Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 16D0665215	**(X3) Date Survey Completed** 04/23/2025
Name of Provider or Supplier Lucas County Health Center	**Street Address, City, State** 1200 North Seventh Street, Chariton, IA	
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**
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 review of the Laboratory Test List and Annual Volume form, lack of proficiency testing records and confirmed by interview with general supervisor #1 (GS #1) at 8:47 am on 4/23/2025, the laboratory failed to verify the accuracy twice annually for heroin testing for four out of four time periods from 1/1/2023 - 12/31/2024. The findings include: 1. The laboratory performed non-waived heroin testing. Refer to D5423. 2. GS #1 confirmed the laboratory did not verify the accuracy of heroin testing twice annually in 2023 or 2024.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by interview with the general supervisor identifier #1 (GS #1) at approximately 8:47 am on 4/23/2025, the laboratory failed to document corrective action for unacceptable PT scores received for one out of six PT events from 1/1/2023 - 12/31/2024. The findings include: 1. For 2024 testing event 3, the laboratory received the following unacceptable scores: *blood gas pH (sample BG-11) 80% *blood gas partial pressure

	of oxygen (sample BG-11) 80% *vancomycin (sample CH-14) 80% 2. GS #1 confirmed at the time of the survey the laboratory did not have corrective action documented for the above unacceptable PT scores.
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 review of the Laboratory Test List and Annual Volume form, prothrombin time (PT), partial thromoplastin time (PTT), and D-dimer records, Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 procedure, blood bank freezer temperature monitoring records, the Power Down/Disaster Blood Storage Freezer and Equipment Control procedures, lack of blood bank refrigerator and freezer alarm check records and confirmed by interview with general supervisor identifier #1, the laboratory failed to follow the procedure for establishing the criteria for quality control (QC) acceptability prior to reporting patient results as specified in D5401; failed to establish the criteria for QC acceptability prior to reporting patient results as specified in D5469; failed to perform two levels of PT and PTT QC each eight hours of patient operation as specified in D5545; failed to store fresh frozen plasma at the appropriate temperature as specified in D5555; failed to perform audible alarm checks of the blood bank freezer and refrigerator as specified in D5555; failed to perform and document corrective action when PT, PTT and D-dimer QC fell outside of acceptable ranges as specified in D5783; and failed to establish a quality assessment program that assessed and identified problems associated with PT, PTT, and D-dimer QC and red blood cell and fresh frozen plasma storage as specified in D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: A. Based on lack of a erythrocyte sedimentation rate (ESR) procedure and confirmed by interview with the general supervisor identifier #1 (GS #1) at 11:54 am on 4/23 /2025, the laboratory failed to have a procedure for the iSED (ESR) test system. The findings include: 1. GS #1 confirmed the laboratory intended to use the iSED operator's manual as the procedure manual for ESR testing. 2. GS #1 confirmed at the time of the survey, the laboratory did not have a copy of the iSED operator's manual. B. Based on review of the prothrombin time (PT) and partial thromboplastin time (PTT) records, Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 series procedure and confirmed by interview with general supervisor identifier #1 (GS

	#1) at approximately 12:16 pm on 4/23/2025, the laboratory failed to follow the procedure for establishing criteria for QC acceptability prior to performing patient samples when the laboratory put into use new lot numbers of PT and PTT reagent on 2 /1/2025. For findings refer to D5469.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, lack of establishment of performance verification records, the Heroin-6AM-monoacetylmorphine test strip and confirmed by interview with General Supervisor identifier #1 (GS #1) at 8:47 am on 4/23/2025, the laboratory failed to establish the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference range for the Heroin-6AM-monoacetylmorphine test kit. The findings include: 1. The Laboratory Test List and Annual Volume form indicated the laboratory performed Heroin testing using the BTNX test kit. 2. The BTNX test strip for Heroin-6AM-monoacetylmorphine (lot DOAG2404014, expiration date 3/31/2026) stated "For Forensic Use Only" making the test system not subject to FDA clearance or approval. 3. In 2023 the laboratory performed heroin testing on 1 patient and in 2024 the laboratory performed heroin testing on 2 patients. 4. GS #1 confirmed at the time of the survey the laboratory had not established the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference range.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form and the GeneXpert System Maintenance log, lack of calibration records and confirmed by interview with general supervisor identifier #1 (GS #1) at 1:20 pm on 4/23/2025, the laboratory failed to perform an annual calibration on the Cepheid GeneXpert test system for two out of two years from 1/1/2023 - 12/31/2024. The findings include: 1. The Laboratory Test List and Annual Volume form indicated the laboratory used the Cepheid GeneXpert test system to perform Influenza A, Influenza B, SARS CoV-2, Respiratory syncytial virus and Streptococcus group A testing. 2. The GeneXpert System Maintenance log states that test system must be calibrated annually. 3. GS #1 confirmed at the time of the survey, the laboratory did not have calibrations from 1/1/2023 - 12/31/2024 for the Cepheid GeneXpert test system.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 review of calibration verification records, chemistry calibration records and confirmed by interview with general supervisor identifier #1 (GS #1) at approximately 10:14 am on 4/23/2025, the laboratory failed to perform calibration verification every six months for one out of two time periods for the analytes procalcitonin, low-density lipoprotein (LDL), total iron binding capacity (TIBC) and glycated hemoglobin from 4/04/2024 - 4/23/2025. The findings include: 1. Procalcitonin, LDL and TIBC testing only have two calibrators and therefore require calibration verification to be performed. 2. GS#1 stated the manufacturer requires calibration verification for the analyte glycated hemoglobin. 3. The laboratory performed calibration verification for the above analytes on 4/4/2024. 4. GS#1 confirmed at the time of the survey, the laboratory did not have records indicating the laboratory performed additional calibration verification records for the above analytes.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical

	parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, prothrombin time (PT) and partial thromboplastin time (PTT) records, Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 series procedure and confirmed by interview with general supervisor identifier #1 (GS #1) at approximately 12:16 pm on 4/23/2025, the laboratory failed to establish the criteria for QC acceptability prior to performing patient samples when the laboratory put into use new lot numbers of PT and PTT reagent on 2/1/2025. The findings include: 1. The Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 series procedure states when using a new lot number of PT or PTT reagent the laboratory must "Assay new lot number of QC material with the new lot of reagent in PTN (prothrombin time) and APTTN (partial thromboplastin time) protocols. Collect a minimum of 30 data points over multiple days and stability limits of control. Calculate the mean, 2 SD (standard deviation) and 3 SD range." 2. GS #1 confirmed the laboratory starting using the following reagents on 2/1/2025: *Innovin lot number 564636, expiration date 11/17/2025 *Actin lot number 575007A, expiration date 8/19/2026 *Calcium Chloride lot number 563943A, expiration date 9/19/2029 *Citrol 1 QC lot number 564898, expiration date 4/21/2027 *Citrol 3 QC lot number 556592, expiration date 6/18/2027 3. GS#1 confirmed that the laboratory did not establish the criteria for QC acceptability prior to performing patient samples when the laboratory put into use new lot numbers of PT and PTT reagent, instead they used the ranges from the previous lot numbers of reagent and QC. 4. The laboratory performs on average of 53 PT tests and 16 PTT tests per month. GS#1 stated at the time of the survey, the laboratory did not know how to pull an electronic report to confirm how many patient PT and PTT samples the laboratory performed in February 2025.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: A. Based on review of prothrobin time (PT) quality control (QC) records and confirmed by interview with general supervisor identifier #1 (GS #1) at 12:16 pm on 4 /23/2025, the laboratory failed to perform two levels of PT QC each eight hours of operation for two out of 70 time periods from 2/1/2025 - 2/28/2025. The findings include: 1. GS #1 confirmed the laboratory would perform two levels of PT QC each eight hours of patient testing. 2. On 2/3/2025 at 9:13 am the laboratory performed level 1 of PT QC, but did not perform level 3 of PT QC. 3. On 2/9/2025 at 1:54 pm the laboratory performed level 1 of PT QC, but did not perform level 3 of PT QC. 4. GS #1 stated at the time of the survey, the laboratory did not know how to pull an electronic report to confirm if the laboratory performed patient samples during the

	above eight hours of operation. B. Based on review of partial thromboplastin time (PTT) quality control (QC) records and confirmed by interview with general supervisor identifier #1 (GS #1) at 12:16 pm on 4/23/2025, the laboratory failed to perform two levels of PTT QC each eight hours of operation for three out of 70 time periods from 2/1/2025 - 2/28/2025. The findings include: 1. GS #1 confirmed the laboratory would perform two levels of PTT QC each eight hours of patient testing. 2. On 2/3/2025 at 9:13 am the laboratory performed level 1 of PTT QC, but did not perform level 3 of PTT QC. 3. On 2/9/2025 at 1:54 pm the laboratory performed level 1 of PTT QC, but did not peroform level 3 of PTT QC. 6. On 2/13/2025 at 8:59 am the laboratory did not perform level 1 or level 3 of PTT QC. 7. GS #1 stated at the time of the survey, the laboratory did not know how to pull an electronic report to confirm if the laboratory performed patient samples during the above eight hours of operation.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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. This STANDARD is not met as evidenced by: A. Based on review of the blood bank freezer temperature monitoring records and the Power Down/Disaster Blood Storage Freezer procedure and confirmed by interview with general supervisor identifier #1 (GS #1) at 1:20 pm on 4/23/2025, the laboratory failed to store fresh frozen plasma at the appropriate temperature for two out of four weeks from 1/27/2025 - 2/28/2025. The findings include: 1. The Power Down /Disaster Blood Storage Freezer procedure stated that fresh frozen plasma must be stored at the appropriate temperature of -18 degrees Celsius or colder. 2. The blood bank freezer temperature wheel confirmed that for the week of 1/27/2025 - 2/4/2025 the temperature reached -14 degrees Celsius. 2. The blood bank freezer temperature wheel confirmed that for the week of 2/10/2025 - 2/17/2025 the temperature reached -10 degrees Celsius. 3. GS #1 stated that periodically the blood bank freezer that stored the fresh frozen plasma would go through an automatic defrost cycle. 4. GS #1 confirmed at the time of the survey, the laboratory failed to store the fresh frozen plasma at the appropriate temperature. B. Based on lack of blood bank temperature alarm check records and the Equipment Quality Control procedure and confirmed by interview with general supervisor #1 (GS #1) at 1:20 pm on 4/23/2025, the laboratory failed to perform quarterly alarm checks of the blood bank refrigerator and freezer for nine out of nine quarters from 1/1/2023 - 4/23/2025. The findings include: 1. The Equipment Quality Control procedure stated the blood bank refrigerator and freezer alarm checks would be performed quarterly. 2. The laboratory stored red blood cell units in the blood bank refrigerator and fresh frozen plasma in the blood bank freezer. 2. GS #1 confirmed at the time of the survey, the laboratory failed to perform the quarterly alarm checks on the blood bank refrigerator and freezer from 1/1/2023 - 4/23 /2025.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

(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:
A. Based on review of prothrombin time (PT) records, the Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 series procedure and confirmed by interview with general supervisor identifier #1 (GS #1) at approximately 12:16 pm on 4/23/25, the laboratory failed to take and document corrective action when the PT quality control (QC) results failed to meet the laboratory's established criteria for acceptability for 27 out of 70 time periods from 2/1/2025 - 2/28/2025. The findings include: 1. GS #1 confirmed the laboratory performed PT QC every eight hours of patient testing. 2. On 2/1/2025 the laboratory started using Citrol 1 QC lot number 564898, expiration date 4/21/2027 and Citrol 3 QC lot number 556592, expiration date 6/18/2027. The laboratory failed to establish the criteria of acceptability for these lot numbers of QC, refer to D5469. 3. The laboratory used the established QC criteria for the previous lot numbers of QC (Citrol 1 QC lot number 564884, expiration date 6 /4/2026 and Citrol 3 QC lot number 556583, expiration date 6/27/2026) which included the following ranges: Citrol 1 QC PT 10.7 seconds - 11.5 seconds Citrol 3 QC PT 44.8 seconds - 50.0 seconds 4. The laboratory had the following out of range PT QC results: *2/1/2025 at 3:09 am Citrol 1 PT - 10.6 seconds and 2/1/2025 at 3:11 am Citrol 3 PT - 43.9 *2/1/2025 at 10:58 am Citrol 3 PT - 43.6 *2/2/2025 at 2:59 am Citrol 3 PT - 44.3 *2/3/2025 at 3:31 am Citrol 1 PT - 10.6 and 2/3/2025 at 3:33 am Citrol 3 PT - 43.6 *2/4/2025 at 1:28 am Citrol 3 PT - 42.8 *2/4/2025 at 9:11 am Citrol 1 PT - 11.6 *2/4/2025 at 7:15 pm Citrol 3 PT - 41.6, rerun at 7:25 pm Citrol 3 PT - 42.2 *2/5/2025 at 6:36 pm Citrol 1 PT - 10.6 *2/6/2025 at 5:17 pm Citrol 1 PT - 10.4 and 2/6/2025 at 5:19 pm Citrol 3 PT - 43.9 *2/11/2025 at 10:19 am Citrol 1 PT - 11.8 and 2/11/2025 at 10:21 pm Citrol 3 PT 50.6 *2/11/2025 at 6:33 pm Citrol 3 PT - 41.2 *2/13/2025 at 5:23 pm Citrol 1 PT - 10.5, rerun at 5:44 Citrol 1 PT - 10.4 and 2/13 /2025 at 5:25 pm Citrol 3 PT - 43.3 *2/14/2025 at 5:21 pm Citrol 3 PT - 44.6 *2/18 /2025 at 1:14 am Citrol 1 PT - 10.6 *2/18/2025 at 9:04 am Citrol 1 PT - 11.6 *2/18 /2025 at 5:42 pm Citrol 3 PT - 43.9 *2/19/2025 at 5:29 pm Citrol 3 PT - 44.0 *2/21 /2025 at 1:19 am Citrol 1 PT - 10.6 *2/21/2025 at 9:09 am Citrol 3 PT - 44.4 *2/21 /2025 at 5:11 pm Citrol 3 PT - 43.5 *2/23/2025 at 7:28 pm Citrol 1 PT - 11.6 *2/24 /2025 at 9:06 am Citrol 1 PT - 11.6 *2/26/2025 at 1:19 am Citrol 3 PT - 42.4, rerun at 2:48 am Citrol 3 PT - 44.4, rerun at 3:50 am Citrol 3 PT 44.4 *2/26/2025 at 5:21 pm Citrol 3 PT - 42.2 *2/27/2025 at 9:18 am Citrol 1 PT - 11.9 *2/27/2025 at 5:23 pm Citrol 3 PT - 41.6 *2/28/2025 at 10:08 am Citrol 3 PT - 42.6 5. For the above QC the laboratory would occasionally document "accept per Westgard". However, Westgard QC rules are based upon calculated standard deviations. The laboratory did not calculate the standard deviation for any of the above out of range QC. 6. GS #1 confirmed at the time of the survey, the laboratory did not have any additional corrective action documented for the out of range QC. 7. The laboratory performs on average of 53 PT tests per month. GS#1 stated at the time of the survey, the laboratory did not know how to pull an electronic report to confirm how many patient PT samples the laboratory performed in February 2025. B. Based on review of partial thromboplastin time (PTT) records, the Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 series procedure and confirmed by interview with general supervisor identifier #1 (GS #1) at approximately 12:16 pm on 4/23/25, the laboratory

failed to take and document corrective action when the PTT quality control (QC) results failed to meet the laboratory's established criteria for acceptability for 30 out of 70 time periods from 2/1/2025 - 2/28/2025. The findings include: 1. GS #1 confirmed the laboratory performed PTT QC every eight hours of patient testing. 2. On 2/1/2025 the laboratory started using Citrol 1 QC lot number 564898, expiration date 4/21/2027 and Citrol 3 QC lot number 556592, expiration date 6/18/2027. The laboratory failed to establish the criteria of acceptability for these lot numbers of QC, refer to D5469. 3. The laboratory used the established QC criteria for the previous lot numbers of QC (Citrol 1 QC lot number 564884, expiration date 6/4/2026 and Citrol 3 QC lot number 556583, expiration date 6/27/2026) which included the following ranges: Citrol 1 QC PT 27.0 seconds - 29.8 seconds Citrol 3 QC PT 55.5 seconds - 63.5 seconds 4. The laboratory had the following out of range PT QC results: *2/1/2025 at 3:09 am Citrol 1 PTT - 26.7 *2/1/2025 at 10:56 am Citrol 1 PTT - 33.2 *2/2/2025 at 2:57 am Citrol 1 PTT - 26.9 *2/3/2025 at 3:13 am Citrol 1 PTT - 26.7 *2/4/2025 at 1:26 am Citrol 1 PTT - 26.7 *2/5/2025 at 1:09 am Citrol 1 PTT - 26.6 *2/6/2025 at 4:02 am Citrol 1 PTT - 26.5 *2/6/2025 at 9:09 am Citrol 1 PTT - 26.7 *2/7/2025 at 1:06 am Citrol 1 PTT - 25.7 *2/7/2025 at 9:08 am Citrol 1 PTT - 26.7 *2/8/2025 at 3:27 am Citrol 1 PTT - 26.7 *2/8/2025 at 2:49 pm Citrol 1 PTT - 26.3 *2/9/2025 at 4:41 am Citrol 1 PTT - 26.9 *2/10/2025 at 2:40 am Citrol 1 PTT - 26.7 *2/11/2025 at 6:31 pm Citrol 1 PTT - 29.9 *2/12/2025 at 4:08 am Citrol 1 PTT - 26.9 *2/13/2025 at 1:27 am Citrol 1 PTT - 26.7 and 2/13/2025 at 1:29 am Citrol 3 PTT - 55.2 *2/13/2025 at 5:25 pm Citrol 3 PTT - 52.5 *2/14/2025 at 1:12 am Citrol 1 PTT - 26.6 *2/17/2025 at 2:39 am Citrol 1 PTT - 26.7 *2/17/2025 at 6:46 pm Citrol 1 PTT - 30.2 and 2/17/2025 at 6:48 pm Citrol 3 PTT 67.6 *2/18/2025 at 1:14 am Citrol 1 PTT - 26.9 *2/19/2025 at 1:18 am Citrol 1 PTT - 26.7 *2/19/2025 at 5:27 pm Citrol 1 PTT - 29.9 and 2/19/2025 at 5:29 pm 64.4 *2/20/2025 at 1:19 am Citrol 1 PTT - 26.7 *2/21/2025 at 1:19 am Citrol 1 PTT - 26.7 *2/21/2025 at 5:11 pm Citrol 1 PTT - 63.7 *2/22/2025 at 2:46 am Citrol 1 PTT - 26.5 *2/25/2025 at 1:16 am Citrol 1 PTT - 26.7 *2/26/2025 at 5:19 pm Citrol 1 PTT - 30.9 5. For the above QC the laboratory would occasionally document "accept per Westgard". However, Westgard QC rules are based upon calculated standard deviations. The laboratory did not calculate the standard deviation for any of the above out of range QC. 6. GS #1 confirmed at the time of the survey, the laboratory did not have any additional corrective action documented for the out of range QC. 7. The laboratory performs on average of 16 PTT tests per month. GS#1 stated at the time of the survey, the laboratory did not know how to pull an electronic report to confirm how many patient PT samples the laboratory performed in February 2025. C. Based on review of D-dimer records and confirmed by interview with general supervisor identifier #1 (GS #1) at approximately 12:16 pm on 4/23/25, the laboratory failed to take and document corrective action when the D-dimer quality control (QC) results failed to meet the laboratory's established criteria for acceptability for three out of 22 time periods from 2/1/2025 - 2/28/2025. The findings include: 1. GS #1 confirmed the laboratory performed D-dimer QC every eight hours of patient testing. 2. GS#1 confirmed that from 2/1/2025 - 2/6/2025 the laboratory used QC level 1 lot number 575607, expiration date 3/20/2025 and QC level 2 lot number 575507, expiration date 3/20/2025. For these lot numbers the laboratory used the following QC ranges: Control 1 D-dimer 0.28 mg/L - 0.42 mg/L Control 2 D-dimer 2.14 mg/L - 3.22 mg/L 3. The laboratory had the following out of range QC results: *2/3/2025 at 10:51 am Control 2 D-dimer - 3.42 *2/4/2025 at 5:43 pm Control 2 D-dimer - 3.62, rerun at 6:11 pm Control 2 D-dimer 3.69, and rerun at 6:55 pm Control 2 D-dimer - 3.48. *2/6/2025 at 4:18 pm Control 1 D-dimer - 0.48, rerun at 5:38 pm Control 1 D-dimer 0.5, and rerun at 6:22 pm Control 1 D-dimer 0.48. Also 2/6/2025 at 4/22 pm Control 2 D-dimer - 3.59, rerun at 4:34 pm Control 2 D-dimer 3.59, rerun at 5:42 Control 2 D-dimer 3.72, and rerun at 6:26 pm Control 2 D-dimer 3.84. 4. For the

	above QC the laboratory would occasionally document "accept per Westgard". However, Westgard QC rules are based upon calculated standard deviations. The laboratory did not calculate the standard deviation for any of the above out of range QC. 5. GS #1 confirmed at the time of the survey, the laboratory did not have any additional corrective action documented for the out of range QC. 6. The laboratory performs on average of 23 D-dimer tests per month. GS#1 stated at the time of the survey, the laboratory did not know how to pull an electronic report to confirm how many patient PT samples the laboratory performed in February 2025. THIS IS A REPEAT DEFICIENCY FROM THE PREVIOUS SURVEY ON 4/25/2023.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, prothrombin time (PT), partial thromoplastin time (PTT), and D-dimer records, Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 procedure, blood bank freezer temperature monitoring records, the Power Down/Disaster Blood Storage Freezer and Equipment Control procedures, lack of blood bank refrigerator and freezer alarm check records and interview with general supervisor identifier #1 (GS #1) at approximately 12:16 pm on 4/23/25, the laboratory failed to establish a quality assessment program that assessed and identified problems related to PT, PTT, D-dimer quality controls (QC) from February 2025 and the storage of red blood cells and fresh frozen plasma for two out of two years from 1/1/2023 - 4/23/2025. The findings include: 1. The laboratory failed to follow procedures for establishing the criteria for QC acceptability prior to reporting patient samples when the laboratory switched to new lot numbers of PT and PTT reagent. Refer to D5401. 2. The laboratory failed to perform two level of QC every 8 hours of patient testing. Refer to D5545. 3. The laboratory failed to establish QC ranges when the laboratory switched to new lot numbers of PT and PTT reagent. Refer to D5469. 4. The laboratory failed to take corrective action when PT, PTT and D-dimer QC fell outside the acceptable ranges. Refer to D5791. 5. The laboratory failed to perform quarterly alarm checks on the blood bank freeze and refrigerator. Refer to D5555. 6. The laboratory failed to store fresh frozen plasma at the appropriate temperature. Refer to D5555.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, prothrombin time (PT), partial thromoplastin time (PTT), and D-dimer records, Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 procedure, blood bank freezer temperature monitoring records, the Power Down/Disaster Blood Storage Freezer and

	Equipment Control procedures, lack of blood bank refrigerator and freezer alarm check records and confirmed by interview with general supervisor identifier #1, the general supervisor failed to ensure that acceptable levels of analytic performance are maintained as specified in D6148.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) (a)(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, prothrombin time (PT), partial thromoplastin time (PTT), and D-dimer records, Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 procedure, blood bank freezer temperature monitoring records, the Power Down/Disaster Blood Storage Freezer and Equipment Control procedures, lack of blood bank refrigerator and freezer alarm check records and confirmed by interview with general supervisor identifier #1 (GS #1) at approximately 2:15 pm on 4/23/2025, the general supervisor failed to monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained for PT, PTT and D-dimer testing for all patients performed from 2/1/2025 - 2/28/2025. Additionally, GS #1 failed to ensure that the laboratory maintained acceptable levels of analytic performance for red blood cell and fresh frozen plasma storage for two out of two years from 1/1/2024 - 4/23/2025. The findings include: 1. GS #1 failed to ensure the laboratory followed procedures for establishing criteria for QC acceptability prior to resorting patient samples when the laboratory switched to new lot numbers of PT and PTT reagent. Refer to D5401. 2. GS #1 failed to ensure the laboratory established the criteria for QC acceptability prior to performing patient samples when the laboratory put into use new lot numbers of PT and PTT reagents on 2/1/2025. Refer to D5469. 3. GS #1 failed to ensure the laboratory performed two levels of PT and PTT QC each eight hours of patient operation. Refer to D5545. 4. GS #1 failed to ensure the laboratory stored fresh frozen plasma at the appropriate temperature. Refer to D5555. 5. GS #1 failed to ensure the laboratory performed quarterly alarm checks on the blood bank freezer and refrigerator. Refer to D5555. 6. GS #1 failed to ensure the laboratory performed and documented corrective action when PT, PTT, and D-dimer quality controls fell outside the acceptable ranges. Refer to D5783. 7. GS #1 failed to ensure the laboratory established a quality assessment program to assess and identify issues with PT, PTT and D-dimer quality controls and the proper storage of red blood cells and fresh frozen plasma. Refer to D5791.