Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472440	09/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Elkview General Hospital	429 West Elm, Hobart, 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 09/04/18 through 09/07/18. The laboratory was found out of compliance with the following CLIA regulations: 493.1201; D5002: Bacteriology 493.1213; D5022: Toxicology 493.1215; D5024: Hematology 493.1250; D5400: Analytic Systems 493.1405; D6000: Laboratory Director Moderate Complexity 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory manager, laboratory director, and chief executive officer during an exit conference performed at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's storage instructions for a waived analyzer. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor Urinalysis testing was performed on the Clinitek Status analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirement for the analyzer. The manufacturer required the operating temperature be maintained within the range of 18 - 30 degrees Celsius; (3) The surveyor reviewed laboratory temperature records between January 2018 through July 2018, which verified the temperature readings were less than 18 degrees Celsius for 1 of 7 months as follows: (a) May 2018 - 4 of 31 temperature readings were documented as less than 18 degrees Celsius (days 20,25,26,27). (4) The surveyor reviewed the records with laboratory manager who stated the temperature of the laboratory had been maintained below 18 degrees Celsius as indicated above.

D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the subspecialty of Bacteriology. Findings include: (1) The laboratory failed to perform a negative and positive control each day of patient Clostridium difficile testing. Refer to D5449; (2) The laboratory failed to perform quality control checks for the urine culture media. Refer to D5477; (3) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology. Findings include: (1) The laboratory failed to perform a negative and positive control each day of patient Urine Drug Screen testing. Refer to D5449; (2) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 laboratory manager, 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 follow the manufacturer's quality control specifications. Refer to D5479; (3) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 manager, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2017 Hematology Event (i) Neutrophils - 3 of 5 results exhibited a negative bias (aa) Sample HSY-03 - SDI of -2.1 (bb) Sample HSY-04 - SDI of -2.3 (cc) Sample HSY-05 - SDI of -2.1 (b) First 2017 Chemistry Core Event (i) CK (Creatine Kinase) - 4 of 5 results exhibited a negative bias (aa) Sample CH-02 - SDI of -3.3 (bb) Sample CH-03 - SDI of -3.5 (cc) Sample CH-04 - SDI of -3.3 (dd) Sample CH-05 - SDI of -3.4 (c) Second 2017 Chemistry Core Event (i) CKMB - 3 of 5 results exhibited a negative bias (aa) Sample CM-06 - SDI of -2.1 (bb) Sample CM-07 - SDI of -2.2 (cc) Sample CM-10 - SDI of -2.5 (ii) D-Dimer - 3 of 5 results exhibited a negative bias (aa) Sample CM-06 - SDI of -2.3 (bb) Sample CM-09 - SDI of -2.9 (cc) Sample CM-10 - SDI of -2.9 (d) First 2018 Chemistry Core Event (i) BG (Blood Gas) - 3 of 5 results exhibited a negative bias (aa) Sample BG-02 - SDI of -2.2 (bb) Sample BG-04 - SDI of -2.4 (cc) Sample BG-05 - SDI of -2.1 (e) Second 2018 Chemistry Core Event (i) D-Dimer - 3 of 5 results exhibited a negative bias (aa) Sample CM-06 - SDI of -2.1 (bb) Sample CM-09 - SDI of -2.5 (cc) Sample CM-10 - SDI of -2.1 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager who stated the biases had not been addressed.
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 laboratory manager, the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Coagulation (i) 2018 second event (aa) PTT (Partial Thromboplastin Time) COA-07 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) The surveyor asked the laboratory manager if the result had been documented as evaluated. The laboratory manager reviewed the records and stated the non-graded result had not been documented as reviewed.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to provide written instructions to clients collecting and referring hematology and chemistry specimens. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex KX-21N analyzer; (i) Hematology specimens were transported to the laboratory from outside home health agencies and long term care facilities. (b) Routine chemistry testing was performed using the Ortho Vitros 350 analyzer; (i) Routine chemistry specimens were transported to the laboratory from outside home health agencies and long term care facilities. (2) The surveyor asked the laboratory manager if instructions (e.g., client service manual) had been written and provided to the home health agencies which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager stated specimen handling instructions had not been written and provided to the clients.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to ensure materials were being stored as required. refer to D5413; (2) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (3) The laboratory failed to visually inspect units of packed red blood cells immediately before distribution. Refer to D5553; (4) 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; (5) The laboratory failed to have a policy for monitoring the effectiveness of their IQCP and failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for establishing normal reference intervals for a new coagulation analyzer. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor a new ACL Elite analyzer was put into use to perform PT/INR (Protime /International Normalized Ratio) and PTT (Partial Thromboplastin Time) on 09/11 /17; (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions for establishing a normal reference interval which stated (the laboratory did not have the instructions, however, the surveyor had a copy of the instructions obtained from other laboratories using the same test system): (a) "You must decide before starting which type of study to perform. Will you perform a full reference interval study or will you be verifying a previous reference interval? Either 120 or 20 normal donors following these screening guidelines": (i) "Donors should be healthy and have no known pathological conditions. Don't use patients (they are at the hospital for a medical reason). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high dose aspirin, etc. Donors should span the adult age range. Pediatric ranges should be established separately. Donors should be equally divided between male/female". (b) In addition, the instructions stated, "If you choose to do a full reference interval study, test 120 donors. Ideally specimens will be analyzed over a number of days, resulting in values that represent average run-to-run variation. If you choose to verify a range, you may use a 20-donor study under specific conditions. The main conditions are as follows: The original site must have done a full reference range study The original site must have used the identical type of analytical system (method, instrument and reagents)". (3) To determine if the laboratory should perform a 20 or 120 sample study, the surveyor asked laboratory manager if the laboratory had ever performed a full reference interval study (120 sample study) on the ACL 1000 analyzer (the previous analyzer). The laboratory manager stated there was no evidence to prove a 120 sample study had ever been performed. Based on the manufacturer's guidelines, the surveyor determined an initial 120 sample study was required, then subsequent studies may be performed using 20 samples due to the following: (a) There was no evidence a 120 sample study had been performed on the previous analyzer (ACL 1000). (4) The surveyor reviewed the implementation records for the analyzer. The following was identified for PT and PTT (a) The lot numbers that were in use when the analyzer was implemented were: (i) PT Reagent - RecombiPlasTin 2G lot #N0378719 (ii) PTT Reagent - SynthASil Lot #N0479501 (b) The normal reference intervals had been established for each test performed on the analyzer as follows: (i) PT and PTT (aa) 22 donors had been utilized. (5) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated the following: (a) The laboratory did not perform the 120 sample study; (6) The following were examples of patient testing performed when the normal reference intervals had not been established for the new analyzer as required: (a) Patient #34 - PT/INR and PTT testing performed on 09/19/17 at 12:22 pm (b) Patient #35 - PT/INR and PTT testing performed on 09/28/17 at 01:07 pm (c) Patient #36 - PT/INR and PTT testing performed on 10/07/17 at 04:35pm (d) Patient #37 - PT/INR and PTT testing performed on 10/18/17 at 04:14 pm (e) Patient #38 - PT/INR and PTT testing performed on 11/07/17 at 10:05 am (f) Patient #39 - PT/INR and PTT testing

	performed on 11/20/17 at 08:59 am (g) Patient #40 - PT/INR and PTT testing performed on 12/01/17 at 06:13 am (h) Patient #41 - PT/INR and PTT testing performed on 12/12/17 at 06:12 am (i) Patient #42 - PT/INR and PTT testing performed on 12/24/17 at 06:17 am (j) Patient #43 - PT/INR and PTT testing performed on 01/30/18 at 03:25 pm (k) Patient #44 - PT/INR and PTT testing performed on 02/15/18 at 06:28 am (l) Patient #45 - PT/INR and PTT testing performed on 03/07/18 at 07:30 pm (m) Patient #46 - PT/INR and PTT testing performed on 03/29/18 at 07:35 am (n) Patient #47 - PT/INR and PTT testing performed on 04/22/18 at 07:46 am (o) Patient #48 - PT/INR and PTT testing performed on 05/04/18 at 11:10 am (p) Patient #49 - PT/INR and PTT testing performed on 05/30/18 at 01:56 pm (q) Patient #50 - PT/INR and PTT testing performed on 06/20/18 at 07:30 am
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's storage instructions, observation of the draw station, and interview with the laboratory manager, the laboratory failed to ensure materials were being stored as required. Findings include: (1) On the first day of the survey, the surveyor observed the outpatient draw station, located directly outside of the laboratory. The following were examples of materials being stored in the area, along with the manufacturer's storage requirements: (a) 5 tubes of BD Vacutainer Buff. Na Citrate 3.2% blood collection tubes (lot #8061550); the storage requirement was 4-25 degrees C; (b) 6 tubes of BD Vacutainer Lithium Heparin blood collection tubes (lot #8032745); the storage requirement was 4-25 degrees C; (c) 30 tubes of BD Vacutainer SST (Serum-Separating Tube) blood collection tubes (lot #8081771); the storage requirement was 4-25 degrees C. (2) The surveyor reviewed temperature records for January 2018 through August 2018 and could not locate documented temperature records for the outpatient draw station; (3) The surveyor asked the laboratory manager if the temperature of the draw station was being monitored. The laboratory supervisor stated the laboratory was not monitoring the temperature of the outpatient draw station.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the

	laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: HEMATOLOGY (1) On the first day of the survey, the laboratory manager stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex KX-21N analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for monthly maintenance were as follows: (a) Clean Orifice (b) Clean WBC/RBC Transducer (3) The surveyor then reviewed maintenance records for 13 months (January 2017 through January 2018). There was no evidence the monthly maintenance had been performed as follows: (a) Clean Orifice (i) Between 02/27/17 and 05/31/17 (4) The surveyor reviewed the records with the laboratory manager, who stated the maintenance had not been performed as required. CHEMISTRY (1) On the first day of the survey, the laboratory manager stated to the surveyor that routine chemistry testing was performed on the Ortho Vitros 350 analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Weekly (i) Clean tray platform and transport arm (ii) Clean cup retainer (iii) Clean diluent bottles (iv) Clean tip locator assembly (v) Clean control unit screen (vi) Clean keypad cover (vii) Inspect, clean and/or replace air filter (3) The surveyor then reviewed maintenance records for 8 months (January 2018 through August 2018). The following was identified: (a) There was no evidence the weekly maintenance had been performed: (i) Between 03/14/18 and 03 /28/18 (4) The surveyor reviewed the records with the laboratory manager, who stated the maintenance had not been performed as required. ARTERIAL BLOOD GAS (1) On the first day of the survey, the laboratory manager stated to the surveyor that Arterial Blood Gas (pH, pO2, pCO2) testing was performed on the Nova Stat Profile pHOx analyzer; (2) On the third day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Weekly (i) Record Electrode Slopes Weekly (3) The surveyor then reviewed maintenance records for 8 months (January 2018 through August 2018). The following was identified: (a) There was no evidence the weekly maintenance had been performed: (i) Between 01 /10/18 and 01/24/18 (ii) Between 05/23/18 and 06/06/18 (4) The surveyor reviewed the records with the laboratory manager, who stated the maintenance had not been performed as required.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform a negative and positive control each day of patient testing. Findings include: MEDTOX SCAN PROFILE II (1) On the first day of the survey, the laboratory manager stated to the surveyor qualitative urine drug screen testing was performed using the MedTox Scan Profile II ER analyzer; (2) Later on the first day of the survey, the laboratory manager stated to the surveyor negative and positive QC

	(quality control) testing were performed each week of patient testing, new lots and shipments; (3) The surveyor asked the laboratory manager if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory manager stated an IQCP had been developed but not documented as approved by the laboratory director. Therefore, the surveyor determined negative and positive QC testing must be performed each day of patient testing; (4) The surveyor reviewed QC and patient testing records from January 2018 through August 2018. The review indicated negative and positive QC testing had not been performed 24 of 24 days of patient testing; (5) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated a positive and negative urine drug screen quality control materials had not been tested each day of patient testing; (6) The following urine drug screen patient testing had occurred when QC testing had not been performed: (a) Patient #1 - testing performed on 01/19/18 (b) Patient #2 - testing performed on 01/25 /18 (c) Patient #3 - testing performed on 02/02/18 (d) Patient #4 - testing performed on 02/06/18 (e) Patient #5 - testing performed on 02/11/18 (f) Patient #6 - testing performed on 02/18/18 (g) Patient #7 - testing performed on 02/23/18 (h) Patient #8 - testing performed on 03/03/18 (i) Patient #9 - testing performed on 03/19/18 (j) Patient #10 - testing performed on 04/03/18 (k) Patient #11 - testing performed on 04 /18/18 (l) Patient #12 - testing performed on 04/29/18 (m) Patient #13 - testing performed on 05/02/18 (n) Patient #14 - testing performed on 05/09/18 (o) Patient #15 - testing performed on 05/30/18 (p) Patient #16 - testing performed on 06/05/18 (q) Patient #17 - testing performed on 06/16/18 (r) Patient #18 - testing performed on 06 /21/18 (s) Patient #19 - testing performed on 07/03/18 (t) Patient #20 - testing performed on 07/10/18 (u) Patient #21 - testing performed on 07/19/18 CLOSTRIDIUM DIFFICILE (1) On the first day of the survey, the laboratory manager stated to the surveyor Clostridium difficile (C. diff) testing was performed using the Wampole C. diff QuikChek Complete test kit; (2) On the second day of the survey, the laboratory supervisor stated the following to the surveyor: (a) The laboratory had been performing negative and positive QC testing with new lot numbers of test kits and had not developed an IQCP; (3) The surveyor reviewed QC and patient testing records from January 2018 through August 2018. The review indicated negative and positive QC testing had not been performed 13 of 13 days of patient testing reviewed; (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated negative and positive QC materials had not been performed each day of patient testing; (5) The following were examples of patient C. diff testing when QC testing had not been performed: (a) Patient #22 - testing performed on 01/03/18 (b) Patient #23 - testing performed on 01/29/18 (c) Patient #24 - testing performed on 02/20/18 (d) Patient #25 - testing performed on 03 /06/18 (e) Patient #26 - testing performed on 03/23/18 (f) Patient #27 - testing performed on 04/02/18 (g) Patient #28 - testing performed on 04/30/18 (h) Patient #29 - testing performed on 05/07/18 (i) Patient #30 - testing performed on 05/21/18 (j) Patient #31 - testing performed on 06/06/18 (k) Patient #32 - testing performed on 07 /06/18 (l) Patient #33 - testing performed on 07/14/18 (m) Patient #34 - testing performed on 08/20/18
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics

	of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform quality control checks for the urine culture media. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed: (a) Urine culture testing, with presumptive identifications (growth or no growth) reported, using Remel TSA (Tryptic Soy Agar) 5% Sheep Blood/EMB (Eosin Metholylene Blue) Agar biplates; (2) The surveyor asked the laboratory manager if quality control (QC) checks (the ability to support growth) were performed on each batch of media, received into the laboratory from 1/1 /18-present. The laboratory manager stated QC testing had not been performed. The surveyor then asked the laboratory manager if an IQCP (Individualized Quality Control Plan) had been developed for the media used in the laboratory. The laboratory manager stated an IQCP had not been developed. Therefore, the surveyor determined QC checks must be performed on each batch of media received, as appropriate; (3) The surveyor reviewed the "Micro Log Specimen" for patient testing between 01/11 /18 through 07/19/18. The lot numbers used for patient testing could not be determined during the review period. The following were examples of patient testing performed when QC had been performed on the media: (a) Patient #61 - Innoculated on 01/11/18 (b) Patient #62 - Innoculated on 02/28/18 (c) Patient #63 - Innoculated on 04/24/18 (d) Patient #64 - Innoculated on 05/30/18 (e) Patient #65 - Innoculated on 06 /04/18 (f) Patient #66 - Innoculated on 06/21/18 (g) Patient #67 - Innoculated on 06/22 /18 (h) Patient #68 - Innoculated on 07/12/18 (i) Patient #69 - Innoculated on 07/19/18
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's quality control specifications. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) A new ACL Elite analyzer was put into use (09/11/17) to perform PT/INR (Protime/International Normalized Ratio) and PTT (Partial Thromboplastin Time); (b) Two levels of Hemosil QC (Quality Control) materials (level 1 and level 3) were tested each hours of patient testing. (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions for the control materials. They stated, "The mean of the control range determined in your laboratory may vary due to the lot of reagent used. Due to differences in reagents and instrumentation, each laboratory should establish its own Target Value and Aceptance Range (mean and standard deviation)"; (3) The surveyor then reviewed quality control records for the current lot numbers of control materials used for patient testing from 09 /11/17 through 03/14/18. The laboratory manager stated the laboratory had used the package insert means and limits for each level of control instead of establishing their own means and limits as stated in the manufacturer's package insert: (a) Hemosil

	Level 1 (Lot# N0277897) and Level 3 (lot #N0177403) - Used from 09/11/17 through third day of the survey; (4) The surveyor reviewed the findings with the laboratory manager who stated the laboratory had not established their own means and limits of acceptability, but instead used the manufacturer's package insert limits; (5) The following were examples of patient PT/INR and PTT testing when the laboratory failed to establish quality control means and limits: (a) Patient #51 - PT/INR and PTT testing performed on 09/20/17 (b) Patient #52 - PT/INR and PTT testing performed on 10/13/17 (c) Patient #53 - PT/INR and PTT testing performed on 11/01/17 (d) Patient #54 - PT/INR and PTT testing performed on 11/27/17 (e) Patient #55 - PT/INR and PTT testing performed on 12/05/17 (f) Patient #56 - PT/INR and PTT testing performed on 12/26/17 (g) Patient #57 - PT/INR and PTT testing performed on 01/19 /18 (h) Patient #58 - PT/INR and PTT testing performed on 02/02/18 (i) Patient #59 - PT/INR and PTT testing performed on 02/21/18 (j) Patient #60 - PT/INR and PTT testing performed on 03/14/18
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 laboratory manager, 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 laboratory manager stated 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 05/04/18 through 08/29/18. For 2 of 84 units checked out by nursing personnel, there was no evidence visual inspections had been performed immediately before distribution; (3) The findings were discussed with the laboratory manager 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 and interview with the laboratory manager, 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 the first day of the survey, the laboratory manager 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 for 2017 through the second day of the survey (09/05/18). The records indicated the alarm checks had not been performed quarterly. They had not been performed between 06/20/17 and 11/01/17; (4) The surveyor reviewed the records with the laboratory manager 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 laboratory manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP, and failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: ALERE TRIAGE METER PRO (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory performed CKMB, Troponin I and D-dimer testing using the Alere Triage Meter Pro analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 11/14/16). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results. There was no evidence of QA reviews since the IQCP effective date; (3) The surveyor reviewed the records with the laboratory manager, and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if QA reviews had been performed since the IQCP had been implemented. The laboratory manager stated a policy had not been written and QA reviews had not been performed. ANALYTIC QUALITY ASSESSMENT (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 ensure materials had been stored as required. Refer to D5413; (c) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (d) The laboratory failed to perform a negative and positive control each day of patient testing. Refer to D5449; (e) The laboratory failed to perform quality control checks for the urine culture media. Refer to D5477; (f) The laboratory failed to follow the manufacturer's specifications for establishing normal reference intervals for a new coagulation analyzer. Refer to D5479; (g) The laboratory failed to visually inspect units of packed red blood cells immediately before distribution. Refer to D5553; (h) 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.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, 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 qualuty control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation and interview with the laboratory manager, 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; (2) The laboratory director failed to ensure materials were being stored as required. Refer to D5413; (3) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429; (4) The laboratory director failed to ensure the manufacturer's quality control specifications were followed. Refer to D5479.
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 laboratory manager, 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 and 2018 proficiency testing records. It was identified for 8 of 22 events, the attestation statements had been signed approximately 2-4 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) First 2017 Chemistry Miscellaneous Event - The samples had been tested on 05/09/17 and the attestation statement had not been signed by the laboratory director until 07/06/17; (b) Second 2017 Chemistry Miscellaneous Event - The samples had been tested on 10/26 /17 and the attestation statement had not been signed by the laboratory director until 01 /04/18; (c) Third 2017 Hematology/Coagulation Event - The samples had been tested on 11/27/17 and the attestation statement had not been signed by the laboratory director until 01/04/18; (d) Second 2017 Microbiology Event - The samples had been tested on 06/24/17 and the attestation statement had not been signed by the laboratory director until 10/16/17; (e) Second 2018 Chemistry Core Event - The samples had been tested on 06/05/18 and the attestation statement had not been signed by the laboratory director until 08/08/18; (f) First 2018 Hematology/Coagulation Event - The samples had been tested on 03/21/18 and the attestation statement had not been signed by the laboratory director until 05/31/18; (g) First 2018 Microbiology Event - The samples had been tested on 03/01/18 and the attestation statement had not been signed by the laboratory director until 05/31/18; (h) Second 2018 Microbiology Event - The samples had been tested on 06/27/18 and the attestation statement had not been signed by the laboratory director until 08/08/18. (2) The surveyor reviewed the findings with the laboratory manager 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.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory manager, the laboratory director failed to ensure a qualuty control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure a negative and positive control each day of patient testing. Refer to D5449; (2) The laboratory director failed to ensure quality control checks for the urine culture media were performed. Refer to D5477.
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 laboratory manager, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure a policy for monitoring the effectiveness of their IQCP, and failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 laboratory manager, 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 materials were being stored as required. Refer to D5413; (3) The technical consultant failed to ensure the manufacturer's instructions for performing maintenance procedures were followed. Refer to D5429; (4) The technical consultant failed to ensure negative and positive control materials were tested each day of patient testing. Refer to D5449; (5) The

	technical consultant failed to ensure quality control checks were performed for the urine culture media. Refer to D5477; (6) The technical consultant failed to ensure the manufacturer's quality control specifications were followed. Refer to D5479.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure that evaluations included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing. Findings include: (1) On the first day of the survey, the laboratory manager stated Crossmatching (ABO/Rh type, Antibody Screen, and Compatibility) testing were performed using the tube method; (2) The surveyor reviewed personnel records for 5 persons performing Crossmatching testing, who had evaluations performed in 2017 and 2018. For 5 of 5 persons, there was no evidence that direct observations of routine patient test performance, including patient preparation, specimen handling, processing, and testing had been included as part of the evaluations. The specific findings were: (a) Testing Person #1 - The evaluation form was completed on 03/04/17 and 08/08/17; (b) Testing Person #2 - The evaluation form was completed on 03/06/17 and 05/30/18; (c) Testing Person #3 - The evaluation form was completed on 03/04/17 and 08/08/18; (d) Testing Person #4 - The evaluation form was completed on 07/06/17 and 08/08/18; (e) Testing Person #5 - The evaluation form was completed on 02/28/18 and 08/13/18. (3) The findings were discussed with the laboratory manager who stated there was no documentation to prove the evaluations above included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing.
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure that evaluations included monitoring the recording and reporting of test results. Findings include: (1) On the first day of the survey, the laboratory manager stated Crossmatching (ABO/Rh type, Antibody Screen, and Compatibility) testing were performed using the tube method; (2) The surveyor reviewed personnel records for 5 persons performing Crossmatching testing, who had evaluations performed in 2017 and 2018. For 5 of 5 persons, there was no evidence that monitoring the recording and reporting of test results had been included as part of the evaluations. The specific findings were: (a) Testing Person #1 - The evaluation form was completed on 03/04/17 and 08/08/17; (b) Testing Person #2 - The evaluation form was completed on 03/06/17 and 05/30/18; (c) Testing Person #3 - The

	evaluation form was completed on 03/04/17 and 08/08/18; (d) Testing Person #4 - The evaluation form was completed on 07/06/17 and 08/08/18; (e) Testing Person #5 - The evaluation form was completed on 02/28/18 and 08/13/18. (3) The findings were discussed with the laboratory manager who stated there was no documentation to prove the evaluations above included monitoring the recording and reporting of test results.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure that evaluations included the review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. Findings include: (1) On the first day of the survey, the laboratory manager stated Crossmatching (ABO/Rh type, Anitbody Screen, and Compatibility) testing were performed using the tube method; (2) The surveyor reviewed personnel records for 5 persons performing Crossmatching testing, who had evaluations performed in 2017 and 2018. For 5 of 5 persons, there was no evidence that a review of test results or worksheets, quality control records, and preventive maintenance records had been included as part of the evaluations. The specific findings were: (a) Testing Person #1 - The evaluation form was completed on 03/04 /17 and 08/08/17; (b) Testing Person #2 - The evaluation form was completed on 03 /06/17 and 05/30/18; (c) Testing Person #3 - The evaluation form was completed on 03 /04/17 and 08/08/18; (d) Testing Person #4 - The evaluation form was completed on 07/06/17 and 08/08/18; (e) Testing Person #5 - The evaluation form was completed on 02/28/18 and 08/13/18. (3) The findings were discussed with the laboratory manager who stated there was no documentation to prove the evaluations above included the review of test results or worksheets, quality control records and preventive maintenance records.