| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 19D0463228 | 07/19/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Desoto Regional Health System | 207 Jefferson Street, Mansfield, LA | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D0000** | A CERTIFICATION SURVEY was performed at DESOTO REGIONAL HEALTH SYSTEM - CLIA # 19D0463228 on July 16, 2018 through July 19, 2018. DESOTO REGIONAL HEALTH SYSTEM was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1240 CONDITION: Preanalytic Systems 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director. 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director. 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing, Technical Consultant. |
| **D5205** | COMPLAINT INVESTIGATIONS<br>CFR(s): 493.1233<br><br>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure for addressing complaints and problems reported to the laboratory. The policy should include a detailed procedure on how to address, document and handle complaints or problems reported to the laboratory. 2. Interview with personnel 4 on July 16, 2018 confirmed the laboratory failed to have a complete policy and procedure manual. |
| **D5207** | COMMUNICATIONS<br>CFR(s): 493.1234 |

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| | The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with personnel 4 on July 16, 2018 confirmed the laboratory failed to have a complete policy and procedure manual. |
| **D5300** | PREANALYTIC SYSTEMS<br>CFR(s): 493.1240<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, record review and interview with personnel, the laboratory system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. The laboratory failed to maintain test requisitions that included the specimen collection date and time as required for four (4) of thirteen (13) patient requisitions reviewed. Refer to D5305. 2. The laboratory failed to ensure patient samples for Potassium (K), Phosphorous (Phos), and Glucose (Glu) are spun and separated within one (1) hour according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for forty two (42) of one hundred seventeen (117) patients reviewed. Refer to D5311 I. 3. The laboratory failed to ensure patient samples for Calcium (CA), are separated from the red cell promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5311 II. 4. The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 5. The laboratory's system failed to monitor, assess, and correct problems identified with the preanalytic system. Refer to D5393. |
| **D5305** | TEST REQUEST<br>CFR(s): 493.1241(c)<br><br>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the |

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| | name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel, the laboratory failed to maintain test requisitions that included the specimen collection date and time as required for four (4) of thirteen (13) patient requisitions reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not establish a written detailed test requisition policy and procedure that addresses the following required information:: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. h) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. 2. Review of a random selection of Patient Test Requisitions from May 3, 2018 through July 13, 2018 revealed the laboratory failed to obtain a written request with the specimen collection date and time as required for the following four (4) patients: NOTE: Complete Metabolic Panel (BMP) includes: Sodium (NA), Potassium (K), Chloride (CL), Carbon Dioxide (CO2), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Total Protein (TP), Albumin (Alb), Calcium (CA), Total Bilirubin (TBil), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), and Aspartate Aminotransferase (AST). Basic Metabolic Panel (BMP) includes: NA, K, CL, CO2, Glu, BUN, and CA. Lipid Panel (Lipid) includes: Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL) and Triglycerides (Trig). Complete Blood Cell count (CBC) which includes: White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt) and an Automated Differential. On July 13, 2018 the laboratory received Patient 39 for a BMP with no specimen collection date/time. On July 9, 2018 the laboratory received Patient 40 for a CMP, Lipid, Prostate Specific Antigen (PSA) and CBC with no specimen collection date/time. On July 9, 2018 the laboratory received Patient 41 for a CMP and Lipid with no specimen collection date/time. On July 2, 2018 the laboratory received Patient 44 for a CMP, Lipid and Thyroid Stimulating Hormone (TSH) with no specimen collection date/time. 2. Interview with Personnel 4 on July 15, 2018 confirmed the laboratory failed to ensure test requisitions contained all the required information for the four (4) patients cited above. |
| **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:
I. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Potassium (K), Phosphorous (Phos), and Glucose (Glu) are spun and separated within one (1) hour according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for forty two (42) of one hundred seventeen (117) patients reviewed. Findings: 1. Observation by surveyor on July 16, 2018 revealed the laboratory maintained a Siemens Dimension EXL for : Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Ammonia (Ammon), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Triglyceride (Trig), Creatine Phosphokinase (CPK), Creatine Kinase MB (CKMB), Hemoglobin A1C) (HgbA1C), Troponin (Trop), Direct Bilirubin (DBil), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Amylase (Amy), Lipase (Lip), Magnesium (Mg), Phosphorous (Phos), Prostate Specific Antigen (PSA), Pro- Brain Natriuretic Peptide (Pro-BNP), Iron (Fe), Total Iron Binding Capacity (TIBC), Ferritin (Fer), Folate (Fol), Vitamin B12 (B12), Alcohol (ETOH), Acetaminophen (Acet), Digoxin (Dig), Phenytoin (Dil), Gentamycin (Gent),Vancomycin (Vanco) and Uric Acid (Uric). Further observation by the surveyor on July 16, 2018 noted the laboratory receiving patient samples for laboratory testing from out side facilities. 2. Review of the Laboratory's Instructions given to outside facilities that the laboratory provides services to revealed "all specimens must be brought to the laboratory immediately after collection." 3. Review of the Siemens Dimension package inserts revealed for: a) For Potassium (K) the package insert states under "Specimen Collection and Handling" that "Specimen tubes should be centrifuged unopened and the serum or plasma should be separated within one hour after venipuncture, as prolonged contact with red cells will cause elevated K results." b) For Glucose (Glu) the package insert states under "Specimen Collection and Handling" that "Glycolysis decreased serum glucose by approximately 5% to 7% per hour in normal uncentrifuged coagulated blood at room temperature. In separated, nonhemolyzed sterile serum, the glucose concentration is generally stable for as long as 8 hours at 25 degrees Celsius and up to 72 hours at 4 degrees Celsius; variability stability is observed with longer storage conditions. Glycolysis can be inhibited and glucose stabilized for as long as 3 days at room temperature by addition of sodium iodoacetate or sodium fluoride (NaF) to the specimen." c) For Phosphorous (Phos) the package insert states under "Specimen Collection and Handling" that the "Serum or plasma should be separated from the red cells within 1 hour because erythrocytes contain phosphate concentrations several times greater than those found in the serum." 4. Review of a random selection of Patient Test Records from May 3, 2018 through July 13, 2018 revealed the laboratory failed to reject the following forty two (42) patients for not meeting manufacturer's requirements for K, Phos, and Glu to be spun and have the serum or plasma separated from the cells within 1 hour: Note: Complete

Metabolic Panel (BMP) includes: Sodium (NA), Potassium (K), Chloride (CL), Carbon Dioxide (CO2), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Total Protein (TP), Albumin (Alb), Calcium (CA), Total Bilirubin (TBil), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), and Aspartate Aminotransferase (AST). Basic Metabolic Panel (BMP) includes: NA, K, CL, CO2, Glu, BUN, and CA. Renal Panel (Renal) includes: NA, K, CL, CO2, Glu, BUN, Creat, Alb, Phos, and CA. On July 13, 2018 Patient 39 was collected for a BMP at 12: 00 PM and not received into the laboratory to be spun and separated until 13:37 PM exceeding the 1 hour time frame to be centrifuged by 37 minutes. On July 9, 2018 Patient 3 was collected for a BMP at 11:00 AM and not received into the laboratory to be spun and separated until 12:38 PM exceeding the 1 hour time frame to be centrifuged by 38 minutes. On July 6, 2018 Patient 42 was collected for a Renal at 11: 00 AM and not received into the laboratory to be spun and separated until 12:38 PM exceeding the 1 hour time frame to be centrifuged by 38 minutes. On July 2, 2018 Patient 43 was collected for a BMP at 10:30 AM and not received into the laboratory to be spun and separated until 11:53 AM exceeding the 1 hour time frame to be centrifuged by 23 minutes. On July 2, 2018 Patient 45 was collected for a BMP at 17: 13 PM and not received into the laboratory to be spun and separated until 19:10 PM exceeding the 1 hour time frame to be centrifuged by 57 minutes. On June 29, 2018 Patient 81 was collected for a Renal at 11:13 AM and not received in the laboratory to be spun and separated until 17:43 PM exceeding the 1 hour time frame to be centrifuged by 270 minutes. On June 29, 2018 Patient 87 was collected for a Renal at 9:08 AM and not received in the laboratory to be spun and separated until 10:23 PM exceeding the 1 hour time frame to be centrifuged by 15 minutes. On June 29, 2018 Patient 80 was collected for a Renal at 8:43 AM and not received in the laboratory to be spun and separated until 17:44 PM exceeding the 1 hour time frame to be centrifuged by 481 minutes. On June 28, 2018 Patient 79 was collected for a Renal at 11:33 AM and not received in the laboratory to be spun and separated until June 29, 2018 at 8:53 AM exceeding the 1 hour time frame to be centrifuged by 1283 minutes. On June 28, 2018 Patient 86 was collected for a Renal at 11:15 AM and not received in the laboratory to be spun and separated until 12:33 PM exceeding the 1 hour time frame to be centrifuged by 18 minutes. On June 26, 2018 Patient 75 was collected for a Renal at 11:21 AM and not received in the laboratory to be spun and separated until June 27, 2018 at 9:14 AM exceeding the 1 hour time frame to be centrifuged by 1253 minutes. On June 26, 2018 Patient 74 was collected for a Renal at 9:22 AM and not received in the laboratory to be spun and separated until June 27, 2018 at 9:14 AM exceeding the 1 hour time frame to be centrifuged by 1382 minutes. On June 26, 2018 Patient 73 was collected for a Renal at 8:42 AM and not received in the laboratory to be spun and separated until June 27, 2018 at 9:14 AM exceeding the 1 hour time frame to be centrifuged by 1412 minutes. On June 25, 2018 Patient 72 was collected for a Renal at 15:03 PM and not received in the laboratory to be spun and separated until June 26, 2018 at 9:01 AM exceeding the 1 hour time frame to be centrifuged by 1018 minutes. On June 25, 2018 Patient 71 was collected for a Renal at 11:55 AM and not received in the laboratory to be spun and separated until June 26, 2018 at 9:02 AM exceeding the 1 hour time frame to be centrifuged by 1207 minutes. On June 25, 2018 Patient 85 was collected for a Renal at 10:35 AM and not received in the laboratory to be spun and separated until 12:10 PM exceeding the 1 hour time frame to be centrifuged by 35 minutes. On June 22, 2018 Patient 84 was collected for a Renal at 10:10 AM and not received in the laboratory to be spun and separated until 11:18 AM exceeding the 1 hour time frame to be centrifuged by 8 minutes. On June 21, 2018 Patient 70 was collected for a Renal at 14:59 PM and not received in the laboratory to be spun and separated until June 22, 2018 at 10.26 AM exceeding the 1 hour time frame to be centrifuged by 1116 minutes. On June 21, 2018 Patient 69 was collected

for a Renal at 14:24 PM and not received in the laboratory to be spun and separated until June 22, 2018 at 11:31 AM exceeding the 1 hour time frame to be centrifuged by 1142 minutes. On June 21, 2018 Patient 83 was collected for a Renal at 10:36 AM and not received in the laboratory to be spun and separated until June 22, 2018 at 11:45 PM exceeding the 1 hour time frame to be centrifuged by 1449 minutes. On June 21, 2018 Patient 68 was collected for a Renal at 8:55 AM and not received in the laboratory to be spun and separated until June 22, 2018 at 10:28 PM exceeding the 1 hour time frame to be centrifuged by 1463 minutes. On June 20, 2018 Patient 67 was collected for a Renal at 10:33 AM and not received in the laboratory to be spun and separated until 12:21 PM exceeding the 1 hour time frame to be centrifuged by 48 minutes. On June 20, 2018 Patient 66 was collected for a Renal at 9:30 AM and not received in the laboratory to be spun and separated until 10:44 AM exceeding the 1 hour time frame to be centrifuged by 14 minutes. On June 19, 2018 Patient 65 was collected for a Renal at 15:14 PM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:25 AM exceeding the 1 hour time frame to be centrifuged by 971 minutes. On June 19, 2018 Patient 64 was collected for a Renal at 14:16 PM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:25 AM exceeding the 1 hour time frame to be centrifuged by 1029 minutes. On June 19, 2018 Patient 63 was collected for a Renal at 11:50 AM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:23 AM exceeding the 1 hour time frame to be centrifuged by 1183 minutes. On June 19, 2018 Patient 62 was collected for a Renal at 10:45 AM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:23 AM exceeding the 1 hour time frame to be centrifuged by 1238 minutes. On June 19, 2018 Patient 60 was collected for a Renal at 9:07 AM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:21 AM exceeding the 1 hour time frame to be centrifuged by 1334 minutes. On June 19, 2018 Patient 61 was collected for a Phos at 10:06 AM and not received in the laboratory to be spun and separated until 11:17 AM exceeding the 1 hour time frame to be centrifuged by 11 minutes. On June 18, 2018 Patient 59 was collected for a Renal at 16:19 PM and not received in the laboratory to be spun and separated until June 19, 2018 at 8:40 AM exceeding the 1 hour time frame to be centrifuged by 921 minutes. On June 13, 2018 Patient 82 was collected for a Renal at 12:05 PM and not received in the laboratory to be spun and separated until 13:22 PM exceeding the 1 hour time frame to be centrifuged by 17 minutes. On June 8, 2018 Patient 57 was collected for a Renal at 11:19 AM and not received in the laboratory to be spun and separated until 13:41 PM exceeding the 1 hour time frame to be centrifuged by 81 minutes. On June 8, 2018 Patient 6 was collected for a BMP at 11:19 AM and not received in the laboratory to be spun and separated until 13:41 PM exceeding the 1 hour time frame to be centrifuged by 81 minutes. On June 7, 2018 Patient 56 was collected for a Renal at 14:37 PM and not received in the laboratory to be spun and separated until 17:35 PM exceeding the 1 hour time frame to be centrifuged by 118 minutes. On June 6, 2018 Patient 55 was collected for a Renal at 9:04 AM and not received in the laboratory to be spun and separated until 10:59 AM exceeding the 1 hour time frame to be centrifuged by 55 minutes. On June 5, 2018 Patient 52 was collected for a Renal at 10:02 AM and not received in the laboratory to be spun and separated until 17:39 PM exceeding the 1 hour time frame to be centrifuged by 397 minutes. On June 5, 2018 Patient 53 was collected for a Renal at 12:18 PM and not received in the laboratory to be spun and separated until 17:43 PM exceeding the 1 hour time frame to be centrifuged by 265 minutes. On May 29, 2018 Patient 47 was collected for a BMP at 14:15 PM and not received into the laboratory to be spun and separated until 17:09 PM exceeding the 1 hour time frame to be centrifuged by 114 minutes. On May 8, 2018 Patient 48 was collected for a BMP at 12:20 PM and not received into the laboratory to be spun and separated until 14:01 PM exceeding the 1

hour time frame to be centrifuged by 41 minutes. On May 3, 2018 Patient 46 was collected for a BMP at 9:30 AM and not received into the laboratory to be spun and separated until 12:13 PM exceeding the 1 hour time frame to be centrifuged by 103 minutes. On February 13, 2018 Patient 19 was collected for a CMP at 8:35 AM and not received in the laboratory to be spun and separated until 10:04 PM exceeding the 1 hour time frame to be centrifuged by 29 minutes. On February 13, 2018 Patient 21 was collected for a Renal at 10:56 AM and not received in the laboratory to be spun and separated until 17:04 PM exceeding the 1 hour time frame to be centrifuged by 308 minutes. 5. Interviews with Personnel 4 on July 18, 2018 revealed she was unaware of the one hour timeframe for K, Phos, and Glu. Personnel 4 confirmed that the patients cited above exceeded the 1 hour time frame set by the manufacturer. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Calcium (CA), are separated from the red cell promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Findings: 1. Observation by surveyor on July 16, 2018 revealed the laboratory maintained a Siemens Dimension EXL for : Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Ammonia (Ammon), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Triglyceride (Trig), Creatine Phosphokinase (CPK), Creatine Kinase MB (CKMB), Hemoglobin A1C) (HgbA1C), Troponin (Trop), Direct Bilirubin (DBil), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Amylase (Amy), Lipase (Lip), Magnesium (Mg), Phosphorous (Phos), Prostate Specific Antigen (PSA), Pro- Brain Natriuretic Peptide (Pro-BNP), Iron (Fe), Total Iron Binding Capacity (TIBC), Ferritin (Fer), Folate (Fol), Vitamin B12 (B12), Alcohol (ETOH), Acetaminophen (Acet), Digoxin (Dig), Phenytoin (Dil), Gentamycin (Gent),Vancomycin (Vanco) and Uric Acid (Uric). Further observation by the surveyor on July 16, 2018 noted the laboratory receiving patient samples for laboratory testing from out side facilities. 2. Review of the Laboratory's Instructions given to outside facilities that the laboratory provides services to revealed "all specimens must be brought to the laboratory immediately after collection." 3. Review of the Siemens Dimension package inserts revealed for Calcium (CA) states under "Specimen Collection and Handling" that the "Serum should be separated from the red cell and analyzed promptly." 4. Review of a random selection of Patient Test Records from May 3, 2018 through July 13, 2018 revealed the laboratory failed to reject the following forty one (41) patients for not meeting manufacturer's requirements for CA to separated the serum/plasma from the red cells promptly. Note: Complete Metabolic Panel (BMP) includes: Sodium (NA), Potassium (K), Chloride (CL), Carbon Dioxide (CO2), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Total Protein (TP), Albumin (Alb), Calcium (CA), Total Bilirubin (TBil), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), and Aspartate Aminotransferase (AST). Basic Metabolic Panel (BMP) includes: NA, K, CL, CO2, Glu, BUN, and CA. Renal Panel (Renal) includes: NA, K, CL, CO2, Glu, BUN, Creat, Alb, Phos, and CA. On July 13, 2018 Patient 39 was collected for a BMP at 12: 00 PM and not received into the laboratory to be spun and separated until 13:37 PM. On July 9, 2018 Patient 3 was collected for a BMP at 11:00 AM and not received into the laboratory to be spun and separated until 12:38 PM. On July 6, 2018 Patient 42 was collected for a Renal at 11:00 AM and not received into the laboratory to be spun and separated until 12:38 PM. On July 2, 2018 Patient 43 was collected for a BMP at 10:30 AM and not received into the laboratory to be spun and separated until 11:53

AM. On July 2, 2018 Patient 45 was collected for a BMP at 17:13 PM and not received into the laboratory to be spun and separated until 19:10 PM. On June 29, 2018 Patient 81 was collected for a Renal at 11:13 AM and not received in the laboratory to be spun and separated until 17:43 PM. On June 29, 2018 Patient 87 was collected for a Renal at 9:08 AM and not received in the laboratory to be spun and separated until 10:23 PM. On June 29, 2018 Patient 80 was collected for a Renal at 8: 43 AM and not received in the laboratory to be spun and separated until 17:44 PM. On June 28, 2018 Patient 79 was collected for a Renal at 11:33 AM and not received in the laboratory to be spun and separated until June 29, 2018 at 8:53 AM. On June 28, 2018 Patient 86 was collected for a Renal at 11:15 AM and not received in the laboratory to be spun and separated until 12:33 PM. On June 26, 2018 Patient 75 was collected for a Renal at 11:21 AM and not received in the laboratory to be spun and separated until June 27, 2018 at 9:14 AM. On June 26, 2018 Patient 74 was collected for a Renal at 9:22 AM and not received in the laboratory to be spun and separated until June 27, 2018 at 9:14 AM. On June 26, 2018 Patient 73 was collected for a Renal at 8:42 AM and not received in the laboratory to be spun and separated until June 27, 2018 at 9:14 AM. On June 25, 2018 Patient 72 was collected for a Renal at 15:03 PM and not received in the laboratory to be spun and separated until June 26, 2018 at 9:01 AM. On June 25, 2018 Patient 71 was collected for a Renal at 11:55 AM and not received in the laboratory to be spun and separated until June 26, 2018 at 9:02 AM. On June 25, 2018 Patient 85 was collected for a Renal at 10:35 AM and not received in the laboratory to be spun and separated until 12:10 PM. On June 22, 2018 Patient 84 was collected for a Renal at 10:10 AM and not received in the laboratory to be spun and separated until 11:18 AM. On June 21, 2018 Patient 70 was collected for a Renal at 14:59 PM and not received in the laboratory to be spun and separated until June 22, 2018 at 10.26 AM. On June 21, 2018 Patient 69 was collected for a Renal at 14:24 PM and not received in the laboratory to be spun and separated until June 22, 2018 at 11:31 AM. On June 21, 2018 Patient 83 was collected for a Renal at 10:36 AM and not received in the laboratory to be spun and separated until June 22, 2018 at 11:45 AM. On June 21, 2018 Patient 68 was collected for a Renal at 8:55 AM and not received in the laboratory to be spun and separated until June 22, 2018 at 10:28 AM On June 20, 2018 Patient 67 was collected for a Renal at 10:33 AM and not received in the laboratory to be spun and separated until 12:21 PM. On June 20, 2018 Patient 66 was collected for a Renal at 9:30 AM and not received in the laboratory to be spun and separated until 10:44 AM. On June 19, 2018 Patient 65 was collected for a Renal at 15:14 PM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:25 AM. On June 19, 2018 Patient 64 was collected for a Renal at 14:16 PM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:25 AM. On June 19, 2018 Patient 63 was collected for a Renal at 11:50 AM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:23 AM. On June 19, 2018 Patient 62 was collected for a Renal at 10:45 AM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:23 AM. On June 19, 2018 Patient 60 was collected for a Renal at 9:07 AM and not received in the laboratory to be spun and separated until June 20, 2018 at 8:21 AM. On June 18, 2018 Patient 59 was collected for a Renal at 16:19 PM and not received in the laboratory to be spun and separated until June 19, 2018 at 8:40 AM. On June 13, 2018 Patient 82 was collected for a Renal at 12:05 PM and not received in the laboratory to be spun and separated until 13:22 PM. On June 8, 2018 Patient 57 was collected for a Renal at 11:19 AM and not received in the laboratory to be spun and separated until 13:41 PM. On June 8, 2018 Patient 6 was collected for a BMP at 11:19 AM and not received in the laboratory to be spun and separated until 13:41 PM. On June 7, 2018 Patient 56 was collected for a Renal at 14:37 PM and not received in the laboratory to be spun and separated until 17:35 PM. On June 6, 2018 Patient 55 was collected for a Renal at

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| | 9:04 AM and not received in the laboratory to be spun and separated until 10:59 AM. On June 5, 2018 Patient 52 was collected for a Renal at 10:02 AM and not received in the laboratory to be spun and separated until 17:39 PM. On June 5, 2018 Patient 53 was collected for a Renal at 12:18 PM and not received in the laboratory to be spun and separated until 17:43 PM. On May 29, 2018 Patient 47 was collected for a BMP at 14:15 PM and not received into the laboratory to be spun and separated until 17:09 PM. On May 8, 2018 Patient 48 was collected for a BMP at 12:20 PM and not received into the laboratory to be spun and separated until 14:01 PM. On May 3, 2018 Patient 46 was collected for a BMP at 9:30 AM and not received into the laboratory to be spun and separated until 12:13 PM. On February 13, 2018 Patient 19 was collected for a CMP at 8:35 AM and not received in the laboratory to be spun and separated until 10:04 PM. On February 13, 2018 Patient 21 was collected for a Renal at 10:56 AM and not received in the laboratory to be spun and separated until 17:04 PM. 5. Interviews with Personnel 4 on July 18, 2018 revealed laboratory policy was for all samples to be brought to the laboratory immediately for processing. Personnel 2 confirmed the specimens above failed to be spun promptly for CA. Personnel 4 confirmed that the patients cited above exceeded the manufacturer and Laboratory Policy for receiving samples immediately into the laboratory for processing. |
| **D5317** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Repeat Deficiency from 2/6/2017 Survey. Based on record review and interview with personnel, the laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of the Laboratory's Manual for outside facilities that utilized the laboratory for testing revealed the manual failed to include detailed instructions that met the instrumentation requirements utilized by the laboratory for: (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. 2. Interview with personnel 4 on July 19, 2018 confirmed the laboratory did not have or provide a service manual for outside facilities that provided information that was current with the instrumentation utilized by the laboratory. Personnel 2 also confirmed the manual available to outside services did not meet the requirements for maintaining the integrity of patient samples to ensure accurate and reliable testing. |
| **D5393** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(b)(c)<br><br>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. |

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| | This STANDARD is not met as evidenced by:<br>Based on observation, record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. A review of patient test records indicates systemic problems with the preanalytic system as follows: a) The laboratory failed to maintain test requisitions that included the specimen collection date and time as required for four (4) of thirteen (13) patient requisitions reviewed. Refer to D5305. b) The laboratory failed to ensure patient samples for Potassium (K), Phosphorous (Phos), and Glucose (Glu) are spun and separated within one (1) hour according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for forty two (42) of one hundred seventeen (117) patients reviewed. Refer to D5311 I. c) The laboratory failed to ensure patient samples for Calcium (CA), are separated from the red cell promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5311 II. d) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. The laboratory had a Quality Assurance Policy that routinely monitored the preanalytic system; however, the monitors failed to identify the deficiencies identified with the preanalytic systems. 3. Interviews with personnel 2, 4 and 13 on July 19, 2018 confirmed the laboratory failed to identify the problems cited with the preanalytic system above. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on observatio, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to ensure patient samples performed on the EPOC Blood Analysis system are analyzed within fifteen (15) minutes according to laboratory policy for twenty six (26) of eighty one (81) patients reviewed.Refer to D5401 II. 3. The laboratory failed to ensure patient samples for Calcium (CA), are analyzed promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5411 I. 4. The laboratory failed to ensure patient samples for Lactic Acid, are analyzed within five (5) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for eighty four (84) of eighty eight (88) patients reviewed. Refer to D5411 II. 5. The laboratory failed to ensure patient samples for Ammonia (Ammon) are analyzed within thirty (30) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable |

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| | testing for two (2) of eight (8) patients reviewed. Refer to D5411 III. 6. The laboratory failed to ensure that blood culture vials and ABX Minoclair solutions are not used beyond their expiration dates. Refer to D5417 I. 7. The laboratory failed to ensure that Blood Bank Quality Control, Coombs Control Cells and Antibody Free Plasma are not used beyond their expiration dates. Refer to D5417 II. 8. The laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Siemens Dimension EXL 200 Chemistry Analyzer. Refer to D5421 I. 9. The laboratory failed to have complete performance specification verification studies for the Med TOX scan and Cartridges for Urine Drug Screen (UDS) testing. Refer to D5421 II. 10. The laboratory failed to ensure the daily cuvette temperature on the Siemens Dimension EXL 200 Chemistry System was maintained between 36.8 - 37.2 degrees Celsius as required by the manufacturer, for three (3) of one hundred eighty one (181) patient test days reviewed. Refer to D5429. 11. The laboratory failed to perform a positive and negative control each day of patient testing for Urine Drug Screen (UDS) testing performed on the MED TOX Scan Analyzer for four (4) of one hundred nineteen (119) patient test days. Refer to D5449. 12. The laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing each day of patient testing, for one (1) of one hundred twenty nine (129) patient test days reviewed. Refer to D5551. 13. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in the Analytic Systems. Refer to D5793. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Test Requisitions to include all the required information: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. h) Any additional information relevant and necessary for |

a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. Complaint Policies and Procedures Communication Policies and Procedures 2. Interview with Personnel 4 on July 16, 2018 confirmed the policy and procedure manual was incomplete II. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples performed on the EPOC Blood Analysis system are analyzed within fifteen (15) minutes according to laboratory policy for twenty six (26) of eighty one (81) patients reviewed. Findings: 1. Observation by surveyor on July 16, 2018 revealed the laboratory maintained a EPOC Blood Analysis System for testing: pH, pCO2, pO2, Sodium (NA), Potassium (K), Ionized Calcium (CA), Chloride (CL), Glucose (Glu), Lactate, Creatinine (Creat), and Hematocrit (Hct). 2. Review of the Laboratory's Policy and Procedure revealed that all samples performed on the EPOC Blood Analysis System are to be analyzed within fifteen (15) minutes. 3. Review of a random selection of Patient Test Records from February 28, 2018 through May 30, 2018 revealed the laboratory failed analyze the following twenty six (26) patients within fifteen (15) minutes according to laboratory policy. NOTE: Basic Metabolic Panel (BMP) consists of Glucose (Glu), Creatinine (Creat), Sodium (NA), Potassium (K), Chloride (CL) and Carbon dioxide (CO2). Arterial Blood Gas (ABG) consists of pH, pO2, and pCO2. On February 28, 2018 Patient 33 was collected for a BMP at 10: 20 AM and analyzed at 10:48 AM exceeding 15 minutes by 3 minutes. On March 22, 2018 Patient 32 was collected for a Lactic Acid at 19:17 PM and analyzed at 20:07 PM exceeding 15 minutes by 5 minutes. On April 9, 2018 Patient 34 was collected for a BMP at 18:26 PM and analyzed at 18:47 PM exceeding 15 minutes by 6 minutes. On April 10, 2018 Patient 175 was collected for a ABG at 16:00 PM and analyzed at 16:16 PM exceeding 15 minutes by 1 minute. On April 16, 2018 Patient 176 was collected for a ABG at 17:58 PM and analyzed at 18:14 PM exceeding 15 minutes by 1 minute. On April 17, 2018 Patient 177 was collected for a ABG at 23:10 PM and analyzed at 23:31 PM exceeding 15 minutes by 6 minute. On April 19, 2018 Patient 178 was collected for a ABG at 12:18 PM and analyzed at 12:35 PM exceeding 15 minutes by 2 minute. On May 4, 2018 Patient 179 was collected for a ABG at 6:59 AM and analyzed at 7:15 AM exceeding 15 minutes by 1 minute. On May 4, 2018 Patient 180 was collected for a ABG at 9:28 AM and analyzed at 9:44 AM exceeding 15 minutes by 1 minute. On May 4, 2018 Patient 181 was collected for a ABG at 21: 00 PM and analyzed at 21:17 PM exceeding 15 minutes by 2 minutes. On May 4, 2018 Patient 182 was collected for a ABG at 21:10 PM and analyzed at 21:29 PM exceeding 15 minutes by 4 minutes. On May 5, 2018 Patient 183 was collected for a ABG at 11:38 AM and analyzed at 11:57 AM exceeding 15 minutes by 4 minutes. On May 18, 2018 Patient 30 was collected for a BMP at 16:00 PM and analyzed at 16:28 PM exceeding 15 minutes by 13 minutes. On May 19, 2018 Patient 184 was collected for a ABG at 6:55 AM and analyzed at 7:13 AM exceeding 15 minutes by 3 minutes. On May 19, 2018 Patient 185 was collected for a ABG at 17:55 PM and analyzed at 18:18 PM exceeding 15 minutes by 8 minutes. On May 22, 2018 Patient 187 was collected for a ABG at 6:14 AM and analyzed at 6:34 AM exceeding 15 minutes by 5 minutes. On May 22, 2018 Patient 187 was collected for a ABG at 13:00 PM and analyzed at 13:18 PM exceeding 15 minutes by 3 minutes. On May 25, 2018 Patient 186 was collected for a ABG at 9:50 AM and analyzed at 10:10 AM exceeding 15 minutes by 5 minutes. On May 25, 2018 Patient 189 was collected for a ABG at 8:00 AM and analyzed at 8:17 AM exceeding 15 minutes by 2 minutes. On May 26, 2018 Patient 190 was collected for a ABG at 00:12 AM and analyzed at 00:30 AM exceeding 15 minutes by 3 minutes. On May 27, 2018 Patient 191 was collected for a ABG at 22:15 PM and analyzed at 22:35 PM exceeding 15 minutes by 5 minutes. On May 30, 2018 Patient 29 was collected at 9:29 AM and analyzed at 11:35 AM exceeding 15 minutes by 111 minutes. On June 8, 2018 Patient 192 was collected for

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| | a ABG at 19:55 PM and analyzed at 20:34 PM exceeding 15 minutes by 24 minutes. On June 12, 2018 Patient 193 was collected for a ABG at 11:09 AM and analyzed at 11:25 AM exceeding 15 minutes by 1 minute. On June 14, 2018 Patient 194 was collected for a ABG at 12:10 PM and analyzed at 12:26 PM exceeding 15 minutes by 1 minute. On June 18, 2018 Patient 195 was collected for a ABG at 22:00 PM and analyzed at 22:45 PM exceeding 15 minutes by 30 minutes. 5. Interviews with Personnel 4 on July 18, 2018 confirmed the specimens above failed to be analyzed within 15 minutes for patient samples performed on the EPOC Blood Analysis Analyzer. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Calcium (CA), are analyzed promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Findings: 1. Observation by surveyor on July 16, 2018 revealed the laboratory maintained a Siemens Dimension EXL for : Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Ammonia (Ammon), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Triglyceride (Trig), Creatine Phosphokinase (CPK), Creatine Kinase MB (CKMB), Hemoglobin A1C) (HgbA1C), Troponin (Trop), Direct Bilirubin (DBil), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Amylase (Amy), Lipase (Lip), Magnesium (Mg), Phosphorous (Phos), Prostate Specific Antigen (PSA), Pro-Brain Natriuretic Peptide (Pro-BNP), Iron (Fe), Total Iron Binding Capacity (TIBC), Ferritin (Fer), Folate (Fol), Vitamin B12 (B12), Alcohol (ETOH), Acetaminophen (Acet), Digoxin (Dig), Phenytoin (Dil), Gentamycin (Gent),Vancomycin (Vanco) and Uric Acid (Uric). Further observation by the surveyor on July 16, 2018 noted the laboratory receiving patient samples for laboratory testing from out side facilities. 2. Review of the Laboratory's Instructions given to outside facilities that the laboratory provides services to revealed "all specimens must be brought to the laboratory immediately after collection." 3. Review of the Siemens Dimension package inserts revealed for Calcium (CA) states under "Specimen Collection and Handling" that the "Serum should be separated from the red cell and analyzed promptly." 4. Review of a random selection of Patient Test Records from May 3, 2018 through July 13, 2018 revealed the laboratory failed to reject the following forty one (41) patients for not meeting manufacturer's requirements for CA to analyze promptly. Note: Complete Metabolic Panel (BMP) includes: Sodium (NA), Potassium (K), Chloride (CL), Carbon Dioxide (CO2), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Total Protein (TP), Albumin (Alb), Calcium (CA), Total Bilirubin (TBil), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), and Aspartate Aminotransferase (AST). Basic Metabolic Panel (BMP) includes: NA, K, CL, CO2, |

Glu, BUN, and CA. Renal Panel (Renal) includes: NA, K, CL, CO2, Glu, BUN, Creat, Alb, Phos, and CA. On July 13, 2018 Patient 39 was collected for a BMP at 12: 00 PM and not reported 14:09 PM. On July 6, 2018 Patient 3 was collected for a BMP at 11:00 AM and not reported until July 9, 2018 at 18:15 PM. On July 6, 2018 Patient 42 was collected for a Renal at 11:00 AM and not reported until 18:15 PM. On July 2, 2018 Patient 43 was collected for a BMP at 10:30 AM and not reported 13:26 PM. On July 2, 2018 Patient 45 was collected for a BMP at 17:13 PM and not reported until 20:07 PM. On June 29, 2018 Patient 81 was collected for a Renal at 11:13 AM and not reported until at 18:43 PM. On June 29, 2018 Patient 87 was collected for a Renal at 9:08 AM and not reported until 10:23 AM. On June 29, 2018 Patient 80 was collected for a Renal at 8:43 AM and not reported until at 18:43 PM. On June 28, 2018 Patient 79 was collected for a Renal at 11:33 AM and not reported until June 29, 2019 at 10:00 AM. On June 28, 2018 Patient 86 was collected for a Renal at 11:15 AM and not reported until at 12:33 PM. On June 26, 2018 Patient 75 was collected for a Renal at 11:21 AM and not reported until June 27, 2019 at 9:50 AM. On June 26, 2018 Patient 74 was collected for a Renal at 9:22 AM and not reported until June 27, 2019 at 10:39 AM. On June 26, 2018 Patient 73 was collected for a Renal at 8:42 AM and not reported until June 27, 2019 at 9:49 AM. On June 25, 2018 Patient 72 was collected for a Renal at 15:03 PM and not reported until June 26, 2019 at 9:38 AM. On June 25, 2018 Patient 71 was collected for a Renal at 11:55 AM and not reported until June 26, 2019 at 9:38 AM. On June 25, 2018 Patient 85 was collected for a Renal at 10:35 AM and not reported until 12:10 PM. On June 22, 2018 Patient 84 was collected for a Renal at 10:10 AM and not reported until 11:18 AM. On June 21, 2018 Patient 70 was collected for a Renal at 14:59 PM and not reported until June 22, 2019 at 11:36 AM. On June 21, 2018 Patient 69 was collected for a Renal at 14:24 PM and not reported until June 22, 2019 at 11:31 AM. On June 21, 2018 Patient 83 was collected for a Renal at 10:36 AM and not reported until June 22, 2019 at 11:45 AM. On June 21, 2018 Patient 68 was collected for a Renal at 8:55 AM and not reported until June 22, 2019 at 12:13 PM. On June 20, 2018 Patient 67 was collected for a Renal at 10:33 AM and not reported until 13:10 PM. On June 20, 2018 Patient 66 was collected for a Renal at 9:30 AM and not reported until 11:22 AM. On June 19, 2018 Patient 65 was collected for a Renal at 15:14 PM and not reported until June 20, 2019 at 16:23 PM. On June 19, 2018 Patient 64 was collected for a Renal at 14:16 PM and not reported until June 20, 2019 at 9:34 AM. On June 19, 2018 Patient 63 was collected for a Renal at 11:50 AM and not reported until June 20, 2019 at 9:07 AM. On June 19, 2018 Patient 62 was collected for a Renal at 10:45 AM and not reported until June 20, 2019 at 9:24 AM. On June 19, 2018 Patient 60 was collected for a Renal at 9:07 AM and not reported until June 20, 2019 at 10:26 AM. On June 18, 2018 Patient 59 was collected for a Renal at 16:19 PM and not reported until June 19, 2018 at 9:40 AM. On June 13, 2018 Patient 82 was collected for a Renal at 12:05 PM and not reported until 13:22 PM. On June 8, 2018 Patient 57 was collected for a Renal at 11:19 AM and not reported until 14:40 PM. On June 8, 2018 Patient 6 was collected for a BMP at 11:19 AM and not reported until 14:40 PM. On June 7, 2018 Patient 56 was collected for a Renal at 14:37 PM and not reported until 18:25 PM. On June 6, 2018 Patient 55 was collected for a Renal at 9:04 AM and not reported until 11:45 AM. On June 5, 2018 Patient 52 was collected for a Renal at 10:02 AM and not reported until June 6, 2019 at 5:08 AM. On June 5, 2018 Patient 53 was collected for a Renal at 12:18 PM and not reported until 18:04 PM. On May 29, 2018 Patient 47 was collected for a BMP at 14:15 PM and not reported until 17:57 PM. On May 8, 2018 Patient 48 was collected for a BMP at 12:20 PM and not reported until 15:46 PM. On May 3, 2018 Patient 46 was collected for a BMP at 9:30 AM and not reported until 12:45 PM. On February 13, 2018 Patient 19 was collected for a CMP at 8:35 AM and not reported until 10:04 AM. On February 13, 2018 Patient 21 was collected for a

Renal at 10:56 AM and not reported until 17:54 PM. 5. Interviews with Personnel 4 on July 18, 2018 revealed she was unaware of the manufacturer's requirement to analyze patient samples for CA promptly. Personnel 2 confirmed the specimens above failed to be analyzed promptly for CA. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Lactic Acid, are analyzed within five (5) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for eighty four (84) of eighty eight (88) patients reviewed. Findings: 1. Observation by surveyor on July 16, 2018 revealed the laboratory maintained a EPOC Blood Analysis System for testing: pH, pCO2, pO2, Sodium (NA), Potassium (K), Ionized Calcium (CA), Chloride (CL), Glucose (Glu), Lactate, Creatinine (Creat), and Hematocrit (Hct). 2. Review of the EPOC Blood Analysis System Operators Manual revealed: a) For Lactate samples are to be tested within five (5) minutes to avoid the effects of glycolysis. b) For pH, pO2, and pCO2 samples are to be tested within thirty (30) minutes. c) For CA samples are to be tested within thirty (30) minutes to avoid artifacts of metabolic activity. d) For Glu samples are to be tested within thirty (3) minutes to avoid effects of glycolysis. 3. Review of a random selection of Patient Test Records from March 22, 2018 through June 30, 2018 revealed the laboratory failed to reject the following eighty four (84) patients for not meeting the manufacturer's requirements for testing Lactic Acid within five (5) minutes after collection. On March 22, 2018 Patient 32 was collected at 19:47 PM and analyzed at 20:07 PM exceeding 5 minutes by 15 minutes. On April 3, 2018 Patient 88 was collected at 9:45 AM and analyzed at 9:59 AM exceeding 5 minutes by 9 minutes. On April 5, 2018 Patient 89 was collected at 15:40 PM and analyzed at 15:49 PM exceeding 5 minutes by 4 minutes. On April 5, 2018 Patient 90 was collected at 14:50 PM and analyzed at 15:32 PM exceeding 5 minutes by 37 minutes. On April 11, 2018 Patient 91 was collected at 12:05 PM and analyzed at 12: 18 PM exceeding 5 minutes by 8 minutes. On April 12, 2018 Patient 92 was collected at 5:20 AM and analyzed at 5:29 AM exceeding 5 minutes by 4 minutes. On April 14, 2018 Patient 93 was collected at 6:48 AM and analyzed at 7:24 AM exceeding 5 minutes by 31 minutes. On April 12, 2018 Patient 94 was collected at 0:17 AM and analyzed at 0:24 AM exceeding 5 minutes by 2 minutes. On April 16, 2018 Patient 95 was collected at 17:48 PM and analyzed at 17:54 AM exceeding 5 minutes by 1 minute. On April 18, 2018 Patient 96 was collected at 8:04 AM and analyzed at 8:13 AM exceeding 5 minutes by 4 minutes. On April 19, 2018 Patient 97 was collected at 20:48 PM and analyzed at 21:03 PM exceeding 5 minutes by 10 minutes. On April 20, 2018 Patient 98 was collected at 7:21 AM and analyzed at 7:39 AM exceeding 5 minutes by 13 minutes. On April 20, 2018 Patient 99 was collected at 8:05 AM and analyzed at 8:14 AM exceeding 5 minutes by 4 minutes. On April 20, 2018 Patient 100 was collected at 14:35 PM and analyzed at 14:43 PM exceeding 5 minutes by 3 minutes. On April 23, 2018 Patient 101 was collected at 19:58 PM and analyzed at 20: 28 PM exceeding 5 minutes by 25 minutes. On April 26, 2018 Patient 104 was collected at 19:55 PM and analyzed at 20:09 PM exceeding 5 minutes by 9 minutes. On April 27, 2018 Patient 105 was collected at 20:23 PM and analyzed at 20:33 PM exceeding 5 minutes by 5 minutes. On April 27, 2018 Patient 106 was collected at 23: 42 PM and analyzed at 23:48 PM exceeding 5 minutes by 1 minute. On April 30, 2018 Patient 108 was collected at 16:27 PM and analyzed at 16:36 PM exceeding 5 minutes by 4 minutes. On April 30, 2018 Patient 109 was collected at 20:47 PM and analyzed at 21:01 PM exceeding 5 minutes by 9 minutes. On May 3, 2018 Patient 110 was collected at 13:03 PM and analyzed at 13:16 PM exceeding 5 minutes by 8 minutes. On May 3, 2018 Patient 111 was collected at 13:36 PM and analyzed at 13: 44 PM exceeding 5 minutes by 3 minutes. On May 3, 2018 Patient 112 was collected at 18:20 PM and analyzed at 18:42 PM exceeding 5 minutes by 17 minutes. On May 4, 2018 Patient 113 was collected at 15:25 PM and analyzed at 15:36 PM exceeding 5

minutes by 6 minutes. On May 7, 2018 Patient 114 was collected at 11:38 AM and analyzed at 11:49 AM exceeding 5 minutes by 6 minutes. On May 9, 2018 Patient 115 was collected at 11:00 AM and analyzed at 11:16 AM exceeding 5 minutes by 11 minutes. On May 9, 2018 Patient 116 was collected at 17:12 PM and analyzed at 17: 33 PM exceeding 5 minutes by 16 minutes. On May 10, 2018 Patient 117 was collected at 00:18 AM and analyzed at 00:52 AM exceeding 5 minutes by 29 minutes. On May 10, 2018 Patient 118 was collected at 14:57 PM and analyzed at 15:08 PM exceeding 5 minutes by 6 minutes. On May 10, 2018 Patient 119 was collected at 10: 33 AM and analyzed at 10:46 AM exceeding 5 minutes by 8 minutes. On May 10, 2018 Patient 120 was collected at 15:08 PM and analyzed at 15:16 PM exceeding 5 minutes by 3 minutes. On May 13, 2018 Patient 121 was collected at 6:42 AM and analyzed at 7:03 AM exceeding 5 minutes by 15 minutes. On May 13, 2018 Patient 122 was collected at 10:28 AM and analyzed at 10:46 AM exceeding 5 minutes by 13 minutes. On May 14, 2018 Patient 123 was collected at 9:19 AM and analyzed at 9:32 AM exceeding 5 minutes by 8 minutes. On May 14, 2018 Patient 124 was collected at 11:33 AM and analyzed at 11:41 AM exceeding 5 minutes by 3 minutes. On May 14, 2018 Patient 125 was collected at 15:49 PM and analyzed at 15:55 PM exceeding 5 minutes by 1 minute. On May 15, 2018 Patient 126 was collected at 2:15 AM and analyzed at 2:29 AM exceeding 5 minutes by 9 minutes. On May 15, 2018 Patient 127 was collected at 10:04 AM and analyzed at 10:18 AM exceeding 5 minutes by 9 minutes. On May 16, 2018 Patient 128 was collected at 6:45 AM and analyzed at 6:57 AM exceeding 5 minutes by 8 minutes. On May 15, 2018 Patient 129 was collected at 14:03 PM and analyzed at 14:10 PM exceeding 5 minutes by 2 minutes. On May 15, 2018 Patient 130 was collected at 18:55 PM and analyzed at 19:12 PM exceeding 5 minutes by 12 minutes. On May 19, 2018 Patient 131 was collected at 7:38 AM and analyzed at 7:44 AM exceeding 5 minutes by 1 minute. On May 19, 2018 Patient 132 was collected at 17:55 PM and analyzed at 19:11 PM exceeding 5 minutes by 71 minutes. On May 19, 2018 Patient 133 was collected at 18:45 PM and analyzed at 19: 04 PM exceeding 5 minutes by 14 minutes. On May 22, 2018 Patient 134 was collected at 11:10 AM and analyzed at 11:23 AM exceeding 5 minutes by 8 minutes. On May 22, 2018 Patient 135 was collected at 16:00 PM and analyzed at 16:12 PM exceeding 5 minutes by 7 minutes. On May 24, 2018 Patient 136 was collected at 9:50 AM and analyzed at 10:11 AM exceeding 5 minutes by 16 minutes. On May 23, 2018 Patient 137 was collected at 15:20 PM and analyzed at 15:45 PM exceeding 5 minutes by 20 minutes. On May 25, 2018 Patient 138 was collected at 9:48 AM and analyzed at 10:09 AM exceeding 5 minutes by 16 minutes. On May 26, 2018 Patient 139 was collected at 00:12 AM and analyzed at 00:29 AM exceeding 5 minutes by 12 minutes. On May 26, 2018 Patient 140 was collected at 15:16 PM and analyzed at 15:29 PM exceeding 5 minutes by 8 minutes. On May 29, 2018 Patient 142 was collected at 8:54 AM and analyzed at 9:06 AM exceeding 5 minutes by 7 minutes. On May 29, 2018 Patient 143 was collected at 11:12 AM and analyzed at 11:19 AM exceeding 5 minutes by 2 minutes. On May 29, 2018 Patient 144 was collected at 16:40 PM and analyzed at 17:00 PM exceeding 5 minutes by 15 minutes. On June 1, 2018 Patient 145 was collected at 23:25 PM and analyzed at 23:52 PM exceeding 5 minutes by 22 minutes. On June 5, 2018 Patient 146 was collected at 3:35 AM and analyzed at 3:55 AM exceeding 5 minutes by 15 minutes. On June 5, 2018 Patient 147 was collected at 10:43 AM and analyzed at 10:50 AM exceeding 5 minutes by 2 minutes. On June 5, 2018 Patient 148 was collected at 15:45 PM and analyzed at 15:53 PM exceeding 5 minutes by 3 minutes. On June 5, 2018 Patient 149 was collected at 18:08 PM and analyzed at 18:22 PM exceeding 5 minutes by 9 minutes. On June 7, 2018 Patient 150 was collected at 14:49 PM and analyzed at 15:01 PM exceeding 5 minutes by 7 minutes. On June 9, 2018 Patient 151 was collected at 12:43 PM and analyzed at 13: 17 PM exceeding 5 minutes by 29 minutes. On June 11, 2018 Patient 152 was

collected at 9:52 AM and analyzed at 10:02 AM exceeding 5 minutes by 5 minutes. On June 11, 2018 Patient 153 was collected at 20:55 PM and analyzed at 21:16 PM exceeding 5 minutes by 16 minutes. On June 15, 2018 Patient 154 was collected at 12: 19 PM and analyzed at 12:28 PM exceeding 5 minutes by 4 minutes. On June 13, 2018 Patient 155 was collected at 16:07 PM and analyzed at 16:14 PM exceeding 5 minutes by 2 minutes. On June 14, 2018 Patient 156 was collected at 8:10 AM and analyzed at 8:20 AM exceeding 5 minutes by 5 minutes. On June 14, 2018 Patient 157 was collected at 8:42 AM and analyzed at 8:51 AM exceeding 5 minutes by 4 minutes. On June 15, 2018 Patient 158 was collected at 4:55 AM and analyzed at 5:13 AM exceeding 5 minutes by 13 minutes. On June 16, 2018 Patient 159 was collected at 6:46 AM and analyzed at 6:52 AM exceeding 5 minutes by 1 minute. On June 17, 2018 Patient 160 was collected at 6:58 AM and analyzed at 8:08 AM exceeding 5 minutes by 65 minutes. On June 16, 2018 Patient 161 was collected at 17:48 PM and analyzed at 18:01 PM exceeding 5 minutes by 8 minutes. On June 18, 2018 Patient 162 was collected at 15:20 PM and analyzed at 15:39 PM exceeding 5 minutes by 14 minutes. On June 18, 2018 Patient 163 was collected at 19:28 PM and analyzed at 19: 45 PM exceeding 5 minutes by 12 minutes. On June 18, 2018 Patient 164 was collected at 23:50 PM and analyzed on June 19, 2018 at 00:03 AM exceeding 5 minutes by 8 minutes. On June 22, 2018 Patient 165 was collected at 13:17 PM and analyzed at 13:28 PM exceeding 5 minutes by 6 minutes. On June 22, 2018 Patient 166 was collected at 16:55 PM and analyzed at 17:12 PM exceeding 5 minutes by 12 minutes. On June 26, 2018 Patient 167 was collected at 14:04 PM and analyzed at 14: 13 PM exceeding 5 minutes by 4 minutes. On June 27, 2018 Patient 168 was collected at 00:50 AM and analyzed at 00:59 AM exceeding 5 minutes by 4 minutes. On June 27, 2018 Patient 169 was collected at 8:38 AM and analyzed at 9:25 AM exceeding 5 minutes by 42 minutes. On June 27, 2018 Patient 170 was collected at 16:15 PM and analyzed at 16:31 PM exceeding 5 minutes by 11 minutes. On June 27, 2018 Patient 171 was collected at 17:18 PM and analyzed at 17:24 PM exceeding 5 minutes by 1 minute. On June 27, 2018 Patient 172 was collected at 18:00 PM and analyzed at 18: 08 PM exceeding 5 minutes by 3 minutes. On June 27, 2018 Patient 173 was collected at 19:48 PM and analyzed at 20:38 PM exceeding 5 minutes by 45 minutes. On June 27, 2018 Patient 174 was collected at 23:40 PM and analyzed on June 28, 2018 at 00: 18 AM exceeding 5 minutes by 23 minutes. 5. Interviews with Personnel 4 on July 18, 2018 revealed she was unaware of the manufacturer's requirement to analyze patient samples for Lactic Acid within five (5) minutes. Personnel 2 confirmed the specimens above failed to be analyzed within 5 minutes for Lactic Acid. III. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Ammonia (Ammon) are analyzed within thirty (30) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for two (2) of eight (8) patients reviewed. Findings: 1. Observation by surveyor on July 16, 2018 revealed the laboratory maintained a Siemens Dimension EXL for : Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Ammonia (Ammon), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Triglyceride (Trig), Creatine Phosphokinase (CPK), Creatine Kinase MB (CKMB), Hemoglobin A1C) (HgbA1C), Troponin (Trop), Direct Bilirubin (DBil), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Amylase (Amy), Lipase (Lip), Magnesium (Mg), Phosphorous (Phos), Prostate Specific Antigen (PSA), Pro- Brain Natriuretic Peptide (Pro-BNP), Iron (Fe), Total Iron Binding Capacity (TIBC), Ferritin (Fer), Folate (Fol), Vitamin B12 (B12), Alcohol (ETOH), Acetaminophen (Acet), Digoxin (Dig),

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| | Phenytoin (Dil), Gentamycin (Gent),Vancomycin (Vanco) and Uric Acid (Uric). 2. Review of the Laboratory's Policy and Procedure Manual which contained a copy of the Siemens Dimension package insert for Ammon revealed that samples are to be analyzed within thirty (30) minutes from collection. 3. Review of a random selection of Patient Test Records from May 3, 2018 through June 28, 2018 revealed the laboratory failed to analyze the following two (2) patients within thirty (3) minutes as required by the manufacturer. On May 10, 2018 Patient 27 was collected at 00:15 AM and not reported until 01:29 AM exceeding the 30 minute time frame by 44 minutes. On June 9, 2018 Patient 28 was collected at 11:55 AM and not reported until 12:33 PM exceeding the 30 minute time frame by 8 minutes. 4. Interview with Personnel 4 on July 18, 2018 confirmed the specimens above failed to be analyzed within 30 minutes for Ammon. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on observation, and interview with laboratory personnel, the laboratory failed to ensure that blood culture vials and ABX Minoclair solutions are not used beyond their expiration dates. Findings: 1. Observation by the surveyors during the tour of the laboratory on July 16, 2018 revealed the following expired items in place for patient testing: One (1) - BD Bactec Peds Plus Culture Vial lot number 7096975 with an expiration date of 2018-01-31. One (1) bottle ABX Minoclair lot number 170206L with an expiration date of 2018-2-06. One (1) bottle ABX Minoclair lot number 161228L with an expiration date of 2017-12-28. 2. Interview with personnel 4 on July 16, 2018 confirmed by observation the items cited were expired and in place for patient testing. II. Based on record review and interview with laboratory personnel, the laboratory failed to ensure that Blood Bank Quality Control, Coombs Control Cells and Antibody Free Plasma are not used beyond their expiration dates. Findings: 1. Interview with Personnel 4 on July 19, 2018 revealed that Blood Bank Quality Control is to be performed and documented every day. Personnel 4 revealed the Antibody Free Plasma is utilized with Immucor Screen Cells 1, 2 and 3 for Antibody Identification. Personnel 4 also revealed the Antibody Free Plasma is taken from known patients with negative antibody screens. Personnel 4 also revealed that the Antibody Free Plasma is utilized for one week and is to be labeled with the Put In Use (PIU) date and the Expiration dates. 2. Review of Blood Bank Quality Control Records from January 1, 2017 through July 16, 2018 revealed the following expired items where documented as being in place for the following thirty (30) days: On September 13, 2017 the laboratory documented the use of: Immucor 0.8% Surgiscreen cells - lot number USS931 with an expiration date of September 6, 2017. Immucor A1 Cells - lot number 111147 with an expiration date of September 8, 2017. Immucor B Cells - lot number 111147 with an expiration date of September 8, 2017. Immucor corQC Cells - lot number 27184 with an expiration date of September 8, 2017. Immucor Coombs Control Cells - lot number 39313 with an expiration date of September 8, 2017. On December 2, 2017 and December 3, 2017 the laboratory documented use of : Immucor corQC Cells - lot number 39323 with an expiration date of December 1, 2017. Immucor Coombs Control Cells - lot number 39313 with an expiration date of December 1, 2017. On December 4, 2017 through December 10, |

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| | 2017 the laboratory documented the use of: Immucor corQC Cells - lot number 43390 with an expiration date of December 1, 2017. For the week of January 22, 2018 through January 28, 2018 the laboratory documented the use of Specimen number 17276 Antibody Free Plasma; however the laboratory failed to document in the Quality Control Records the PIU and Expiration dates on the QC document. For the week of April 2, 2018 through April 8, 2018 the laboratory documented the use of Specimen number 555854 Antibody Free Plasma; the laboratory documented the PIU date as April 2, 2018; however the laboratory failed to document in the Quality Control Records the Expiration date on the QC document. For the week of April 16, 2018 through April 22, 2018 the laboratory documented the use of Specimen number 557690 Antibody Free Plasma; the laboratory documented the PIU date as April 16, 2018; however the laboratory failed to document in the Quality Control Records the Expiration date on the QC document. 3. Review of Corrective Action Logs for the dates cited above revealed the laboratory failed to identify the use or having expired items in place for patient testing and failed to ensure the PIU and Expiration dates are documented every day as policy states. 4. Review of Patient Test Records for the dates cited above revealed the following patients were tested and reported utilizing the expired items; On December 5, 2017: Patient 200 was tested and reported for ABO, Rh, Antibody Screen (AbScr) and Crossmatch (xmatch) for three (3) units of Packed Red Blood Cells (PRBC). NOTE all three (3) units were transfused to the patient. Patient 201 was tested and reported for ABO, Rh, AbScr and xmatch for two (2) units of PRBC. NOTE both (2) units were transfused to the patient. On December 9, 2017: Patient 203 was tested and reported for ABO, Rh, and AbScr. On December 10, 2017: Patient 204 was tested and reported for ABO, Rh, AbScr and Direct Antiglobulin testing. NOTE; Patient test Records were not looked at for the failure of documentation for the use of the Antibody Free Plasma - the laboratory must also review those dates. 2. Interview with personnel 4 on July 19, 2018 confirmed the laboratory failed to identify the issues with expired material in Blood Bank testing. Personnel 4 confirmed the laboratory documented the use of testing patients with expired material in Blood Bank. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Siemens Dimension EXL 200 Chemistry Analyzer. Findings: 1. Observation by surveyor during the laboratory tour on July 5, 2018 revealed the laboratory utilizes the Dimension EXL 200 Chemistry Analyzer for patient testing. 2. Review of Task 1 and 3 Form submitted to the surveyor on July 5, 2018 revealed the laboratory performed Vitamin D testing. Interview with the Laboratory Director revealed that the laboratory began testing Vitamin D in September 2017. 3. Review of the laboratory's verification of performance specification revealed studies for: a) |

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| | Accuracy a) Precision: day to day and operator variance. b) linearity for reportable range c) Reference Range. The laboratory failed to include: Simple Precision. 4. Interview with Personnel 4 on July 18, 2018 revealed technical representative performed the simple precision study when installing the method on the Siemens Dimension EXL 200 Chemistry Analyzer. II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Med TOX scan and Cartridges for Urine Drug Screen (UDS) testing. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 16, 2018 revealed the laboratory was utilizing the MED TOX Scan Analyzer along with the MED TOX Panel Cartridges for performing UDS testing for: Amphetamine (Amph), Methamphetamine (Methamph), Barbiturate (Barb), Benzodiazepine (BZO), Buprenorphine (Bup), Cannabinoids (THC), Cocaine (COC), Ecstasy (MDMA), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Phencyclidine (PCP), Propoxyphene (PPX), and Tricyclic Antidepressants (TCA). 2. Interview with Personnel 4 on July 16, 2018 revealed the laboratory installed the MED TOX Scan and Cartridge System in March 2017. 3. Review of the laboratory's verification of performance specification revealed: a) Correlation Study between the Alere iScreen Drugs of Abuse Dip test and the MED TOX scan and Cartridge System. b) Precision: day-to-day, and run-to-run between March 10, 2017 through April 13, 2017. The laboratory failed to include the following: a) Simple Precision b) Reportable Range. NOTE: The laboratory failed to document who performed any of the testing. 4. Interview with Personnel 4 on July 16, 2018 confirmed the laboratory failed to have a complete performance verification study performed prior to patient testing. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the laboratory failed to ensure the daily cuvette temperature on the Siemens Dimension EXL 200 Chemistry System was maintained between 36.8 - 37.2 degrees Celsius as required by the manufacturer, for three (3) of one hundred eighty one (181) patient test days reviewed. Findings: 1. Review of Laboratory Test Menu revealed the laboratory performed Alanine aminotransferase (ALT), Albumin (ALB), Alcohol (ETOH), Alkaline phosphatase (ALP), Ammonia (Ammon), Amylase (Amy), Aspartate aminotransferase (AST), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatine phosphokinase (CK), Creatine phosphokinase MB Fraction (CKMB), Creatinine (Creat), Folate (Fol), Ferritin (Ferr), Glucose (Glu), Glycosylated Hemoglobin (Hgb A1C), Iron (Fe), Total Iron Binding Capacity (TIBC), Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Pro- Brain Natiuretic Peptide (Pro-BNP), Prostate Specific Antigen (PSA), Total Protein (TP), Sodium (NA), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Blood Urea Nitrogen (BUN), Total Bilirubin (TBil), Direct Bilirubin (DBil), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Triglyceride (Trig), Troponin (Trop), Uric Acid (Uric), Vitamin B12 (B12), Vitamin D (VitD), Acetaminophen (ACTM), Digoxin (DGNA), Gentamycin (Gent), Phenytoin (PTN), Vancomycin (Vanco), testing on the Siemens Dimension EXL 200 Chemistry Analyzer. 2. Review of |

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| | Siemens Dimension Expand Plus Chemistry System Daily Maintenance Log reflected the laboratory was to document a daily temperature reading of the cuvette temperature - which should be maintained between 36.8 - 37.2 degrees Celsius. 3. Review of the Siemens Dimension EXL 200 Chemistry System Operators Manual revealed that when the cuvette temperatures exceeded 36.8 - 37.2 degrees Celsius, no patient results were to be turned out and that Dimension technical service should be contacted. 4. Review of the Siemens Dimension Expand Plus Chemistry maintenance logs from January 1, 2018 through June 30, 2018 revealed the laboratory failed to ensure that the cuvette temperature was maintained between 36.8 - 37.2 degrees Celsius as required by the manufacturer for the following three (3) dates: On February 26, 2018 - a reading of 36.7 degrees Celsius was documented. On February 27, 2018 - a reading of 36.7 degrees Celsius was documented. On February 28, 2018 - a reading of 36.7 degrees Celsius was documented. 5. Review of Corrective Action Logs revealed the laboratory failed to document corrective action for the three (3) days cited above. 6. Interview with personnel 4 on July 19, 2018 confirmed the laboratory failed to ensure the cuvette temperature were maintained between 36.8 - 37.2 degrees Celsius and failed to take corrective action as required by the manufacturer for the three (3) days cited above. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and interview with personnel the laboratory failed to perform a positive and negative control each day of patient testing for Urine Drug Screen (UDS) testing performed on the MED TOX Scan Analyzer for four (4) of one hundred nineteen (119) patient test days. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 16, 2018 revealed the laboratory was utilizing the MED TOX Scan Analyzer along with the MED TOX Panel Cartridges for performing UDS testing for: Amphetamine (Amph), Methamphetamine (Methamph), Barbiturate (Barb), Benzodiazepine (BZO), Buprenorphine (Bup), Cannabinoids (THC), Cocaine (COC), Ecstasy (MDMA), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Phencyclidine (PCP), Propoxyphene (PPX), and Tricyclic Antidepressants (TCA). 2. Review of the Laboratory's Policy and Procedure Manual revealed for the MED TOX Scan Analyzer and Cartridges testing personnel are to perform both electronic and a positive and negative control each day of patient testing. 3. Review of a random selection of Patient Test Records and Quality Control Records for the MED TOX Scan and Cartridges from January 1, 2018 through June 30, 2018 revealed the following four (4) patients were tested and reported without performing a positive and negative control. On March 20, 2018 - Patient 197. On March 23, 2018 - Patient 198. On March 26, 2018 - Patient 199. On April 14, 2018 - Patient 196. 4. Interview with personnel 4 on July 18, 2018 confirmed that a positive and negative control is to be performed and documented each day of patient testing. Personnel 4 confirmed the laboratory failed to document a positive and negative control for the patients and dates cited above. |
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| **D5551** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(a)(f)<br><br>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel, the laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing every day for one (1) of one hundred twenty nine (129) test days reviewed. Findings: 1. Review of the laboratory Blood Bank Procedure Manual reflected quality controls for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing were to be performed (daily) each day of patient testing, and prior to patient testing. Interview with Personnel 4 confirmed on July 19, 2018 that quality control for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing were to be performed each day of patient testing and prior to patient testing. 2. Review of Blood Bank Quality Control Worksheets and patient test records from January 1, 2017 through July 17, 2017 revealed the laboratory failed to perform and document daily quality control prior to patient testing for: On September 3, 2017 - no quality control was performed. Quality control was documented on September 2, 2017 then again on September 4, 2017. 3. Review of Quality Assurance records revealed the laboratory failed to identify and take corrective action to ensure there was no outcome to any patients. 4. Interview with personnel 4 on July 19, 2018 revealed she was unaware the laboratory failed to perform quality control for September 3, 2017. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in the Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems with the analytic system as follows: a) The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. b) The laboratory failed to ensure patient samples performed on the EPOC Blood Analysis system are analyzed within fifteen (15) minutes according to laboratory policy for twenty six (26) |

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| | of eighty one (81) patients reviewed. Refer to D5401 II. c) The laboratory failed to ensure patient samples for Calcium (CA), are analyzed promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5411 I. d) The laboratory failed to ensure patient samples for Lactic Acid, are analyzed within five (5) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for eighty four (84) of eighty eight (88) patients reviewed. Refer to D5411 II. e) The laboratory failed to ensure patient samples for Ammonia (Ammon) are analyzed within thirty (30) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for two (2) of eight (8) patients reviewed. Refer to D5411 III. f) The laboratory failed to ensure that blood culture vials and ABX Minoclair solutions are not used beyond their expiration dates. Refer to D5417 I. g) The laboratory failed to ensure that Blood Bank Quality Control, Coombs Control Cells and Antibody Free Plasma are not used beyond their expiration dates. Refer to D5417 II. h) The laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Siemens Dimension EXL 200 Chemistry Analyzer. Refer to D5421 I. i) The laboratory failed to have complete performance specification verification studies for the Med TOX scan and Cartridges for Urine Drug Screen (UDS) testing. Refer to D5421 II. j) The laboratory failed to ensure the daily cuvette temperature on the Siemens Dimension EXL 200 Chemistry System was maintained between 36.8 - 37.2 degrees Celsius as required by the manufacturer, for three (3) of one hundred eighty one (181) patient test days reviewed. Refer to D5429. k) The laboratory failed to perform a positive and negative control each day of patient testing for Urine Drug Screen (UDS) testing performed on the MED TOX Scan Analyzer for four (4) of one hundred nineteen (119) patient test days. Refer to D5449. l) The laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing each day of patient testing, for one (1) of one hundred twenty nine (129) patient test days reviewed. Refer to D5551. 2. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. 3. Interview with personnel 2, 4 and 13 on July 19, 2007 confirmed the laboratory failed to identify the deficiency cited above. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for five (5) of five (5) new pieces of equipment and for establishing Quality Control performance specifications for the Biomerieux Biofire Filmarray Analyzer. Refer to D 6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 3. The Laboratory |

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| | Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D 6021. 5. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6023. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031. |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(ii)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;<br><br>This STANDARD is not met as evidenced by:<br>Based on observations, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for two (2) of two (2) new analyzers. Findings: 1. The laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Siemens Dimension EXL 200 Chemistry Analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance specification verification studies for the Med TOX scan and Cartridges for Urine Drug Screen (UDS) testing. Refer to D5421 II. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to maintain test requisitions that included the specimen collection date and time as required for four (4) of thirteen (13) patient requisitions reviewed. Refer to D5305. 2. The laboratory failed to ensure patient samples for Potassium (K), Phosphorous (Phos), and Glucose (Glu) are spun and separated within one (1) hour according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for forty two (42) of one hundred seventeen (117) patients reviewed. Refer to D5311 I. 3. The laboratory failed to ensure patient samples for Calcium (CA), are separated from the red cell promptly |

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| | according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5311 II. 4. The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 5. The laboratory failed to ensure patient samples performed on the EPOC Blood Analysis system are analyzed within fifteen (15) minutes according to laboratory policy for twenty six (26) of eighty one (81) patients reviewed.Refer to D5401 II. 6. The laboratory failed to ensure patient samples for Calcium (CA), are analyzed promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5411 I. 7. The laboratory failed to ensure patient samples for Lactic Acid, are analyzed within five (5) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for eighty four (84) of eighty eight (88) patients reviewed. Refer to D5411 II. 8. The laboratory failed to ensure patient samples for Ammonia (Ammon) are analyzed within thirty (30) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for two (2) of eight (8) patients reviewed. Refer to D5411 III. 9. The laboratory failed to ensure that blood culture vials and ABX Minoclair solutions are not used beyond their expiration dates. Refer to D5417 I. 10. The laboratory failed to ensure that Blood Bank Quality Control, Coombs Control Cells and Antibody Free Plasma are not used beyond their expiration dates. Refer to D5417 II. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform a positive and negative control each day of patient testing for Urine Drug Screen (UDS) testing performed on the MED TOX Scan Analyzer for four (4) of one hundred nineteen (119) patient test days. Refer to D5449. 2. Interview with personnel 4 on July 18, 2018 confirmed that a positive and negative control is to be performed and documented each day of patient testing. Personnel 4 confirmed the laboratory failed to document a positive and negative control for the patients and dates cited above. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory |

director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic and analytic system as follows: a) The laboratory failed to maintain test requisitions that included the specimen collection date and time as required for four (4) of thirteen (13) patient requisitions reviewed. Refer to D5305. b) The laboratory failed to ensure patient samples for Potassium (K), Phosphorous (Phos), and Glucose (Glu) are spun and separated within one (1) hour according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for forty two (42) of one hundred seventeen (117) patients reviewed. Refer to D5311 I. c) The laboratory failed to ensure patient samples for Calcium (CA), are separated from the red cell promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5311 II. d) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. e) The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. f) The laboratory failed to ensure patient samples performed on the EPOC Blood Analysis system are analyzed within fifteen (15) minutes according to laboratory policy for twenty six (26) of eighty one (81) patients reviewed. Refer to D5401 II. g) The laboratory failed to ensure patient samples for Calcium (CA), are analyzed promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5411 I. h) The laboratory failed to ensure patient samples for Lactic Acid, are analyzed within five (5) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for eighty four (84) of eighty eight (88) patients reviewed. Refer to D5411 II. i) The laboratory failed to ensure patient samples for Ammonia (Ammon) are analyzed within thirty (30) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for two (2) of eight (8) patients reviewed. Refer to D5411 III. j) The laboratory failed to ensure that blood culture vials and ABX Minoclair solutions are not used beyond their expiration dates. Refer to D5417 I. k) The laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Siemens Dimension EXL 200 Chemistry Analyzer. Refer to D5421 I. l) The laboratory failed to have complete performance specification verification studies for the Med TOX scan and Cartridges for Urine Drug Screen (UDS) testing. Refer to D5421 II. m) The laboratory failed to ensure the daily cuvette temperature on the Siemens Dimension EXL 200 Chemistry System was maintained between 36.8 - 37.2 degrees Celsius as required by the manufacturer, for three (3) of one hundred eighty one (181) patient test days reviewed. Refer to D5429. n) The laboratory failed to perform a positive and negative control each day of patient testing for Urine Drug Screen (UDS) testing performed on the MED TOX Scan Analyzer for four (4) of one hundred nineteen (119) patient test days. Refer to D5449. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality

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| | Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5393 and D5793. 3. Interview with personnel 2, 4 and 13 on July 19, 2018 confirmed the laboratory failed to identify the deficiencies cited above. |
| **D6023** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(6)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, instrument maintenance records and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to ensure the daily cuvette temperature on the Siemens Dimension EXL 200 Chemistry System was maintained between 36.8 - 37.2 degrees Celsius as required by the manufacturer, for three (3) of one hundred eighty one (181) patient test days reviewed. Refer to D5429. 2. Interview with personnel 4 on July 19, 2018 confirmed the laboratory failed to ensure the cuvette temperature were maintained between 36.8 - 37.2 degrees Celsius and failed to take corrective action as required by the manufacturer for the three (3) days cited above. |
| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Test Requisitions to include all the |

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| | required information: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. h) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. Complaint Policies and Procedures Communication Policies and Procedures 2. Interview with Personnel 4 on July 16, 2018 confirmed the policy and procedure manual was incomplete |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight for the laboratory. Refer to D6036. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on July 16, 2018 revealed that personnel 2 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to obtain a written request from the physician for seven (7) of nine (9) patients reviewed. Refer to D5301. b) The laboratory failed maintain test requisitions that included all the required information for nine (9) of nine (9) patients. Refer to D5305. c) The laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Refer to D5311 I. d) The laboratory failed to ensure that a specimen stability study was performed to support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Refer to D5311 II. e) The laboratory failed to document the date and time specimens are received into the laboratory for nine (9) of nine (9) patients reviewed. Refer to D5313. f) The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and |

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| | outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. g)) The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. h) The laboratory failed to ensure patient samples performed on the EPOC Blood Analysis system are analyzed within fifteen (15) minutes according to laboratory policy for twenty six (26) of eighty one (81) patients reviewed. Refer to D5401 II. i) The laboratory failed to ensure patient samples for Calcium (CA), are analyzed promptly according to the manufacturer and Laboratory Policy for ensuring the integrity of patient samples for accurate and reliable testing for forty one (41) of one hundred seventeen (117) patients reviewed. Refer to D5411 I. j) The laboratory failed to ensure patient samples for Lactic Acid, are analyzed within five (5) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for eighty four (84) of eighty eight (88) patients reviewed. Refer to D5411 II. k) The laboratory failed to ensure patient samples for Ammonia (Ammon) are analyzed within thirty (30) minutes according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable testing for two (2) of eight (8) patients reviewed. Refer to D5411 III. l) The laboratory failed to ensure that blood culture vials and ABX Minoclair solutions are not used beyond their expiration dates. Refer to D5417 I. m) The laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Siemens Dimension EXL 200 Chemistry Analyzer. Refer to D5421 I. n) The laboratory failed to have complete performance specification verification studies for the Med TOX scan and Cartridges for Urine Drug Screen (UDS) testing. Refer to D5421 II. o) The laboratory failed to ensure the daily cuvette temperature on the Siemens Dimension EXL 200 Chemistry System was maintained between 36.8 - 37.2 degrees Celsius as required by the manufacturer, for three (3) of one hundred eighty one (181) patient test days reviewed. Refer to D5429. p) The laboratory failed to perform a positive and negative control each day of patient testing for Urine Drug Screen (UDS) testing performed on the MED TOX Scan Analyzer for four (4) of one hundred nineteen (119) patient test days. Refer to D5449. 3. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5393 and D5793. 4. Interview with personnel 2, 4 and 13 on July 19, 2018 confirmed the laboratory failed to identify the deficiencies cited above. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6087. 2. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6093. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6094. |

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| **D6087** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(iii)<br><br>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable test results. Findings: 1. The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. The laboratory failed to ensure that Blood Bank Quality Control, Coombs Control Cells and Antibody Free Plasma are not used beyond their expiration dates. Refer to D5417 II. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy and procedure manual, quality control and patient test records and interview with personnel, the Laboratory Director failed to ensure the laboratory documented the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing every day for one (1) of one hundred twenty nine (129) test days reviewed. Refer to D5551 |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to ensure that Blood Bank Quality Control, Coombs Control Cells and Antibody Free Plasma are not used beyond their expiration dates. Refer to D5417 II. b) The laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing each day of patient testing, for one (1) of one hundred twenty nine (129) patient test days reviewed. Refer to D5551. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors |

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| | failed to identify the deficiencies identified. 3. Interview with personnel 2, 4 and 13 on July 19, 2018 confirmed the laboratory failed to identify the deficiency cited above. |