Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150363	06/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hca Houston Healthcare Er 24/7 Alvin,	2860 South Gordon St, Alvin, 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 found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts records for 2019, laboratory policies and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 2 of 2 attestation statements. Findings include: 1. A review of the laboratory's American Association of Bioanalysts records from 2019 (Chemistry Q1 2019 and Chemistry Q2 2019)revealed the laboratory director failed to documentation of the laboratory director signing the attestation statements. 2. Further review of the American Association of Bioanalysts records from 2019 (Chemistry Q1 2019 and Chemistry Q2 2019) revealed the technical consultant's signature on the following attestations statements: A. Chemistry Q1 2019- Comprehensive Chemistry B. Chemistry Q1 2019- D-Dimer 3. A review of the laboratory's policies revealed the laboratory did not have documentation of the laboratory director delegating the responsibility of signing proficiency testing attestation statements to the technical consultant. 4. An interview with testing person #8 (as listed on the CMS 209 form, signed by the laboratory director on 6/19/19) on 6

	/19/19 at 10:00 in the nurse's station revealed the attestation statements had not been signed by the laboratory director and the laboratory did not have documentation of the laboratory director delegating the responsibilities to the technical consultant. This confirmed the above findings.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 a review of the CMS 155 report and the American Association of Bioanalysts proficiency testing records, the laboratory failed to obtain a score of at least 80% for the analytes Albumin and Chloride for Q1 Chemistry 2019 event. Findings include: 1. A review of the CMS 155 report revealed the laboratory received a score of 60% for the American Association of Bioanalysts Q1 Chemistry 2019 event for Albumin and Chloride. 2. A review of the American Association of Bioanalysts Q1 Chemistry 2019 proficiency testing records revealed the following analytes had unsatisfactory scores: Analyte Specimen Reported Value Grading Range Albumin 2 5.9 6 - 7.3 Albumin 4 4.2 4.4 - 5.4 Chloride 3 111 97 - 108 Chloride 4 125 109 - 121 For Albumin and Chloride, 2 of 5 proficiency testing results received an unsatisfactory score resulting in a grade of 60% for each analyte.
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 the laboratory's personnel records and staff interview, it was revealed that the laboratory failed to have documentation of a competency assessment for 1 of 1 technical consultants. Findings include: 1. A review of the laboratory's personnel records for the technical consultant (as listed on the CMS 209 form signed by the laboratory director on 6/19/19) revealed a form titled "Technical Consultant Competency Evaluation". Further review of the "Technical Consultant Competency Evaluation" form revealed the technical consultant's name was listed at the top of the form, there was a date stamp of 6/1/19, the boxes to the left of the 9 elements of the competency assessment were not checked, and there was no signature or date of review from the laboratory director. 2. The laboratory was asked to provide documentation of the technical consultant's competency assessment. No documentation was provided. 3. A review with the administrative laboratory director on 6/19/19 at 11:15 in the nurse's station confirmed that there was not a competency assessment completed for the technical consultant.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without

	analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on laboratory's American Association of Bioanalysts records for Q1 Chemistry 2019 and staff interview, revealed the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program. Findings include: 1. A review of the American Association of Bionanlysts results for Q1 Chemistry 2019 revealed the following analytes were scored as not graded and had a '?' next to the reported value: A. Alanine Aminotransferase (ALT) specimen 2 B. Partial Pressure of Carbon Dioxide (pCO2) specimen 1 American Association of Bioanalysts defines that "?= This score may not truly evaluate performance for this specimen which was not graded because of lack of participant consensus." 2. A review of the American Association of Bioanalysts results for Q1 Chemistry 2019 revealed the following analytes were scored as not graded and had a '#' next to the reported value: A. Alanine Aminotransferase (ALT) specimen 5 B. Chloride specimen 1 C. Chloride specimen 2 D. Chloride specimen 5 E. Sodium specimen 1 F. Sodium specimen 3 G. Sodium specimen 4 H. Sodium specimen 5 American Association of Bioanalysts defines that "# = This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." 3. An interview with the Administrative laboratory director on 6/19/19 at 10:40 in the nurse's station revealed the laboratory failed to have documentation verifying the accuracy of the above analytes that were scored as not graded by the proficiency testing program. This confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to monitor and evaluate overall quality and correct identified problems in analytic systems as evidenced by: 1. The laboratory failed to have documentation of a procedure of how to perform corrective actions for Complete Blood Count (CBC) results with flags. Refer to D5403 2. The laboratory failed to follow the manufacturer's instructions to verify the shipping temperature of test cartridges for the Abbott i-STAT CG4 (pH, pCO2, pO2, TCO2); Protime (PT), hCG testing cartridges. Refer to D5411-A 3. The laboratory failed to follow the manufacturer's instructions to analyze i-STAT testing within 10 minutes of collection for pH, pCO2, PO2 , and TCO2 testing on the Abott iSTAT point of care analyzer. Refer to D5411-B 4. The laboratory failed to monitor the correct manufacturer-defined range for room temperature. Refer to D5413 5. the laboratory failed to ensure linearity studies and verification patient normal ranges were performed for the

	Medonic M-series hematology analyzer. Refer to D5421-A 6. The laboratory failed to document complete verification studies for Abbott i-STAT and Triage Meter point of care analyzer. Refer to D5421-B 7. The laboratory failed to have documentation of monitoring quality control values over time for CKMB, Troponin, Myoglobin, and D-dimer. Refer to D5441 8. 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, DDimer and iSTAT hCG, Protime (PT), and Blood gas to every 30 days. Refer to D5445
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 manufacturer's instructions for the Medonic M-series hematology analyzer, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of a procedure of how to perform corrective actions for Complete Blood Count (CBC) results with flags. The finding were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (Art. no 1504283 December 2012) under the section titled "System Information Messages" revealed the following flags and corrective actions to perform to resolve them: a) BD b) NM c) OM d) TM Corrective action: "Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 2. A review of 50 patient results from May 28, 2019 to June 18, 2019 identified the following results which were reported to the provider with flags: Date ID Flag 06/14 8039317 BD 06/17 7010113 OM 3. A review of the laboratory's procedures, revealed the laboratory failed to have a protocol for addressing flags on CBC results which would ensure only accurate and reliable results were reported to the provider. 4. A interview with testing personnel number 8 (as listed on Form CMS 209 on 06/19/2019 at 0950 hours in the nurse's station revealed the laboratory would allow samples with flags to sit for a few minutes and retest the sample. If the flag was

	resolved, the facility would report the results. If the flags did not resolve, the laboratory would report the results and let the provider decide if additional testing was required. This confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on direct observation, review of manufacturer's instructions, review of environmental records from January 2019 to June 19, 2019 (the day of the survey), and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to verify the shipping temperature of test cartridges for the Abbott i-STAT CG4 (pH, pCO2, pO2, TCO2); Protime (PT), hCG testing cartridges. The findings were: 1. Based on direct observation in the laboratory on June 19,2019 at 1010 hours during the initial tour of the laboratory, the laboratory had the following iSTAT test cartridges available for patient testing: Abbott i-STAT CG4 Lot D18350 Abbott i-STAT hCG lot 104F183101168 Abbott i-STAT PT lot 354T182920181 2. Review of the manufacturer's instructions for the Abbott i-STAT (Art: 714376-OOR, Rev. Date 10/10/14) in chapter 14 "Quality Control," stated, "Verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container." 3. Review of the laboratory records available revealed no documentation of the laboratory monitoring the temperature of the i-STAT cartridges received for testing. 4. In an interview with primary testing personnel on 06/19/19 at 1130 in the nurse's station confirmed the findings. She acknowledged that she should document the recording or save the thermometers. B. Based on review of the manufacturer's instructions, laboratory test records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to analyze i-STAT testing within 10 minutes of collection for pH, pCO2, PO2 , and TCO2 testing on the Abott iSTAT point of care analyzer. Findings were: 1. Review of the manufacturer's instructions for the Abbott i-STAT (Art: 714376-OOR, Rev. Date 10/10/14) in chapter 10 under time to test revealed " for the most accurate results, test samples immediately after drawing. Samples for lactate must be tested immediately. Samples for pH, pCO2, pO2, TCO2, and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes. 2. Review of the laboratory policy SS3 I-STAT CG4 Procedure (effective date 6/24/18) under sample volume, test timing revealed "within 3 minutes after collection, samples collected in capillary tubes, both with and without anticoagulant, samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant; within 10 minutes after collection, samples collected with anticoagulant for the measurement of pH, pCO2, PO2 ,TCO2." 3. Random review of the laboratory test records from November 2018 to June 2019 revealed the following 4 of 20 patient test records that had documentation of pH, pCO2, pO2, TCO2 analyzed and reported after 10 minutes of sample collection. Patient ID 8042301 Date/time collection: 5/28/19 at 1425 Date /time analysis: 5/28/19 at 1441 elapsed time: 16 minutes Patient ID 7269902 Date /time collection: 3/23/19 at 0830 Date/time analysis: 3/23/19 at 0957 elapsed time: 87 minutes Patient ID 556024 Date/time collection: 3/18/19 at 0433 Date/time analysis: 3 /18/19 at 0445 elapsed time: 12 minutes Patient ID 7006435 Date/time collection: 2/22

	/19 at 0955 Date/time analysis: 2/22/19 at 1018 elapsed time: 23 minutes 4. An interview with the primary testing person on 6/19/19 at 1320 hours in the nurse's station confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the manufacturer's instructions for the Quidel Triage Cardiac Panel, review of the manufacturer's instructions for the Quidel D-dimer test, review of the laboratory's room temperature records, review of patient test records, and staff interview, it was revealed the laboratory failed to monitor the correct manufacturer-defined range for room temperature. 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 manufacturer's instructions for the Quidel Triage Cardiac Panel (PN26584en Rev. A 2018/04) under the section titled "Storage and Handling Requirements" revealed: "Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20C to 24C)." This range is equivalent to 68F to 75.2F. 3. A review of the manufacturer's instructions for the Quidel Triage D-dimer tests (pn26589en Rev. A 2018/04) under the section titled "Storage and Handling Requirements" revealed: "Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20C to 24C)." This range is equivalent to 68F to 75.2F. 4. A review of the laboratory's room temperature records from March 2019 to May 2019 revealed the laboratory's defined acceptable temperature range as 39 - 77F. Further review of the records identified the following days were the documented room temperature was outside the manufacturer's defined acceptable range: Date Temperature 03/06 75.3 03/12 75.7 03 /13 76.2 03/15 75.3 03/18 75.4 03/21 75.7 03/22 76.0 03/23 76.2 03/25 76.6 03/26 76.0 03/27 75.5 03/28 76.3 03/29 75.9 03/30 76.5 04/01 75.6 04/03 76.1 04/04 76.3 04 /06 76.5 04/07 76.9 04/08 76.1 04/11 76.4 04/12 76.7 04/14 76.4 04/15 76.5 04/16 76.5 04/18 75.6 04/19 76.0 04/20 75.5 04/21 76.6 04/22 76.5 04/23 76.2 04/24 77.0 04 /26 76.3 04/28 76.3 04/29 75.3 04/30 75.8 05/02 75.7 05/04 76.3 05/06 76.9 05/07 76.7 05/08 75.4 05/09 75.9 05/11 75.5 05/13 75.4 05/16 75.8 05/26 75.3 4. A review of patient test records from March 2019 to May 2019 identified the following patients whose samples were tested on days when the documented room temperature was outside the manufacturer's acceptable range: Date Visit Number 03/12 7059002 03/18 7059592 7059555 7059506 7059505 03/21 7059885 7059871 03/22 7059943 03/22 7059983 03/25 7060245 03/26 7060307 7060301 7060261 03/27 7060356 03/28 7060464 7060443 04/07 7061237 7061280 04/11 7061595 04/12 7061653 04/14 7061838 7061842 04/15 8000015 8000017 04/16 8000153 04/22 8000577 04/29 8001232 04/30 8001323 05/04 8001623 05/06 8001800 8001765 8001750 8001748 05 /07 8001900 05/09 8001983 8001979 05/11 8002183 05/16 8002533 05/26 8003355 5. An interview with testing personnel number 8 (as listed on Form CMS 209) on 06

	/19/2019 at 1115 hours in the lab - after her review of the records- confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: A. Based on review of the verification studies performed on the laboratory's Medonic M-series hematology analyzer in March 2014, review of patient test records, and staff interview, it was revealed the laboratory failed to ensure linearity studies and verification patient normal ranges were performed. The findings were: 1. A review of the laboratory's verification studies performed on the Medonic M-series hematology analyzer in March 2014 revealed the laboratory failed to have documentation of performing linearity studies and of verifying patient normal ranges used for result interpretation. 2. A review of patient test records revealed the laboratory identified the following patient normal ranges: a) Adult male WBC 4.5 - 11.0 LYM% 24.0 - 44.0 MID% 0.0 - 10.0 GRAN% 35.0 - 77.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 RBC 4.50 - 5.90 HGB 13.5 - 17.5 HCT 37.0 - 53.0 MCV 80.0 - 100.0 MCH 26.0 - 44.0 MCHC 32.0 - 36.0 RDW% 11.5 - 13.1 PLT 250 - 450 MPV 6.5 - 10.0 b) Adult female WBC 4.5 - 11.0 LYM% 24.0 - 44.0 MID% 0.0 - 10.0 GRAN% 35.0 - 77.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 RBC 4.00 - 5.20 HGB 12.0 - 16.0 HCT 33.0 - 51.0 MCV 80.0 - 100.0 MCH 26.0 - 34.0 MCHC 32.0 - 36.0 RDW% 11.5 - 13.1 PLT 250 - 450 MPV 6.5 - 10.0 c) BLOOD WBC 3.5 - 10.0 LYM% 25.0 - 50.0 MID% 2.0 - 15.0 GRAN% 35.0 - 80.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 RBC 3.5 - 5.50 HGB 11.5 - 16.5 HCT 35.0 - 55.0 MCV 75.0 - 100.0 MCH 25.0 - 35.0 MCHC 31.0 - 38.0 RDW% 11.0 - 16.0 PLT 100 - 450 MPV 8.0 - 11.0 3. The laboratory was asked to provide documentation of performing linearity studies and of verifying the patient normal ranges currently in use. No documentation was provided. 4. An interview with testing personnel number 8 (as listed on Form CMS 209) on 06/19/2019 at 0920 hours in the nurse's station revealed the required studies had not been performed. This confirmed the findings. Key WBC white blood cell LYM% percent lymphocytes MID% percent mixed cells GRAN% percent granulocytes LYM lymphocytes MID mixed cells GRAN granulocytes RBC red blood cells HGB hemoglobin HCT hematocrit MCV mean corpuscular volume MCH mean corpuscular hemoglobin MCHC mean corpuscular hemoglobin concentration RDW% red cell distribution width PLT platelets MPV mean platelet volume 38387 B. Based on review of the laboratory's verification records and confirmed in interview, the laboratory failed to document complete verification studies for Abbott i-STAT and Triage Meter point of care analyzer. The findings were: 1. Review of laboratory records available for review revealed no documentation of accuracy, precision, reportable range and normal ranges for pH, PCO2, PO2, HCO3, TCO2 sO2, and Lactate on the Abbott i-STAT analyzer using the Abbott i-STAT CG4 cartridges. 2. Review of laboratory records available for review revealed no documentation of accuracy, precision, and normal ranges for Protime on the Abbott i-STAT analyzer .

	3. Review of laboratory records available for review revealed no documentation of accuracy, precision, reportable range and normal ranges for hCG on the Abbott i-STAT analyzer . 4. Review of laboratory records available for review revealed no documentation of normal ranges study for CKMB, Troponin, Myoglobin, and D-dimer Triage Meter point of care analyzer. 5. An interview with the primary testing person on 6/19/19 at 1017 hours confirmed the above findings. Key: PCO2 - partial pressure or carbon dioxide PO2 - partial pressure of oxygen BEecf - base excess in the extracellular fluid compartment HCO3 - bicarbonate TCO2 - total carbon dioxide sO2 - oxygen saturation
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: A. Based on review of the laboratory's test menu, review of the laboratory's quality control records from August 2018 to June 2019 (the day of the survey), and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values over time for CKMB, Troponin, Myoglobin, and D-dimer. 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 August 2018 to June 2019 revealed the laboratory failed to have a mechanism in place to monitor quality control values for CKMB, Troponin, Myoglobin and D-dimer over time to detect shifts and trends. 3. The laboratory was asked to provide documentation of monitoring quality control values over time. No documentation was provided. 4. An interview with testing personnel number 8 (as listed on Form CMS 209) on 06/19 /2019 at 1300 hours by the front desk revealed the laboratory did not monitor quality control values over time. This confirmed the findings. Key CKMB: creatine kinase: muscle brain 38387 B. Based on review of the laboratory's test menu, review of the laboratory's quality control records from August 2018 to June 2019 (the day of the survey), and staff interview, the laboratory failed to have documentation of monitoring quality control values over time for Abbott i-STAT CG4 (pH, pCO2, pO2, TCO2, Lactate); Protime (PT), and hCG testing. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed the following tests on the Abbott i-STAT: CG4 (pH, pCO2, pO2, TCO2, and Lactate); Protime (PT), hCG testing. hCG lot 371108, exp 12/31/19 hCG lot 351106, exp 10/31/19 hCG lot 372104, exp 8/31/19 hCG log 351106, exp 10/31/19 CG4 lot 101104, exp 8/31/19 CG4 lot 121104, exp 8/31/19 CG4 lot 121098, exp 2/28/19 CG4 lot 101098, exp 2/28 /19 PT lot 281103, exp 7/31/19 PT lot 291103, exp 7/31/19 PT lot 281100, exp 4/30 /19 PT lot 291100, exp 4/30/19 2. A review of the laboratory's quality control records from January to June 2019 revealed no documentation of the laboratory monitoring

	quality control values for CG4 (pH, pCO2, pO2, TCO2); Protime (PT), hCG testing over time to detect shifts and trends. 3.An interview with primary testing personnel on 06/19/2019 at 1300 hours 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 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, DDimer and iSTAT hCG, Protime (PT), and iSTAT - CG4 to every 30 days. a) Triage - CKMB, Myoglobin, Troponin, DDimer b) iSTAT - CG4 (pH, pCO2, pO2, TCO2, Lactate); PT, hCG Findings were: a) Triage - Cardiac (CKMB, Myoglobin, Troponin), DDimer 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. Random review of laboratory patient test records from January to May 2019 revealed the laboratory performed Triage testing. Patient ID date Test 542993 3/14/19 Cardiac, Ddimer 968411 3/18/19 Cardiac, Ddimer 8039317 6/14/19 Cardiac, Ddimer 8039095 4/22/19 Cardiac 7271270 4/09/19 Cardiac 8038696 4/15/19 Cardiac 8038698 4/15/19 Cardiac 8038830 4/17/19 Cardiac, Ddimer 8042268 5/28/19 Cardiac 358478 5/28/19 Cardiac, Ddimer 8042448 5/29/19 Cardiac 8042603 5/31/19 Cardiac 8043654 6/13/19 Cardiac 8043818 6/15/19 Cardiac 8043973 6/18/19 Cardiac 8044039 6/18/19 Cardiac 7265364 1/28/19 Ddimer 3. An interview with the primary testing person on 6/19/19 at 1310 hours in the nurse's station confirmed the above findings. She was unaware the laboratory needed to perform the daily quality control for 30 days. b) iSTAT - CG4 (pH, pCO2, pO2, TCO2, Lactate); PT, hCG 4. 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) and Protime (PT), for 30 days. 5. 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 day for the iSTAT Lactate and hCG for 30 days. 6. Random review of laboratory patient test records from January to May 2019 revealed the laboratory performed i-STAT testing. Patient ID Date Test 7268743 3/10/19 PT, CG4 556024 3/18/19 CG4 7006435 2/22 /19 CG4 7269902 3/23/19 PT, CG4 8042301 5/28/19 CG4 8042268 5/28/19 PT 7201195 5/18/19 PT 8040270 5/04/19 hCG 8040640 5/09/19 hCG 7269714 3/21/19 PT 7269072 3/21/19 CG4 7269948 4/08/19 hCG 7271120 4/08/19 hCG 7270891 4/04

	/19 hCG 7267517 2/23/19 PT 282733 2/24/19 hCG 1004031 2/05/19 PT 7006435 2/22 /19 CG4 7263632 1/04/19 PT 7263723 1/07/19 hCG 7210352 1/13/19 PT7264822 1 /22/19 hCG 971947 1/21/19 hCG 405999 1/18/19 hCG 7. An interview with the primary testing person on 6/19/19 at 1310 hours in the nurse's station confirmed the above findings. She was unaware the laboratory needed to perform the daily quality control every 8 hours for 30 days for pH, pCO2 (partial pressure of carbon dioxide), PO2 (partial pressure of oxygen), and Protime (PT) and 30 days for Lactate and hCG. key: IQCP - Individualized Quality Control Plan
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of patient test records, review of the laboratory's quality assessment records, and staff interview, it was revealed the laboratory's quality assessment failed to identify that Complete Blood Counts (CBC) results were reported to providers with the correct patient normal ranges. The findings were: 1. A review of patient test records revealed the laboratory identified the following patient normal ranges: a) Adult male WBC 4.5 - 11.0 LYM% 24.0 - 44.0 MID% 0.0 - 10.0 GRAN% 35.0 - 77.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 RBC 4.50 - 5.90 HGB 13.5 - 17.5 HCT 37.0 - 53.0 MCV 80.0 - 100.0 MCH 26.0 - 44.0 MCHC 32.0 - 36.0 RDW% 11.5 - 13.1 PLT 250 - 450 MPV 6.5 - 10.0 b) Adult female WBC 4.5 - 11.0 LYM% 24.0 - 44.0 MID% 0.0 - 10.0 GRAN% 35.0 - 77.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 RBC 4.00 - 5.20 HGB 12.0 - 16.0 HCT 33.0 - 51.0 MCV 80.0 - 100.0 MCH 26.0 - 34.0 MCHC 32.0 - 36.0 RDW% 11.5 - 13.1 PLT 250 - 450 MPV 6.5 - 10.0 c) BLOOD WBC 3.5 - 10.0 LYM% 25.0 - 50.0 MID% 2.0 - 15.0 GRAN% 35.0 - 80.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 RBC 3.5 - 5.50 HGB 11.5 - 16.5 HCT 35.0 - 55.0 MCV 75.0 - 100.0 MCH 25.0 - 35.0 MCHC 31.0 - 38.0 RDW% 11.0 - 16.0 PLT 100 - 450 MPV 8.0 - 11.0 2. Further review of patient test records from May 28, 2019 to June 18, 2019 revealed the following patient who's results were reported out utilizing the "Blood" normal range rather than the age/sex specific ranges (adult male or adult female): Date Medical Record Number 05/28 8042322 358478 05 /29 8042448 05/31 8042603 8042703 06/01 8042745 8042752 1009387 7254046 06 /02 8042773 8042784 1009447 06/03 8042884 8042918 06/04 8042963 8042987 06 /05 8043037 7267076 06/06 8043088 8043100 8043148 520263 06/07 8043156 06/08 8043255 1019708 06/09 7271092 06/11 7266801 06/12 8043589 8043613 06/13 8043654 7215331 06/14 8043722 8039317 8043757 8043765 06/15 8043818 06/16 8043833 7260094 06/18 8043972 8043973 8044039 3. An interview with testing personnel number 8 (as listed on Form CMS 209) on 06/19/2019 at 1015 hours in the nurse's station - after her review of the records- confirmed the findings. Key WBC white blood cell LYM% percent lymphocytes MID% percent mixed cells GRAN% percent granulocytes LYM lymphocytes MID mixed cells GRAN granulocytes RBC red blood cells HGB hemoglobin HCT hematocrit MCV mean corpuscular volume MCH mean corpuscular hemoglobin MCHC mean corpuscular hemoglobin concentration RDW% red cell distribution width PLT platelets MPV mean platelet volume
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR

	CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007, D6013, and D6020)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology and Chemistry. Refer to D5411, D5413
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies performed on the Medonic M-series hematology analyzer and staff interview, it was revealed the laboratory director failed to ensure the studies were complete. The findings were: 1. The laboratory director failed to ensure the required studies for linearity and verification of patient normal ranges were performed (refer to D5421). 2. The laboratory director failed to document his approval of the studies.
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-A, B, D5445
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory director failed to ensure that a quality assessment program was established and maintained to assure the quality of laboratory services provided. Findings include: 1. A review of the laboratory's policies revealed the laboratory director failed to have a written quality assessment policy for the laboratory. 2. The laboratory was asked to provide documentation of a quality assessment policy. No documentation was provided. 3. An interview with the administrative laboratory director on 6/19/19 at 1:30 in the nurse's station revealed there was not a quality assessment policy. This confirmed the above findings.
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 laboratory policies, verification studies, quality control records, and confirmed in interview, the technical consultant failed to provide technical oversight of the laboratory. (Refer to D6040, D6042)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures

	performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records, calibration records, and patient test records found that the technical consultant failed to ensure the laboratory documented complete verification studies for the Alere Triage meter and Medonic M-Series hematology analyzer. (See D5421-A, B)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the quality control program had been maintained for the Alere Triage meter and Abbott i-STAT analyzer. (See D5441-A, B, D5445)
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 laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education to determine the qualifications of 6 of 8 testing personnel to perform moderately complex 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 the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education for 6 of 8 testing personnel to qualify them to perform moderately complex testing. Findings include: 1. A review of laboratory personnel records revealed the laboratory failed to have documentation for 6 of 8 testing personnel qualifying them to perform moderately complex testing. The personnel records did show that the 6 personnel had associates degrees in applied science, but no documentation of at least a minimum of a high school diploma or GED. 2. The laboratory was asked to provide the documentation of education for 6 of 8 testing personnel. No documentation was provided. 3. An interview with testing person #8 (as listed on the CMS 209 form, signed by the laboratory director on 6/19 /19) on 6/19/19 at 10:00 in the nurse's station confirmed that only 2 personnel records had a copy of the high school diplomas and the laboratory did not have the documentation on the other 6 testing personnel.