| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br>45D2123288 | **(X3) Date Survey Completed**<br>03/20/2019 |
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| **Name of Provider or Supplier**<br>Central Hospital Of Bowie, Lp | **Street Address, City, State**<br>705 E Greenwood Avenue, Bowie, 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 |
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| **D0000** | Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were 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 45 CFR 493.803 Successful Participation 493.1250 Analytic Systems 493.1403 Moderate Complexity Laboratory Director 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 Dallas Regional Office (RO) 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 |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent |

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| | with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the CMS 155 report, American Proficiency Institute (API) Proficiency Testing (PT) records and staff interview, the laboratory failed to meet the requirements of participating in PT for the specialty of chemistry and hematology, as evidenced by: 1. The laboratory failed attain a score of at least 80 percent for myoglobin analyte for 1 of 2 PT testing events (2018 Chemistry Core 3rd Event). Refer to D2087 2. The laboratory failed to participate in 2017 (1ST, 2ND, and 3rd Events) and 2018 (1st Event) Chemistry proficiency testing. Refer to D2089 3. The laboratory failed to attain a score of at least 80 percent for all hematology analytes in PT for 1 of 3 testing events in 2018 (2018-1st Event.) Refer to D2121 4. The laboratory failed to attain an overall testing event score of at least 80% for 2 of 3 hematology events which constitutes unsatisfactory performance. Refer to D2122 5. The laboratory failed to participate in 2017 (1ST, 2ND, and 3rd Events) and 2018 (3rd Event) Hematology proficiency testing. Refer to D2123 6. The laboratory failed to attain an acceptable score of 80% or greater for the specialty of Hematology in 2 out of 3 consecutive testing events. (2018 1st and 3rd Events). Refer to D2131 |
| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review American Proficiency Institute (API) Chemistry proficiency testing records for 2018 (2nd and 3rd Events) and staff interview, the laboratory failed attain a score of at least 80 percent for myoglobin analyte for 1 of 2 PT testing events (2018 Chemistry Core 3rd Event). Findings included: 1. Review of the API 2018 Chemistry Core 3rd Event comparative evaluation report revealed the following: Sample CM-13; Reported result=15.0; Expected Result=154.6-276.0; Performance=Unacceptable Sample CM-14; Reported result=121.0 Expected Result=61.0-107.7; Performance=Unacceptable Overall Score 60% The laboratory failed to attain an acceptable score of at least 80% for the Myoglobin analyte. 2. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 0800 hours in the conference room. |
| **D2089** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(c)<br><br>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two |

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| | proficiency testing events.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the CMS 155 report, the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, the laboratory failed to participate in 2017 (1st, 2nd, and 3rd Events) and 2018 (1st Event) Chemistry proficiency testing. The findings included: 1. Review of the CMS-155 proficiency testing report for 2017 (1st, 2nd, and 3rd Events) and 2018 (1st Event) for routine chemistry, pH blood gas, PO2 blood gas, PCO2 blood gas, CK ISO, and MG revealed no scores for the laboratory. 2. Review of the American Proficiency Institute (API) proficiency testing records revealed that the laboratory did not participate in Chemistry proficiency testing for 2017 (1st, 2nd, and 3rd Events) and 2018 (1st Event). Further review of records revealed that the laboratory submitted chemistry proficiency testing results under the facility's previous CLIA number which had been terminated 12/14/2015. 3. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 0800 hours in the conference room. Word Key: PO2=Partial pressure of oxygen PCO2=Partial pressure of carbon dioxide CK ISO=Creatine kinase isoenzymes MG=Magnesium |
| **D2121** | HEMATOLOGY<br>CFR(s): 493.851(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the CMS 155 report, the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, the laboratory failed to attain a score of at least 80 percent for all hematology analytes for 1 of 3 PT testing events in 2018 (2018-1st Event). 1. Review of the CMS-155D proficiency testing report for Hematology 2018 (1st, 2nd, and 3rd Events) for hematology revealed the following score for the Red Blood Cell (RBC) and Hematocrit (HCT) analytes: Hematology 2018 1st Event RBC 0% HCT 40% 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the following: Hematology 2018 1st Event: RBC Sample HEM-01; Reported result=2.49; Expected Result= 2.15-2.43; Unacceptable RBC Sample HEM-02; Reported result=4.80; Expected Result= 4.09-4.62; Unacceptable RBC Sample HEM-03; Reported result=6.09; Expected Result= 5.11-5.77; Unacceptable RBC Sample HEM-04; Reported result=4.12; Expected Result= 3.58-4.05; Unacceptable RBC Sample HEM-05; Reported result=7.16; Expected Result= 6.18-6.98; Unacceptable Overall Score of 0% HCT Sample HEM-01; Reported result=38; Expected Result= 32-37; Unacceptable HCT Sample HEM-03; Reported result=51; Expected Result= 43-49; Unacceptable HCT Sample HEM-05; Reported result=57; Expected Result= 49-56; Unacceptable Overall Score of 40% The laboratory failed to attain an acceptable score of at least 80% for the RBC and HCT analytes. 3. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 0800 hours in the conference room. |
| **D2122** | HEMATOLOGY<br>CFR(s): 493.851(b) |

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| | Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the CMS 155 report, American Proficiency Institute (API) hematology proficiency testing records (2018 1st, 2nd, and 3rd Events), and staff interview, it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for 2 of 3 events which constitutes unsatisfactory performance. The findings included: 1. Review of the CMS-155D proficiency testing report for Hematology 2018 (1st, 2nd, and 3rd Events) for hematology revealed the following unsatisfactory performances: Hematology 2018 1st Event 73% Hematology 2018 3rd Event 0% 2. A review of American Proficiency Institute Hematology proficiency testing records from 2018 (1st, 2nd, and 3rd Events) revealed the following unsatisfactory performances: Hematology 2018 1st Event 73% Hematology 2018 3rd Event 0% 3. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 0800 hours in the conference room. |
| **D2123** | HEMATOLOGY<br>CFR(s): 493.851(c)<br><br>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the CMS 155 report, the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to participate in 2017 (1st, 2nd, and 3rd Events) and 2018 (3rd Event) Hematology proficiency testing. The findings included: 1. Review of the CMS-155D proficiency testing report for 2017 (1st, 2nd, and 3rd Events) for hematology revealed no scores for the laboratory. Review of the testing report for 2018 (3rd Event) revealed 0% for all hematology analytes tested. 2. Review of the American Proficiency Institute (API) proficiency testing records revealed that the laboratory did not participate in Hematology proficiency testing for 2017 (1st, 2nd, and 3rd Events) and 2018 (3rd Event). Further review of records revealed that the laboratory submitted hematology proficiency testing results under the facilities previous CLIA number which has been terminated 12/14/2015 for 2017 (1st, 2nd, and 3rd Events). 3. The above findings were confirmed in an interview with laboratory representatives on 03 /20/2019 at 0800 hours in the conference room. |
| **D2131** | HEMATOLOGY<br>CFR(s): 493.851(g)<br><br>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is |

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| | unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review the CMS-155 report and the laboratory's American Proficiency Institute (API) hematology proficiency testing records for 2018 (1st, 2nd, and 3rd Events), the laboratory failed to attain an acceptable score of 80% or greater for the specialty of Hematology in 2 out of 3 consecutive testing events. (2018 1st and 3rd Events). Findings: 1. Review of the CMS-155 proficiency testing report for Hematology 2018 (1st, 2nd, and 3rd Events) for hematology revealed the following unsatisfactory performances: Hematology 2018 1st Event 73% Hematology 2018 3rd Event 0% 2. A review of American Proficiency Institute Hematology proficiency testing records from 2018 (1st, 2nd, and 3rd Events) revealed the following unsatisfactory performances: Hematology 2018 1st Event 73% Hematology 2018 3rd Event 0% |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, review of the laboratory's American Proficiency Institute's (API) Chemistry - Core proficiency testing records from 2018 (2nd and 3rd Events), and staff interview, it was revealed the laboratory failed to have documentation of laboratory director review for 2 of 2 proficiency testing events. Findings included: 1. Review of the laboratory policy titled "Laboratory Quality Plan" (Effective 01/10/2018) in the section titled "Proficiency Testing" stated the following: "All corrective action and ungraded results must be reviewed by the Laboratory Medical Director. Additionally, it is good practice for each participant in the proficiency testing to review their graded results. All forms must be reviewed by the laboratory management and the laboratory medical director and filed appropriately." 2. A review of the laboratory's American Proficiency Institute's Chemistry - Core proficiency testing records from 2018 (2nd and 3rd Events) revealed the laboratory director failed to review the following proficiency testing records: a. 2018 Chemistry Core 2nd Event b. 2018 Chemistry Core 3rd Event The myoglobin analyte received a score of 60%. No corrective action was documented 3. The laboratory was asked to provide documentation of laboratory director review of the results or documentation of the delegation of this responsibility. No documentation was provided. 4. The above findings were confirmed in an interview with laboratory representatives on 03/20 /2019 at 0800 hours in the conference room. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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. |

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| | This CONDITION is not met as evidenced by:<br>Based on review of laboratory policy, manufacturer's instructions, laboratory verification records, laboratory quality control records, review of the laboratory's patient test records, direct observation, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements. Findings included: 1. The laboratory failed to follow its own policy for performing calibration verification every 6 months ensure the accuracy of all analytes tested. Refer to D5401 2. The laboratory failed to ensure that Complete Blood Count (CBC) results with flags were verified prior to reporting these results to the provider. Refer to 5403 3. The laboratory failed to ensure room temperature ranges were within the operating specifications for the Alere Triage chemistry analyzer. Refer to D5413 4. The laboratory failed to establish CBC normal patient ranges for different ages and genders. Refer to D5421 5. The laboratory failed to have a system in place to detect immediate error, monitor errors over time, and the accuracy and precision of Coulter AcT Diff 2 hematology analyzer and Piccolo Express chemistry analyzer test performance with current and accurate statistical parameters. Refer to D5441 I,II 6. The laboratory failed to provide documentation of a complete IQCP for the Alere Triage. Refer to D5445 |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, Beckman Coulter AcT Diff 2 (Serial Number 472370/AH31253), Alere Triage (Serial Numbers 69155 and 69185) analyzers and Piccolo Express (Serial Number 22156) chemistry analyzer calibration records and staff interview, the laboratory failed to follow its own policy for performing calibration verification every 6 months ensure the accuracy of all analytes tested. Findings included: 1. Review of the laboratory policy titled "Laboratory Quality Plan" (Effective 01/10/2018) in the section titled "Guidelines for Calibration/Verification and Frequency" stated the following: "Cardiac and moderate chemistry; Calibration Verification; 6 months Hematology: Calibration Verification; 6 months" Note: Cardiac chemistry is performed on the Alere Triage analyzer, moderate chemistry is performed on the Piccolo Express analyzer and hematology testing is performed on the Coulter AcT Diff 2 analyzer. 2. Review of Beckman Coulter AcT Diff 2 hematology analyzer calibration verification records from 2017 through 3/20/2019 revealed that calibration verification had NOT been performed on the analyzer since 09/26/2017. This is an elapsed period of 18 months. 3. Review of Alere Triage records revealed the laboratory had 2 analyzers and utilized the analyzers to test the following cardiac chemistry analytes: D-Dimer, myoglobin, troponin, and Creatine Kinase - Myocardial Band (CK-MB). Review of Alere Triage calibration records from 2016 through 3/20/2019 revealed that calibration verification had NOT been performed on each analyzer since 12/07/2016. This is an elapsed period of 27 months. 4. Review Piccolo Express records revealed the laboratory utilized the analyzer to test the following moderate complexity chemistry analytes: Glucose, Blood Urea Nitrogen (BUN), Creatinine, Sodium, Potassium, Chloride, Carbon dioxide, Calcium, |

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| | Phosphorus, Magnesium, Albumin, and Lactate. Further review of the Piccolo Express calibration records from 2017 through 3/20/2019 revealed that calibration verification had NOT been performed on the analyzer since 11/19/2017. This is an elapsed period of 16 months. 5. The laboratory failed to follow its own policy for performing calibration verification every 6 months to ensure the accuracy of all analytes tested. 6. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 1224 hours in the conference room. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions for the Beckman Coulter AcT Diff 2 (Serial Number 472370/AH31253), laboratory policies, random review of patient test records, and staff interview, it was revealed that the laboratory failed to ensure that Complete Blood Count (CBC) results with flags were verified prior to reporting these results to the provider. Findings included: 1. The Beckman Coulter AcT Diff 2 manufacturer's instructions in the section titled "Parameter Codes and Flags" revealed the following flag indicators, messages, descriptions, and actions: "Report results immediately if there are no flags and if the results are within your reference ranges ... ...If any flag appears, review the results according to your laboratory's protocol." Further review of the manufacturer's instructions revealed the following Flags /Indications/Suggested Actions: "L; Low result; Follow your laboratory's protocol. X; X flag indicates that one of the multiple Aperture Alert criteria was not met.; Thoroughly mix and rerun; If flag repeats, clean the aperture. *; If on WBC and differential only, 35 fL count interference check failed; Possible interference with WBC count; Verify results according to your laboratory's protocol." 2. The laboratory was asked to provide a procedure for the Beckman Coulter AcT Diff 2 hematology analyzer that included a policy/protocol for review of CBC flagged results. No procedure was provided. The laboratory failed to have a policy to ensure that the results with flags are verified prior to reporting the results to the provider. 3. A random review of patient records from 03/01/2019 through 03/14/2019 from the AcT Diff 2 analyer revealed 10 of 26 patients with flagged CBC results. The following patient results with flags were reported to the provider without verification of the |

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| | result: a. 03/02/2019 Patient 010010580 Flag * for LY, MO, GR, and RDW No documentation of result verification. b. 03/09/2019 Patient 010010656 Flag * for LY, MO, and GR No documentation of result verification c. 03/10/2019 Patient 010010580 Flag * for LY, MO, and GR No documentation of result verification d. 03 /11/2019 Patient 010010682 Flag * for LY, MO, and GR No documentation of result verification e. 03/11/2019 Patient 010010688 Flag * for WBC, LY, MO, and GR No documentation of result verification f. 03/11/2019 Patient 010010675 Flag * for WBC, LY, MO, GR, PLT, and MPV No documentation of result verification g. 03/12 /2019 Patient 010010709 Flag * for LY, MO, and GR No documentation of result verification h. 03/13/2019 Patient 010010712 Flag * for LY, MO, and GR No documentation of result verification i. 03/13/2019 Patient 010010729 Flag * for LY, MO, and GR No documentation of result verification j. 03/14/2019 Patient 010010734 Flag * for MO No documentation of result verification 4. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 1224 hours in the conference room. The laboratory director stated that the facility was utilizing the AcT Diff 2 operator's manual as the procedure manual. Word Key: CBC=Complete Blood Count WBC= White Blood Count RBC=Red Blood Count HCT=Hematocrit HGB=Hemoglobin MCV=Mean Corpuscular Volume MCHC= Mean Corpuscular Hemoglobin Concentration MCH= Mean Corpuscular Hemoglobin PLT=Platelet LY=Lymphocyte GR=Granulocyte MO=Monocyte MPV=Mean platelet volume RDW=Red blood cell distribution width |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of manufacturer's instructions for Alere Triage test devices, laboratory environmental records (02/2018, 07/2018 and 10/2018), and confirmed in interview, the laboratory failed to ensure room temperature ranges were within the operating specifications for the Alere Triage chemistry analyzer for 8 of 90 days. Findings included: 1. The manufacturer's instructions for the Alere Triage test devices (BNP, D-Dimer and Cardiac Profile) stated the following in the section titled "Storage and Handling Requirements": "Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20-24 C or 68-75 F)." 2. Review of the laboratory environmental records, (02/2018, 07/2018 and 10/2018), titled "Temperature Log" revealed the laboratory defined an acceptable room temperature range 59 to 77 F. Further review of the environmental records revealed that the room temperature was sometimes documented in degrees Celsius. This is NOT the room temperature range of 68 -75 F (20 -24 C) specified by the manufacturer. The following days were outside of the accepted manufacturer's range of 68 -75 F (20 -24 C): 02/27/2018; Temperature = 77 F 02/28/2018; Temperature = 77 F 07/06/2018; Temperature = 65 F 07/09/2018; Temperature = 76 F 07/15/2018; Temperature = 76 F 07/19/2018; Temperature = 65 F 07/25/2018; Temperature = 77 F 07/30/2018; Temperature = 77 F 3. The above findings were confirmed in an |

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| | interview with laboratory representatives on 03/20/2019 at 1224 hours in the conference room. II. Based on review of laboratory temperature charts from 2018 and staff interview, the laboratory failed to document room temperature in the designated unit of measurement for 9 of 12 months to ensure that the recorded temperature was within the defined range. Findings included. 1. Review of the laboratory 2018 environmental records titled "Temperature Log" revealed the laboratory defined an acceptable room temperature range 59 to 77 F. Temperatures for the following months were recorded were in degrees Celsius: March 2018; April 2018, May 2018, June 2018; August 2018, September 2018, October, 2018, November 2018, December 2018 The laboratory failed to define the equivalent temperature from Fahrenheit to Celsius. 3. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 1224 hours in the conference room. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the laboratory verification studies (performed 08/15/2016) for the Beckman Coulter AcT Diff 2 hematology analyzer, laboratory records and staff interview, it was revealed that the laboratory failed to establish CBC normal patient ranges for different ages and genders. Findings included: 1. Review of a random review patient records from 03/01/2019 through 03/14/2019 revealed 26 of 26 reports with the following normal ranges for CBC results: WBC=4.5-10.5 RBC=4.00-6.00 HGB=11.0-18.0 HCT=35.0-60.0 MCV=80.0-99.9 MCH=27.0-31.0 MCHC=33.0-37.0 RDW%=11.6-13.7 PLT=150-450 MPV=7.8-11.0 LYM%=20.5-51.1 MONO%-1.7-9.3 GRA%=42.2-75.2 LYM#=1.2-3.4 MONO#=0.1-0.6 GRAN#=1.4-6.5 2. The random review patient records from 03/01/2019 through 03/14/2019 revealed the following 2 patients with the same normal ranges: Patient 3369/78 year old/Male Patient 3367/84 year old/Female The laboratory performs 1100 hematology tests annually. 3. The laboratory was asked to provide documentation of verification of CBC normal ranges based on patient gender and age. No documentation was provided. 4. During an interview on 03/20/2019 at 1224 hours in the conference room, laboratory representatives confirmed that the laboratory used the same CBC normal ranges for all patients. II. Based on review of the laboratory verification studies for the Piccolo Express chemistry analyzer (performed 11/19/2017), for the Alere Triage chemistry analyzer (performed 12/07/2016), and the Abbott iSTAT blood gas analyzer (performed 12/01/2016), and laboratory records and staff interview, it was revealed that the laboratory failed to verify patient normal ranges. Findings included: 1. Review of Piccolo Express verification studies and laboratory records revealed the following moderate complexity chemistry analytes tested on the analyzer and the corresponding normal ranges utilized by the laboratory: Analyte/Normal Range Glucose / 73-118 Blood Urea Nitrogen (BUN) / 7-22 Creatinine / 0.6-1.2 Sodium / 128-145 Potassium / 3.6-5.1 Chloride / 98-108 Carbon dioxide / 18-33 Calcium / 8.0-10.3 Phosphorus / 2.2-4.1 Magnesium / 1.6-2.3 Albumin / 3.3-5.5 Lactate / 0.53-2.10 |

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| | 2. Review Alere Triage verification studies and laboratory records revealed the following moderate complexity chemistry analytes tested on the analyzer and the corresponding normal ranges utilized by the laboratory: Analyte/Normal Range: D-Dimer / 0.0-9990 CK-MB / 0.0-4.3 Myoglobin / 0.0-107 Troponin / 0.00-0.05 3. Review Abbott iSTAT verification studies and laboratory records revealed the following moderate complexity arterial blood gas chemistry analytes tested on the analyzer and the corresponding normal ranges utilized by the laboratory: Analyte /Normal Range: pH / 7.35-7.45 PCO2 / 35-45 PO2 / 70-100 4. In an interview 03/20 /2019 at 1224 hours in the conference room, the laboratory director was asked to provide documentation of verification of Piccolo, Triage, and iSTAT normal ranges. No documentation was provided. This confirmed the above findings. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of manufacturer's package inserts, random review Beckman Coulter AcT Diff 2 hematology analyzer quality controls (QC) records (07/2018, 11 /2018, 12/2018, 01/2019, 02/2019, and 03/2019), direct observation and staff interview, the laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of Coulter Act Diff 2 test performance with current and accurate statistical parameters. Findings included: 1. Review of the package insert for Coulter 4C Plus Cell Controls revealed the following acceptable limits for each level of control: Level Abnormal Low; Lot# 062000; Expiration date 2018-05-11 Limits: WBC 3.7-4.7 LY 24.3-38.3 MO 8.8-16.8 GR 49.9-61.9 LY# 0.8-1.8 MO# 0.2-0.8 GR# 1.8-3.0 RBC 2.09-2.59 HGB 5.7-7.1 HCT 15.4-20.8 MCV 73.2-81.2 MCH 24.4-30.4 MCHC 32.0-38.8 RDW 13.5-18.5 PLT 51-91 MPV 8.6-11.6 Level Normal; Lot# 077200; Expiration Date 2018-05-11 Limits: WBC 8.4-9.8 LY 36.5-46.5 MO 9.1-17.1 GR 39.4-51.4 LY# 3.0-4.6 MO# 0.7-1.7 GR# 3.2-5.0 RBC 3.81-4.31 HGB 11.3-13.1 HCT 31.9-37.9 MCV 81.5-90.5 MCH 26.7-33.3 MCHC 31.3-38.7 RDW 12.6-15.6 PLT 185-265 MPV 8.6-12.6 Level Abnormal High; Lot# 081500; Expiration Date 2018-05-12 Limits: WBC 18.2-20.6 LY 43.2-53.2 MO 11.0-21.0 GR 30.8-40.8 LY# 7.9-10.9 MO# 1.9-4.3 GR# 5.5-8.3 RBC 4.89-5.49 HGB 16.4-18.2 HCT 45.7-53.7 MCV 90.7-100.7 MCH 29.7-36.9 MCHC 31.2-38.4 RDW 10.8-14.8 PLT 357-477 MPV 9.1-13.1 2. Review of the package inserts for the following lot numbers of Coulter 4C Plus Cell Control material and random review of each lot number's WBC QC range revealed the acceptable limits for all analytes ARE Lot Number dependent: Abnormal Low; Lot# 061200; Expiration 2018-01-22 WBC 3.6-4.6 Abnormal Low; Lot# 061700; Expiration 2018-04-03 WBC 3.3-4.3 Normal; Lot #076400; Expiration Date 2018-01-21 WBC 8.2-9.6 Normal; Lot #076900; Expiration Date 2018-04-01 WBC 7.9-9.3 Abnormal High; |

Lot# 080700; Expiration Date 2018-01-28 WBC 19.3-16.9 Abnormal High; Lot# 081200; Expiration Date 2018-04-02 WBC 17.4-19.8 3. A random review of Beckman Coulter Act Diff 2 hematology analyzer QC records revealed the laboratory failed to update the AcT Diff hematology analyzer with current QC material lot numbers, expiration dates and acceptable limits. The following laboratory QC printouts revealed the limits used to monitor the accuracy and precision of the Coulter AcT Diff 2 hematology analyzer: Level L(Low); Date 07/06/2018 (This date is beyond the lot number expiration date) Lot# 062000; Expiration Date 05-11-2018 Limits: WBC 3.7-4.7 LY 24.3-38.3 MO 8.8-16.8 GR 49.9-61.9 LY# 0.8-1.8 MO# 0.2-0.8 GR# 1.8-3.0 RBC 2.09-2.59 HGB 5.7-7.1 HCT 15.4-20.8 MCV 73.2-81.2 MCH 24.4-30.4 MCHC 32.0-38.8 RDW 13.5-18.5 PLT 51-91 MPV 8.6-11.6 Level N (Normal); Date 07/06/2018(This date is beyond the lot number expiration date) Lot# 077200; Expiration Date 05-11-18 Limits: WBC 8.4-9.8 LY 36.5-46.5 MO 9.1-17.1 GR 39.4-51.4 LY# 3.0-4.6 MO# 0.7-1.7 GR# 3.2-5.0 RBC 3.81-4.31 HGB 11.3-13.1 HCT 31.9-37.9 MCV 81.5-90.5 MCH 26.7-33.3 MCHC 31.3-38.7 RDW 12.6-15.6 PLT 185-265 MPV 8.6-12.6 Level H (High); Date 07/06/2018 (This date is beyond the lot number expiration date) Lot# 081500; Expiration Date 05-12-18 Limits: WBC 18.2-20.6 LY 43.2-53.2 MO 11.0-21.0 GR 30.8-40.8 LY# 7.9-10.9 MO# 1.9-4.3 GR# 5.5-8.3 RBC 4.89-5.49 HGB 16.4-18.2 HCT 45.7-53.7 MCV 90.7-100.7 MCH 29.7-36.9 MCHC 31.2-38.4 RDW 10.8-14.8 PLT 357-477 MPV 9.1-13.1 The laboratory failed to update the Beckman Coulter Act Diff 2 hematology analyzer with the current lot number QC acceptable limits. The limits associated with lot numbers 062000 (Low), 077200 (Normal), and 081500 (High) remained programmed into the analyzer. 4. Quality control records revealed that on 07/19/2018, EACH level (Low, Normal, High) of control material was programmed with the same lot number of 813404 and expiration date of 11/19/2018. The limits associated with lot numbers 062000 (Low), 077200 (Normal), and 081500 (High) remained programmed into the analyzer. Random review of quality control records revealed this lot number (813404) and expiration date (11-19-2018) for each level of control material remained programmed into the instrument through 12/31/2018. The QC limits associated with lot numbers 062000 (Low), 077200 (Normal), and 081500 (High) remained programmed into the analyzer through 12/31/2018. 5. A tour of the laboratory on 03/20/2019 at 1200 hours revealed the following lot numbers of hematology control material currently in use. Review of the Streck Para 12 Extend package inserts for the lot numbers revealed the following acceptable control limits for each lot number: Streck Para 12 Extend control material: Low; Lot# 90210422; Expiration date 2019-07-29 WBC 1.9-2.7 LY 43.3-63.3 MO 1.7-13.7 GR 29.6-49.6 LY# 0.6-1.8 MO# 0.0-0.4 GR# 0.1-1.7 RBC 2.06-2.46 HGB 4.9-5.9 HCT 15.2-19.2 MCV 69.9-81.9 MCH 21.4-26.4 MCHC 27.9-34.9 RDW 14.8-24.8 PLT 43-93 MPV 7.8-10.8 Normal; Lot# 90210423; Expiration date 2019-07-29 WBC 7.6-9.6 LY 19.1-37.1 MO 5.0-15.0 GR 52.9-70.9 LY# 1.2-3.6 MO# 0.6-1.2 GR# 3.3-7.3 RBC 4.55-4.05 HGB 10.3-11.7 HCT 29.6-38.6 MCV 72.4-86.4 MCH 23.1-28.1 MCHC 28.8-35.8 RDW 13.5-23.5 PLT 172-242 MPV 8.0-11.0 High; Lot# 90210424; Expiration date 2019-07-29 WBC 19.6-24.6 LY 8.4-20.4 MO 5.2-15.2 GR 67.5-83.5 LY# 1.2-5.2 MO# 1.1-3.5 GR# 13.2-20.2 RBC 5.06-5.66 HGB 14.2-16.2 HCT 42.5-51.5 MCV 80.7-94.7 MCH 25.9-30.9 MCHC 28.8-35.8 RDW 12.3-22.3 PLT 460-630 MPV 8.1-11.1 6. A random review of AcT Diff 2 hematology analyzer QC printouts from 01/2019 through 03/20/2109 revealed Lot number 813404 was still programmed for EACH level (Low, Normal, High) of control material with an expiration date of 11/19/2018. The limits associated with lot numbers 062000 (Low), 077200 (Normal), and 081500 (High) remained programmed into the analyzer. Because the facility failed to ensure that the correct lot number, expiration date and statistical parameters (Limits) for the 3 levels of hematology control material currently in use were programmed into the hematology analyzer, the laboratory failed

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| | to have a system in place to detect immediate error, to monitor errors over time, and the accuracy and precision of Coulter Act Diff 2 test performance with current and accurate statistical parameters. 7. The laboratory performs 1100 hematology tests annually. 8. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 1224 hours in the conference room. II. Based on review of manufacturer's package inserts, random review of Piccolo Express chemistry analyzer quality controls (QC) records (04/2018 through 02/2019), and staff interview, the laboratory failed to have a system in place to detect immediate error, monitor errors over time, and the accuracy and precision of Piccolo test performance with current and accurate statistical parameters. Findings included: 1. Review of Bioresource Technology chemistry control package insert (Document #PI9010; REV 06/28/2017) revealed the following quality control material lot numbers/assigned values used for each analyte: The following lot number of quality control material was used by the laboratory from 04/2018 through 09/2018. Lot number 1705005 (Level 1) / 1705005-2 (Level 2); Expiration date 09/2018 Glucose 59-82 237-327 BUN 16-25 49-61 CRE 0.7-1.9 4.1-6.5 Na 116-131 140-159 K 2.4-3.4 5.7-6.9 Cl 83-100 104-124 CO2 10-20 20-32 Ca 6.6-8.6 10.6-13.3 Phos 1.9-2.8 4.6-6.7 Mg 1.29-1.6 3.7-5.1 Alb 2.1-3.4 3.3-5.2 Lac 1.41-2.03 2.92-4.20 2. Review of Bioresource Technology chemistry control package insert (Document #PI9010; REV 11/30/2017) revealed the following quality control material lot numbers/assigned values used for each analyte: The following lot number of quality control material was used by the laboratory from 10/2018 through 02/2019. Lot number 1710030-1 (Level 1) / 1710030-2 (Level 2); Expiration date 02/2019 Glucose 57-78 223-308 BUN 16-24 47-58 CRE 0.7-1.9 3.9-6.2 Na 114-129 141-159 K 2.2-3.2 5.3-6.5 Cl 83-99 104-124 CO2 9-19 17-29 Ca 6.4-8.4 10.5-13.1 Phos 2.2-3.2 4.8-6.9 Mg 1.3-1.7 3.7-5.1 Alb 2.2-3.5 3.4-5.5 Lac 1.01-1.45 2.85-4.10 2. Review of the Piccolo Express chemistry analyzer quality controls (QC) records from 10/2018 through 02/2019 revealed the laboratory utilized Bioresource Technology quality control material Lot numbers 1710030-1 and 1710030-2. The following assigned values for each analyte were programmed into the Piccolo Express analyzer: Glucose 58-82 237-327 BUN 16-25 49-61 CRE 0.7-1.9 4.1-6.5 Na 116-131 140-159 K 2.4-3.4 5.7-6.9 Cl 83-100 104-124 CO2 10-20 18-30 Ca 6.6-8.6 10.6-13.3 Phos 2.3-3.3 4.6-6.7 Mg 1.2-1.6 3.7-5.1 Alb 2.1-3.4 3.3-5.2 Lac 1.41-2.03 2.92-4.20 The acceptable assigned values programmed into the Piccolo Express analyzer did NOT reflect the acceptable assigned values for the quality control material lot numbers currently in use by the laboratory. The assigned values programmed into the analyzer represented the previous lot number values (Lot numbers 1710030-1 (Level 1) / 1710030-2 (Level 2). The laboratory failed to ensure CURRENT and ACCURATE statistical parameters were used to detect immediate error and to monitor error over time, and the accuracy and precision of Piccolo Express test performance. 3. The laboratory performs 2500 chemistry tests annually. 4. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 1224 hours in the conference room. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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 |

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| | laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of the laboratory's Individualized Quality Control Plan (IQCP) for the modification of the frequency of quality control testing performed on the Alere Triage chemistry analyzers, and staff interview, it was revealed the laboratory failed to provide documentation of a complete IQCP for the Alere Triage. Findings included: 1. A tour of the laboratory on 03/20/2019 at 1200 hours revealed 2 Alere Triage chemistry analyzers (Serial Numbers 69155 and 69185) that performed D-dimer, CK-MB, Troponin, and Myoglobin testing. 2. Review of the documentation for the Alere Triage IQCP included a cover sheet signed by the laboratory director on 12/01/2018 that stated, "Central Hospital of Bowie performed an evaluation of the Abbott Piccolo Individualized Quality Control Plan." This document did NOT name the Alere Triage analyzer as the instrument for this IQCP. 3. Further review of the documentation for the Alere Triage IQCP included a Risk Assessment and Quality Control Plan for Troponin, CKMB, and BNP that references the Abbot iSTAT chemistry analyzer on pages 8, 9, 21, 22, 23, 24, 25, 26, 27, 28, 33, 37, 41, 43, 44, 45 and 46. The IQCP did not relate Risk Assessment to the Alere Triage analyzer. The IQCP did not include D-Dimer and Myoglobin analytes as part of the plan. 4. Review of the documentation of the 30-day assessment of external quality control material did NOT indicate which of the 2 Alere Triage analyzers was evaluated. The laboratory was asked to provide 30-day external quality control assessment for each analyzer. No documentation was provided. The laboratory failed to have a COMPLETE IQCP for the Alere Triage chemistry analyzers that included a risk assessment and a 30-day external quality control assessment for each instrument. 5. The above findings were confirmed in an interview with laboratory representatives on 03/20/2019 at 1224 hours in the conference room. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy, quality control records, patient test results and staff interview, the laboratory failed to ensure an effective QA (quality assessment) system was in place to monitor, assess, and correct problems in the laboratory. Findings included: 1. Review of the laboratory policy titled "Laboratory Quality Plan" in the section titled "QA Monitoring" stated, "Each laboratory section has identified indicators to monitor quality of operations. Indicators may be pre-analytic, analytic, or post-analytic. An effort has been made to select indicators that support the patient safety goals. When appropriate, trends are evaluated deviation from baseline. Regular reports are made to quality assurance committees and the Medical Director regarding performance and improvement opportunities." 2. Review of laboratory records for the Coulter AcT Diff 2 hematology analyzer, Abbott iSTAT blood gas analyzer, Alere Triage chemistry analyzer, and the Piccolo Express chemistry analyzer revealed the following performance and improvement |

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| | opportunities: a. The laboratory failed to follow its own policy for performing calibration verification every 6 months ensure the accuracy of all analytes tested. Refer to D5401 b. The laboratory failed to ensure that Complete Blood Count (CBC) results with flags were verified prior to reporting these results to the provider. Refer to 5403 c. The laboratory failed to ensure room temperature ranges were within the operating specifications for the Alere Triage chemistry analyzer. Refer to D5413 d. The laboratory failed to have a system in place to detect immediate error, to monitor errors over time, and the accuracy and precision of Coulter AcT Diff 2 hematology analyzer and Piccolo Express chemistry analyzer test performance with current and accurate statistical parameters. Refer to D5441 e. The laboratory failed to provide documentation of a complete IQCP for the Alere Triage. Refer to D5445 3. During an interview on 03/20/2019 at 1224 hours in the conference room, laboratory representatives were asked to provide documentation of quality assessment reports. No documentation was provided. This confirmed the above findings. |
| **D5813** | TEST REPORT<br>CFR(s): 493.1291(g)<br><br>The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and confirmed in staff interview, it was revealed the laboratory failed to have documentation to define critical values for WBC, Myoglobin, CKMB, and Myoglobin analytes. Findings included: 1. Review of the laboratory policy titled "Critical Lab Values and Read Back Procedure" (Effective date 08/01/2016) revealed the laboratory failed to have documentation of defined critical values for WBC, Myoglobin, CKMB, and Myoglobin analytes. 2. The laboratory was asked to provide documentation of critical values for WBC, Myoglobin, CKMB, and Myoglobin. No documentation was provided. 3. The above findings were confirmed in an interview with laboratory representatives on 03/20 /2019 at 1224 hours in the conference room. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of manufacturer's instructions, laboratory policy, laboratory records, and laboratory proficiency testing, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D6016. 2. The laboratory director failed to review, evaluate, and identify problems requiring corrective action for 2 of 2 proficiency testing events. Refer to D6018 3. The Laboratory Director failed to ensure 2 of 14 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6029 |
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| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2131 |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory policy, review of the laboratory's American Proficiency Institute's (API) Chemistry - Core proficiency testing records from 2018 (2nd and 3rd Events) and staff interview, it was revealed the laboratory director failed to review, evaluate, and identify problems requiring corrective action for 2 of 2 proficiency testing events. (Refer to D5211) |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of laboratory records, patient test results, and manufacturer's instructions, the Laboratory Director failed to ensure that QA (quality assessment) and QC (quality control) programs were monitored and maintained, as |

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| | evidenced by: 1. The laboratory failed to ensure an effective QA (quality assessment) system was in place to monitor, assess, and correct problems in the laboratory. Refer to D5793 |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review CMS-209 from, testing personnel records and staff interview, the laboratory director failed to ensure 2 of 14 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6065 |
| **D6045** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(7)<br><br>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to ensure the laboratory had documentation of training for performing moderate complexity testing (Coulter Act Diff 2 hematology analyzer, the Piccolo Express chemistry analyzer, the Alere Triage chemistry analyzer, and the Abbott iSTAT blood gas analyzer) for 3 of 14 testing personnel. Refer to D6066 |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation for 2 of 14 testing persons met the qualifications required to perform moderate complexity testing. (Refer to D6065) |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS |

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| | CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(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<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 2 of 14 testing persons met the qualifications required to perform moderate complexity testing. Finding included: 1. Review of the CMS-209 form submitted by the laboratory revealed 14 testing persons who performed moderate complexity testing. 2. Review of personnel records revealed the laboratory failed to have qualifying education documentation for the following testing persons: a. Testing person #9 No high school diploma, Associate Degree in a chemical, physical, or biological science, or medical technology, Bachelor of Science degree in a chemical, physical, biological or clinical science, or medical technology provided. b. Testing person #10 Records did not include an evaluation of education to determine equivalent foreign to United States education. 3. The above findings were confirmed by laboratory representatives on 03/20/2019 at 0800 hours |
| **D6066** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(4)(ii)<br><br>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of training for 3 of 14 testing personnel for moderately complex testing on the Coulter Act Diff 2 hematology analyzer, the Piccolo Express chemistry analyzer, the Alere Triage chemistry analyzer, and the Abbott iSTAT blood gas analyzer. The findings included: 1. Review of the CMS-209 form submitted by the laboratory revealed 14 testing persons who performed moderate complexity testing. 2. Based on a review of personnel records, 3 of 14 testing personnel did not have documentation of training. 3. The laboratory was asked to provide documentation of appropriate training. No documentation was provided. The above findings were confirmed by laboratory representatives on 03/20/2019 at 0800 hours. |