Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472787	03/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Newman Memorial Hospital	905 S Main St, Shattuck, 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 03/05/19 through 03/07/19. The findings were reviewed with the technical consultant, general supervisor, testing person #1, chief operating officer and interim chief nursing officer during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1405; D6000: Laboratory Director, Moderate Complexity 493.1409; D6033: Technical Consultant
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. The following was identified for 5 of 16 testing events: (a) Third 2018 Hematology/Coagulation Event (i) The attestation was not signed by the laboratory director or designee; (b) Second 2018 Microbiology Event (i) The attestation was not

	signed by the laboratory director or designee; (c) First 2018 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee; (d) Third 2018 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee; (e) Second 2018 Chemistry Miscellaneous Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the technical consultant and testing person #1 who stated the attestations had not been signed as indicated above.
D5024	HEMATOLOGY CFR(s): 493.1215 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. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #1, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for establishing normal reference intervals for a new coagulation analyzer. Refer to D5411; (2) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791; (3) The laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population for coagulation testing. Refer to D5807.
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 technical consultant and testing person #1, the laboratory failed to review and evaluate proficiency testing results. Findings include: BIASES (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2018 Chemistry Core Event (i) D-Dimer - 3 of 5 results exhibited a negative bias (aa) CM-01 - SDI of -2.1 (bb) CM-03 - SDI of -2.0 (cc) CM-04 - SDI of -2.4 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the technical consultant and testing person #1, and asked if the biases had been addressed. The technical consultant and testing person #1 stated the biases had not been addressed. FAILURES (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. The following failures were identified, in which corrective action documentation could not be located: (a) Third 2017 Chemistry Core Event (i) pCO2 - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (b) Third 2017 Hematology Event (i) Blood Cell identification - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (2) The surveyor asked the technical

	consultant and testing person #1 if corrective action had been taken for the failures. After reviewing the records, the technical consultant and testing person #1 stated corrective action had not been taken for the failures.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2018 Second Event (aa) BCI (Blood Cell Identification) sample BCI-13 (bb) BCI sample BCI-14 (cc) BCI sample BCI-10 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the technical consultant and testing person #1 if the results had been documented as evaluated. The technical consultant and testing person #1 reviewed the records and stated the non-graded results had not been documented as reviewed. NOTE: D5215 was cited on the recertification survey performed on 05/10,11,12/17
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #1, the laboratory failed to follow the manufacturer's instructions. Findings include: (1) On the third day of the survey, the technical consultant and testing person #1 stated to the surveyor the Sysmex CA-660 analyzer was put into use to perform PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplastin Time) and D-Dimer testing on 08/11 /17; (2) The surveyor reviewed the manufacturer's instructions for establishing a normal reference interval (the manufacturer required the establishment of a reference interval with a new analyzer). The manufacturer referred the reader to CLSI C28-A3c for information about establishing a reference interval which stated, "As indicated in this document, the working group endorses its previous recommendation that the best means to establish a reference interval is to collect samples from a sufficient number of qualified reference individuals to yield a minimum of 120 samples for analysis, by nonparametric means, for each partition (eg, sex, age range)." In addition, the

	manufacturer required the following for establishing a normal reference interval: (a) "Donors must be from a healthy population (no known pathological conditions)"; (b) "Donors should not take any medications, including aspirin". (3) The surveyor reviewed the implementation records for the analyzer. The following was identified for PT, PTT and D-Dimer: (a) The lot numbers that were in use when the analyzer was implemented (and currently in use) were: (i) PT Reagent - Siemens Dade Innovin lot #539364 (ii) PTT Reagent - Siemens Actin FSL lot #556902 (iii) D-Dimer - Siemens Innovance lot #47320 (b) The normal reference intervals had been established for PT, PTT and D-Dimer as follows: (i) 21 donors had been utilized for PT, PTT and D-Dimer (instead of the 120 donors as required for establishment studies for a new analyzer); (ii) 10 of the 21 donors did not meet the criteria as follows: (aa) 9 donors were on aspirin therapy (bb) 1 donor had a known pathological condition (Hypothyroidism) (4) The surveyor reviewed the records with the technical consultant and testing person #1 who stated the following: (a) The laboratory did not perform the 120 sample study; (b) 10 of the 21 donors did not meet the healthy population criteria. (5) The following were examples of patient testing performed when the normal reference intervals had not been established for the new analyzer as required: (a) PT /INR (i) Patient #1 - Testing performed on 09/01/17 (ii) Patient #2 - Testing performed on 09/05/17 (iii) Patient #3 - Testing performed on 09/12/17 (iv) Patient #5 - Testing performed on 09/21/17 (v) Patient #7 - Testing performed on 10/02/17 (vi) Patient #9 - Testing performed on 10/09/17 (vii) Patient #10 - Testing performed on 10 /23/17 (viii) Patient #12 - Testing performed on 11/06/17 (ix) Patient #13 - Testing performed on 11/16/17 (x) Patient #14 - Testing performed on 11/24/17 (xi) Patient #16 - Testing performed on 01/11/18 (xii) Patient #19 - Testing performed on 02/03 /18 (xiii) Patient #20 - Testing performed on 02/12/18 (ix) Patient #22 - Testing performed on 03/08/18 (xv) Patient #23 - Testing performed on 03/20/18 (xvi) Patient #24 - Testing performed on 03/29/18 (xvii) Patient #26 - Testing performed on 04/18 /18 (xviii) Patient #30 - Testing performed on 06/30/18 (xiv) Patient #31 - Testing performed on 07/12/18 (xx) Patient #33 - Testing performed on 08/15/18 (xxi) Patient #36 - Testing performed on 10/02/18 (xxii) Patient #37 - Testing performed on 11/05 /18 (xxiii) Patient #38 - Testing performed on 12/13/18 (b) PTT (i) Patient #4 - Testing performed on 09/14/17 (ii) Patient #6 - Testing performed on 09/25/17 (iii) Patient #8 - Testing performed on 10/09/17 (iv) Patient #17 - Testing performed on 01 /15/18 (v) Patient #18 - Testing performed on 01/30/18 (vi) Patient #21 - Testing performed on 02/25/18 (vii) Patient #22 - Testing performed on 03/08/18 (viii) Patient #23 - Testing performed on 03/20/8 (ix) Patient #25 - Testing performed on 04/05/18 (x) Patient #27 - Testing performed on 05/03/18 (xi) Patient #29 - Testing peformed on 06/01/18 (xii) Patient #32 - Testing performed on 07/25/18 (xiii) Patient #34 - Testing performed on 08/29/18 (xiv) Patient #35 - Testing performed on 09/15/18 (c) D-Dimer (i) Patient #11 - Testing performed on 10/26/17 (ii) Patient #15 - Testing performed on 01/03/18 NOTE: D5411 previously cited on recertification survey performed on 05/15,16,17/17
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to perform a negative and positive control material each day of patient testing. Findings include: CLOSTRIDIUM DIFFICILE (1) On the first day of the survey, the technical consultant and testing person #1 stated to the surveyor Clostridium difficile testing was performed using the Alere C. Diff Quik Chek Complete test kit; (2) The surveyor asked the technical consultant and testing person #1 if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The technical consultant and testing person #1 stated an IQCP had been developed and approved by the laboratory director on 02/19/19. Therefore, the surveyor determined negative and positive QC (quality control) materials must be performed each day of patient testing before the laboratory director approved the IQCP on 02/19/19; (3) The surveyor reviewed QC and patient testing records for November 2017 through January 2018. The review indicated negative and positive QC materials had not been performed 4 of 4 days of patient testing reviewed. The specific days were 11/05/17, 01/08/18, 01/18/18 and 01/26/18; (4) The surveyor reviewed the records with the technical consultant and testing person #1. The technical consultant and testing person #1 stated negative and positive QC materials had not been performed each day of patient testing prior to implementing the IQCP. ARTERIAL BLOOD GAS TESTING (1) On the first day of the survey, the technical consultant and testing person #1 stated to the surveyor Arterial Blood Gas (G3+ cartridge: pH, pCO2, pCO2) testing was performed using the Abbott iSTAT analyzer; (2) The surveyor asked the technical consultant and testing person #1 if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The technical consultant and testing person #1 stated an IQCP had been developed and approved by the laboratory director on 02/19/19. Therefore, the surveyor determined negative and positive QC (quality control) materials must be performed each day of patient testing before the laboratory director approved the IQCP on 02/19/19; (3) The surveyor reviewed QC and patient testing records for December 2018 through January 2019. The review indicated negative and positive QC materials had not been performed 3 of 3 days of patient testing reviewed. The specific days were 01/20/19, 01 /21/19 and 01/25/19; (4) The surveyor reviewed the records with the technical consultant and testing person #1. The technical consultant and testing person #1 stated negative and positive QC materials had not been performed each day of patient testing prior to implementing the IQCP. IMMUNOHEMATOLOGY TESTING (1) On the first day of the survey, the laboratory supervisor stated to the surveyor that the laboratory performed the following Immunohematology testing: (a) Type and Screen Testing - consisted of ABO/Rh and Antibody Screen; (b) Crossmatch Testing - consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)); (2) On the second day of the survey, the surveyor reviewed records for Immunohematology testing performed during May 2017 through January 2018. Quality control testing had not been performed for 2 of 11 days when patient Type and Screen or Crossmatch testing had been performed as follows: (a) Patient #49 - A Type and Screen was performed on 05 /25/17. A positive ABO control, positive and negative Rh controls, positive and negative AHG (Anti-human globulin) controls, and positive Antibody Screen control had not been documented as performed; (b) Patient #50 - A crossmatch was performed on 07/27/17 (two units of O Positive Packed Red Blood Cells were transfused). A positive ABO control, positive and negative Rh controls, positive and negative AHG (Anti-human globulin) controls, and positive Antibody Screen control had not been documented as performed. (3) The surveyor reviewed the records with the technical consultant and testing person #1, who stated there was no evidence quality control testing had been performed as indicated above.

D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 technical consultant and testing person #1, the laboratory failed to comply with 21 CFR 606.160(b)(3)(ii). The laboratory failed to visually inspect units of packed red blood cells immediately before distribution. Findings include: (1) On the second day of the survey, the technical consultant and testing person #1 stated to the surveyor, the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) The surveyor reviewed patient blood bank records from 05/25/17 through 12/03/18. For 7 of 37 units checked out by the laboratory, there was no evidence a visual inspection had been performed immediately before distribution; (3) The findings were discussed with the technical consultant and testing person #1 who stated visual inspections were being performed, but not documented.
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, written policy and interview with the technical consultant, general supervisor and testing person #1, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: BLOOD BANK THERMOGRAPH CHARTS (1) On the second day of the survey, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor reviewed 19 refrigerator charts dated from 12/29/17 through 06/01/18. The review indicated that 5 of 19 charts had not been changed by the 7th day of usage as follows: (a) Chart #6 - The chart was put into use on 09/07/18 and removed on 09 /28/19 (22 days); (b) Chart #11 - The chart was put into use on 10/26/18 and removed on 11/03/18 (9 days); (c) Chart #12 - The chart was put into use on 11/03/18and removed on 11/12/18 (10 days); (d) Chart #14 - The chart was put into use on 11/19 /18 and removed on 12/10/18 (22 days); (e) Chart #16 - The chart was put into use on 12/17/18 and removed on 12/25/18 (9 days). (3) The surveyor reviewed the charts with the technical consultant and testing person #1, who stated the charts had not been changed by the 7th day of usage as indicated above. BLOOD BANK ALARM

	CHECK (1) On the first day of the survey, the technical consultant and the general supervisor stated to the surveyor 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 the second day of the survey, the laboratory manager stated to the surveyor Blood Bank alarms were checked quarterly for high/low activation; (3) The surveyor reviewed the refrigerator alarm check records from June 2017 through February 2019. The records indicated the alarm checks had not been performed quarterly. They had not been performed between 05/30/18 and 02/22/19; (4) The surveyor reviewed the records with the technical consultant and testing person #1 who stated the alarm checks had not been performed quarterly as required.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant and testing person #1, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for establishing normal reference intervals for a new coagulation analyzer. Refer to D5411; (b) The laboratory failed to perform a negative and positive control each day of patient testing. Refer to D5449; (c) The laboratory failed to visually inspect units of packed red blood cells immediately before distribution. Refer to D5553; (d) The laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected. Refer to D5555.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population and failed to make appropriate reference ranges available. Findings include: HEMATOLOGY (1) On the first day of the survey, the technical consultant and testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex XNL-450 analyzer; (2) On the third day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 02/11/19 at 09:44 pm; the second report was for an adult female patient with the testing performed

	on 03/06/19 at 06:50 pm. Both reports included the same reference intervals for the CBC parameter of RBC (Red Blood Cell) which was: (a) RBC - 4.37 - 5.80 x 10E12 /L (3) The surveyor reviewed the findings with the technical consultant and testing person #1, who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals. COAGULATION NORMAL REFERENCE RANGE (1) On the third day of the surveyor, the technical consultant and testing person #1 stated the Siemens CA-660 analyzer was put into use on 08/11/17; (2) The surveyor reviewed the implementation records for the current lot numbers of reagents. The following was identified: (a) PT Reagent (i) Siemens Dade Innovin, lot #549704 put into use on 04/18/18; (ii) The normal reference range that had been established was 8.3 - 11.5 seconds. (3) The surveyor then reviewed a patient PT report: (a) Patient #1 - Testing performed on 03 /06/19 with the following reference range: (i) PT reference range of 9.3 - 11.4 seconds. (4) The surveyor reviewed the findings with the technical consultant and testing person #1 who stated the established normal reference ranges for PT were not included on the patient report.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions and interview with the technical consultant and testing person #1, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer to D6016; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021. (4) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions and interview with the technical consultant and testing person #1, the laboratory director failed to ensure test

	methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the laboratory followed manufacturer's instructions for establishing normal reference intervals for a new coagulation analyzer. Refer to D5411.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. It was identified for 1 of 16 events, the attestation statements had been signed approximately 3 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Second 2018 Immunohematology Event - The samples had been tested on 08/17 /18 and the attestation statement had not been signed by the laboratory director until 11 /16/18. (2) The surveyor reviewed the findings with the technical consultant and testing person #1 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that 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 a review of records, manufacturer's instructions, observation and interview with the technical consultant and testing person #1, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)

	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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure verified coagulation reference ranges were available. Refer to D5807.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation and interview with laboratory manager, 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 establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation and interview with technical consultant and testing person #1, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the manufacturer's instructions were followed for establishing normal reference intervals for a new coagulation analyzer. Refer to D5411; (2) The technical consultant failed to ensure reference intervals were determined as appropriate for the laboratory's patient population for coagulation testing. Refer to D5807.