

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472824	(X3) Date Survey Completed 05/05/2021
Name of Provider or Supplier Memorial Hospital Of Texas County Authority	Street Address, City, State 520 Medical Drive, Guymon, OK	
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 recertification survey was performed on 05/03,04,05/2021. Immediate Jeopardy was determined during the survey due to issues identified with Coagulation testing. The laboratory voluntarily ceased patient testing, which abated the Immediate Jeopardy. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1403; D6000: Laboratory Director, Moderate Complexity 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director, technical consultant #1, technical consultant #2, and the laboratory manager during an exit conference performed at the conclusion of the survey.
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory failed to ensure the requirements were met for the specialty of Hematology for Coagulation and D-dimer testing. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (2) The laboratory failed to ensure D-dimer control materials were stored as required for 11 of 11 months. Refer to D5413; (3) The laboratory failed to verify the performance specification of precision, failed to ensure the demonstrated reportable range was utilized, and failed to ensure the verification data had been evaluated prior to implementing the new test for D-Dimer testing. Refer to D5421; (4) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on the coagulation analyzer. Refer to D5429</p>

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On 05/03/2021, the surveyor reviewed personnel records for competency assessments performed during 2019, 2020, and to date in 2021. There was no evidence competencies had been performed for technical consultant #1 and technical consultant #2 based on their job responsibilities; (2) The surveyor asked the laboratory manager if a written policy to evaluate the technical consultants, based on job responsibilities, was available and if competencies had been performed during the review period. The laboratory manager stated to the surveyor on 05/03/2021 at 12:30 pm, a policy to evaluate the technical consultants based on job responsibilities had not been written; and competencies had not been performed.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to evaluate the accuracy of Ammonia and Vitamin D testing at least twice annually. Findings include: (1) On 05/03/2021 at 09:30 am, the laboratory manager stated the following to the surveyor: (a) Ammonia testing was performed on the Beckman Coulter Unicel DxC 600, denoted by the laboratory at Bonnie; (b) Vitamin D testing was performed on the Beckman Coulter Access 2 analyzer. (2) The surveyor reviewed 2020 and 2021 proficiency testing records. Since the laboratory had not enrolled and participated in proficiency testing for Ammonia and Vitamin D testing, the surveyor determined the laboratory must verify the accuracy of the testing at least twice annually; (3) The surveyor asked the laboratory manager if the accuracy of Ammonia and Vitamin D testing had been verified in 2020 and to date in 2021. The laboratory manager stated on 05/03/2021 at 01:50 pm, the accuracy had not been verified; (4) The following were examples of patient Ammonia or Vitamin D testing performed when the accuracy of the testing had not been verified: (a) Patient #746703 - Vitamin D testing performed on 02/19/2020 (b) Patient #746703 - Vitamin D testing performed on 02/20/2020 (c) Patient #746487 - Ammonia testing performed on 02/23/2020 (d) Patient #750551 - Vitamin D testing performed on 07/14/2020 (e) Patient #750579 - Vitamin D testing performed on 07/15/2020 (f) Patient #753559 - Ammonia testing performed on 10/24/2020 (g) Patient #755078 - Vitamin D testing performed on 12/15/2020 (h) Patient #755372 - Vitamin D testing performed on 12/22/2020 (i) Patient #756855 - Vitamin D testing performed on 02/05/2021 (j) Patient #756951 - Ammonia testing performed on 02/08/2021 (k) Patient #757128 - Vitamin D testing performed on 02/10/2021 (l) Patient #757003 - Ammonia testing performed

on 02/15/2021 (m) Patient #758112 - Vitamin D testing performed on 03/16/2021 (n) Patient #758269 - Vitamin D testing performed on 03/22/2021 (o) Patient #758791 - Ammonia testing performed on 04/07/2021 (p) Patient #759362 - Vitamin D testing performed on 04/23/2021 (q) Patient #759585 - Vitamin D testing performed on 04/30/2021

D5317

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

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the laboratory failed to provide written instructions to clients collecting and referring hematology, coagulation, and urinalysis specimens. Findings include: (1) On 05/03/2021 at 09:30 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter Unicel DxH 600 analyzer as the primary method and the Beckman Coulter DxH 520 analyzer as the back-up method; (i) Hematology specimens were transported to the laboratory from local home health agencies, nursing homes, and clinics. (b) The laboratory performed routine urinalysis testing using the Clinitek Status + (waived test method) and microscopic urine sediment examinations; (i) Urine specimens were transported to the laboratory from local home health agencies, nursing homes, and clinics. (c) The laboratory performed coagulation testing, which consisted of PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) using the Sysmex CA-600 analyzer; (i) Coagulation specimens were transported to the laboratory from local home health agencies, nursing homes, and clinics. (2) The surveyor asked the laboratory manager if instructions (e.g., client service manual) had been written and provided to the home health agencies, nursing homes, and clinics which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager stated on 05/03/2021 at 09:45 am, specimen handling instructions had not been written and provided to the clients.

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 a review of records, manufacturer's instructions, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On 05/03/2021 at 09:30 am, the laboratory manager stated the following to the surveyor: (a) The Sysmex CA-600 analyzer was

used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean and the ISI (International Sensitivity Index) value specific for the lot number of Innovin reagent); (b) The following reagent lot numbers were put into use on 03/01/2021: (i) PT - Innovin reagent, lot #549758 (ii) PTT - Actin reagent, lot #562626 (iii) Siemens Ci-Trol control level 1 lot #564809 (iv) Siemens Ci-Trol control level 3 lot #556527A (2) On 05/04/2021, the surveyor reviewed the manufacturer's instructions contained in the "Siemens Sysmex CA-600 Installation Guide" for implementing new reagents, which stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (a) Section titled "Verification of Reference Range" (i) "20 Normal Individuals * 10 males; 10 females * Medication History: no aspirin, no hormones, no herbal supplements * 20 is the minimum requirement for statistical validity"; (ii) "Assay samples on current and new lot number reagents simultaneously or within 10 minutes of each other. This data can be used in Section II"; (iii) "Calculate mean and 2 SD range"; (iv) "MNPT for INR calculation should be the geometric mean". (b) Section titled, "Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number reagents simultaneously or within 1 hour of each other"; (v) "Calculate Linear Regression statistics". (c) Section titled, "Quality Control" (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTTN protocols"; (ii) Collect a minimum of 30 data points over multiple days and stability limits of control"; (iii) Calculate the mean, 2 SD and 3 SD range". (3) The surveyor reviewed the ISI (International Sensitivity Index) and the Normal Patient Mean that had been programmed into the analyzer, with the assistance of the laboratory manager, and reviewed the records for the lot changes. The following was identified: (a) PT - Innovin reagent, lot #549758 (i) There was no documentation to prove the normal range study had been performed, although a normal patient mean value of 10.9 had been programmed into the analyzer's memory; (ii) The package insert for the Innovin reagent showed an ISI of 1.01 and an ISI of 1.07 had been programmed into the analyzer's memory; (iii) There was no documentation to prove the method correlation had been performed using 20 normal and 20 abnormal samples with the current and new lot number of reagents simultaneously. (b) PTT - Actin reagent, lot #562626 (i) There was no documentation to prove the normal range study had been performed; (ii) There was no documentation to prove the method correlation had been performed using 20 normal and 20 abnormal samples with the current and new lot number of reagents simultaneously. (c) Siemens Ci-Trol control level 1 lot #564809 (i) The records showed the laboratory had assayed the new lot of quality control material using 20 data points instead of 30 data points as required. (d) Siemens Ci-Trol control level 3 lot #556527A (i) The records showed the laboratory had assayed the new lot of quality control material using 20 data points instead of 30 data points as required. (4) The surveyor reviewed the records and the findings with the laboratory manager, technical consultant #1, and technical consultant #2. The laboratory manager, technical consultant #1, and technical consultant #2 stated the following to the surveyor on 05/04/2021 at 03:30 pm: (a) The laboratory did not perform a normal range study for PT and PTT; (b) For the values programmed into the analyzer to calculate the INR, it could not be determined where the normal patient PT mean of 10.9 and the ISI of 1.07 came from; (c) The laboratory did not perform method correlation for PT and PTT using 20 normal and 20 abnormal samples with

the current and new lot number of reagents simultaneously; (d) The laboratory had utilized 20 data points to assay the new lots of quality control materials for level 1 and level 3, instead of 30 data points; (e) The laboratory had not followed the manufacturer's instructions for implementing the coagulation reagents. (5) The following were examples of patient testing performed: (a) Patient #747545 - PT testing performed on 03/02/2021 (b) Patient #753828 - PT testing performed on 03/05/2021 (c) Patient #757834 - PT and PTT testing performed on 03/08/2021 (d) Patient #757878 - PT testing performed on 03/09/2021 (e) Patient #758043 - PT and PTT testing performed on 03/13/2021 (f) Patient #758104 - PT and PTT testing performed on 03/15/2021 (g) Patient #758376 - PT and PTT testing performed on 03/22/2021 (h) Patient #758524 - PT and PTT testing performed on 03/26/2021 (i) Patient #758602 - PT and PTT testing performed on 03/30/2021 (j) Patient #758693 - PT testing performed on 04/01/2021 (k) Patient #758886 - PT and PTT testing performed on 04/07/2021 (l) Patient #759136 - PT and PTT testing performed on 04/15/2021 (m) Patient #759179 - PT and PTT testing performed on 04/19/2021 (n) Patient #759327 - PT and PTT testing performed on 04/22/2021 (o) Patient #759408 - PT and PTT testing performed on 04/25/2021 (p) Patient #759327 - PT and PTT testing performed on 04/27/2021 (q) Patient #759552 - PT and PTT testing performed on 04/29/2021 (r) Patient #759621 - PT and PTT testing performed on 05/01/2021 (s) Patient #759629 - PT and PTT testing performed on 05/02/2021 (t) Patient #759649 - PT and PTT testing performed on 05/03/2021 (u) Patient #759700 - PT and PTT testing performed on 05/04/2021

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory failed to ensure materials were stored as required for 11 of 11 months. Findings include: (1) On 05/04/2021 at 03:45 pm, the surveyor observed the contents of the following freezers, which were frost-free freezers. The following control materials were being stored in the freezers, with the manufacturer's storage requirements: (a) Whirlpool Freezer - Denoted by the laboratory as "Coag Ref/Freezer" (i) Bio-Rad Liquid Assayed Multiqual controls - 6 boxes containing 12 bottles each of level 1 lot #45871 and 6 boxes containing 12 bottles each of level 3 lot #45873; the storage requirement was -20 to -70 degrees C (Centigrade). In addition, the instructions contained in the package insert stated, "For optimum performance, avoid storing this product in a frost-free freezer". (b) Frigidaire Freezer - Denoted by the laboratory as "White Freezer" (i) Bio-Rad Liquichek Cardiac Markers Plus Control LT controls - 3 boxes containing 6 bottles each of level 1 lot #67651 and 3 boxes containing 6 bottles each of level 3 lot #67653; the storage requirement was -20 to -70 degrees C. In addition, the instructions contained in the package insert stated, "Do not store this product in a frost-free freezer". (c) Crosley Freezer - Denoted by the laboratory as "Freezer #2" (i) Bio-Rad Liquid Assayed

Multiquel controls - 6 boxes containing 12 bottles each of level 1 lot #45871 and 6 boxes containing 12 bottles each of level 3 lot #45873; the storage requirement was -20 to -70 degrees C (Centigrade). In addition, the instructions contained in the package insert stated, "For optimum performance, avoid storing this product in a frost-free freezer"; (ii) Bio-Rad Liquichek Cardiac Markers Plus Control LT controls - 3 boxes containing 6 bottles each of level 1 lot #67651 and 3 boxes containing 6 bottles each of level 3 lot #67653; the storage requirement was -20 to -70 degrees C. In addition, the instructions contained in the package insert stated, "Do not store this product in a frost-free freezer"; (iii) Quidel Triage Total 5 Controls - 3 boxes containing 6 bottles each of level 2 lot #67642; the storage requirement was -20 degrees C and colder. (2) The laboratory manager explained the following to the surveyor on 05/04/2021 at 04:00 pm: (a) The Bio-Rad Liquid Assayed Multiquel controls were used to perform quality control (QC) procedures for Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase, AST (Aspartate Aminotransferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, Cholesterol, CK (Creatine Kinase), CO2 (Carbon Dioxide), Creatinine, Direct Bilirubin, Lipase, Magnesium, Phosphorus, and Uric Acid testing performed on the Beckman Coulter Unicel DxC analyzer, denoted by the laboratory as "Bonnie"; and to perform QC procedures for Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, Cholesterol, CK, CO2, and Creatinine testing performed on the Beckman Coulter Unicel DxC analyzer, denoted by the laboratory as "Clyde"; (b) The Bio-Rad Liquichek Cardiac Markers Plus Control LT controls were used to perform QC procedures for CKMB and Troponin I testing performed on the Beckman Coulter Access 2 analyzer; (c) The Quidel Triage Total 5 Controls were used to perform QC procedures for D-dimer testing performed on the Quidel Triage Meter Pro analyzer. (3) The surveyor reviewed temperature records for 11 months (June 2020 through April 2021). In addition to the freezers being frost-free, the documented temperatures were warmer than -20 C (the warmest temperature allowed for the materials) during 11 of 11 months for the freezers as follows: (a) Coag Ref/Freezer (i) June 2020 - 30 of 30 documented temperatures were warmer than -20 degrees C (ii) July 2020 - 31 of 31 documented temperatures were warmer than -20 degrees C (iii) August 2020 - 30 of 31 documented temperatures were warmer than -20 degrees C (iv) September 2020 30 of 30 documented temperatures were warmer than -20 degrees C (v) October 2020 - 31 of 31 documented temperatures were warmer than -20 degrees C (vi) November 2020 - 30 of 30 documented temperatures were warmer than -20 degrees C (vii) December 2020 - 31 of 31 documented temperatures were warmer than -20 degrees C (viii) January 2021 - 18 of 31 documented temperatures were warmer than -20 degrees C (ix) February 2021 - 20 of 28 documented temperatures were warmer than -20 degrees C (x) March 2021 - 25 of 30 documented temperatures were warmer than -20 degrees C (xi) April 2021 - 30 of 30 documented temperatures were warmer than -20 degrees C (b) White Freezer (i) June 2020 - 9 of 30 documented temperatures were warmer than -20 degrees C (ii) July 2020 - 9 of 31 documented temperatures were warmer than -20 degrees C (iii) August 2020 - 8 of 31 documented temperatures were warmer than -20 degrees C (iv) September 2020 - 7 of 30 documented temperatures were warmer than -20 degrees C (v) October 2020 - 10 of 31 documented temperatures were warmer than -20 degrees C (vi) November 2020 - 11 of 30 documented temperatures were warmer than -20 degrees C (vii) December 2020 - 12 of 31 documented temperatures were warmer than -20 degrees C (viii) January 2021 - 3 of 30 documented temperatures were warmer than -20 degrees C (ix) February 2021 - 8 of 28 documented temperatures were warmer than -20 degrees C (x) March 2021 - 9 of 31 documented temperatures were warmer than -20 degrees C (xi) April 2021 - 5 of 30 documented temperatures were warmer than -20 degrees C (c) Freezer #2 (i) June 2020 - 28 of 30 documented temperatures were warmer than

-20 degrees C (ii) July 2020 - 31 of 31 documented temperatures were warmer than -20 degrees C (iii) August 2020 - 31 of 31 documented temperatures were warmer than -20 degrees C (iv) September 2020 - 30 of 30 documented temperatures were warmer than -20 degrees C (v) October 2020 - 31 of 31 documented temperatures were warmer than -20 degrees C (vi) November 2020 - 30 of 30 documented temperatures were warmer than -20 degrees C (vii) December 2020 - 31 of 31 documented temperatures were warmer than -20 degrees C (viii) January 2021 - 30 of 30 documented temperatures were warmer than -20 degrees C (ix) February 2021 - 28 of 28 documented temperatures were warmer than -20 degrees C (x) March 2021 - 31 of 31 documented temperatures were warmer than -20 degrees C (xi) April 2021 - 30 of 30 documented temperatures were warmer than -20 degrees C (3) The surveyor reviewed the records with the laboratory manager, who stated on 05/04/2021 at 04:09 pm, the laboratory was not aware the manufacturer did not allow storage of the materials in a frost-free freezer, and the freezer temperatures were unacceptable as shown above.

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:

Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the demonstrated reportable ranges were utilized for 2 of 3 new test methods; failed to verify the performance specification of precision for 1 of 3 new test methods; and failed to ensure the verification data had been evaluated prior to implementing the new test for 2 of 3 new test systems. Findings include: C-REACTIVE PROTEIN (1) On 05/03/2021 at 09:30 am, the laboratory manager stated to the surveyor the laboratory began performing CRP (C-Reactive Protein) on the Beckman Coulter Unicel DxC 600 analyzer, denoted by the laboratory as Bonnie, on 02/23/2021; (2) On 05/05/2021, the surveyor reviewed the performance specification records for the new test and identified the laboratory had demonstrated a reportable range of 0.8-14.8 mg/dl; (3) The surveyor reviewed the records with the laboratory manager and requested documentation to ensure the laboratory was utilizing the reportable range that had been demonstrated by the laboratory. The laboratory manager provided the reportable range that had been programmed into the analyzer, which was the manufacturer's reportable range of 0.5-20 mg/dl, instead of the reportable range of 0.8-14.8 mg/dl that had been demonstrated by the laboratory; (4) The surveyor reviewed the findings with the laboratory manager, who stated on 05/05/2021 at 02:05 pm, the laboratory was not using the reportable range that had been demonstrated by the laboratory. D-DIMER (1) On 05/03/2021 at 09:30 am, the laboratory manager stated to the surveyor the laboratory began performing D-dimer testing using the Quidel Triage Meter Pro 01/2020 (the exact date could not be determined); (2) The surveyor reviewed the performance specification records for the new test system and identified the following: (a) There was no evidence the precision had been demonstrated; (b) The laboratory had demonstrated a reportable range of

169-3320 ng/ml; (c) There was no evidence the data had been reviewed and evaluated by the laboratory until 09/30/2020. (3) The surveyor reviewed the records with the laboratory manager and asked if the precision had been demonstrated, if the laboratory was using the reportable range that had been demonstrated, and if the laboratory had reviewed and evaluated the data prior to 09/30/2020. The laboratory manager stated the following to the surveyor on 05/03/2020 at 04:05 pm: (a) The precision had not been demonstrated; (b) The laboratory was using the manufacturer's reportable range of 100-5000 ng/ml instead of the reportable range of 169-3320 that had been demonstrated by the laboratory; (c) The data had not been reviewed and evaluated by the laboratory until 09/30/2020. MRSA (1) On 05/03/2021 at 09:30, the laboratory manager stated to the surveyor the laboratory began performing MRSA (Methicillin Resistant Staphylococcus aureus) testing using the Cepheid Gene Xpert analyzer on 10/22/2020; (2) The surveyor reviewed the performance specification records for the new test system and identified that, although the laboratory demonstrated the accuracy and precision of the test system (a qualitative test), there was no evidence the data had been reviewed and evaluated by the laboratory as acceptable until 11/02/2020; (3) The surveyor reviewed the records with the laboratory manager and asked if the laboratory had reviewed and evaluated the data prior to 11/02/2020. The laboratory manager stated to the surveyor on 05/03/2020 at 04:20 pm, the data had not been reviewed and evaluated by the laboratory until 11/02/2020. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 2 of 2 analyzers. Findings include: SYSMEX CA-600 ANALYZER (1) On 05/03/2021 at 09:40 am, the laboratory manager stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing was performed using the System CA-600 analyzer; (2) On 05/04/2021, the surveyor reviewed reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer titled, "Sysmex CA-600 Maintenance Checklist". The weekly and quarterly requirements were as follows: (a) Weekly (i) Clean Instrument Interior/Exterior (b) Quarterly (i) Clean DI H2O Rinse Bottle with Alcohol (ii) Perform LED Calibration (iii) Clean Filters Under Front of Analyzer (3) The surveyor then reviewed maintenance records from December 2019 through April 2021. Weekly and Quarterly maintenance had not been documented as performed as follows: (a) Weekly (i) Between 12/06/2019 and 01/17/2020 (ii) Between 01/31/2020 and 02/14/2020 (iii) Between 04/03/2020 and 05/07/2020 (iv) Between 05/22/2020 and 06/19/2020 (v) Between 06/19/2020 and 07/03/2020 (vi)

Between 12/23/2020 and 01/07/2021 (vii) Between 04/16/2021 and 04/29/2021 (b) Quarterly (i) Clean DI H2O Rinse Bottle with Alcohol not documented as performed after 12/12/2019; (ii) Perform LED Calibration not documented as performed between 03/11/2020 and after 10/27/2020; (iii) Clean Filters Under Front of Analyzer not documented as performed after 12/12/2019. (4) The surveyor reviewed the records with the laboratory manager, who stated on 05/04/2021 at 12:45 pm, the weekly and quarterly maintenance procedures had not been performed as identified above; (5) Refer to D5411 for examples of patient testing performed. BECKMAN COULTER ACCESS 2 ANALYZER (1) On 05/03/2021 at 09:30 am, the laboratory manager stated to the surveyor, the laboratory performed Vitamin B12 testing using the Beckman Coulter Access 2 analyzer; (2) On 05/05/2021, the surveyor reviewed reviewed the manufacturer's maintenance requirements as stated in the "Access 2 Instructions for Use" manual. Section 6 "Maintenance" included requirements for Daily maintenance which stated, "If you use the Access 2 system to process the Vitamin B12 assay, you should also run the Special Clean routine at the end of every day or whenever the instrument will not process samples for 8 hours or more"; (3) The surveyor reviewed patient logs and maintenance logs for testing performed from February 2020, July 2020, and January 2021 through April 2021. The Special Clean routine had not been documented as performed for 16 of 16 days of patient Vitamin B12 testing reviewed: (a) Patient #746443 - testing performed on 02/12/2020 (b) Patient #750551 - testing performed on 07/14/2020 (c) Patient #750605 - testing performed on 07/16/2020 (d) Patient #756039 - testing performed on 01/13/2021 (e) Patient #756157 - testing performed on 01/15/2021 (f) Patient #756255 - testing performed on 01/18/2021 (g) Patient #756473 - testing performed on 01/25/2021 (h) Patient #756885 - testing performed on 02/05/2021 (i) Patient #757128 - testing performed on 02/13/2021 (j) Patient #757996 - testing performed on 03/11/2021 (k) Patient #758023 - testing performed on 03/12/2021 (l) Patient #758264 - testing performed on 03/22/2021 (m) Patient #758335 - testing performed on 03/25/2021 (n) Patient #758916 - testing performed on 04/08/2021 (o) Patient #759093 - testing performed on 04/14/2021 (p) Patient #759367 - testing performed on 04/23/2021 (4) The surveyor reviewed the findings with the laboratory manager, technical consultant #1, and technical consultant #2. All stated on 05/05/2021 at 10:45 am, the Special Clean procedure had not been performed as required.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the laboratory failed to perform a negative and positive control material 1 of 8 days of patient testing. Findings include: (1) On 05/03/2021 at 09:30 am, the laboratory manager stated the following to the surveyor: (a) The laboratory began performing MRSA (Methicillin Resistant Staphylococcus aureus) testing using the Cepheid Gene Xpert analyzer on 10/22/2020; (b) Negative and positive quality control (QC) materials were performed each day of patient testing. (2) The surveyor reviewed QC and patient testing records from 10/22/2020 through 03/26/2021. The review showed

that negative and positive QC materials had not been performed 1 of 8 days of patient testing reviewed. The specific day was 11/02/2020; 4) The surveyor reviewed the records with the laboratory manager, who stated on 05/04/2021 at 03:15 pm, negative and positive QC materials had not been performed each day of patient testing.

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 a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, technical consultant #1 and technical consultant #2, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (b) The laboratory failed to ensure materials were stored as required for 11 of 11 months. Refer to D5413; (c) The laboratory failed to ensure the demonstrated reportable ranges were utilized for 2 of 3 new test methods; failed to verify the performance specification of precision for 1 of 3 new test methods; and failed to ensure the verification data had been evaluated prior to implementing the new test for 2 of 3 new test systems. Refer to D5421; (d) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (e) The laboratory failed to perform a negative and positive control material 1 of 8 days of patient testing. Refer to D5449.

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 a review of records manufacturer's instructions, observation, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.

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 a review of records and interview with the laboratory manager, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the demonstrated reportable ranges were utilized for 2 of 3 new test methods; failed to verify the performance specification of precision for 1 of 3 new test methods; and failed to ensure the verification data had been evaluated prior to implementing the new test for 2 of 3 new test systems. Refer to D5421.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory failed to ensure the laboratory followed the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (2) The laboratory director failed to ensure materials were stored as required for 11 of 11 months. Refer to D5413; (3) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and

	<p>maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to evaluate the accuracy of Ammonia and Vitamin D testing had been verified at least twice annually. Refer to D5217.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, technical consultant #1 and technical consultant #2, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (3) The technical consultant failed to evaluate personnel performing moderate complexity testing at least annually for 1 of 4 persons. Refer to D6054.</p>
<p>D6035</p>	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b)</p>

The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 3 of 4 competency evaluations performed. Findings include: (1) On 05/03/2021, the surveyor reviewed records for 4 persons performing moderate complexity testing in 2020 and to date in 2021 (laboratory manager, who is also listed as testing person #1, testing person #2, testing person #3, and testing person #5). The records showed the evaluation for 3 of 4 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 01/15/2021 and 02/16/2020 evaluations had been performed by the laboratory manager/testing person #1 (this person had earned an Associates Degree in Science); (b) Testing Person #3 - The 01/13,30/2021 evaluations had been performed by the laboratory manager/testing person #1; (c) Testing Person #5 - The 01/17/2020 and 01/17/2021 evaluation had been performed by the laboratory manager/testing person #1. (2) The surveyor reviewed the records with the laboratory laboratory manager on 05/03/2021 at 12:23 pm, and explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory manager

stated to the surveyor on 05/03/2021 at 12:25 pm, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.

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 a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the accuracy of Ammonia and Vitamin D testing had been verified at least twice annually. Refer to D5217; (2) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (3) The technical consultant failed to ensure materials were stored as required for 11 of 11 months. Refer to D5413; (4) The technical consultant failed to ensure the demonstrated reportable ranges were utilized for 2 of 3 new test methods; failed to ensure the performance specification of precision had been verified for 1 of 3 new test methods; and failed to ensure the verification data had been evaluated prior to implementing the new test for 2 of 3 new test systems. Refer to D5421; (5) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions for performing maintenance procedures. Refer to D5429.

D6054

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 at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the technical consultant failed to evaluate personnel performing moderate complexity testing at least annually for 1 of 4 persons. Findings include: (1) On 05/03/2021, the surveyor reviewed personnel records for 4 persons who performed moderate complexity testing during 2019, 2020, and to date in 2021. For 1 of the 4 persons (laboratory manager /testing person #1), there was no evidence annual evaluations had been performed since 10/22/2018; (2) The surveyor reviewed the findings with the laboratory manager who stated on 05/03/2021 at 12:15 pm, the annual evaluations had not been performed as indicated above.