

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472320	(X3) Date Survey Completed 11/20/2020
Name of Provider or Supplier Mangum Regional Medical Center	Street Address, City, State 1 Wickersham Drive, Mangum, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 11/19,20/2020. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory supervisor and technical consultant at the conclusion of the survey.
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records, and interview with the laboratory supervisor, the laboratory failed to ensure the requirements were met for the specialty of Hematology for D-dimer testing. Findings include: (1) The laboratory failed to perform two levels of quality control testing each eight hours of D-dimer testing. Refer to D5545; (2) The laboratory failed to demonstrate precision and verify the reference range; and failed to ensure the demonstrated reportable range was utilized for D-dimer testing. Refer to D5421.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor and technical consultant, the laboratory failed to have a written general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On 11/19/2020, surveyor #2 reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence competencies had been performed for the general supervisor based on job responsibilities; (2) Surveyor #2 asked the laboratory supervisor and technical consultant if a written policy to evaluate the general supervisor, based on job responsibilities, was available and if competencies had been performed during the review period. Both stated to surveyor #2 on 11/19/2020 at 01:00 pm, a policy to evaluate the general supervisor based on job responsibilities had not been written; and competencies had not been performed.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor and technical consultant, the laboratory failed to review and evaluate proficiency testing results for 2 of 21 events. Findings include: (1) On 11/19/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following failures: (a) Third 2019 Hematology Event (i) Neutrophil, seg, or band - The laboratory failed the results for 1 of 5 samples (DIF-03); (b) First 2020 Hematology Event (i) Monocytes - The laboratory failed the results for 1 of 5 samples (DIF-01). (2) Surveyor #2 could not locate evidence in the records proving the failures had been addressed; (3) Surveyor #2 reviewed the records with the laboratory supervisor and technical consultant, and asked if corrective action had been taken and documented for the failures. The laboratory supervisor stated on 11/19/2020 03:40 pm corrective action had not been taken.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:
Based on a review of a written policy and interview with the laboratory supervisor, the laboratory failed to follow the written policy for performing platelet poor plasma checks. Findings include: (1) On 11/19/2020 at 11:00 am, the laboratory supervisor stated the following to surveyor #1: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Sysmex CA-660 analyzer; (b) The laboratory had a policy to ensure the specimens tested on the analyzer were platelet poor. (2) Surveyor #1 reviewed the policy titled, "Platelet Poor Plasma" which stated, "The laboratory will run 6 Platelet poor plasma

samples every 6 months"; (3) Surveyor #1 then reviewed records for 2020 and identified the platelet-poor plasma checks that had been performed on 02/24/2020 and 08/05/2020 had not been performed utilizing 6 samples as required by policy, instead, the checks had been performed utilizing 5 samples; (4) Surveyor #1 reviewed the records and policy with the laboratory supervisor who stated on 11/19/2020 at 02:00 pm, the laboratory had not followed their written policy.

D5411

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On 11/19/2020 at 11:30 am, the laboratory supervisor stated the following to surveyor #1: (a) The Sysmex CA-660 analyzer was used to perform PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (b) The following reagent lot numbers were put into use 10/15/2020: (i) PT - Innovin reagent, lot #549736 (ii) PTT - Actin FSL reagent, lot #562626 (2) Surveyor #1 reviewed the manufacturer's instructions contained in the "Lot Roll-Over Procedure" for implementing new reagents, which stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (a) Section titled "Verification of Reference Range" (i) "20 Normal Individuals * 10 males; 10 females * Medication History: no aspirin, no hormones, no herbal supplements * 20 is the minimum requirement for statistical validity"; (ii) "Assay samples on current and new lot number reagents simultaneously or within 10 minutes of each other. This data can be used in Section II"; (iii) "Calculate mean and 2 SD range"; (iv) "MNPT for INR calculation should be the geometric mean". (b) Section titled, "Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number reagents simultaneously or within 1 our of each other"; (v) "Calculate Linear Regression statistics". (3) Surveyor #1 reviewed the records for the lot changes with the following identified: (a) PT-Innovin reagent, lot #549736 (i) Normal Range Study - The records showed that, although the laboratory had utilized 37 donors, they were not evenly divided between males and females. The laboratory had utilized 28 females and 9 males. (ii) Method Correlation - The records showed the laboratory had used 68 samples, which consisted of 37 normals and 31 abnormals. The abnormal samples did not span the reportable range of the assay (ranged from 16.1-49.9) and a linear regression had not been calculated. (3) Surveyor #1 reviewed the findings with the laboratory supervisor who stated on 11/19/2020 at 1:20 pm, the manufacturer's instructions had not been followed for the reagent lot changes as specified above.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory supervisor, the laboratory failed to demonstrate precision and verify the reference range; and failed to ensure the demonstrated reportable range was utilized for D-dimer testing. Findings include: (1) On 11/19/2020 at 1:45 pm, the laboratory supervisor stated to surveyor #1 the laboratory began performing D-dimer testing using the Quidel Triage Meter Pro analyzer on 09/26/2019; (2) Surveyor #1 reviewed the performance specification records with the following identified: (a) There was no evidence the precision had been demonstrated; (b) There was no evidence the reference range (normal range) had been verified; (c) The laboratory had demonstrated a reportable range of 271-3950. (3) Surveyor #1 then reviewed the records with the laboratory supervisor and asked if there was documentation to prove the precision had been demonstrated, the reference range had been verified and to ensure the laboratory was utilizing the reportable range that had been demonstrated by the laboratory. The laboratory supervisor stated the following to the surveyor on 11/19/2020 at 2:00 pm: (a) There was no documentation to prove the precision had been demonstrated and the reference range had been verified; (b) The laboratory was using the manufacturer's reportable range of 100-5000, instead of the reportable range of 271-3950 that had been demonstrated by the laboratory. (4) Refer to D5545 for examples of patient D-dimer testing.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor and technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for the Dimension EXL 200 analyzer. Findings include: (1) On 11/19/2020 at 11:42 am, the laboratory supervisor stated to surveyor #2 *CMP, *Lipid Profile, Ammonia, Amylase, BNP (B-Type Natriuretic Peptide), CK (Creatine Kinase), CKMB, Direct Bilirubin, LD (Lactate Dehydrogenase), Lipase, Magnesium, Phosphorus, Uric Acid, Myoglobin, Troponin T, Hemoglobin A1c, HCG (Human Chorionic Gonadotropin), PSA, T4 (Thyroxine), TSH (Thyroid Stimulating Hormone), T3 (Triiodothyronine), Acetaminophen, Digoxin, Dilantin, Alcohol, Salicylate, Valproic Acid, and Vancomycin testing were performed on the Siemens Dimension EXL 200 analyzer; (2) On 11/20/2020, surveyor #1 reviewed the manufacturer's maintenance

requirements as stated on the manufacturer's weekly and monthly maintenance logs titled, "Dimension EXL with LM and Dimension EXL 200 integrated chemistry system Weekly/Monthly Maintenance". The requirements were as follows: (a) Weekly (i) Clean Outside of R2 Probe (ii) Clean Outside of HM Wash Probes (c) Monthly (i) Clean Clot Check Drain on IMT Port (ii) Replace IMT Pump Tubing (iii) Clean IMT System (iv) Replace/Clean Air Filters (v) Stylette HM Wash Probes (vi) Replace HM Pump Heads (vii) Clean R1/R2 Drain (viii) Clean R3 Drain (3) Surveyor #1 then reviewed maintenance records from January through October 2020. The following was identified: (a) Weekly - Not documented as performed between (aa) 05/18/2020 and 06/01/2020 (bb) 09/21/2020 and 10/05/2020 (ii) Monthly (aa) Clean R1/R2 drain not documented as performed in January 2020 (bb) Clean Clot Check Drain on IMT Port not documented as performed in July 2020 (4) Surveyor #1 reviewed the records with the laboratory supervisor who stated on 11/20/2020 at 02:10 pm, the maintenance had not been performed as shown above. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein *Lipid Profile - Total Cholesterol, HDL Cholesterol, Triglyceride

D5537

ROUTINE CHEMISTRY

CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
 Based on a review of records, and interview with the laboratory supervisor, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 2 of 164 patients. Findings include: (1) On 11/20/2020, the laboratory supervisor stated the following to surveyor #1: (a) Blood gas testing (pH, pCO2, pO2) was performed on the iSTAT 1 analyzer using the CG4+ cartridge; (b) Two levels of quality control (QC) materials were tested each 8 hours of patient testing. (2) Surveyor #1 reviewed QC and patient records for testing performed from 01/05/2020 through 11/20/2020 and identified that QC had not been performed each 8 hours of patient testing for 2 of 164 patients tested: (a) Patient tested at 05:41 pm on 03/08/2020; Level 1 and level 3 QC had not been performed after 12:46 on 03/07/2020 (b) Patient tested at 07:55 pm on 09/08/2020; Level 1 and level 3 QC had not been performed after 02:19 pm on 09/07/2020 (3) Surveyor #1 reviewed the records with the laboratory supervisor who stated on 11/20/2020, QC testing had not been performed each 8 hours of patient testing as shown above.

D5545

HEMATOLOGY

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the laboratory supervisor, the laboratory failed to perform two levels of quality control testing each eight hours of D-dimer testing 25 of 25 days of patient testing. Findings include: (1) On 11/19/2020 at 11:00 am, the laboratory supervisor stated the following to surveyor #1: (a) The laboratory began using the Quidel Triage Meter Pro analyzer to perform D-dimer testing on 09/26/2019; (b) Two levels of quality control (QC) materials were performed monthly and with each lot number of test devices. (2) Surveyor #1 asked the the laboratory supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory supervisor stated to surveyor #1 on 11/19/2020 at 01:50 pm the laboratory had not developed an IQCP. Therefore, surveyor #1 determined two levels of QC testing must be performed each eight hours of patient testing; (3) The surveyor reviewed QC and patient testing records during October 2019, December 2019, February 2020, May 2020, August 2020, and October 2020. The review showed two levels of QC testing had not been performed each eight hours of patient D-dimer testing (QC had not been performed on the days of patient testing) for 25 of 25 days of patient testing reviewed; (4) The surveyor reviewed the records with the laboratory supervisor, who stated on 11/19/2020 at 02:00 pm two levels of D-dimer QC testing had not been performed each eight hours of patient testing; (5) The following patient D-dimer testing had occurred when two levels of QC had not been performed (patient number represents the patient ID number): (a) Patient #37909 - testing performed on 10/01/2019 (b) Patient #40116 - testing performed on 10/27/2019 (c) Patient #43917 - testing performed on 12/05/2019 (d) Patient #44570 - testing performed on 12/14/2019 (e) Patient #44737 - testing performed on 12/18/2019 (f) Patient #49263 - testing performed on 02/10/2020 (g) Patient #49660 - testing performed on 02/13/2020 (h) Patient #49822 - testing performed on 02/15/2020 (i) Patient #50353 - testing performed on 02/20/2020 (j) Patient #50947 - testing performed on 02/28/2020 (k) Patient #51022 - testing performed on 02/29/2020 (l) Patient #55340 - testing performed on 05/04/2020 (m) Patient #56300 - testing performed on 05/15/2020 (n) Patient #56910 - testing performed on 05/28/2020 (o) Patient #62498 - testing performed on 08/11/2020 (p) Patient #63223 - testing performed on 08/20/2020 (q) Patient #63681 - testing performed on 08/25/2020 (r) Patient #63722 - testing performed on 08/26/2020 (s) Patient #63963 - testing performed on 08/27/2020 (t) Patient #64074 - testing performed on 08/28/2020 (u) Patient #64207 - testing performed on 08/31/2020 (v) Patient #66960 - testing performed on 10/07/2020 (w) Patient #67388 - testing performed on 10/13/2020 (x) Patient #67637 - testing performed on 10/16/2020 (y) Patient #68746 - testing performed on 10/28/2020

D5555

IMMUNOHEMATOLOGY
 CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the laboratory supervisor and

technical consultant, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected. Findings include: (1) On 11/19/2020 at 10:55 am, the laboratory supervisor stated to surveyor #2 that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 11/20/2020, surveyor #2 reviewed the quarterly refrigerator alarm records for 2019 and 2020. The records indicated the alarm checks had not been performed quarterly. They had not been performed between 09/13/2019 and 01/29/2020; (3) Surveyor #2 reviewed the records with the laboratory supervisor and technical consultant. The laboratory supervisor stated on 11/20/2020 at 03:35 pm, the alarm checks had not been performed quarterly as required.

D5559

IMMUNOHEMATOLOGY
CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of written policies and interview with the laboratory supervisor and nurse manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 7 of 8 units of packed red blood cells. Findings include: (1) On 11/19/2020 at 10:55 am, the laboratory supervisor stated to surveyor #2 that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) Surveyor #2 reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood Administration" under the section titled, "Monitoring during Infusion", stated: (a) "Vital signs are taken immediately prior to obtaining the blood, with fifteen (15) minutes after initiating the transfusion; every 15 minutes for the first hour, every 30 minutes for one hour, then every hour until 1 hour AFTER the transfusion had been discontinued."; (3) Surveyor #2 then reviewed records for 8 units of PRBCs (Packed Red Blood Cells) that had been transfused between 06/04/2019 through 04/06/2020 for 3 patients, and identified the following for 7 of 8 units: (a) Vitals within 15 minutes after initiating the infusion (i) Patient #10012724 - Transfused with 1 unit of PRBCs (unit #W091019267556) on 08/26/2019. The infusion started at 10:52 am and the next documented vital was taken at 11:10 am (18 minutes later); (ii) Patient #10018352 - Transfused with 1 unit of PRBCs (unit #W091020181473) on 04/06/2020. The infusion started at 11:20 am and the next documented vital was taken at 11:43 (23 minutes later). (b) Vital Signs every 15 minutes for the first hour (i) Patient #19910400 - Transfused with 1 unit PRBCs (unit #W091019204515) on 06/04/2019. The infusion started at 12:45 pm and ended at 03:45 pm. Vitals were taken at 01:00 pm, 01:15 pm and 02:15 pm (1 hour later); (ii) Patient #10012724 - Transfused with 1 unit of PRBCs (unit #W091019273613) on 08/26/2019. The infusion started at 01:00 pm and ended at 03:35 pm. Vitals were taken at 01:15 pm and 01:45 pm (30 minutes

later); (iii) Patient #10013058 - Transfused with 1 unit of PRBCs (unit #W091019317844) on 09/13/2019. The infusion started at 09:40 am and ended at 11:50 am. Vitals were taken at 09:55 am, 10:10 am, and 10:40 (30 minutes later); (iv) Patient #10013058 - Transfused with 1 unit of PRBCs (unit #W0910336175) on 09/17/2019. The infusion started at 04:56 am and ended at 07:18 am. Vitals were taken at 05:11 am, 05:31 am (20 minutes later); (c) One hour post infusion (i) Patient #19910400 - Transfused with 1 unit of PRBCs (unit #W091019204515) on 06/04/2019. The infusion started at 12:45 pm and ended at 03:45 pm. The last documented vital after the infusion was stopped was taken at 03:45 pm; (ii) Patient #10012724 - Transfused with 1 unit of PRBCs (unit #W091019273613) on 08/26/2019. The infusion started at 01:00 pm and ended at 03:35 pm. The last documented vital after the infusion was stopped was taken at 03:35 pm; (iii) Patient #10013058 - Transfused with 1 unit of PRBCs (unit #W091019313186) on 09/13/2019. The infusion started at 12:40 pm and ended at 02:00 pm. The last documented vital after the infusion was stopped was taken at 02:15 pm; (iv) Patient #10013058 - Transfused with 1 unit of PRBCs (unit #W0910336175) on 09/17/2019. The infusion started at 04:56 am and ended at 07:18 am. The last documented vital after the infusion was stopped was taken at 07:18 am; (v) Patient #10018352 - Transfused with 1 unit of PRBCs (unit #W091020181477) on 04/06/2020. The infusion started at 03:33 pm and ended at 05:59 pm. The last documented vital after the infusion was stopped was taken at 05:39 pm. (4) Surveyor #2 reviewed the findings with the director of nursing. The nurse manager stated on 11/20/2020 at 03:30 pm, the written policy and procedure for blood administration had not been followed as indicated above.

D5791

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

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

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, written policies, observation, and interview with the laboratory supervisor, technical consultant, and nurse manager, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the written policy for performing platelet poor plasma checks. Refer to D5401; (b) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Refer to D5411; (c) The laboratory failed to demonstrate precision and verify the reference range; and failed to ensure the demonstrated reportable range was utilized for D-dimer testing. Refer to D5421; (d) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for the Dimension EXL 200 analyzer. Refer to D5429; (e) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 2 of 164 patients. Refer to 5537; (f) The laboratory failed to perform two levels of quality control testing each eight hours of D-dimer testing 25 of 25 days of patient testing. Refer to D5545; (g) The laboratory failed to ensure units of blood were stored under appropriate

	<p>conditions that included an adequate temperature alarm system that is regularly inspected. Refer to D5555; (h) The laboratory failed to ensure that written policies provided safety for individuals being transfused for 7 of 8 units of packed red blood cells. Refer to D5559.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure verification procedures for a new test system were adequate to determine the performance characteristics of a new test system. Findings include: (1) The laboratory director failed to ensure the laboratory demonstrated precision and verified the reference range; and failed to ensure the demonstrated reportable range was utilized for D-dimer testing. Refer to D5421.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p>

	<p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure two levels of quality control testing had been performed each eight hours of D-dimer testing. Refer to D5545.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.</p>
<p>D6035</p>	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State</p>

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

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor and technical consultant, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 1 of 6 competency evaluations performed. Findings include: (1) On 11/19/2020, surveyor #2 reviewed records for 6 persons performing moderate complexity testing in 2018, 2019, and 2020. The records showed the evaluation for 1 of 6 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 12/07/2018 evaluation had been performed by the laboratory supervisor (this person had earned an associate degree in an applied science). (2) Surveyor #2 reviewed the records with the laboratory supervisor and technical consultant and explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory supervisor stated on 11/19/2020 at 04:30 pm, the above evaluation had been performed by an individual who did not meet the educational qualifications of a technical consultant.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor and technical consultant, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for 1 of 2 testing persons. Findings include: (1) On 11/19/2020, surveyor #2 reviewed 2019 and 2020 personnel records. The following was identified: (a) Testing Person #5 - The initial training for this person was completed on 09/03/2019. There was no evidence that a semiannual evaluation had been performed (due 03/20); (2) Surveyor #2 reviewed the records with the laboratory supervisor and technical consultant who stated on 11/19/2020 at 04:30 pm there were no records to prove the above person had been evaluated semiannually.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor and technical consultant, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 5 of 6 testing persons. Findings include: (1) On 11/19/2020 at 10:05 am, the laboratory supervisor stated to surveyor #2: (a) D-Dimer testing was performed in the laboratory using the Alere Triage Meter; (b) CBC (Complete Blood Count) was performed in the laboratory using the Sysmex XN 550; (c) Blood Gas testing was performed in the laboratory using the iSTAT analyzer; (d) Routine Chemistry testing was performed in the laboratory using the Dimension EXL 200 analyzer; (e) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing was performed in the laboratory using the Sysmex CA 660 analyzer; (f) Serum Ketone testing was performed in the laboratory using the Biorex K-Chek tablets; (g) Wet Prep examinations were performed in the laboratory; (h) KOH examinations were performed in the laboratory; (i) Urinalysis testing was performed in the laboratory using the Clintek Advantus analyzer; (j) Urine Drug testing was performed in the laboratory using the Med/Tox Scan analyzer. (2) Surveyor #2 then reviewed 2019 and 2020 personnel records for 7 persons performing the above testing. The records showed that evaluations had been performed but not signed by the laboratory director or designee as follows: (a) Testing Person #1 - Evaluation performed on 06/01/2020; (b) Testing Person #2 - Evaluation performed on 06/01/2020; (c) Testing Person #3 - Evaluations performed on 06/24/2020; (d) Testing Person #4 - Evaluations performed on 04/20/2019 and 06/29/2020; (e) Testing Person #5 - Evaluations performed on 06/01/2020. (3) Surveyor #2 reviewed the findings with laboratory supervisor and technical consultant. The laboratory supervisor stated on 11/19/2020 at 12:00 pm the above evaluations were not signed by the laboratory director and/or designee as indicated above.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case,

prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory supervisor and technical consultant, the technical supervisor failed to ensure evaluations included all high complexity testing performed for 5 of 6 testing persons. Findings include: (1) On 11/19/2020 at 10:25 am, the laboratory supervisor stated to surveyor #2: (a) High Complexity Testing Includes: (i) Immunohematology - Crossmatches, including ABO /Rh typing, Antibody screens, Compatibility testing using the tube method. (2) Surveyor #2 then reviewed 2019 and 2020 personnel records for 7 persons performing the above testing. The records showed that evaluations had been performed but not signed by the laboratory director or designee as follows: (a) Testing Person #1- Evaluation performed on 06/01/2020; (b) Testing Person #2 - Evaluation performed on 06/01/2020; (c) Testing Person #3 - Evaluations performed on 06/24/2020; (d) Testing Person #4 - Evaluations performed on 04/20/2019 and 06/29/2020; (e) Testing Person #5 - Evaluations performed on 06/01/2020. (4) Surveyor #2 reviewed the findings with laboratory supervisor and technical consultant. The laboratory supervisor stated on 11/19/2020 at 12:05 pm the above evaluations were not signed by the laboratory director and/or the technical supervisor as indicated above.