

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1086159	(X3) Date Survey Completed 11/30/2020
Name of Provider or Supplier Victory Medical Center	Street Address, City, State 2110 W Ben White Blvd, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1240 Condition: Preanalytic systems; 493.1250 Condition: Analytic systems; 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
D3007	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to ensure there was a working interface between the Laboratory Information System (LIS) and Electronic Medical Records (EMR). Findings follow. On November 12, 2020 at 0900 hours surveyor observed testing personnel #1 manually scanning patient test results into the EMR. Interview with testing personnel #1 on the CMS form 209 on November 12, 2020 at 0915 hours in the laboratory acknowledged she manually scans test reports into the EMR because the interface between the LIS and EMR was not working and has not worked for months.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

This STANDARD is not met as evidenced by:

I. Based on review of data logs, user manual, and interview, the laboratory failed to retain all testing records for at least 2 years on the Act Diff II Hematology analyzer 1 1 /2 out of 3 months reviewed. Findings follow. A. Random review of the Act Diff II Hematology analyzer (used until June 16, 2019) data logs for a three-month period from Oct 1, 2018 - Dec 29, 2018 showed missing data logs from Oct 1, 2018 - Nov 17, 2018. B. Review of the Beckman Coulter Act Diff II Operator's Guide, PN4237495BC March 2017, under 4.1 Printing Stored Sample Results stated, "the instrument automatically saves up to 250 patient results (numerical only, excluding histograms)." C. Interview with testing personnel (TP) #1 on the CMS form 209 on November 11, 2020 at 0930 hours in the laboratory acknowledged the LIS does not capture all runs from the Beckman Coulter, the original [patient or QC] runs were not retained, and the instrument was not set to print each sample run. Data logs on the Act Diff II were printed every 30-60 days, but some data would drop off and was no longer available to print. II. Based on review of quality control (QC) testing records, and interview, the laboratory failed to retain all testing records on the Siemens Advia 500 Hematology analyzer for 2 of 2 months reviewed. Findings follow. A. Random review of QC records printed from the LIS for the Siemens Advia 560 Hematology analyzer (resumed on June 26, 2019) from Feb 2020 and Oct 2020 showed all passing QC runs with each day of testing, but there were no repeated runs in situations when QC failed. B. Interview with TP #1 on November 11, 2020 at 1000 hours acknowledged the LIS only retained one QC value for each day per level, and she did not retain instrument print-outs. Failed runs of QC and original patient runs were not retained on the LIS because the LIS overrides the results when they repeated the sample. The laboratory had switched to the Siemens Advia 560 and plans to make backups of the files but has not started that yet. This is a repeat deficiency from survey conducted on 06/17/2018. KEY: LIS = Laboratory Information System

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure, proficiency testing (PT) records and interview, the laboratory failed to verify the accuracy of results for each analyte and specialty assigned a proficiency testing score of 100% when the laboratory failed to test specimens and submit to the PT agency for Hematology and Chemistry test systems in 2 out of 6 events reviewed. Findings follow. A. Review of the American Academy of Family Physicians (AAFP) PT records from the 2nd (B) and 3rd (C) events of 2019 showed the laboratory failed to test specimens and submit to the PT agency for Hematology. 1. Review of the 2019 B and 2019 C Proficiency Testing Evaluation form for White Blood Cell Count, Lymphocyte percent (%), Monocyte %, Monocyte/Mixed %, Granulocyte %, Red Blood Cell Count, Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume) and Platelet Count showed "Not Graded - Changed Instrument Method." Further review showed the laboratory was given a false score of a 100%. 2. Review of the AAFP 2019 B event

paperwork showed the samples were received on May 17, 2019 and the submission deadline was June 26, 2019. 3. Review of patient testing records showed the Act Diff II hematology analyzer was suspended on June 16, 2019, and the Advia 560 Hematology analyzer had resumed patient testing on June 26, 2019 for White Blood Cell Count, Lymphocyte (%), Monocyte %, Granulocyte %, Eosinophil %, Basophil %, Red Blood Cell Count, Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume) and Platelet Count. 4. From July 2019 to April 2020, 6137 Complete Blood Counts had been performed on the Advia 560. 5. Interview with testing personnel (TP) #1 on the CMS form 209 on November 11, 2020 at 1300 hours in the laboratory acknowledged the testing platform and test menu had changed and the previous Laboratory Director had not updated the information with AAFP before he left. B. Review of the American Academy of Family Physicians (AAFP) PT records from the 2nd (B) and 3rd (C) events of 2019 showed the laboratory failed to test specimens and submit to the PT agency for Chemistry. 1. Review of the 2019 B & C Proficiency Testing Evaluation form for Sodium, Potassium, Chloride, CO2 (Bicarbonate), Calcium, Creatinine, Glucose, Urea Nitrogen, Albumin, Alkaline Phosphatase, ALT (Alanine Transferase), AST (Aspartate Aminotransferase), Total Bilirubin, Total Protein, Total Cholesterol, Cholesterol HDL (High Density Lipoprotein), Triglycerides, Direct Bilirubin, Iron, Urine Microalbumin showed "Not Graded - Changed Instrument Method." Further review showed the laboratory was given a false score of a 100%. 2. Review of the AAFP 2019 B event paperwork showed the samples were received on May 17, 2019. Review of the AAFP 2019 C event paperwork showed the samples were received on Oct 9, 2019. 3. Review of patient testing records showed the Beckman Coulter AU480 chemistry analyzer began patient testing on May 1, 2019 for Sodium, Potassium, Chloride, CO2, Calcium, Creatinine, Glucose, Urea Nitrogen, Albumin, Alkaline Phosphatase, ALT, AST, Total Bilirubin, Total Protein, Total Cholesterol, Cholesterol HDL (High Density Lipoprotein), Triglycerides, Amylase, Direct Bilirubin, Magnesium, and Iron. 4. 5204 patients were tested for Sodium in 2019. 5. Interview with testing personnel (TP) #1 on the CMS form 209 on November 11, 2020 at 1300 hours in the laboratory acknowledged the testing platform and test menu had changed and the previous Laboratory Director had not updated the information with AAFP before he left. TP #1 explained, for example the laboratory didn't get urine specimens for urine testing. TP #1 did not have access to update the platform with AAFP, and the testing menus were completely different. TP #1 confirmed PT samples were not tested.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of manufacturer's instructions for use, laboratory policies and procedures, verification studies, patient test records and interview with facility personnel, the laboratory failed to meet the requirements for pre analytic systems when testing patient blood specimens using the Siemens Advia 560 hematology analyzer and the Beckman Coulter AU 480 Chemistry analyzer. The laboratory failed

to follow the manufacturer's instructions for testing blood specimens for Complete Blood Count (CBC) within 7 hours of collection using the Siemens Advia 560 hematology analyzer. The Laboratory failed to follow the manufacturer's instructions for testing blood specimens for bicarbonate (CO₂) within 24 hours of collection using the Beckman Coulter AU 480. (see D5311)

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions for use, laboratory policies and procedures, patient requisitions, patient test reports, patient testing volume, and interview, the laboratory failed to follow the manufacturer's instructions when testing blood specimens for Bicarbonate (CO₂) within 24 hours of collection using the Beckman Coulter AU480 chemistry analyzer. Findings follow. 1. Review of the Beckman Coulter AU Instructions for Use for Bicarbonate (CO₂), BAOSR5X37 11 (rev June 2020), under Specimen Storage and Stability stated, "Once separated from cells, Bicarbonate in serum and plasma is stable for 24 hours when stored at 20 - 25C and protected from exposure to air." 2. Review of the laboratory's written policy and procedure titled Bicarbonate (CO₂) (reviewed by the Laboratory Director on 10/06/2019), under Specimen Storage and Stability stated, "Once separated from cells, Bicarbonate in serum and plasma is stable for 24 hours when stored at 20 - 25C and protected from exposure to air." And under "Additional handling conditions as designated by this laboratory" stated, "Samples collected at offsite locations will be collected and placed in the Refrigerator." 3. Surveyor observed the receipt of 62 requisitions for patient testing on 11/12/2020 at 0930 in the laboratory. Of those 62 requisitions, 31 patient reports were provided at the time of the survey. Of the 31 patient reports, 17 requested Comprehensive Metabolic Panels that included CO₂ testing. 4. Review of 17 of 17 paired requisition forms and patient reports for CO₂ tested on November 12, 2020 found the laboratory tested patient specimens that were greater than 24 hours old as listed below by Patient ID: a. 173171: collected 11/11/2020 at 1139 hours and tested on 11/12/2020 at 1824 hours (30 hours and 45 minutes later); b. 292730: collected 11/11/2020 at 1233 hours and tested on 11/12/2020 at 1733 hours (29 hours and 00 minutes later); c. 265959: collected 11/11/2020 at 1222 hours and tested on 11/12/2020 at 1729 hours (29 hours and 07 minutes later); d. 295881: collected 11/11/2020 at 1033 hours and tested on 11/12/2020 at 1742 hours (31 hours and 5 minutes later); e. 195885: collected 11/11/2020 at 1035 hours and tested on 11/12/2020 at 1818 hours (31 hours and 43 minutes later); f. 242283: collected 11/11/2020 at 0812 hours and tested on 11/12/2020 at 1836 hours (34 hours and 24 minutes later); g. 237804: collected 11/11/2020 at 0848 hours and tested on 11/12/2020 at 1815 hours (33 hours and 27 minutes later); h. 193697: collected 11/10/2020 at 1457 hours and tested on 11/12/2020 at 1854 hours (51 hours and 57 minutes later); i. 237042: collected 11/10/2020 at 1600 hours and tested on 11/12/2020 at 0851 hours (50 hours and 51 minutes later); j. 261530: collected 11/10/2020 at 0814 hours and tested on 11/12/2020 at 1827 hours (58 hours and 13 minutes later); k. 293525:

collected 11/11/2020 at 0849 hours and tested on 11/12/2020 at 1806 hours (33 hours and 17 minutes later); l. 272251: collected 11/11/2020 at 1029 hours and tested on 11/12/2020 at 1830 hours (32 hours and 1 minute later); m. 146218: collected 11/11/2020 at 1344 hours and tested on 11/12/2020 at 1754 hours (28 hours and 10 minutes later); n. 147274: collected 11/11/2020 at 1301 hours and tested on 11/12/2020 at 1720 hours (28 hours and 19 minutes later); o. 147912: collected 11/11/2020 at 1321 hours and tested on 11/12/2020 at 1809 hours (28 hours and 48 minutes later); p. 295635: collected 11/11/2020 at 1245 hours and tested on 11/12/2020 at 1748 hours (29 hours and 3 minutes later); q. 286945: collected 11/11/2020 at 1345 hours and tested on 11/12/2020 at 1841 hours (28 hours and 56 minutes later). 5. Review of the CMS form 116 showed an annual test volume of 6000 for CO2. 6. Interview of testing personnel #1 on the CMS form 209 on November 11, 2020 at 1350 hours confirmed that she would pick up specimens from the three clinics each morning and bring them to the laboratory for testing. The specimens picked up each morning were collected the previous day and stored in the refrigerator until she picked them up. 28428 Based on review of manufacturer's instructions for use, laboratory policies and procedures, patient test records and interview with facility personnel, the laboratory failed to follow the manufacturer's instructions for testing blood specimens for Complete Blood Counts (CBC) using the Siemens Advia 560 hematology analyzer. The findings included: 1. Review of the Advia 560 Analyzer Operator's Manual (Rev. A 2015-06) found on page 50 under the heading Sample Collection and Handling: "Analyze blood samples within 7 hours of collection." 2. Review of the laboratory's written policy titled CBC Advia 560 (effective date 07/01/2019) found on page 2 under the heading SPECIMEN STORAGE AND STABILITY "5. Stored Specimen Stability: a. If stored at 4-8 degrees C within 6 hours of collection, EDTA blood samples with normal results may be analyzed up to 72 hours without significant loss of differential stability. b. Sample stability at room temperature is 8 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours. This may be minimized by refrigeration." 3. Review of patient test records found the laboratory had tested 6137 patient specimens for CBC between June 1, 2019 and November 10, 2020. Review of 30 patient reports tested on November 12, 2020 found the laboratory tested 30 of 30 patient specimens that were greater than 7 hours old. Accession 28424- collected 11/11/2020 at 12:33 PM and tested 29 hours 39 and minutes later on 11/12/2020 at 6:12 PM. Accession 28428- collected 11/11/2020 at 11:39 AM and tested 30 hours and 34 minutes later on 11/12/2020 at 6:13 PM Accession 28431 - collected 11/11/2020 at 12:22 PM and tested 29 hours and 52 minutes later on 11/12/2020 at 6:14 PM. Accession 28434- collected 11/11/2020 at 10:35 AM and tested 31 hours and 40 minutes later on 11/12/2020 at 6:15 PM Accession 28438 - collected 11/11/2020 at 10:33 AM and tested 31 hours and 43 minutes later on 11/12/2020 at 6:16 PM. Accession 28442- collected 11/11/2020 at 09:52 AM and tested 32 hours and 25 minutes later on 11/12/2020 at 6:17 PM. Accession 28446 - collected 11/11/2020 at 08:07 AM and tested 8 hours and 42 minutes later on 11/12/2020 at 6:18 PM Accession 28448 - collected 11/11/2020 at 08:02 AM and tested 34 hours and 17 minute later on 11/12/2020 at 6:19 PM. Accession 28450 - collected 11/11/2020 at 09:05 AM and tested 33 hours and 15 minutes later on 11/12/2020 at 6:20 PM Accession 28453 - collected 11/11/2020 at 08:48 AM and tested 33 hours and 33 minutes later on 11/12/2020 at 6:21 PM Accession 28455- collected 11/11/2020 at 08:44 AM and tested 33 hours and 38 minutes later on 11/12/2020 at 6:22 PM Accession 28458 - collected and tested 23 hours and 45 minutes later on 11/12/2020 at 6:23 PM. Accession 28463 - collected 11/10/2020 at 4:00 PM and tested 50 hours and 25 minutes later on 11/12/2020 at 6:25 PM Accession 28461 - collected 11/10/2020 at 2:57 PM and tested 51 hours and 27 minutes later on 11/12/2020 at 6:24 PM Accession 28458 - collected 11/10/2020 at 2:25 PM and tested 51 hours and 59 minutes later on 11/12/2020 at 6:24 PM Accession

28467 - collected 11/10/2020 at 8:14 AM and tested 58 hours and 12 minutes later on 11/12/2020 at 6:26 PM Accession 28470 - collected 11/11/2020 at 8:49 AM and tested 33 hours and 38 minutes later on 11/12/2020 at 6:27 PM Accession 28472 - collected 11/11/2020 at 09:50 AM and tested 32 hours and 38 minutes later on 11/12/2020 at 6:28 PM Accession 28476 - collected 11/11/2020 at 10:29 AM and tested 32 hours later on 11/12/2020 at 6:29 PM Accession 28482 - collected 11/11/2020 at 7:57 AM and tested 34 hours and 33 minutes later on 11/12/2020 at 6:30 PM Accession 28484 - collected 11/11/2020 at 2:42 PM and tested 27 hours and 49 minutes later on 11/12/2020 at 6:31 PM Accession 28489 - collected 11/11/2020 at 1:44 PM and tested 28 hours and 48 minutes later on 11/12/2020 at 6:32 PM Accession 28492 - collected 11/11/2020 at 12:56 PM and tested 29 hours and 37 minutes later on 11/12/2020 at 6:33 PM Accession 28495 - collected 11/11/2020 at 1:01 PM and tested 29 hours and 33 minutes later on 11/12/2020 at 6:34 PM Accession 28500 - collected 11/11/2020 at 4:23 PM and tested 26 hours and 12 minutes later on 11/12/2020 at 6:35 PM Accession 28505 - collected 11/11/2020 at 12:45 PM and tested 29 hours and 51 minutes later on 11/12/2020 at 6:36 PM Accession 28507 - collected 11/11/2020 at 1:21 PM and tested 29 hours and 16 minutes later on 11/12/2020 at 6:37 PM Accession 28510 - collected 11/11/2020 at 1:45 PM and tested 28 hours and 53 minutes later on 11/12/2020 at 6:38 PM Accession 28513 - collected 11/11/2020 at 09:45 AM and tested 32 hours and 55 minutes later on 11/12/2020 at 6:40 PM Accession 28517 - collected 11/11/2020 at 08:21 AM and tested 34 hours and 3 minutes later on 11/12/2020 at 6:24 PM Accession 28519 - collected 11/11/2020 at 09:12 AM and tested 33 hours and 30 minutes later on 11/12/2020 at 6:42 PM 5. Interview of Testing Person one on the CMS report 209 Laboratory Personnel Report conducted on November 11, 2020 at 1:50 PM confirmed that she would pick up specimens from the three clinics each morning, and transport them to the laboratory for testing. The specimens picked up each morning were collected the previous day, and stored in the refrigerator until she picked them up. She would transport the specimens to the laboratory for testing. She would spend her morning accessioning the specimens, and would typically test them in the afternoon. Analytes included in the CBC : White Blood Cell (WBC) Red Blood Cell (RBC) Hemoglobin (Hgb) Hematocrit (Hct) Mean Corpuscular Volume (MCV) Mean Corpuscular Hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC)

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policies and procedures and interview of facility personnel found the laboratory failed to have a written policy to monitor, assess and correct problems in the pre-analytic laboratory systems. The laboratory failed to follow the manufacturer's storage and handling instructions for CBC and CO2 blood specimens as defined by the manufacturer. (See D5311)

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 observations, manufacturer's instructions for use and assay sheet, review of temperature records laboratory policies and procedures, patient testing records, verification of performance specifications, quality control (QC) records, and interview of facility personnel, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems in testing performed in Chemistry and Hematology. Findings follow. 1. The laboratory failed to store Bio-Rad Quality control materials in a non-frost-free freezer as directed by the manufacturer (refer to D5411). 2. The laboratory failed to verify the manufacturer's reference ranges and failed to establish alternative storage and stability criteria for Bicarbonate (CO₂) specimens stored at refrigerated temperatures greater than 24 hours when tested on the Beckman Coulter AU480 chemistry analyzer (refer to D5421). 3. The laboratory failed to define the acceptable limits of QC as required by the manufacturer, and of their own policy on the Beckman Coulter AU480 chemistry analyzer for 22 out of 24 analytes reviewed (refer to D5469). 4. The laboratory failed to ensure QC results met the laboratory's criteria for acceptability before reporting patient test results for testing performed on the Beckman Coulter AU480 chemistry analyzer (refer to D5481). 5. The laboratory failed to document all corrective action taken when QC failed (refer to D5781).

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:

Based on observations, review of Bio-Rad quality control manufacturer instructions, review of temperature records and interview of facility personnel, the laboratory failed to store Bio-Rad Quality control materials in a non-frost-free freezer as directed by the manufacturer. The findings included: 1. Observations made in the laboratory on November 12, 2020 at 11:08 AM found the laboratory stored the following BIO RAD quality control materials in the Whynter freezer SN 340-96930501. Surveyor observed the temperature of this freezer to be -20 C. Stored in this freezer were the following quality control materials: BIO RAD Liquid Assayed Multiquel Control 1 lot 45811 (6 of 12 bottles) BIO RAD Liquid Assayed Multiquel Control 3 lot 45813 (6 of 12 bottles) BIO RAD Liquichek Immunology Control 1 lot 68941 (5 of 6 bottles) BIO RAD Liquichek Immunology Control 1 lot 68943 (5 of 6 bottles) BIO RAD Liquichek Diabetes Control 1 lot 55731 (1 of 3 bottles) BIO RAD Liquichek Diabetes Control 3 lot 55733 (1 of 3 bottles) 2. Review of Bio-Rad Quality Control manufacturer instructions, under " Storage and Stability " , states: " This product is stable until the expiration date when stored unopened at -20 C to -70 C. For optimum performance, avoid storage in a frost-free freezer. Store vials away from light. " 3.

Review of the laboratory's environmental records between July 2020 and November 2020 found the laboratory did not record freezer temperature measurements in July and August of 2020. Further review found the laboratory recorded a temperature of -20 C for 19 days in September, 22 days in October and 8 days in November. 4. Interview of testing person one conducted on November 12/2020 at 11:30 AM found the frost free Whynter freezer was purchased and installed September 3, 2020 specifically for the storage of quality control materials

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:

I. Based on review of the manufacturer's instructions for use, laboratory policies and procedures, patient testing records, verification of performance specifications, and observation, the laboratory failed to verify the manufacturer's reference ranges and failed to establish alternative storage and stability criteria for Bicarbonate (CO₂) specimens stored at refrigerated temperatures greater than 24 hours when tested on the Beckman Coulter AU480 chemistry analyzer. Findings follow. 1. Review of the Beckman Coulter AU Instructions for Use for Bicarbonate (CO₂), BAOSR5X37 11 (rev June 2020), under Specimen Storage and Stability stated, "Once separated from cells, Bicarbonate in serum and plasma is stable for 24 hours when stored at 20 - 25C and protected from exposure to air. Based on specific needs, each laboratory may establish alternative storage and stability information according to good laboratory practice or from alternative reference documentation." 2. Review of the laboratory's procedure for Bicarbonate (CO₂) (reviewed by the Laboratory Director on 10/06/2019), under Specimen Storage and Stability stated, "Once separated from cells, Bicarbonate in serum and plasma is stable for 24 hours when stored at 20 - 25C and protected from exposure to air." Under "additional handling conditions as designated by this laboratory:" stated "Samples collected at offsite locations will be collected and placed in the refrigerator. They will be transported by the Victory Medical Center courier to the Main Campus for processing." 3. Surveyor observed the receipt of 62 requisitions for patient testing on 11/12/2020 at 0930 in the laboratory. Of those 62 requisitions, 31 patient reports were provided at the time of the survey. Of the 31 patient reports, 17 requested Comprehensive Metabolic Panels that included CO₂ testing. 4. Review of 17 of 17 paired requisition forms and patient reports for CO₂ tested on November 12, 2020 found the laboratory tested patient specimens that were greater than 24 hours old and refrigerated as listed below by Patient ID: a. 173171: collected 11/11/2020 at 1139 hours and tested on 11/12/2020 at 1824 hours (30 hours and 45 minutes later); b. 292730: collected 11/11/2020 at 1233 hours and tested on 11/12/2020 at 1733 hours (29 hours and 00 minutes later); c. 265959: collected 11/11/2020 at 1222 hours and tested on 11/12/2020 at 1729 hours (29 hours and 07 minutes later); d. 295881: collected 11/11/2020 at 1033 hours and tested on 11/12/2020 at 1742 hours (31 hours and 5 minutes later); e. 195885: collected 11/11/2020 at 1035 hours and tested on 11/12/2020 at 1818 hours (31 hours and 43 minutes later); f.

242283: collected 11/11/2020 at 0812 hours and tested on 11/12/2020 at 1836 hours (34 hours and 24 minutes later); g. 237804: collected 11/11/2020 at 0848 hours and tested on 11/12/2020 at 1815 hours (33 hours and 27 minutes later); h. 193697: collected 11/10/2020 at 1457 hours and tested on 11/12/2020 at 1854 hours (51 hours and 57 minutes later); i. 237042: collected 11/10/2020 at 1600 hours and tested on 11/12/2020 at 0851 hours (50 hours and 51 minutes later); j. 261530: collected 11/10/2020 at 0814 hours and tested on 11/12/2020 at 1827 hours (58 hours and 13 minutes later); k. 293525: collected 11/11/2020 at 0849 hours and tested on 11/12/2020 at 1806 hours (33 hours and 17 minutes later); l. 272251: collected 11/11/2020 at 1029 hours and tested on 11/12/2020 at 1830 hours (32 hours and 1 minute later); m. 146218: collected 11/11/2020 at 1344 hours and tested on 11/12/2020 at 1754 hours (28 hours and 10 minutes later); n. 147274: collected 11/11/2020 at 1301 hours and tested on 11/12/2020 at 1720 hours (28 hours and 19 minutes later); o. 147912: collected 11/11/2020 at 1321 hours and tested on 11/12/2020 at 1809 hours (28 hours and 48 minutes later); p. 295635: collected 11/11/2020 at 1245 hours and tested on 11/12/2020 at 1748 hours (29 hours and 3 minutes later); q. 286945: collected 11/11/2020 at 1345 hours and tested on 11/12/2020 at 1841 hours (28 hours and 56 minutes later).

5. Review of the verification of performance specifications for the modified test system of Bicarbonate (CO₂) for accuracy, precision, reportable range of test results, normal patient values, and any other pertinent characteristics revealed the laboratory did not have documentation of establishment studies for alternative storage and stability for CO₂. 6. Review of the CMS form 116 showed an estimated annual test volume of 6000 for CO₂. 7. Surveyor observation on November 12, 2020 at 1000 showed a validation study had not been done on Bicarbonate to include specimens stored outside the manufacturer's specifications.

II. Based on review of the verification of performance specifications, laboratory policies and procedures, patient testing records, and interview, the laboratory failed to verify the patient reference ranges for testing performed on the Beckman Coulter AU480 chemistry analyzer. Findings follow.

1. Review of the verification of performance specifications for the Beckman Coulter AU480 showed no normal reference range study available for review. 2. Random review of the laboratory's policies and procedures titled a. ISE (Sodium, Potassium, Chloride), effective 3/4/2019, on page 8, b. Total Protein, effective 3/4/2019, on page 6, c. Magnesium, effective 3/4/2019, on page 5, d. Hemoglobin A1C, effective 3/4/2019, on page 8, e. Glucose, effective 3/4/2019, on page 5, f. Cholesterol, effective 3/4/2019, on page 6, g. and Alkaline Phosphatase (ALP), effective 3/4/2019, on page 5 under "Expected reference ranges in this laboratory" stated, "Victory Medical will be adopting the published Beckman Reference Range." 3. Review of patient testing records showed the laboratory began using the Beckman Coulter AU480 Chemistry analyzer for testing on May 1, 2019 for Sodium, Potassium, Chloride, Calcium, Creatinine, Glucose, Urea Nitrogen, Albumin, Alkaline Phosphatase (ALP), ALT (Alanine Transferase), AST (Aspartate Aminotransferase), Total Bilirubin, Total Protein, Phosphorus, Total Cholesterol, Cholesterol HDL (High Density Lipoprotein), Triglycerides, Amylase, Gamma Glutamyl Transpeptidase (GGT), Lipase, Direct Bilirubin, Magnesium, Iron, TIBC (Total Iron Binding Capacity), Ferritin, Urine Microalbumin, and Urine Creatinine. 4. Interview with testing personnel #1 on the CMS form 209 on November 12 at 1000 hours in the laboratory confirmed a normal reference range study was not available for review at the time of the survey. This is a repeat deficiency from survey conducted on 06/17/2018.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure, manufacturer's instructions for use and assay sheet, quality control (QC) records, and interview, the laboratory failed to define the acceptable limits of QC as required by the manufacturer, and of their own policy on the Beckman Coulter AU480 chemistry analyzer for 22 out of 24 analytes reviewed. Findings follow. 1. Review of the laboratory's policy and procedure titled "Preanalytical Testing (Maintenance, Calibration, and Quality Control)" (rev 10/04/2019), under VI. Quality Control Plan stated, under "Statistical Quality Control - Acceptable Limits:" stated "A. Manufacturer's established parameters of mean and standard deviation are verified by repetitive testing (multiple QC determinations). See Procedure for Verification of New Lot Number of Assayed Controls. B. Many manufacturers recommend that each laboratory establish its own mean and acceptable ranges and use the published ranges of the assayed control as a guide. In this case, the laboratory needs to create its own ranges through multiple QC determinations. See Procedure for Implementation of New Lot Number of Control..." Under the "Procedure for implementation of New Lot Number of Controls:" stated "1. Run all levels of controls in duplicate over a period of 10 or more days, to achieve a minimum of 20 results per level. 2. Calculate the mean, standard deviation (SD) and coefficient of variation (CV) from the data for each QC level. Lot numbers should be indicated on the evaluation form. 3. Evaluate the statistics: a. Assayed Controls: Determine if the difference between the observed mean and the expected mean is acceptable... 4. Compare the observed CV to the historic CV for that QC level. (Note: historic CV represents the precision of that test system with that control level over time). Six months is generally an adequate timeframe to establish the historic CV. The observed CV will mostly likely be less than the historic CV. 5. Establish the working control ranges from the mean and standard deviation or the historic CV. 6. Enroll in a peer group program when available and submit data on a monthly basis. 7. Review monthly statistics or more frequently as needed. Compare observed statistics to QAP reports with peer group comparison. Changes may be made to these working control ranges when the monthly QC review is done and compared with the numbers obtained with the peer group comparison." 2. Review of the laboratory's policy and procedure titled Preanalytical Testing (Maintenance, Calibration, and Quality Control) under the Quality Control Policy stated, "under General Chemistry: Beckman Coulter AU480 Chemistry Analyzer" listed each test Urine Microalbumin, Creatinine, CO₂ (Carbon Dioxide), Glucose, Potassium, Sodium, ALP (Alkaline Phosphatase), AST (Aspartate Aminotransferase), ALT (Alanine Transferase), Total Cholesterol, Cholesterol HDL (High Density Lipoprotein), BUN (Blood Urea Nitrogen), Triglycerides, Magnesium, Phosphorus, Lipase, GGT (Gamma Glutamyl Transpeptidase), Amylase, Iron, Hemoglobin A1C and defined the "Multi Rules Used" as "within 2SD of the

established mean." 3. Review of the Bio Rad Liquid Assayed Multiquant control package insert for Lot 48501 and 48503 (rev 2018 01) under Assignment of Values stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analysis and are specific for this lot or product...It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 4. The following analytes for Beckman Coulter AU Systems were listed for Lots 45801 and 45803 for Levels 1 and 3 on the Bio Rad Liquid Assayed Multiquant (rev 2018 01), respectively, with the following ranges: a. Alkaline Phosphatase: Level 1 mean 32.4, range 20.6 - 44.2 (1SD 3.93); Level 3 mean 324, range 231 - 418 (1SD 31) b. Alanine Transferase: Level 1 mean 28.6, range 20.8 - 36.5 (1SD 2.6); Level 3 mean 181, range 140 - 222 (1SD 14) c. Amylase: Level 1 mean 31.4, range 23.3 - 39.5 (1SD 2.7); Level 3 mean 242, range 198 - 286 (1SD 15) d. Aspartate Aminotransferase: Level 1 mean 37.7, range 27.0 - 48.3 (1SD 3.6); Level 3 mean 229, range 162 - 296 (1SD 22) e. Bilirubin (Direct): Level 1 mean 0.304, range 0.223 - 0.386 (1SD 0.027); Level 3 mean 2.57, range 2.15 - 2.99 (1SD 0.14) f. Bilirubin (Total): Level 1 mean 0.614, range 0.488 - 0.741 (1SD 0.042); Level 3 mean 6.84, range 5.95 - 7.73 (1SD 0.30) g. Calcium: Level 1 mean 6.17, range 5.58 - 6.76 (1SD 0.20); Level 3 mean 13.0, range 11.9 - 14.1 (1SD 0.37) h. Carbon Dioxide (CO₂): Level 1 mean 16.8, range 12.7 - 21.0 (1SD 1.38); Level 3 mean 27.4, range 21.5 - 33.4 (1SD 1.98) i. Chloride: Level 1 mean 76.0, range 72.8 - 79.2 (1SD 1.1); Level 3 mean 114, range 110 - 119 (1SD 1.5) j. Cholesterol (HDL): Level 1 mean 28.7, range 22.0 - 35.3 (1SD 2.22); Level 3 mean 77.0, range 62.4 - 91.6 (1SD 4.87) k. Cholesterol (Total): Level 1 mean 110, range 96.2 - 124 (1SD 4.6); Level 3 mean 269, range 237 - 300 (1SD 10.5) l. Gamma Glutamyl Transpeptidase Level 1 mean 23.5, range 16.8 - 30.2 (1SD 2.2); Level 3 mean 107, range 75.9 - 138 (1SD 10.4) m. Glucose: Level 1 mean 59.7, range 53.3 - 66.1 (1SD 2.1); Level 3 mean 354, range 320 - 388 (1SD 11) n. Iron: Level 1 mean 77.4, range 64.9 - 90.0 (1SD 4.2); Level 3 mean 248, range 218 - 278 (1SD 10) o. Lipase: Level 1 mean 22.1, range 15.1 - 29.0 (1SD 2.3); Level 3 mean 153, range 121 - 184 (1SD 10.5) p. Magnesium: Level 1 mean 1.13, range 0.920 - 1.35 (1SD 0.072); Level 3 mean 3.96, range 3.45 - 4.47 (1SD 0.17) q. Phosphorus: Level 1 mean 1.74, range 1.46 - 2.03 (1SD 0.10); Level 3 mean 6.81, range 5.98 - 7.64 (1SD 0.28) r. Potassium: Level 1 mean 2.51, range 2.36 - 2.66 (1SD 0.05); Level 3 mean 7.56, range 7.17 - 7.94 (1SD 0.13) s. Protein Serum (Total): Level 1 mean 3.94, range 3.51 - 4.38 (1SD 0.145); Level 3 mean 6.81, range 6.10 - 7.52 (1SD 0.24) t. Sodium: Level 1 mean 114, range 109 - 119 (1SD 3.3); Level 3 mean 157, range 152 - 163 (1SD 1.8) u. Triglycerides: Level 1 mean 101, range 86.5 - 116 (1SD 4.9); Level 3 mean 228, range 196 - 259 (1SD 10.5) v. Urea Nitrogen (BUN): Level 1 mean 15.0, range 12.8 - 17.2 (1SD 0.7); Level 3 mean 67.2, range 59.5 - 75.0 (1SD 2.6). 5. Review of the monthly QC reports printed from the LIS showed the mean and 2SD for each analyte. The following represented the laboratory's established ranges (2SD) for the random month of March 2020: a. Alkaline Phosphatase: Level 1 range 21.1 - 44.9 (1SD 5.95) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 233 - 419 (1SD 46.5) [equivalent to the manufacturer's 3SD published ranges] b. Alanine Transferase: Level 1 range 17.3 - 31.3 (1SD 3.5) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 124 - 200 (1SD 19) [equivalent to the manufacturer's 3SD published ranges] c. Amylase: Level 1 range 26.0 - 42.6 (1SD 4.15) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 204 - 294 (1SD 22.5) [equivalent to the manufacturer's 3SD published ranges] d. Aspartate Aminotransferase: Level 1 range 25.0 - 48.0 (1SD 5.75) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 147 - 287 (1SD 35) [equivalent to the manufacturer's 3SD published ranges] e. Bilirubin (Direct): Level 1 range 0.218 - 0.376 (1SD 0.0395) [equivalent to the manufacturer's 3SD published ranges]; Level

3 range 2.38 - 3.22 (1SD 0.21) [equivalent to the manufacturer's 3SD published ranges] f. Bilirubin (Total): Level 1 range 0.488 - 0.726 (1SD 0.0595) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 5.94 - 7.68 (1SD 0.435) [equivalent to the manufacturer's 3SD published ranges] g. Calcium: Level 1 range 5.77 - 6.89 (1SD 0.28) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 11.8 - 14.2 (1SD 0.6) [equivalent to the manufacturer's 3SD published ranges] h. Carbon Dioxide (CO₂): Level 1 range 11.6 - 19.4 (1SD 1.95) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 20.6 - 32.2 (1SD 2.9) [equivalent to the manufacturer's 3SD published ranges] i. Chloride: Level 1 range 72.8 - 79.4 (1SD 1.65) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 114 - 122 (1SD 2) [equivalent to the manufacturer's 3SD published ranges] j. Cholesterol (HDL): Level 1 range 22.0 - 33.6 (1SD 2.9) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 67.2 - 96.6 (1SD 7.35) [equivalent to the manufacturer's 3SD published ranges] k. Cholesterol (Total): Level 1 range 90.0 - 116 (1SD 6.5) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 242 - 306 (1SD 16) [equivalent to the manufacturer's 3SD published ranges] l. Gamma Glutamyl Transpeptidase Level 1 range 17.3 - 30.5 (1SD 3.3) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 79 - 141 (1SD 15.5) [equivalent to the manufacturer's 3SD published ranges] m. Glucose: Level 1 range -2.4 - 123.6 (1SD 31.5) [ranges greater than the manufacturer's 3SD published ranges]; Level 3 range 326 - 392 (1SD 16.5) [equivalent to the manufacturer's 3SD published ranges] n. Iron: Level 1 range 69.7 - 95.9 (1SD 6.55) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 220 - 282 (1SD 15.5) [equivalent to the manufacturer's 3SD published ranges] o. Lipase: Level 1 range 12.3 - 25.7 (1SD 3.35) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 112 - 172 (1SD 15) [equivalent to the manufacturer's 3SD published ranges] p. Magnesium: Level 1 range -0.42 - 2.64 (1SD 0.765) [ranges greater than the manufacturer's 3SD published ranges]; Level 3 range 3.51 - 4.51 (1SD 0.25) [equivalent to the manufacturer's 3SD published ranges] q. Phosphorus: Level 1 range 1.62 - 2.18 (1SD 0.14) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 6.13 - 7.73 (1SD 0.40) [equivalent to the manufacturer's 3SD published ranges] r. Potassium: Level 1 range 2.42 - 2.74 (1SD 0.08) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 6.89 - 7.67 (1SD 0.195) [equivalent to the manufacturer's 3SD published ranges] s. Protein Serum (Total): 3.35 - 4.19 (1SD 0.21) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 6.20 - 7.56 (1SD 0.34) [equivalent to the manufacturer's 3SD published ranges] t. Sodium: Level 1 range 107 - 117 (1SD 2.5) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 152 - 164 (1SD 3) [ranges greater than the manufacturer's 3SD published ranges] u. Triglycerides: Level 1 range 83.2 - 110 (1SD 6.7) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 184 - 234 (1SD 12.5) v. Urea Nitrogen (BUN): Level 1 range 12.6 - 17.0 (1SD 1.1) [equivalent to the manufacturer's 3SD published ranges]; Level 3 range 59.1 - 76.3 (1SD 4.3) [ranges greater than the manufacturer's 3SD published ranges] 6. Interview with testing personnel (TP) #1 on the CMS form 209 on November 12, 2020 at 1030 hours in the laboratory confirmed she used the package insert means and ranges and has now adjusted the ranges to 2SD [With the new lot of Liquid Assayed Multiquel Lot 45810, on October 27, 2020].

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test

results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure, quality control (QC) records, patient testing records, and interview, the laboratory failed to ensure QC results met the laboratory's criteria for acceptability before reporting patient test results for testing performed on the Beckman Coulter AU480 chemistry analyzer. Findings follow. I. Review of the laboratory's policy and procedure titled "Preanalytical Testing (Maintenance, Calibration, and Quality Control)" (rev 10/04/2019) under the Quality Control Policy stated, "under General Chemistry: Beckman Coulter AU480 Chemistry Analyzer" listed each test Urine Microalbumin, Creatinine, CO₂ (Carbon Dioxide), Glucose, Potassium, Sodium, ALP (Alkaline Phosphatase), AST (Aspartate Aminotransferase), ALT (Alanine Transferase), Total Cholesterol, Cholesterol HDL (High Density Lipoprotein), BUN (Blood Urea Nitrogen), Triglycerides, Magnesium, Phosphorus, Lipase, GGT (Gamma Glutamyl Transpeptidase), Amylase, Iron, Hemoglobin A1C and defined the "Multi Rules Used" as "within 2SD of the established mean." II. Random review of the monthly quality control print-outs from March 2020 from the LabDaq LIS system for the analytes performed on the Beckman Coulter AU480 showed QC runs were accepted with O2 flags (out 2SD) and patients were reported. Note: The laboratory's 2SD range was actually a 3SD range, refer to D5469. A. Review of QC records for Calcium showed patients were reported when only one level of QC was within acceptable range on 9 out of 14 days of patient testing. The Liquid Assayed Multiquel Level 3, Lot 45803, acceptable range was 11.8 - 14.2. 1. On 3/02/2020, the laboratory obtained a value of 14.4 with an O2 flag; 2. on 3/03/2020, the laboratory obtained a value of 14.6 with an O2 flag; 3. on 3/05/2020, the laboratory obtained a value of 14.3 with an O2 flag; 4. on 3/06/2020, the laboratory obtained a value of 14.6 with an O2 flag; 5. on 3/09/2020, the laboratory obtained a value of 14.6 with an O2 flag; 6. on 3/10/2020, the laboratory obtained a value of 14.5 with an O2 flag; 7. on 3/11/2020, the laboratory obtained a value of 14.8 with an O2 flag; 8. on 3/13/2020, the laboratory obtained a value of 14.7 with an O2 flag; 9. on 3/30/2020, the laboratory obtained a value of 14.3 with an O2 flag. a. On 3/02/2020, 63 patient test results were reported as identified by accession number: 24594, 24595, 24596, 24597, 24598, 24599, 24600, 24602, 24603, 24604, 24605, 24606, 24608, 24609, 24610, 24611, 24612, 24613, 24615, 24616, 24617, 24618, 24619, 24670, 24671, 24672, 24673, 24674, 24675, 24676, 24677, 24679, 24680, 24681, 24683, 24684, 24685, 24686, 24687, 24688, 24690, 24691, 24692, 24693, 24694, 24695, 24696, 24697, 24698, 24699, 24700, 24701, 24702, 24703, 24704, 24705, 24706, 24707, 24708, 24709, 24710, 24712, 24713. b. On 3/03/2020, 39 patient test results were reported as identified by accession number: 24718, 24719, 24720, 24721, 24722, 24723, 24724, 24725, 24726, 24728, 24729, 24730, 24731, 24733, 24734, 24735, 24736, 24737, 24738, 24739, 24740, 24741, 24742, 24743, 24744, 24745, 24746, 24747, 24748, 24749, 24750, 24751, 24752, 24753, 24754, 24755, 24756, 24858, 24759. c. On 3/05/2020, 35 patient test results were reported as identified by accession number: 24727, 24783, 24808, 24809, 24810, 24811, 24812, 24813, 24814, 24815, 24816, 24817, 24818, 24819, 24820, 24821, 24822, 24823, 24824, 24825, 24826, 24827, 24828, 24829, 24830, 24831, 24832, 24833, 24834, 24835, 24836, 24837, 24838, 24840, 24841. d. On 3/06/2020, 78 patient test results were reported as identified by accession number: 24843, 24844, 24845, 24846, 24847, 24848, 24849, 24850, 24851, 24852, 24855, 24856, 24858, 24859, 24860, 24861, 24862, 24863, 24865, 24866, 24867, 24868, 24869, 24870, 24871, 24872, 24873, 24874, 24877, 24878, 24879, 24880, 24881, 24882, 24883, 24884, 24885, 24886, 24887, 24888, 24889, 24890, 24891, 24892,

24893, 24894, 24895, 24896, 24897, 24898, 24899, 24900, 24901, 24902, 24903, 24904, 24905, 24906, 24907, 24908, 24909, 24910, 24911, 24912, 24913, 24914, 24915, 24916, 24917, 24918, 24919, 24920, 24921, 24922, 24923, 24924, 24925, 24926. e. On 3/09/2020, 28 patient test results were reported as identified by accession number: 24961, 24963, 24964, 24965, 24966, 24968, 24969, 24970, 24971, 24972, 24973, 24974, 24975, 24976, 24977, 24979, 24980, 24981, 24982, 24983, 24984, 24985, 24986, 24987, 24988, 24989, 24990, 24991. f. On 3/10/2020, 42 patient test results were reported as identified by accession number: 24992, 24993, 24994, 24995, 24996, 24997, 24998, 24999, 25023, 25024, 25025, 25026, 25027, 25028, 25029, 25030, 24962, 25031, 25032, 25033, 25035, 25036, 25037, 25038, 25039, 25040, 25041, 25042, 25043, 25044, 25045, 25046, 25048, 25049, 25050, 25051, 25052, 25053, 25054, 25055, 25056, 25057. g. On 3/11/2020, 42 patient test results were reported as identified by accession number: 25058, 25059, 25060, 25061, 25062, 25063, 25064, 25066, 25067, 25068, 25069, 25070, 25071, 25072, 25073, 25074, 25075, 25076, 25077, 25078, 25079, 25080, 25081, 25082, 25083, 25084, 25085, 25086, 25087, 25088, 25089, 25090, 25092, 25093, 25094, 25095, 25096, 25098, 25099, 25100, 25101, 25102. h. On 3/13/2020, 63 patient test results were reported as identified by accession number: 25121, 25124, 25127, 25128, 25129, 25130, 25131, 25132, 25133, 25134, 25135, 25136, 25137, 25138, 25139, 25140, 25141, 25142, 25143, 25144, 25145, 25146, 25147, 25149, 25150, 25151, 25183, 25184, 25190, 25191, 25192, 25193, 25194, 25195, 25196, 25197, 25198, 25199, 25200, 25201, 25202, 25203, 25204, 25205, 25206, 25207, 25208, 25209, 25210, 25211, 25212, 25213, 25214, 25216, 25217, 25218, 25219, 25221, 25222, 25223, 25224, 25225, 25226. Patient data was not obtained for 3/19/2020 and 3/30/2020. B. Review of QC records for Iron showed patients were reported when only one level of QC was within acceptable range on 5 out of 11 days of patient testing. The Liquid Assayed Multiqual Level 1, Lot 45801, acceptable range was 69.7 - 95.9. 1. On 3/02/2020, the laboratory obtained a value of 65.0 with an O2 flag; 2. on 3/09/2020, the laboratory obtained a value of 69.0 with an O2 flag; 3. on 3/13/2020, the laboratory obtained a value of 68.1 with an O2 flag; 4. on 3/19/2020, the laboratory obtained a value of 69.1 with an O2 flag; 5. on 3/30/2020, the laboratory obtained a value of 99.0 with an O2 flag. The Liquid Assayed Multiqual Level 3, Lot 45803, acceptable range was 220 - 282. 6. On 3/30/2020, the laboratory obtained a value of 290.0 with an O2 flag. (Both levels of QC were out of range on 3/30/2020). C. Review of QC records for TIBC (Total Iron Binding Capacity) showed patients were reported when only one level of QC was within acceptable range on 5 out of 11 days of patient testing. The Liquid Assayed Multiqual Level 1, Lot 45801, acceptable range was 101 - 143. 1. On 3/05/2020, the laboratory obtained a value of 149.0 with an O2 flag; 2. on 3/09/2020, the laboratory obtained a value of 153.0 with an O2 flag; 3. on 3/10/2020, the laboratory obtained a value of 150.0 with an O2 flag; 4. on 3/11/2020, the laboratory obtained a value of 146.0 an O2 flag; 5. on 3/13/2020, the laboratory obtained a value of 146.0 with an O2 flag. D. Review of QC records for Magnesium showed patients were reported when only one level of QC was within acceptable range on 5 out of 11 days of patient testing. The Liquid Assayed Multiqual Level 3, Lot 45803, acceptable range was 3.51 - 4.51. 1. On 3/02/2020, the laboratory obtained a value of 4.7 with an O2 flag; 2. on 3/09/2020, the laboratory obtained a value of 4.6 with an O2 flag; 3. on 3/13/2020, the laboratory obtained a value of 4.6 with an O2 flag; 4. on 3/19/2020, the laboratory obtained a value of 4.6 with an O2 flag; 5. on 3/23/2020, the laboratory obtained a value of 4.7 with an O2 flag. E. Review of QC records for Creatinine showed patients were reported when only one level of QC was within acceptable range on 6 out of 14 days of patient testing. The Liquid Assayed Multiqual Level 3, Lot 45803, acceptable range was 5.61 - 6.79. 1. On 3/03/2020, the laboratory obtained a value of 7.0 with an O2 flag; 2. on 3/05/2020, the laboratory obtained a value of 7.0

with an O2 flag; 3. on 3/06/2020, the laboratory obtained a value of 7.0 with an O2 flag; 4. on 3/09/2020, the laboratory obtained a value of 7.0 with an O2 flag; 5. on 3/23/2020, the laboratory obtained a value of 6.9 with an O2 flag; 6. on 3/26/2020, the laboratory obtained a value of 6.8 with an O2 flag. F. Review of QC records for ALP showed patients were reported when only one level of QC was within acceptable range on 4 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 1, Lot 45801, acceptable range was 21.1 - 44.9. 1. On 3/09/2020, the laboratory obtained a value of 20.0 with an O2 flag; 2. on 3/10/2020, the laboratory obtained a value of 19.0 with an O2 flag; 3. on 3/19/2020, the laboratory obtained a value of 21.0 with an O2 flag; 4. on 3/23/2020, the laboratory obtained a value of 21.0 with an O2 flag. G. Review of QC records for Albumin showed patients were reported when only one level of QC was within acceptable range on 3 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 1, Lot 45801, acceptable range was 2.01 - 2.51. 1. On 3/02/2020, the laboratory obtained a value of 2.60 with an O2 flag; 2. on 3/11/2020, the laboratory obtained a value of 2.60 with an O2 flag; 3. on 3/30/2020, the laboratory obtained a value of 2.60 with an O2 flag. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 3.92 - 4.68. 4. On 3/02/2020, the laboratory obtained a value of 4.80 with an O2 flag; 5. on 3/11/2020, the laboratory obtained a value of 4.70 with an O2 flag. (Both levels of QC were out of range on 3/02/2020 and 3/11/2020). H. Review of QC records for Total Protein showed patients were reported when only one level of QC was within acceptable range on 2 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 1, Lot 45801, acceptable range was 3.35 - 4.19. 1. On 3/02/2020, the laboratory obtained a value of 4.2 with an O2 flag; 2. on 3/30/2020, the laboratory obtained a value of 4.3 with an O2 flag. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 6.2 - 7.56. 3. On 3/02/2020, the laboratory obtained a value of 7.8 with an O2 flag. (Both levels of QC were out of range on 3/02/2020). I. Review of QC records for Phosphorus showed patients were reported when only one level of QC was within acceptable range on 4 out of 10 days of patient testing. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 6.13 - 7.73. 1. On 3/09/2020, the laboratory obtained a value of 8.00 with an O2 flag; on 3/10/2020, the laboratory obtained a value of 8.10 with an O2 flag; on 3/13/2020, the laboratory obtained a value of 7.80 with an O2 flag. The Liquid Assayed Multiquial Level 1, Lot 45801, acceptable range was 1.62 - 2.18. On 3/25/2020, the laboratory obtained a value of 2.20 with an O2 flag. J. Review of QC records for Carbon Dioxide showed patients were reported when QC was unacceptable on 1 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 1, Lot 45801 acceptable range was 11.6 - 19.4. 1. On 3/02/2020, the laboratory obtained a value of 11.00 with an O2 flag. The Liquid Assayed Multiquial Level 3, Lot 45803 acceptable range was 20.6 - 32.2. 2. On 3/02/2020, the laboratory obtained a value of 19.00 with an O2 flag. (Both levels of QC were out of range on 3/02/2020). a. On 3/02/2020, 63 patient test results were reported as identified by accession number: 24594, 24595, 24596, 24597, 24598, 24599, 24600, 24602, 24603, 24604, 24605, 24606, 24608, 24609, 24610, 24611, 24612, 24613, 24615, 24616, 24617, 24618, 24619, 24670, 24671, 24672, 24673, 24674, 24675, 24676, 24677, 24679, 24680, 24681, 24683, 24684, 24685, 24686, 24687, 24688, 24690, 24691, 24692, 24693, 24694, 24695, 24696, 24697, 24698, 24699, 24700, 24701, 24702, 24703, 24704, 24705, 24706, 24707, 24708, 24709, 24710, 24712, 24713. K. Review of QC records for BUN showed patients were reported when only one level of QC was within acceptable range on 2 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 59.1 - 76.3. 1. On 3/02/2020, the laboratory obtained a value of 78.0 with an O2 flag; 2. on 3/03/2020, the laboratory obtained a value of 77.0 with an O2 flag. L. Review of QC records for Glucose showed patients were reported when only one level of QC was within acceptable range on 1 out of 14 days

of patient testing. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 326 - 392. 1. On 3/13/2020, the laboratory obtained a value of 123.0 with an O2 flag. M. Review of QC records for Sodium showed patients were reported when only one level of QC was within acceptable range on 1 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 152 - 164. 1. On 3/02/2020, the laboratory obtained a value of 166 with an O2 flag. N. Review of QC records for Potassium showed patients were reported when only one level of QC was within acceptable range on 1 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 6.89 - 7.67. 1. On 3/02/2020, the laboratory obtained a value of 7.80 with an O2 flag. O. Review of QC records for Chloride showed patients were reported when only one level of QC was within acceptable range on 1 out of 14 days of patient testing. The Liquid Assayed Multiquial Level 3, Lot 45803, acceptable range was 114 - 122. 1. On 3/26/2020, the laboratory obtained a value of 113.0 with an O2 flag. P. Review of QC records for % (percent) Hemoglobin A1C from March 2020 using Liquicheck Diabetes control for Level 1 (Lot 38591) and Level 3 (Lot 38593) showed 1 out of 10 QC runs were out of range. The laboratory's QC ranges matched the unassayed package inserts. Review of the LIS QC reports showed for Level 1 the mean was 5.15, and 2SD was 1.30 (acceptable range of 3.85 - 6.45), and for Level 3 the mean was 13.6 and 2SD was 2.20 (acceptable range of 11.4 - 15.8). 1. On 3/2/2020 the laboratory obtained a QC result for Level 3 of 10.75 with the O2 flag. Q. Review of QC records for % Hemoglobin A1C from October 2020 using Liquicheck Diabetes control for Level 1 (Lot 55731) and Level 3 (Lot 55733) showed 1 out of 19 QC runs were out of range. Review of the LIS QC reports showed for Level 1 the mean was 5.19, and 2SD was 0.26 (acceptable range of 4.93-5.45). 1. On 10/6/2020 the laboratory obtained a QC result for Level 1 of 4.88 with the O2 flag and a comment that stated "2sd allowable". III. Interview with testing personnel (TP) #1 on the CMS form 209 on November 12, 2020 at 1140 in the laboratory acknowledged O2 flag means the QC result is at 2SD, if outside that, the flag is O3. And, the laboratory does not perform corrective action unless the result is flagged O3. Additional interview with TP #1 on November 12, 2020 at 1655 in the laboratory acknowledged LabDaq flagged yellow for QC results from 2SD to 3SD (O2), and red if outside 3SD (O3).

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure, quality control (QC) testing records and interview, the laboratory failed to document all corrective action taken when QC failed. Findings follow. 1. Review of the laboratory's policy and procedure titled Preanalytical Testing (Maintenance, Calibration, and Quality Control) (rev 10/04/2019) under the Quality Control Results, Interpretation, and Corrective Action

section stated, "All remedial and corrective actions taken to resolve the problem must be documented in the Corrective Action Log." 2. Random review of QC records on the Siemens Advia 560 Hematology analyzer from Feb 2020 and Oct 2020 showed one level of QC per day of testing. 3. Interview with testing personnel #1 on the CMS form 209 on November 12, 2020 at 0900 hours in the laboratory acknowledged the Advia only prints the last QC run for the day, per level, and there's no good way to document corrective action taken. Corrective action is currently documented at the end of the month on the monthly QC report, and she remembers what corrective action to document at the end of the month because she is the only one operating the instrument.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratories policies and procedures, quality control records, patient test records, verification records, and confirmed in interview, the quality assessment system used by the laboratory failed to identify and correct problems in the analytic systems. (Refer to D5411, D5421, D5469, D5481, and D5781)

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 observations, review of Bio-Rad quality control manufacturer instructions, review of temperature records, verification of performance specifications, laboratory policies and procedures, patient testing records, manufacturer's instructions for use and assay sheet, quality control (QC) records, proficiency testing (PT) records, and interview found that the laboratory director failed to provide technical and scientific oversight of the laboratory. (See D6007, D6013 D6018, D6022, D6024 and D6028.)

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 review of the manufacturer's instructions for use, review of temperature records, laboratory policies and procedures, patient testing records, verification of performance specifications, observation and interview of facility personnel, the laboratory director failed to monitor and evaluate the overall quality of the preanalytic and analytic systems; and correct problems in testing performed in Chemistry and Hematology. Findings follow. 1. The laboratory failed to follow the manufacturer's instructions for the storage and handling of blood specimens used for testing Bicarbonate and Complete Blood Counts (CBC). (refer to D5311) 2. The laboratory failed to store Bio-Rad Quality control materials in a non-frost-free freezer as directed by the manufacturer (refer to D5411). 3. The quality assessment system used by the laboratory failed to identify and correct problems in analytic systems. (refer to D 5791)

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 manufacturer's instructions for use, laboratory policies and procedures, patient testing records, verification of performance specifications, and observation, the laboratory director failed to establish alternative storage and stability criteria for Bicarbonate (CO₂) specimens stored at refrigerated temperatures greater than 24 hours when tested on the Beckman Coulter AU480 chemistry analyzer. (refer to 5421)

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure, proficiency testing (PT) records and interview, the laboratory director failed to 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

when they failed to verify the accuracy of each analyte and specialty assigned a proficiency testing score that does not reflect laboratory test performance for Hematology and Chemistry test systems in 2 out of 6 events reviewed (refer to D5215).

D6022

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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on the laboratory's policy and procedure, manufacturer's instructions for use and assay sheet, quality control (QC) records, patient testing records, and interview, the laboratory director failed to ensure the quality control and quality assessment programs were established and maintained to identify failures in quality as they occurred. Findings follow. 1. The laboratory failed to define the acceptable limits of QC as required by the manufacturer, and of their own policy on the Beckman Coulter AU480 chemistry analyzer (refer to D5469). 2. The laboratory failed to ensure QC results met the laboratory's criteria for acceptability before reporting patient test results in March 2020 for testing performed on the Beckman Coulter AU480 chemistry analyzer (refer to D5481).

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure, quality control (QC) testing records and interview, the laboratory director failed to ensure corrective action was taken when QC failures occurred (refer to D5781).

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the

appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on direct observation, Review of the CMS 116 and confirmed in interview, the Laboratory Director failed to employ a sufficient number of laboratory personnel to accurately receive specimens and perform tests and report test results. Findings included: 1. On November 12, 2020 at 0900 hours surveyor observed testing personnel #1 manually scanning patient test results into the EMR. Testing person one had removed specimens from transport bags and had sorted requisitions into a box to be accessioned. 62 patient requisitions were found in the box to be accessioned. Manual entry of each of the patient requisitions was required before she could begin testing the specimens. 2. Review of the CMS 116 form (obtained during the inspection) signed by the laboratory director on 11/10/2020 found the laboratory reported annual test volumes as follows: Hematology 5500 tests Chemistry 126,405 tests Toxicology 14400 tests Urinalysis 2400 tests 3. Review of the CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 11/5/2020 (received during the inspection) the laboratory listed one testing person. 4. The laboratory failed to meet the preanalytic condition (See D5300) 5. The laboratory failed to meet the analytic condition (See D 5400) 6. Interview of testing person one on the CMS form 209 on November 11, 2020 at 1350 hours confirmed that it was her responsibility to pick up specimens from the three clinics each morning and bring them to the laboratory for testing. 7. Interview of testing person one on the CMS form 209 on November 12, 2020 at 0915 hours in the laboratory acknowledged she manually scans test reports into the EMR because the interface between the LIS and EMR was not working and has not worked for months. After she scans her reports, she began accessioning specimens picked up that morning during her route to work. She confirmed that specimens picked up each morning were collected the previous day, and stored in the refrigerator until she picked them up for testing. She would transport the specimens to the laboratory for testing and upon arrival, she would remove the specimens and requisitions from the bags for accessioning . She would spend her morning accessioning the specimens, and would typically test them in the afternoon. She went on to say she was the only one working in the laboratory and did not have any assistance in transporting the specimens to the laboratory for testing, or when manual accessioning was required. (refer to D3007)

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
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 observations, review of Bio-Rad quality control manufacturer instructions, review of temperature records, verification of performance specifications, laboratory policies and procedures, patient testing records, manufacturer's instructions for use and assay sheet, quality control (QC) records, proficiency testing (PT) records, validation studies, review of the laboratory's personnel records, and confirmed in interview with laboratory staff, the technical consultants failed to provide technical

and scientific oversight. 1. The technical consultant failed to provide technical and scientific oversight of the laboratory (refer to D6036). 2. The technical consultant failed to ensure the laboratory participated in the proficiency testing program for Hematology and Chemistry test systems in 2 out of 6 events reviewed (refer to D6041). 3. The technical consultant failed to ensure that a quality control program had been established and maintained to ensure the accuracy and reliability of results obtained when using the Beckman AU Chemistry analyzer for patient testing . (See D6042) 4. The technical consultant performing competency assessments on one of one testing personnel after the installation of the Siemens ADVIA 560 hematology analyzer and the Beckman Coulter AU480 chemistry analyzer (refer to D6055).

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on observations, review of Bio-Rad quality control manufacturer instructions, review of temperature records, verification of performance specifications, laboratory policies and procedures, patient testing records, manufacturer's instructions for use and assay sheet, quality control (QC) records, and interview the technical consultant failed to provide technical and scientific oversight of the laboratory. Findings follow. 1. The laboratory failed to store Bio-Rad Quality control materials in a non-frost-free freezer as directed by the manufacturer (refer to D5411). 2. The laboratory failed to verify the patient reference ranges for testing performed on the Beckman Coulter AU480 chemistry analyzer (refer to 5421). 3. The laboratory failed to ensure QC results met the laboratory's criteria for acceptability before reporting patient test results in March 2020 for testing performed on the Beckman Coulter AU480 chemistry analyzer (refer to D5481). 4. The laboratory failed to document all corrective action taken when QC failed (refer to D5781). 5. The quality assessment system used by the laboratory failed to identify and correct problems in the analytic systems (refer to D5791).

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure, proficiency testing (PT) records and interview, the technical consultant failed to ensure the laboratory tested specimens and submitted results to the PT agency for Hematology and Chemistry test systems in 2 out of 6 events reviewed (refer to D5215).

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:

Based on review of the laboratory's policy and procedure, manufacturer's instructions for use and assay sheet, quality control (QC) records, and interview, the technical consultant failed to ensure a quality control program was established to define the acceptable limits of QC as required by the manufacturer, and of their own policy on the Beckman Coulter AU480 chemistry analyzer (refer to D5469).

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the validation studies, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on one of one testing personnel after the installation of the Siemens ADVIA 560 hematology analyzer and the Beckman Coulter AU480 chemistry analyzer. The findings included: 1. Review of the laboratory's Validation studies found the laboratory installed the Advia 560 hematology analyzer in June 2019 and the Beckman Coulter AU chemistry analyzer in March 2019. 2. A review of the laboratory's personnel records found documented training for the Beckman AU 480 completed 03/2019 and on June 5, 2019 for the Siemens Advia 560. Competency assessment for testing person one conducted in 2019 was dated completed on 12/17/2019. Additional competency assessments were requested but not provided. 3. Interview of testing Person one on the CMS report 209 Laboratory Personnel Report conducted November 11, 2020 at 9:37 AM in the laboratory confirmed there were no additional competency assessments available for review.