Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475185	01/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Northeastern Health System, Tahlequah	1400 E Downing St, Tahlequah, 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 01/21,22,23,24/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, cardiopulmonary department director, AVP of quality, safety, and accreditation, AVP of clinical nursing, AVP operational nursing, technical consultant #1, and laboratory manager during an exit conference performed at the conclusion of the survey.
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 technical consultant #1 and the laboratory manager, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee, or analyst(s) for 4 of 20 events. Findings include: (1) On the second day of the survey, surveyor #1 and surveyor #3 reviewed 2018 and 2019 proficiency testing records, with the following identified: (a) Third 2018 Hematology/Coagulation Event - The attestation statement had not been signed by the analyst(s); (b) Third 2018 Chemistry Core Event - The attestation statement had not been signed by the analyst(s); (c) First 2019 Hematology/Coagulation Event -

	The attestation statement had not been signed by the laboratory director or designee; (d) Third 2019 Hematology/Coagulation Event - The attestation statement had not been signed by the laboratory director/designee. (2) Surveyor #1 reviewed the records with technical consultant #1 and the laboratory manager. Both stated the attestation statements had not been signed by the the laboratory director or analyst(s), as indicated above. D2015 was cited on the recertification survey performed on 03/12, 13,14,15,16/18.
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 technical consultant #1 and the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for 1 of 20 events. Findings include: (1) On the second day of the survey, surveyor #1 and surveyor #3 reviewed 2018 and 2019 proficiency testing records and identified the following failures: (a) Second 2018 Chemistry Miscellaneous Event (i) Body Fluid Cholesterol - The laboratory failed the results for 2 of 3 samples (BCH-04 and BCH-06); (ii) Body Fluid pH (quantitative) - The laboratory failed the result for 1 of 3 samples (BCH-05); (iii) Parathyroid Hormone - The laboratory failed the result for 1 of 3 samples (IAT-06). (2) The records were then reviewed further by the surveyors. There was no evidence corrective action had been taken for the above failures; (3) Surveyor #1 reviewed the records with technical consultant #1 and the laboratory manager, and asked if corrective actions had been taken and documented for the failures. Both stated corrective actions had not been taken. D5211 was cited on the recertification survey performed on 03/12/,13,14,15,16/18.
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 technical consultant #1 and the laboratory manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 1 of 20 events. Findings include: (1) On the second day of the survey, surveyor #1 and surveyor #3 reviewed 2018 and 2019 proficiency testing records. The review verified the laboratory did not address results that were not graded by the proficiency testing program as follows: (a) First 2019 Microbiology Event for Susceptibility Testing (i) Cefotetan - The result had not been evaluated by the proficiency testing program. Under "Expected Result" it stated, "See Data Summary." There was no evidence the laboratory reviewed the data summary to evaluate their result; (ii) Cefuroxime - The result had not been evaluated by the proficiency testing program. Under "Expected

	Result" it stated, "See Data Summary." There was no evidence the laboratory reviewed the data summary to evaluate their result. (2) Surveyor #1 reviewed the records with technical consultant #1 and the laboratory manager. Both stated the laboratory had not evaluated the results that were not graded by the proficiency testing program.
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 policies and procedures and interview with technical consultant #1, the laboratory failed to have written procedures for all testing performed by the laboratory. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors the laboratory put the Diesse Mini-Cube automated ESR (Erythrocyte Sedimentation Rate) analyzer into use on 08/21/19; (2) On the third day of the survey, surveyor #2 reviewed the laboratory's policy and procedure manual, but could not locate a written procedure for performing ESR testing using the Diesse Mini-Cube analyzer. The procedure manual contained the operator's manual for the Streck ESR Auto-Plus (used by the analyzer prior to the Diesse Mini-Cube); (3) Surveyor #2 reviewed the findings with technical consultant #1 and asked if the laboratory had a written procedure available. Technical consultant #1 stated to surveyor #2 the laboratory did not have a written procedure for the new test device. 39088 Based on a review of written policies and interview with technical consultant #1 and the laboratory manager, the laboratory failed to ensure written policies were followed for the identification of outpatients receiving blood transfusions, for 2 of 2 patients. Findings include: (1) On the second day of the survey, technical consultant #1 and the laboratory manager stated the laboratory collected Blood Bank specimens prior to admission for Blood Bank testing; (2) Surveyor #3 reviewed the hospital policy regarding positive identification of outpatients. Policy, titled "BLOOD BANK ARMBANDS - OUTPATIENTS" stated the following: (a) "PROCEDURE: On Day of Specimen Collection: (i) "1. Initiate Blood Bank Outpatient Questionnaire. a. Fill in blanks for procedure date and name. b. Answer blood bank history questions. c. Obtain patient signature and date. d. Have patient read and sign the Consent/Refusal to Receive Blood Products." (ii) "2. When specimen is collected, complete the second section of questionnaire. Complete all information on the band." (iii) "3. Bring questionnaire, blood bank identification armband, specimens and labels to Blood Bank." (iv) "4. Perform testing according to policy." (v) "5. Attach blood bank identification band to questionnaire and place in designated folder in blood bank." (3) Surveyor #3 reviewed 2 outpatients and identified the following: (a) Patient #11858 - Blood Bank specimen collected on 10/07/19; There was no documentation of a Bank Bank Outpatient Questionnaire in the patient's EMR; (b) Patient #96021 - Blood Bank specimen collected on 10/08/19; There was no documentation of a Bank Bank Outpatient Questionnaire in the patient's EMR. (4) Surveyor #3 reviewed the findings with technical consultant #1 and the laboratory manager, who stated the Blood Bank questionnaires could not be located as indicated above.
D5409	PROCEDURE MANUAL

	CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of written policies and procedures, and interview with technical consultant #1, the laboratory failed to indicate procedures no longer in use as discontinued, with the discontinued date. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors the laboratory performed automated ESR (Erythrocyte Sedimentation Rate) testing using the Diesse Mini-Cube analyzer, which was put into use on 08/21/19 and replaced the Streck ESR Auto Plus; (2) On the third day of the survey, surveyor #2 reviewed the laboratory's written policies and procedures and identified the manufacturer's operating manual for the Streck ESR Auto Plus, which was used as the procedure for the device. A note "Analyzer Retired" was attached to the manual but the date of discontinuance was not documented; (3) Surveyor #2 reviewed the findings with technical consultant #1 who stated the manufacturer's operating manual had not been dated with the discontinued date. NOTE: D5409 was cited at the recertification survey performed 03/12/18-03/16 /2018.
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 technical consultant #1, the laboratory manager, and testing person #4, the laboratory failed to follow the manufacturer's instructions for the testing performed in the laboratory. Findings include: RSV (1) On the first day of the survey, technical consultant #1 stated to the surveyors RSV (Respiratory Syncytial Virus) antigen testing was performed using the BD Veritor RSV test device and the BD System Reader with nasal wash specimens collected in transport media; (2) Surveyor #2 reviewed the manufacturer's package insert for the RSV test system. Under the heading "Reporting of Results" it stated, (a) "Negative Test: Negative for the presence of RSV antigen. Infection due to RSV cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. A negative test is presumptive and it is recommended that these results be confirmed by viral cell culture or an FDA-cleared RSV molecular assay." (3) Surveyor #2 asked technical consultant #1 if the laboratory reported negative RSV patient test results as presumptive and if they were confirmed by viral cell culture or molecular assay. Technical consultant #1 stated to surveyor #2 negative RSV results were reported as final and follow-up viral cultures or molecular assays were not performed when the RSV results were negative; (4) The RSV testing logs were reviewed for 3 months (January, May, and August 2019). Surveyor #2 identified during the review period, the laboratory had not confirmed 26 of 26 negative patient RSV results by a viral cell culture or by molecular assay on 8 of the 93 days reviewed. The specific days of

testing when negative RSV results had not been confirmed, were as follows: (a) January 2019-Days: 01,07,14,20,31 (b) May 2019-Days: 04,25 (c) August 2019-Day: 25 INFLUENZA A AND B (1) On the first day of the survey, technical consultant #1 stated to the surveyors Influenza A&B antigen testing was performed using the BD Veritor Influenza A+B test device and the BD System Reader with specimens collected by nasal wash and nasalpharyngeal swab in transport media; (2) Surveyor #2 reviewed the manufacturer's package insert for the Influenza test system. Under the heading "Intended Use" it stated, (a) "A Negative test is presumptive and it is recommended that these results be confirmed by viral cell culture or an FDA-cleared Influenza A and B molecular assay;" (b) "Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions." (3) Surveyor #2 asked technical consultant #1 if the laboratory reported negative Influenza A and B patient test results as presumptive and if they were confirmed by viral cell culture or molecular assay. Technical consultant #1 stated to surveyor #2 negative Influenza A and B results were reported as final and follow-up viral cultures or molecular assays were not performed when the results were negative; (4) The Influenza A and B testing logs were reviewed for 3 months (January, May, and August 2019). Surveyor #2 identified during the review period, the laboratory had not confirmed 288 of the 288 patient samples negative for Influenza A and Influenza B results by a viral cell culture or by molecular assay on 43 of the 92 days reviewed. The specific days of testing when negative Influenza A and Influenza B results had not been confirmed were as follows: (a) January 2019-Days: 01,02,03,04,07, 08,09,10,11,12,13,14,15,16,17, 18,19,20,21,22, 23,24,25,26,27,28 (b) May 2019-Days: 03,08,14,18,20,30 (c) November 2019-Days: 01,06,11, 14,16,18,19,21,25,28,29 PT/INR AND PTT (1) On the first day of the survey, technical consultant #1 stated to the surveyors the ACL Top 300 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) (the INR was calculated using the PT reference interval mean) and PTT (Partial Thromboplastin Time) testing; (2) Surveyor #2 observed the refrigerator where the testing reagents were stored and identified the following reagents and QC (Quality Control) materials (testing person #4 verified with surveyor #2 the reagents were currently in use): (a) PT - HemosIL RecombiPlasTin 2G, Lot #N0696813 (b) PTT - HemosIL SynthASil, Lot #N0696834 (c) HemosIL Normal Control, Lot #N0394776 (d) HemosIL Abnormal Control, Lot #556507 (3) Surveyor #2 then reviewed the manufacturer's instructions contained in the "Changing Lot Numbers" for implementing new lot numbers of reagents, which stated: (a) "Reference Interval should be established whenever there is a change in Lot number of reagent and at least once a year;" (b) In addition, the manufacturer stated the following: (i) "Follow these screening guidelines:" (aa) "Donors should be healthy" (i.e. have no known pathological conditions, no in-patients, should not be on medication affecting coagulation, including but not limited to oral contraceptives, estrogen therapy (HRT), anticoagulants, high-dose aspirin, etc.); (bb) "Pediatric ranges should be established separately;" (cc) "Donors should be equally divided between male/female;" (dd) "The original site must have done a full reference range study;" (ee) "20-donor study: Your 20 donors must fairly represent your population and the population of the original study." (4) Surveyor #2 reviewed the lot change records from 2018 through 2019. In the Normal Reference Interval study performed between 09/29/19-10/04/19, surveyor #2 identified the laboratory used 9 normal pediatric donor samples instead of the 20 required by the manufacturer, as follows: (a) PT: (i) RecombiPlasTin 2G, Lot #N0696813 (Put into use on 10/21 /19); (ii) The laboratory used samples from 4 normal pediatric male donors (between 3 and 13 years old) and 5 normal pediatric female donors (between 3 and 18 years old); (iii) There was no documentation in the records why the laboratory had not used 20 normal pediatric donor samples. (b) PTT: (i) SynthASil, Lot #N0696834 (Put into

	use on 10/22/19); (ii) The laboratory used samples from 4 normal pediatric male donors (between 3 and 13 years-old) and 5 normal pediatric female donors (between 3 and 18 years old); (iii) There was no documentation in the records why the laboratory had not used 20 normal pediatric donor samples. (5) The findings were reviewed with technical consultant #1 and technical consultant #2, who stated the manufacturer's instructions had not been followed for the reagent lot change as specified above and stated there was no documentation in the records why the laboratory failed to collect the 20 normal patient samples to verify the pediatric normal reference interval, as required by the manufacturer.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to ensure the cryostat was stored as required by the manufacturer for 3 of 12 months. Findings include: (1) On the third day of the survey, the laboratory manager stated to surveyor #3 the laboratory prepared frozen sections using the Leica CM 1860 Cryostat. The sections were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by the pathologist; (2) Surveyor #3 reviewed the manufacturer's requirement for humidity of, "Relative humidity, maximum 60% (non-condensing),"; (3) Surveyor #3 then reviewed humidity records for 12 months (January 2019 through December 2019). It was identified that documented humidity readings were greater than 60% on days of patient testing for 3 of 12 months reviewed as follows: (a) June 2019 - 1 of 30 days (i) 06/18/19 - 63% (b) July 2019 - 1 of 31 days (i) 07/29/19 - 72% (c) September 2019 - 2 of 32 days (i) 09/13/19 - 62% (ii) 09/17/19 - 63% (4) Surveyor #3 reviewed the records with the laboratory manager who stated the cryostat had not been stored according to manufacturer's instructions as listed above. D5413 was cited on the recertification survey performed on 03/12/,13,14,15,16/18.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to ensure containers of staining materials had been labeled with lot numbers and

	expiration dates. Findings include: (1) On the third day of the survey, the laboratory manager stated to surveyor #3: (a) Frozen sections were performed in the frozen section room located near the surgery department; (b) The specimens were stained using H&E (Hematoxylin & Eosin). (2) Surveyor #3 observed the current staining materials with technical consultant #2. The following was identified: (a) The Coplin jar containing the Hematoxylin stain and the Coplin jar containing the Eosin stain had not been labeled with the manufacturer's lot numbers and expiration dates; (3) Surveyor #3 explained to the laboratory manager the containers must be labeled with the lot numbers and expiration dates of the materials.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to use materials that had not expired. Findings include: (1) On the third day of the survey, the laboratory manager stated to surveyor #3, frozen sections were performed in the frozen section room located near the surgery department; (2) The surveyor observed the bottle labeled, "Amm. H2O" stored in the cabinet of the frozen section room, with an expiration date of 12/19/19; (3) Surveyor #3 showed the bottle to the laboratory manager and asked if it was currently being used for patient testing. The laboratory manager stated it could not be determined if the bottle labeled "Ammon. H2O" was currently in use and was not aware it had expired. D5417 was cited on the recertification survey performed on 03/12/,13,14,15,16/18.
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 perform maintenance procedures as required by the manufacturer of the cryostat. Findings include: (1) On the third day of the survey, the laboratory manager stated to surveyor #3 the Leica Cryostat was used to perform frozen sections; (2) Surveyor #3 reviewed the manufacturer's annual requirements located in Section 9.3 of the Operator's Manual, which required the following maintenance: (a) "At least once a year, have the instrument inspected by a qualified service engineer authorized by Leica". (3) Surveyor #3 then reviewed records from January through December 2019 and identified the following: (a) There was no documentation to prove the annual maintenance had performed in 2019. (4) Surveyor #3 reviewed the findings with the laboratory manager. The laboratory manager stated the annual maintenance had not been documented as performed in 2019. D2015 was cited on the recertification survey performed on 03/12,13,14,15,16 /18.

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and the laboratory manager, the laboratory failed to perform calibration verification procedures at least once every 6 months for the analyte Ammonia. Findings include: (1) On the fourth day of the survey, the laboratory manager stated to surveyor #1 Ammonia testing was performed using two Cobas 6000 analyzers (the analyzers were denoted by the laboratory as CE1 and CE2); (2) Surveyor #1 reviewed 2019 calibration records with technical consultant #1, and identified calibration procedures had been performed with two levels of calibrators. Since the calibration procedures included only two levels, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) Surveyor #1 reviewed calibration verification records for 2018 and 2019 for both analyzers, and identified calibration verification had not been performed for Ammonia as follows: (a) Analyzer CE1 - Between 05/15/18 and 10/20 /19; (b) Analyzer CE2 - Between 04/26/18 and 12/27/18. (4) Surveyor #1 then reviewed the records with the laboratory manager, who stated calibration verification procedures had not been performed for the analyte Ammonia as indicated above.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (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 technical consultant #1, the

	laboratory failed to test one control material each 8 hours of operation when performing manual counts using a hemacytometer during 4 of 5 months reviewed. Findings include (1) On the first day of the survey, technical consultant #1 stated to the surveyors the laboratory performed manual WBC (White Blood Cell) and RBC (Red Blood Cell) counts on CSF (Cerebral Spinal Fluid) and body fluids using a hemacytometer; (2) On the third day of the survey, surveyor #2 reviewed the "Hematology Body Fluid Control Log" from 5 months-August 2018; February, August, October, and November 2019. The QC (Quality Control) logs did not include the time the QC materials had been tested during 4 of the 5 months reviewed when 11 patients had been tested. The specific findings follow: (a) August 2018: (i) On 08/29 /18, QC Level 1 (Lot #81270411) and Level 2 (Lot #81270413) had been tested, but the time had not been documented; (ii) Manual WBC and RBC counts had been performed on CSF from Patient #21016210: Tube #1 and Tube #4; (iii) There was no documentation which proved the laboratory tested one level of QC materials each 8 hours of patient manual cell count testing. (b) August 2019: (i) QC Level 1 (Lot #92100411) and Level 2 (Lot #92100413) had been tested on 08/10/19, 08/13/19, 08 /14/19, 08/16/19, 08/18/19, and 08/30/19, but the times had not been documented; (ii) Manual WBC and RBC counts had been performed, as follows: (aa) 08/10/19, on CSF from Patient #230520; (bb) 08/13/19, on CSF from Patient #087119; (cc) 08/14/19, on CSF from Patient, Accession #58-19-226-0030; (dd) 08/16/19, on CSF from Patient #35800; (ee) 08/18/19, on Ascites fluid from Patient #1009143; (ff) 08/30/19, on CSF from Patient, Accession #58-19-242-0539; (iii) There was no documentation which proved the laboratory tested one level of QC materials each 8 hours of patient manual cell count testing. (c) October 2019: (i) QC Level 1 (Lot #92100411) and Level 2 (Lot #92100413) had been tested on 10/04/19 and 10/22/19, but the times had not been documented; (ii) Patient manual WBC and RBC counts had been performed, as follows: (aa) 10/04/19, on CSF from Patient, Accession #58-19-277-0496; (bb) 10/22 /19, on CSF from Patient #1036959; (cc) 10/22/19, on CSF from Patient, Accession #58-19-295-0670; (iii) There was no documentation which proved the laboratory tested one level of QC materials each 8 hours of patient manual cell count testing. (d) November 2019: (i) QC Level 1 (Lot #92100411) and Level 2 (Lot #92100413) had been tested on 11/13/19, but the time had not been documented; (ii) Manual WBC and RBC counts had been performed on CSF from Patient, Accession #58-19-317-0400; (iii) There was no documentation which proved the laboratory tested one level of QC materials each 8 hours of patient manual cell count testing. (3) Surveyor #2 reviewed the records with technical consultant #1, who stated to surveyor #2 the times the QC had been performed had not been documented on the logs. NOTE: D5543 was cited on the recertification survey performed on 03/12/18-03/16/18.
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 technical consultant #1 and the laboratory manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 20 of 21 packed red blood cell units. Findings include: (1) On the second day of the survey, technical consultant #1 and 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 the hospital policy regarding transfusion reactions. The policy titled, "Blood and Blood Products Transfusion and Reaction" stated the following: (a) " TRANSFUSION RECORD REQUEST: SECTION IV: Transfusion:" (i) "This section is used to record the person starting the transfusion, person verifying the transfusion, blood band number, time of transfusion start and completion, vital signs for pre-infusion, 10 minutes after start of infusion and post infusion, the person stopping transfusion and if a possible transfusion reaction has occurred." (b) "INFUSION:" (i) "7. c. At the patient's bedside, prior to initiation of the transfusion, two people (RN, provider, paramedic, LPN, or med-tech) must verify the following data together:" (ii) "d. check unit of blood, requisition, and the patient's identification band to match: 1. The Name and hospital number with blood unit 2. The unit number of blood and requisition tag 3. The ABO and Rh type with requisition and tag 4. The expiration date with requisition and tag 5. The type of blood component 6. The Donor Number 7. The Blood Bank Armband Identification number" (iii) "10. If the anticipated infusion rate must be so slow that the entire unit cannot be infused within 4 hours, the provider may order the unit to be "split" and given in 2 or more portions. The order to "split" must be communicated to the Blood Bank before transfusion has begun. TRANSFUSION OF RED BLOOD CELLS WILL BE COMPLETED WITHIN 4 HOURS." (iv) "13. Assess the patient closely. Vital signs should be monitored periodically throughout the transfusion. Vital signs, including blood pressure, pulse, respiration, and temperature will be taken 10 minutes after infusion started." (v). "15. Take Post-transfusion vital signs." (vi). "16. The RN will be responsible for making sure the transfusion forms are completed with no blanks." "a. Indicated when transfusion was started, stopped, vital signs, and presence or absence of suspected reactions." (vii). "17. Record all nursing interventions, including donor number of units infused and the patient's response to the transfusion in the Electronic Medical Record. Vital signs taken frequently are documented on the Shift Assessment in the EMR. Blood volume is documented on the Shift Assessment under "New Intake" in the EMR." (3) Surveyor #3 then reviewed records for 21 units of PRBCs (Packed Red Blood Cells) transfused between 06/30/19 and 10/30/19 for 11 patients, with the following identified: (a) Infusion (i) Start time of the infusion (a) Patient #267718 - Transfused with 1 unit of PRBCs (unit # W091019222412) on 07/01/19. There was no documentation indicating the start time of the infusion. (ii) Completion time of the infusion (a) Patient #267718 - Transfused with 1 unit of PRBCs (unit #W091019222412) on 07/01/19. There was no documentation indicating the completion time of the infusion; (b) Patient #331935 - Transfused with 1 unit of PRBCs (unit #W091019319823) on 10/15/19. There was no documentation indicating the completion time of the infusion; (c) Patient #10967 -Transfused with 1 unit of PRBCs (unit #W091019296284) on 09/04/19. There was no documentation indicating the completion time of the infusion; (d) Patient #1015940 - Transfused with 1 unit of PRBCs (unit #W091019293990) on 10/01/19. There was no documentation indicating the completion time of the infusion; (e) Patient #1015940 - Transfused with 1 unit of PRBCs (unit #W091019222412) on 10/02/19. There was no documentation indicating the completion time of the infusion. (iii) Vital Signs 10 minutes after transfusion begins (a) Patient #11858 - Transfused with 1 unit of PRBCs (unit #W091019288347)

on 10/19/19 at 10:16 am vitals taken at 12:19 (2 hours and 3 minutes after transfusion started); (b) Patient #11858 - Transfused with 1 unit of PRBCs (unit # W091019316265) on 10/19/19 at 12:16 am vitals taken at 12:19 (3 minutes after transfusion started); (c) Patient #1022310 - Transfused with 1 unit of PRBCs (unit #W091019319563) on 10/15/19 at 12:18 pm vitals taken at 03:20 pm (3 hours and 2 minutes after transfusion started); (d) Patient #1022310 - Transfused with 1 unit of PRBCs (unit #W091019300835) on 10/15/19 at 03:56 pm vitals taken at 05:11 pm (1 hour and 15 minutes after transfusion started); (e) Patient #96021 - Transfused with 1 unit of PRBCs (unit #W091019351533) on 10/22/19 at 11:23 am vitals taken at 11:43 (20 minutes after transfusion started); (f) Patient #96021 - Transfused with 1 unit of PRBCs (unit #W091019299677) on 10/22/19 at 12:54 pm vitals taken at 1:31pm (37 minutes after transfusion started). (iv) Post-transfusion vital signs (a) Patient #10967 - Transfused with 1 unit of PRBCs (unit #W091019296284) on 09/04/19. There was no evidence of post-transfusion vital signs documentation; (b) Patient #1884 - Transfused with 1 unit of PRBCs (unit #W09101919859700) on 08/17/19. There was no evidence of post-transfusion vital signs documentation. (v) Blood volume (a) Patient #267718 - Transfused with 1 unit of PRBCs (unit #W09119220332) on 07/01/19. There was no evidence of blood volume documentation; (b) Patient #1036273 - Transfused with 1 unit of PRBCs (unit #W091019338226) on 10/22/19. There was no evidence of blood volume documentation. (vi) Transfusion reaction (a) Patient #10967 - Transfused with 1 unit of PRBCs (unit #W091019296284) on 09/04/19. There was no documentation of the presence or absence of a transfusion reaction; (b) Patient #1884 - Transfused with 1 unit of PRBCs (unit #W091019296007) on 08/16/19. There was no documentation of the presence or absence of a transfusion reaction; (c) Patient #1884 - Transfused with 1 unit of PRBCs (unit #W09101928804800) on 08/17/19. There was no documentation of the presence or absence of a transfusion reaction; (d) Patient #1884 - Transfused with 1 unit of PRBCs (unit #W09101918859700) on 08/17/19. There was no documentation of the presence or absence of a transfusion reaction; (e) Patient #1884 - Transfused with 1 unit of PRBCs (unit #W09101926960900) on 08/18 /19. There was no documentation of the presence or absence of a transfusion reaction; (f) Patient #1011251 - Transfused with 1 unit of PRBCs (unit #W091019338406) on 10/04/19. There was no documentation of the presence or absence of a transfusion reaction; (g) Patient #1036273 - Transfused with 1 unit of PRBCs (unit #W091019338226) on 10/22/19. There was no documentation of the presence or absence of a transfusion reaction; (h) Patient #96021- Transfused with 1 unit of PRBCs (unit #W091019351533) on 10/22/19. There was no documentation of the presence or absence of a transfusion reaction. (vii) PRBC Unit number (a) Patient #267718 - Transfused with 1 unit of PRBCs (unit #W091019220332) on 07/01/19. There was no evidence the blood unit number was documented in the patient's EMR (Electronic Medical Record); (b) Patient #1015940 - Transfused with 1 unit of PRBCs (unit #W091019293990) on 10/01/19. There was no evidence the blood unit number was documented in the patient's EMR; (c) Patient #1015940 - Transfused with 1 unit of PRBCs (unit #W091019222412) on 10/02/19. There was no evidence the blood unit number was documented in the patient's EMR. (viii) Transfusion of PRBCs within 4 hours (a) Patient #1036273 - Transfused with 1 unit of PRBCs (unit #W091019324382) on 10/21/19. The start time of the infusion was 06:27 pm and completion time of 10:35 pm (4 hours and 8 minutes). (ix) The ABO and Rh type with requisition and tag of the donor unit (a) Patient #1884 -The laboratory performed an ABO and Rh type on 8/16/19 and documented the patient's blood type as A positive in the laboratory computer system; (b) Surveyor #3 reviewed the patient's transfusion record in the hospital computer system and identified the patient's blood type, entered by the transfusion nurse, had been documented as AB negative (patient's blood type was A positive); (c) Surveyor #3 showed the clerical error to technical consultant #1

	and the laboratory manager, and asked if any corrections to the clerical error had been made before transfusion; (d) Technical consultant #1 and the laboratory manager stated the clerical error had not been corrected before the patient was transfused. (4) The above transfusion records were reviewed with technical consultant #1 and the laboratory manager. Both stated the records were not complete as indicated above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and the laboratory manager, the laboratory failed to ensure corrective actions were taken when quality control was not performed for 1 of 12 months. Findings include: (1) At the beginning of the survey, technical consultant #1 and the laboratory manager stated the following to surveyor #3: (a) The CCU (Critical Care Unit) laboratory performed the following tests: (i) ACT (Activated Clotting Time) using the ACT cartridge on the Abbott iSTAT1 analyzer (Serial Number: 338237); (ii) Arterial Blood Gas and Chemistry testing using the CG8+ (pH, pCO2, pO2, Glucose, Hemoglobin, Hematocrit, Ionized Calcium, Sodium, and Potassium) cartridge on the Abbott iSTAT1 analyzer (Serial Number: 338237). (b) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (c) The results for two levels of control materials must be acceptable in order to report patient results. (2) On the fourth day of the survey, surveyor #3 then reviewed ACT cartridge and CG8+ cartridge quality control records for testing performed from January 2019 through December 2019. For the review period, the following was identified for 1 of 12 months: (a) Quality control results could not be located for May 2019. (3) Surveyor #3 asked technical consultant #1 and the laboratory manager if two levels of quality control for ACT cartridge and CG8+ cartridge testing had been performed. Technical consultant #1 and the laboratory manager both stated ACT cartridge and CG8+ cartridge monthly quality control had not been performed in May 2019.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure test reports included information required for interpretation of urine drug screen testing for 2 of 2 patient reports. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors, the laboratory performed urine drug screen testing using the Profile-V MedTox Scan Reader System; (2) Surveyor #2 reviewed the manufacturer's instructions (package insert) for the test system. It stated, "The Profile-V MedTox Scan Drugs of Abuse Test System provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS), High Performance Liquid Chromatography (HPLC) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained;" (3) Surveyor #2 reviewed 2 patient test reports of urine drug screen testing (Patient #1015630-testing performed on 01/21/20 and Patient #1051209, testing performed on 01/23/20), and identified the reports did not include the manufacturer's statement that urine drug screen results were preliminary and were to be confirmed by a more specific alternate chemical method; (4) Surveyor #2 reviewed the findings with technical consultant #1, who stated the urine drug screen test result reports did not include the statement urine drug screen test results were preliminary and must be confirmed by an alternate method.
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 technical consultant #1 and 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 for 2 of 20 events. Findings include: (1) On the second day of the survey, surveyor #1 and surveyor #3 reviewed 2018 and 2019 proficiency testing records. It was identified for 2 of 20 events, the attestation statements had been signed approximately 2-3 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) First 2018 Microbiology Event - The sample testing had been completed on 02/28/18 and the attestation statement had not been signed by the laboratory director until 04/12/18; (b) Third 2018 Immunology /Immunohematology Event - The sample testing had been completed on 12/10/18 and the attestation statement had not been signed by the laboratory director until 03/05/19. (2) Surveyor #1 reviewed the findings with technical consultant #1 and 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. D6016 was cited on the recertification survey performed on 03/12,13,14,15,16/18.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and the laboratory manager, the laboratory director failed to ensure proficiency testing reports were reviewed for 5 of 20 events. Findings include: (1) On the second day of the survey, surveyor #1 and surveyor #3 reviewed 2018 and 2019 proficiency testing records. The Performance Evaluations included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following events had not been signed and dated as reviewed by the laboratory director or designee: (a) Second 2018 Immunology/Immunohematology Event (b) Second 2018 Chemistry Miscellaneous Event (c) First 2019 Immunology/Immunohematology Event (d) First 2019 Microbiology Event (e) Second 2019 Hematology/Coagulation Event (2) Surveyor #1 reviewed the records with technical consultant #1 and the laboratory manager. Both stated, the graded evaluations as indicated above, had not been signed and dated as reviewed by the laboratory director or designee. D2015 was cited on the recertification survey performed on 03/12,13,14,15,16/18.
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 technical consultant #1 and the laboratory manager, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 7 of 7 testing persons. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors urine microscopic testing was performed in the laboratory; (2) Surveyor #1 then reviewed personnel records for 7 persons performing urine microscopic testing in the laboratory (laboratory manager, technical consultant #2, testing person #6, testing person #2, testing person #17, testing person #19, and testing person #13). The records showed that evaluations had been performed as follows: (a) Laboratory Manager - Performed on 05/29/18 and 03/12/19 (b) Technical Consultant #2 - Performed on 05/29/18 and 12 /04/19 (c) Testing Person #6 - Performed on 12/04/19 (d) Testing Person #2 - Performed on 05/29/18 and 03/13/19 (e) Testing Person #17 - Performed on 12/04/19

	(f) Testing Person #19 - Performed on 08/26/19 (g) Testing Person #13 - Performed on 05/29/18, 003/13/19, and 12/04/19 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of urine microscopic testing; (4) The surveyor reviewed the findings with technical consultant #1 and the laboratory manager. Both stated the above evaluations did not include urine microscopic testing. D2015 was cited on the recertification survey performed on 03/12,13,14,15,16/18.