Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409775	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Nemhs Trinity Hospital Lab	315 Knapp St, Wolf Point, MT	

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	Based on an on-site recertification survey conducted on 9/10/18-9/12/18, deficiencies were cited for Trinity Hospital Lab in Wolf Point, MT.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to sign 6 proficiency testing attestation statements between 1/1/17 and 9/10/18. The findings include: 1. A review on 9/10/18 at 4:45 p.m. of the American Proficiency Institute (API) binders from 2017 and 2018 lacked the laboratory director's signature on 6 attestations. a. 2017 event 2-miscellaneous chemistry. b. 2017 event 2-microbiology. c. 2017 event 3-hematology/coagulation. d. 2017 event 3- immunology /immunohematology. e. 2018 event 1-chemistry core. f. 2018 event 1-hematology /coagulation. 2. On 9/10/18 at 4:45 p.m., staff member A stated the API binder is to be signed by the laboratory director each site visit. A sticky note is placed on each page to be signed before the laboratory director visit. 3. A review on 9/10/18 at 5:00 p.m. of the API binders included unsigned attestations without a sticky note on the page. 4. A review on 9/11/18 at 8:46 a.m. of the General Lab-Proficiency Testing policy in PolicyStat included instructions that "during the Laboratory Medical Director's visit, all attestation sheets for submitted and completed Proficiency Surveys will be signed by the Laboratory Medical Director."
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to retain Pentra 400 calibration data from 9/11/16-9/10/18, failed to retain the previous mean of the patient normal range for one of two lots of RecombiPlasTin 2G, and quality control data on chocolate agar from 2/1/18 through 9/10/18. The findings include: 1) ABX Pentra 400 Calibration Data. a. On 9/10/18 at 3:00 p.m., an ABX Pentra 400 analyzer was observed in the laboratory. b. On 9/10/18 at 3:00 p.m., staff member A stated the Pentra 400 is used for high sensitivity C-reactive protein (hsCRP), rheumatoid factor, urine creatinine, and vancomycin. c. A review on 9/11/18 at 2:07 p. m. of the Pentra binders lacked calibration data for any of the Pentra 400 tests. d. On 9 /11/18 at 2:07 p.m., staff member A stated the calibrations were not printed and could not get the data off the analyzer. 2) Mean of the Patient Normal Range. a. On 9/10/18 at 3:00 p.m., a Stago ACL Elite coagulation analyzer was observed in the laboratory. b. A review on 9/11/18 at 2:56 p.m., of the coagulation binders lacked the calculation of the mean of the patient normal range for the previous lot number of RecombiPlasTin 2G reagent (N0378719) used approximately 8/2017-9/2018. A current mean of 11.4 seconds for the current lot number of RecombiPlasTin (N0285578) was the only calculation of the mean of the patient normal range located. c. On 9/11/18 at 3:15 p.m., staff member stated the old patient mean data was not found. 3) Chocolate Agar Quality Control Records. a. On 9/11/18 at 4:12 p.m., Remel chocolate agar plates were observed in the microbiology refrigerator. b. A review on 9 /11/18 at 4:38 p.m. of the microbiology binder containing weekly quality control results lacked documentation of sterility, growth, and plate condition for new lots of chocolate media received after 1/30/18. c. On 9/11/18 at 4:55 p.m., staff member A stated the sterility and growth for chocolate agar should be documented in the computer program Kapios but the testing personnel have not entered any data for media into the Kapios program. d. On 9/11/18 at 4:55 p.m., staff member B stated growth and sterility are completed weekly on chocolate agar but are not documented anywhere at this time.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to verify the accuracy of fetal fibronectin from 1/1/17 through 9/10/18. The findings include: 1. On 9/10/18 at 3:00 p.m. a Hologic TLi analyzer was observed in the laboratory. 2. On 9/10 /18 at 3:00 p.m., staff member stated fetal fibronectin was performed on the TLi analyzer. 3. A review on 9/10/18 at 4:25 p.m. of the 2017 and 2018 American Proficiency Institute (API) binders lacked documentation for fetal fibronectin. 4. On 9 /10/18 at 4:25 p.m., staff member A stated the enrollment was missed in 2018. 5. A review on 9/10/18 at 4:50 p.m. of the API 2018 Renewal Order Form lacked enrollment for fetal fibronectin.

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 observation, record review, and interview, the laboratory failed to follow written procedures (see D5401), verify the reportable range of new analytes (see D5421), document biochemical quality controls (see D5471), document media physical characteristics resulting in a repeat deficiency (see D5477), properly store blood products (see D5555), compare test results (see D5775), and document corrective action for high temperatures (see D5781). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results and adequacy of blood products issued to patients.
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 observation, record review, and interview, the laboratory failed to follow written procedures for performing blood bank refrigerator alarm checks from 1/1/17-9 /10/18, for performing coagulation quality controls (QC) every 12 hours from 5/1/18-9 /10/18, for performing fetal fibronectin (FFN) QC every week between 12/1/17-2/1 /18, and for performing serum human chorionic gonadotropin (shCG) QC every month from 8/1/17-8/31/17. The findings include: 1. Blood Bank Refrigerator Alarm Checks. a. A review on 9/11/18 at 11:47 a.m., of the Blood Bank-Maintaining and Responding to Alarms on the Helmer Blood Bank Refrigerator with Alarm Monitoring included instructions to quarterly test the lower level and higher level alarms activation. b. A review on 9/11/18 4:00 p.m. of the 2017 blood bank refrigerator alarm checks documented two alarm checks performed in 2017 (July and September) and two alarm checks performed in 2018 (March and June). c. On 9/11/18 at 4:00 p.m., staff member A stated they were not done and were missed. 2. Coagulation QC. a. A review on 9/11/18 at 10:30 a.m. of the NEMHS (Northeast Montana Health Services) IQCP (Individualized Quality Control Plan) for ACL Elite Analyzer procedure included "two levels of external controls are to be performed and documented each time a new lot number of reagent is opened; in addition, two levels of external controls will be performed every 12 hours to ensure reagent stability." b. A review on 9/11/18 at 2:24 p.m. of the prothrombin (PT) QC results between 5/1/18 and 9/11/18 included 31 days without controls run every 12 hours. 1. 5/8/18. 2. 5/13 /18. 3. 5/20/18. 4. 5/19/18. 5. 5/23/18. 6. 5/27/18. 7. 6/2/18. 8. 6/3/18. 9. 6/9/18. 10. 6 /16/18. 11. 6/17/18. 12. 6/18/18. 13. 6/24/18. 14. 6/27/18. 15. 6/28/18. 16. 6/30/18. 17.

	7/1/18. 18. 7/7/18. 19. 7/9/18. 20. 7/11/18. 21. 7/12/18. 22. 7/15/18. 23. 7/16/18. 24. 7/19/18. 25. 7/22/18. 26. 7/25/18. 27.7/28/18. 28. 7/29/18. 29. 8/26/18. 30. 9/3/18. 31. 9/8/18. c. A review on 9/11/18 at 2:24 p.m. of the partial thromboplastin time (PTT) QC results between 5/1/18 and 9/11/18 included 62 days without controls run every 12 hours. 1. 5/5/18. 2. 5/6/18. 3. 5/8/18. 4. 5/9/18. 5. 5/11/18. 6. 5/14/18. 7. 5/15/18. 8. 5/19/18. 9. 5/20/18. 10. 5/23/18. 11. 5/26/18. 12. 5/27/18. 13. 5/28/18. 14. 6/2/18. 15. 6/3/18. 16. 6/6/18. 17. 6/7/18. 18. 6/9/18. 19. 6/10/18. 20. 6/13/18. 21. 6/14/18. 22. 6/16/18. 23. 6/17/18. 24. 6/18/18. 25. 6/20/18. 26. 6/24/18. 27. 6/27/18. 28. 6/28/18. 29. 6/30/18. 30. 7/1/18. 31. 7/3/18. 32. 7/7/18. 33. 7/8/18. 34. 7/11/18. 35. 7/12/18. 36. 7/14/18. 37. 7/15/18. 38. 7/16/18. 39. 7/18/18. 40. 7/19/18. 41. 7/21/18. 42. 7/22/18. 43. 7/25/18. 44. 7/27/18. 45. 7/28/18. 46. 7/31/18. 47. 8/2/18. 48. 8/8/18. 49. 8/10/18. 50. 8/12/18. 51. 8/13/18. 52. 8/14/18. 53. 8/16/18. 54. 8/23/18. 55. 8/26/18. 56. 8/27/18. 57. 8/29/18. 58. 8/30/18. 59. 9/1/18. 60. 9/3/18. 61. 9/8/18. 62. 9/9/18. d. On 9/11/18 at 2:24 p.m., staff member A stated they were not following the IQCP. 3. Weekly FFN QC. a. A review on 9/11/18 at 11:01 a.m. of the FFN QC stored in the Kapios computer program lacked QC performed in December of 2017 and January of 2018. b. On 9/11/18 at 11:01 a.m., staff member A stated the controls were supposed to be performed monthly. c. On 9/11/18 at 11:01 a.m., a review of the NEMHS IQCP for Hologic TLiIQ System required "two levels of external controls are to be performed and documented each time a new lot number of reagent is opened; in addition, two levels of external controls will be performed weekly to ensure reagent stability." 4. shCG Monthly QC. a. A review on 9/11/18 at 2:00 p.m. of the QC records stored in the Kapios computer program lacked shCG controls performed in August of 2017. b. On 9/11/18 at 2:00 p.m., staff member A stated the IQCP requires monthly controls to be performed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to obtain performance specifications for the reportable range of test results for 9 of 49 new analytes. The findings include: 1. A review on 9/10/18 at 5:05 p.m. of the EP Evaluator documents for the 49 new analytes added since the last survey lacked the reportable range for 9 analytes. a. Dehydroepiandrosterone sulfate (DHEA-S). b. Estradiol. c. Follicle stimulating hormone (FSH). d. Luteinizing hormone (LH). e. Progesterone. f. Testosterone. g. Cortisol. h. Sex-hormone binding globulin (SHBG). i. Parathyroid hormone (PTH). 2. On 9/10/18 at 5:05 p.m., staff member A stated the results were compared to another laboratory and they cannot get the paperwork from them.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i)

	Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document positive and negative quality controls (QC) for five biochemical reactions from 2/1/18 through 9/10 /18. The findings include: 1. On 9/11/18 at 4:12 p.m. a review of the microbiology binder lacked documentation of positive and negative QC for catalase, coagulase, oxidase, indole, and optochin after the paper log was discontinued in 1/30/18. 2. On 9 /11/18 at 4:12 p.m., staff member A stated QC was supposed to be documented in the Kapios computer program instead of on the paper log. No controls were documented in Kapios. 3. On 9/11/18 at 4:32 p.m., staff member B stated the controls for biochemical reactions are performed each day of use but are not documented.
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: This is a repeat deficiency. Based on observation, record review, and interview, the laboratory failed to document the physical characteristics of seven of seven media types before use from 2/1/18 through 9/10/18. The findings include: 1. On 9/11/18 at 4:12 p.m., seven media types from Remel were observed in the laboratory refrigerator, including blood plates, blood/MacConkey biplates, MacConkey plates, chocolate plates, carrot broth, group b strep detection plates, and thioglycollate broth. 2. A review on 9/11/18 at 4:50 p.m. of the microbiology binder lacked documentation of media physical characteristics for each new lot of media received since the discontinuance of the paper log sheets on 1/30/18. 3. A review on 9/11/18 at 4:50 p.m. of the NEMHS (Northeast Montana Health Services) IQCP (Individualized Quality Control Plan) for Commercial Media required "visual inspection of representative units of all media for any physical defects or contamination upon receipt." It also required "maintenance of logs to record media received, any defects observed and any interactions with manufacturer about defective media." 4. On 9/11/18 at 4:50 p.m., staff member B stated it has not been documented since March 2018. 5. On 9/11/18 at 4:55 p.m., staff member A stated the sterility and growth for chocolate agar should be documented in the computer program Kapios but the testing personnel have not entered any data for media into the Kapios program.
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 record review and interview, the laboratory failed to store blood products under appropriate conditions between one and six degrees Celsius from 1/1/17 through 9/10/18. The findings include: 1. A review on 9/11/18 at 2:46 p.m. of the weekly temperature charts included frequent high temperature spikes and prolonged high temperatures above 6 degrees Celsius. Corrective action for storage of the blood was not documented for the listed high temperature spikes and prolonged high temperatures. No documentation of moving the blood to another refrigerator was located for the times listed. a. January 2017 Weekly temperature charts included 7 high temperature spikes or extended elevated temperatures between 1/1/17-1/8/17. Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 1/7/17-1/15/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 1/15/17-1/22/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 1/22/17-1/29/17. b. February 2017 Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 1/29 /17-2/5/17. Weekly temperature charts included 1 extended elevated temperature between 2/5/17-2/12/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 2/22/17-2/26/17. c. March 2017 Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 2/26/17-3/3/17. Weekly temperature charts included 1 extended elevated temperature between 3/9/17-3/10/17. d. April 2017 Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 3 /26/17-4/2/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 4/2/17-4/10/17. Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 4/10 /17-4/17/17. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 4/17/17-4/23/17. Weekly temperature charts included 1 high temperature spike or extended elevated temperature between 4/29/17-4 /30/17. e. May 2017 Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 4/30/17-5/1/17. f. July 2017 Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 7/2/17-7/9/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 7/9/17-7/15/17. Weekly temperature charts included 1 extended elevated temperature on 7/18/17. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 7/22/17-7/29/17. g. August 2017 Weekly temperature charts included 1 extended elevated temperature between 8/1/17-8/2/17. Weekly temperature charts included 1 high temperature spike or extended elevated temperature between 8 /12/17-8/19/17. h. September 2017 Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 8/26/17-9/2/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 9/2/17-9/10/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 9/10/17-9/17/17.

	Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 9/23/17-9/30/17. i. October 2017 Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 10/3 /17-10/7/17. Weekly temperature charts included 1 extended elevated temperature on 10/10/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 10/14/17-10/22/17. Weekly temperature charts included 1 high temperature spike on 10/24/17. j. November 2017 Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 10/29/17-11/5/17. Weekly temperature charts included 1 extended elevated temperature between 11/7/17 and 11/8/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 11/19/17-11/26/17. k. December 2017 Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 11/26/18-12/3/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 12/3/17-12/10/17. Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 12/10/17-12/17/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 12/17/17-12/28/17. l. January 2018 Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 1/8/18-1/14/18. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 1/14/18-1/21/18. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 1/21/18-1/28 /18. m. February 2018 Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 1/28/18-2/4/18. Weekly temperature charts included 1 high temperature spike on 2/6/18. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 2/10 /18-2/17/18. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 2/17/18-2/25/18. n. March 2018 Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 2/25/18-3/4/18. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 3/4/18-3/11/18. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 3/18/18-3/21/18. o. April 2018 Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 4/1/18-4/8/18. Weekly temperature charts included 1 high temperature spike between 4/22/18-4/29/18. p. May 2018 Weekly temperature charts included 1 high temperature spike between 5/6/18-5/13/18. q. July 2018 Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 7/2/18-7/9/18. Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 7/9/18-7/17/18. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 7/17/18-7/23/18. 3. On 9/11/18 at 4:00 p.m., staff member A stated the blood was currently moved to a different refrigerator and the temperature monitored every four hours due to the failure of the refrigerator.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to twice a year evaluate the troponin test results performed on the Alere Triage analyzer against the Tosoh AIA-900 from 9/11/16 through 9/10/18. The findings include: 1. On 9/10 /18 at 3:00 p.m., a Tosoh AIA-900 analyzer and an Alere Triage analyzer were observed in the laboratory. 2. On 9/10/18 at 3:00 p.m., staff member A stated troponin was performed on the Tosoh and Triage analyzers. 3. A review on 9/12/18 at 8:05 a. m. lacked documentation of comparisons between the troponin on the Alere Triage analyzer and the Tosoh AIA-900 analyzer. 4. On 9/12/18 at 8:05 a.m., staff member A stated the backup Alere analyzer was used when the Tosoh was down for approximately four days. The lab performed proficiency testing at that time on the backup analyzer but did not compare the results to the other analyzer.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document corrective actions for frequent high temperatures on the blood bank refrigerator from 1/1/17 to 9 /10/18. The findings include: 1. A review on 9/11/18 at 11:42 a.m. of the Blood Bank-Maintaining and Responding to Alarms on the Helmer Blood Bank Refrigerator with Alarm Monitoring procedure included steps to mute the alarm and look for previous notations on the wheel from other alarms. Instructions for documenting corrective action for the alarm, unmuting the alarm, and monitoring to verify the temperature corrected was not included in the procedure. Further, it states the "temperature alarm should activate when the temperature is greater than 6.0 degrees Celsius." The procedure was not approved by the current laboratory director. 2. A review on 9/11/18 at 2:46 p.m. of the daily temperature log sheets, weekly temperature charts, and the end of month review forms included frequent high temperature spikes without corrective action, extended periods of high temperatures without corrective action, discrepant results between the daily and weekly temperature forms, and no documentation of alarms sounding despite the frequent high temperatures between 1/1 /17 and 9/10/18. Review of the daily temperature log sheets, weekly temperature charts, and end of month review forms was performed by the laboratory director without documentation of corrective action. a. January 2017 Daily temperature log sheet included no out of range temperatures. Weekly temperature charts included 7 high temperature spikes or extended elevated temperatures between 1/1/17-1/8/17. Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 1/7/17-1/15/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 1/15/17-1/22/17.

Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 1/22/17-1/29/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 4/20 /17. b. February 2017 Daily temperature log sheet included no out of range temperatures. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 1/29/17-2/5/17. Weekly temperature charts included 1 extended elevated temperature between 2/5/17-2/12/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 2/22/17-2/26/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 4/20 /17. c. March 2017 Daily temperature log sheet included no out of range temperatures. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 2/26/17-3/3/17. Weekly temperature charts included 1 extended elevated temperature between 3/9/17-3/10/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 4/20/17. d. April 2017 Daily temperature log sheet included 2 out of range temperatures (4/7/17 and 4/21/17) without corrective action documented. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 3/26/17-4/2/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 4/2/17-4/10/17. Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 4/10/17-4/17/17. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 4/17/17-4/23/17. Weekly temperature charts included 1 high temperature spike or extended elevated temperature between 4/29/17-4/30/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 4/20 /17. e. May 2017 Daily temperature log sheet included 1 out of range temperature (5/4 /17) without corrective action documented. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 4/30/17-5/1/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 10/16/17. f. July 2017 Daily temperature log sheet included no out of range temperatures. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 7 /2/17-7/9/17. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 7/9/17-7/15/17. Weekly temperature charts included 1 extended elevated temperature on 7/18/17. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 7/22 /17-7/29/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 10/16/17. g. August 2017 Daily temperature log sheet included no out of range temperatures. Weekly temperature charts included 1 extended elevated temperature between 8/1/17-8

/2/17. Weekly temperature charts included 1 high temperature spike or extended elevated temperature between 8/12/17-8/19/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 10/16/17. h. September 2017 Daily temperature log sheet included no out of range temperatures. Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 8/26/17-9/2/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 9/2/17-9/10/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 9/10/17-9/17/17. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 9/23/17-9/30/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 10/16/17. i. October 2017 Daily temperature log sheet included only 2 days of out of range temperatures with proper corrective action (10/1/17-10/2/17). Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 10/3/17-10/7/17. Weekly temperature charts included 1 extended elevated temperature on 10/10/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 10/14/17-10/22/17. Weekly temperature charts included 1 high temperature spikes on 10/24/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. j. November 2017 Daily temperature log sheet included 2 out of range temperatures (11/1/17 and 11/24/17) without corrective action. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 10/29/17-11/5/17. Weekly temperature charts included 1 extended elevated temperature between 11/7/17 and 11/8/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 11/19/17-11/26/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. k. December 2017 Daily temperature log sheet included 1 out of range temperature (12/14/17) without corrective action. Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 11/26/18-12/3/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 12/3/17-12/10/17. Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 12/10/17-12/17/17. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 12/17/17-12/28/17. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. l. January 2018 Daily temperature log sheet included 5 out of range temperatures (1/11/18, 1/25/18-1/28/18) without corrective action. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 1/8/18-1/14/18. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 1/14/18-1/21/18. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 1/21/18-1/28/18. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of

	corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 4/5/18. m. February 2018 Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 1/28 /18-2/4/18. Weekly temperature charts included 1 high temperature spike on 2/6/18. Weekly temperature charts included 5 high temperature spikes or extended elevated temperatures between 2/10/18-2/17/18. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 2/17/18-2/25/18. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 4/5/18. n. March 2018 Weekly temperature charts included 6 high temperature spikes or extended elevated temperatures between 2/25/18-3/4/18. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 3/4/18-3/11/18. Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 3/18/18-3/21/18. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. The Laboratory Director reviewed all these forms on 4/5 /18. o. April 2018 Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 4/1/18-4/8/18. Weekly temperature charts included 1 high temperature spike between 4/22/18-4/29/18. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. p. May 2018 Weekly temperature charts included 1 high temperature spike between 5/6/18-5/13/18. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. q. July 2018 Weekly temperature charts included 2 high temperature spikes or extended elevated temperatures between 7/2/18-7/9/18. Weekly temperature charts included 4 high temperature spikes or extended elevated temperatures between 7/9/18-7/17/18. Weekly temperature charts included 3 high temperature spikes or extended elevated temperatures between 7/17/18-7/23/18. No documentation of alarms sounding was documented. Corrective action was not documented for the out of range temperatures. The end of month review form lacked documentation of corrective action during the out of range temperatures. 3. On 9/11/18 at 4:00 p.m., staff member A stated a new fridge is going to be ordered due to the problems with the blood bank refrigerator but could not remember if alarms sounded with the out of range temperatures.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to ensure the environmental conditions of the blood bank refrigerator were appropriate (see D6083), ensure the bacteriology test methodologies provide quality results (repeat deficiency, see D6085), ensure adequate verification procedures are completed

	(see D6086), ensure personnel perform test methods as required (see D6087), ensure attestation statements are signed (see D6089), ensure quality assessment programs identify failures (see D6094), and ensure corrective actions were taken (see D6096). The cumulative effect of these systemic problems resulted in the laboratory director's inability to provide overall management and direction, and ensure the accuracy and reliability of patient test results and blood products issued to patients.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the environmental conditions of the blood bank refrigerator were appropriate from 1/1/17 through 9/10/18. See D5555.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to ensure the bacteriology test methodologies provide quality results resulting in a repeat deficiency from 2/1/18 through 9/10/18. See D5471 and 5477.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure verification procedures included accuracy of the entire reference range for 9 of 49 new analytes. See D5421.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to

	ensure the personnel perform test methods as required in the procedure manuals from 1/1/17 through 9/10/18. See D5401.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure six proficiency testing attestation statements are signed by the laboratory director between 1/1/17 and 9/10/18. See D2009.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to ensure the quality assessment programs were established and maintained to identify failures in retention (see D3031), proficiency testing and accuracy verification (see D2009 and D5417), adherence to procedures (see D5401), verification of new analytes (see D5421), incomplete quality control (see D5471 and D5477), blood storage (see D5555), comparison of test results (see D5775), and corrective action (see D5781) from 9/11/16 through 9/10/18.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure necessary corrective action was taken to correct frequent high temperature deviations on the blood bank refrigerator from 1/1/17 through 9/10/18. See D5555 and D5781.