messages, under "Introduction" stated, "The Medonic M-Series has several parameter and system information messages related to the measured parameters and the instrument. These messages alert the operator of possible pathologic samples and parameter value and instrument errors." 4. Further review of the operator's manual under, "System Information Messages" stated: "TM Message: WBC [white blood cells] DIFF [differential]: Too many WBC population found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 5. Review of the laboratory's policy for CBC did not include a procedure to resolve the CBC flags. 6. Random review of PT test records from 2022 to 2023 indicated one of five PT events with the specimen testing with the following flags. 2022 API 3rd event Hematology ID -9 Flag TM 7. An interview with Director of Clinical Operations on 08/04/2023 at 1440 hours in the office confirmed the above findings. She stated that the laboratory typically sends out all CBC flags for confirmation but that it is not in their policy.
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 quality control records from August 2022 to June 2023, and confirmed in interview, the laboratory failed to monitor quality control values over time for nine of nine chemistry tests: Abbott i-STAT CG4 (pH, pCO2, pO2, TCO2, Lactate) and b-HCG; PathFast Cardiac Profile (CKMB, Myoglobin, Troponin). The findings included: 1. Random review of the laboratory's quality control records from August 2022 to June 2023 indicated the laboratory performed quality control for the following tests: CG4 (pH, pCO2, pO2, TCO2, and Lactate), hCG, CKMB, Myoglobin, and Troponin testing. iSTAT CG4 Control level 1 lot 301154, exp 10/31/2023 Control level 2 lot 321154, exp 10/31/2023 Control level 2 lot 321157, exp 01/31/2024 iSTAT BhCG Control level 1 lot 351155, exp 11/30/2023 Control level 3 lot 371159, exp 03/31/2024 PathFast Cardiac Profile Control level 1 lot 67651, exp 11/30/2023 Control level 2 lot 67663, exp 03/31/2024 2. Further review of the laboratory's quality control records from August 2022 to June 2023 revealed no documentation of the laboratory monitoring quality control values for the above lot numbers for CG4 (pH, pCO2, pO2, TCO2), hCG, CKMB, Myoglobin, and Troponin testing over time to detect shifts and trends for eleven of eleven months reviewed. 3.An interview with Director of Clinical Operations on 08/04/2023 at 1330 hours in the office 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: A. Based on review of the laboratory policy, laboratory quality control records from 2022 and 2023, patient test records, and confirmed in interview, the laboratory IQCP (Individualized Quality Control Plan) failed to document 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 two of two tests on the iSTAT analyzer: CG4 (pH, pCO2, pO2, TCO2) and bHCG to

	every 30 days. a) iSTAT - CG4 (pH, pCO2, pO2, TCO2) b) iSTAT bHCG Findings included: 1. Review of the IQCP summary report for the iSTAT bHCG and CG4 stated "based on our assessment and data review, we will continue to perform external positive and negative controls monthly (30 days) with each new lot/shipment, with each new untrained tester, and calibrations as recommended by manufacturer." a) iSTAT - CG4 (pH, pCO2, pO2, TCO2) 2. 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 every 8 hours for the iSTAT pH, pCO2 (partial pressure of carbon dioxide), PO2 (partial pressure of oxygen) for 30 days. b) iSTAT bHCG 3. 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 iSTAT bHCG for 30 days. 4. Review of the laboratory CMS 116 records revealed the laboratory performed 5000 chemistry testing annually. 5. An interview with the Director of Clinical Operations on 08/04/2023 at 1300 hours in the office confirmed the above findings. B. Based on review of the laboratory quality control records, patient test records, and confirmed in interview, the laboratory failed to document a complete IQCP to include the Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan for three of three tests on the PathFast Immunoanalyzer: Cardiac (Troponin, CMKB, Myoglobin), DDimer, and proBNP to modify the daily quality control frequency to every 28 days. Findings included: 1. Review of laboratory records available indicated the laboratory began Cardiac (Troponin, CMKB, Myoglobin), DDimer, and proBNP patient testing using the PathFast Immunoanalyzer in 2018. 2. Review of laboratory records available revealed no documentation of the RA, QCP, and a QA plan for Cardiac (Troponin, CMKB, Myoglobin), DDimer, and proBNP to modify the quality control frequency to every 28 days. 3. Review of the laboratory CMS 116 records revealed the laboratory performed 5000 chemistry testing annually. 4. An interview with the Director of Clinical Operations on 08/04/2023 at 1300 hours in the office confirmed the above findings. She stated the IQCP for the Cardiac tests were from the previous analyzer Triage. It had not been updated when they switched analyzers in 2018.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 quality control and patient test records from 2022 to 2023, and confirmed in interview, the laboratory failed to establish the acceptable ranges for four of ten quality control lot numbers for

	the CKMB (Creatine kinase-MB), DDimer, and Myoglobin testing on the PathFast Immunoanalyzer. Findings included: 1. Review of the Biorad instructions for use stated "the mean values and corresponding +/- 3SD [standard deviation] ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product...it is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." Liquichek DDimer Control (2023-02, 5872-00S) Liquichek Cardiac Markers Plus Control LT (2023-02, 16000202-00S) 2. Review of the laboratory policy Quality Control Guidelines stated "to accept a run, controls must read within +2 standard deviations of the mean. If it does not read within +2 SD, reject the run and troubleshoot. Hold patient results." 3. Random review of the quality control data from 2022 and 2023 indicated the laboratory used the ranges from the package insert with no documentation of establishing the ranges for the following three of five analytes: CKMB, DDimer, and Myoglobin. DDimer Liquichek DDimer Control Low Level lot 17004 , exp 05/31 /2023 acceptable range 0.545 - 1.01 Liquichek DDimer Control Level 1 lot 74421, exp 07/31/2025 acceptable range 1.07-1.99 CKMB, Myoglobin Liquichek Cardiac Markers Plus Control LT level 1 Lot 67651, 11/30/2023 CKMB acceptable range: 1.58 - 3.68 ng/mL Myoglobin acceptable range: 26.3 - 48.9 ng/mL Liquichek Cardiac Markers Plus Control LT level 2 Lot 67663, 03/31/2024 CKMB acceptable range: 35.5-65.9 ng/mL Myoglobin acceptable range: 125-231 ng/mL 4. An interview with the Director of Clinical Operations on 08/04/2023 at 1510 hours in the office confirmed the above findings. She was unaware the ranges used were 3 SDs.
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 the laboratory's policy, quality control reports from August 2022 and June 2023 and confirmed in interview, the laboratory failed to document all corrective actions taken when hematology quality control was outside of established operating parameters for five of twenty days reviewed. Findings included: 1. A review of the laboratory's policy Quality Assessment Program under Quality Control stated "For each test system, we have control procedures that monitor the accuracy and precision of the complete analytical process. We perform quality control (QC) in the manner and at the frequency recommended by the manufacturer of each waived and non-waived test method (or more frequent as established by our laboratory). We follow the CMS QC requirements for all test systems see CLIA sec 493, 1256-1273 for specifics. We evaluate out-of-control situations to ensure proper corrective action is taken and quality control results are acceptable before patient results are reported. When quality control problems are found, we will consider the relationship to maintenance, calibration, and personnel competency." 2. A review of the laboratory's quality control records from August 2022 to June 2023 indicated the following five of twenty quality control failures without documentation of corrective actions taken. 08 /06/2022 lot 220531 WBC 2.1 K/uL (acceptable range 3.1 K/uL -3.7 K/uL) RBC 1.49

	M/uL (acceptable range 2.11 M/uL - 2.35 M/uL) HGB 3.8 g/dL (acceptable range 5.1 g/dL - 5.7 g/dL) HCT 9.4 % (acceptable range 12.2% - 17.2%) 08/07/2022 lot 2220531 WBC 1.5 K/uL (acceptable range 3.1 K/uL -3.7 K/uL) RBC 0.93 M/uL (acceptable range 2.11 M/uL - 2.35 M/uL) HGB 2.3 g/dL (acceptable range 5.1 g/dL - 5.7 g/dL) HCT 5.8 % (acceptable range 12.2% - 17.2%) 08/14/2022 Lot 2220532 WBC 11.4 K/uL (acceptable range 8.1 K/uL - 9.3 K/uL) RBC 4.91 M/uL (acceptable range 3.98 M/uL - 4.34 M/uL) HGB 14.0 g/dL (acceptable range 11.5g/dL - 12.3g/dL) HCT 38.6% (acceptable range 30.9% - 36.9%) 09/21/2022 lot2220532 WBC 7.1 K /uL (acceptable range 8.1 K/uL - 9.3 K/uL) RBC 3.41 M/uL (acceptable range 3.98 M /uL - 4.34 M/uL) HGB 10.0 g/dL (acceptable range 11.5g/dL - 12.3g/dL) HCT 27.3% (acceptable range 30.9% - 36.9%) 10/05/2022 WBC 7.9 K/uL (acceptable range 8.1 K /uL - 9.3 K/uL) 3. Review of the above dates revealed the laboratory performed CBC (complete blood count) testing for the following 10 patients. 08/06/2022 Patient ID: M000033743, M0000106725 08/07/2022 Patient ID: M0000104652, M000010574 08 /14/2022 Patient ID: M00000107083, M0000107098 09/21/2022 Patient ID: M0000108840, M000015235 10/05/2022 Patient ID: M0000104068, M0000101132 4. An interview with the Director of Clinical Operations on 08/04/2023 at 1250 hours in the office confirmed the above findings. glossary: WBC - white blood cells RBC - red blood cells HGB - hemoglobin HCG - hematocrit
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory quality assessment records, review of laboratory procedures, and review of quality control records, the laboratory's quality assessment policies failed to monitor, assess, and correct problems in analytic systems. Findings included: 1. The laboratory failed to have documentation of monitoring quality control values over time for nine of nine chemistry tests: Abbott i-STAT CG4 (pH, pCO2, pO2, TCO2, Lactate) and b-HCG; PathFast Cardiac Profile (CKMB, Myoglobin, Troponin). Refer to D5441 2. The laboratory IQCP (Individualized Quality Control Plan) failed to document 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 two of two tests on the iSTAT analyzer: CG4 (pH, pCO2, pO2, TCO2) and bHCG to every 30 days. Refer to D5445-A 3. The laboratory failed to document a complete IQCP for three of three tests on the PathFast Immunoanalyzer: Cardiac (Troponin, CMKB, Myoglobin), DDimer, and proBNP. refer to D5445-B 4. The laboratory failed to document all corrective actions taken when hematology quality control was outside of established operating parameters for five of twenty days reviewed. Refer to D5783