

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0387204	(X3) Date Survey Completed 11/07/2024
Name of Provider or Supplier Jefferson County Health Center	Street Address, City, State 2000 S Main Street, Fairfield, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observations made during the survey, review of blood culture media quality control (QC) certificates and the Media Individualized Quality Control Plan (IQCP) and confirmed by interview with the general supervisor identifier #2 (GS2) at 9:38 am on 10/31/2024, the laboratory failed to retain blood culture media QC certificates for all lot numbers of blood culture media used between 1/1/2023 - 10/31/2024. The findings include: 1. The Media IQCP states the laboratory will retain blood culture media QC certificates as proof of quality control. 2. Observations made during the survey revealed the laboratory used Bactec Peds Plus, Bactec Lytic Anaerobe, and Bactec Lytic Aerobe blood culture media. 3. At the time of the survey, GS2 confirmed the laboratory did not retain the lot numbers and expiration dates of all blood culture media used from 1/1/2023 - 10/31/2024. In addition, the laboratory did not retain the media QC certificates for all blood culture media used from 1/1/2023 - 10/31/2024.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p>

This STANDARD is not met as evidenced by:
Based on review of Wisconsin State Laboratory of Hygiene (WSLH) and College of American Pathologists (CAP) proficiency testing records and confirmed by interview with General Supervisor (GS) #1 at 8:43 am on 10/31/2024, the laboratory failed to perform a self evaluation when the laboratory received four ungraded PT scores from one out of six testing events from 01/01/2023- 10/31/2024. The findings include: 1. For 2023 1st event, the laboratory received ungraded PT test scores for the following: *WSLH PT 2023-Bacti_Viral 1: Cepheid GeneXpert Xpress MVP Bacterial vaginosis- specimen VPM-1; Cepheid GeneXpert Xpress MVP Candida group- specimen VPM-1; Cepheid GeneXpert Xpress MVP Bacterial vaginosis- specimen VPM-2; and Cepheid GeneXpert Xpress MVP Candida group- specimen VPM-3. 2. At the time of the survey, GS #1 confirmed the laboratory did not perform a self evaluation for the ungraded PT test scores listed above.

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 Wisconsin State Laboratory of Hygiene (WSLH) and College of American Pathologists (CAP) proficiency testing (PT) records and confirmed by interview with General Supervisor (GS) #1 at 8:43 am on 10/31/2024, the laboratory failed to take and document corrective action for four unacceptable PT scores from two out of six PT testing events from 01/01/2023- 10/31/2024. The findings include: 1. For 2023 testing event 1, the laboratory received unacceptable PT test scores for the following: *WSLH PT 2023- Bacti_Viral 1- Cepheid GeneXpert Xpress MVP Candida group (specimen VPM-3); Blood culture anaerobic organism ID (specimen MC-4); and SARS-CoV-2 (specimen CM-5) 2. For 2024 testing event 1, the laboratory received unacceptable PT test scores for the following: *WSLH PT 2024- Bacti_Viral 1- Cepheid GeneXpert MRSA/SA (specimen MR-2) 3. At the time of the survey, GS #1 confirmed the laboratory did not take and document corrective action for the unacceptable PT test scores listed above.

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 laboratory policies and procedures, Individualized Quality Control Plans (IQCP), the Laboratory Test List and Annual Volumes report, quality control records, MicroScan Dried Gram Positive and MicroScan Dried Gram Negative instructions for use, Cobas 8000 Core/ISE maintenance records, blood bank alarm check records, coagulation lot study documents, the 12/15/2022 survey plan of

correction, and lack of training records, and confirmed by interview with general supervisor identifier #1, general supervisor identifier #2, and general supervisor identifier #3 the laboratory failed to meet the analytic systems requirements in 493.1251 through 493.1283 by failing to have written policies and procedures as specified in D5401; failing to follow manufacturer's instructions when performing quality controls as specified in D5411; failing to perform and document maintenance as specified in D5429; failing to perform two levels of quality controls according to the IQCP as specified in D5445; failing to perform blood bank alarm checks as specified in D5555; failing to perform and document corrective action when quality control results fell outside the established ranges as specified in D5783; and failing to take effective corrective action to resolve quality control issues as specified in D5793.

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 review of laboratory policies and procedures and confirmed by interview with the general supervisor identifier #2 (GS2) at 9:38 am on 10/31/2024, the laboratory failed to have procedures for three out of eight microbiology test systems. The findings include: 1. At the time of the survey, the laboratory did not have a written procedure for the Beckman Coulter DxM 1040 Walkaway (including quality control requirements), the BioFire FilmArray, and the BD Bactec - FX Top. 2. GS2 confirmed the laboratory routinely performed patient testing using the Beckman Coulter DxM 1040 Walkaway, the BioFire FilmArray, and the BD Bactec - FX Top test systems.

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 review of bacteriology quality control (QC) records and MicroScan Dried Gram Positive and MicroScan Dried Gram Negative instructions for use (IFU) and confirmed by interview with general supervisor identifier #2 (GS2) at 9:38 am on 10/31/2024, the laboratory failed to following the manufacturer's instructions for performing gram positive and gram negative substrate (biochemical) QC for two out of two lot numbers of identification panels used from 9/9/2024 - 10/31/2024. The findings include: 1. The MicroScan Dried Gram Positive IFU states for each new lot of gram positive identification panels the laboratory must perform QC using: Staphylococcus aureus ATCC 29213, Enterococcus faecalis ATCC 29212, Streptococcus bovis ATCC 49147, and Micrococcus luteus ATCC 49732. 2. On 9/10/2024 the laboratory started using lot number 2025-08-22 of gram positive

identification panels. The laboratory performed QC using the following organisms: Enterococcus faecalis ATCC 29212, Staphylococcus aureus ATCC 4330, Staphylococcus aureus 29213, Staphylococcus aureus BAA-975, and Echerichia coli ATCC 35218. 3. GS2 confirmed the laboratory did not use organisms Streptococcus bovis ATCC 49147, and Micrococcus luteus ATCC 49732 to perform QC on lot number 2025-08-22 of gram positive identification panels. 4. The MicroScan Dried Gram Negative IFU states for each new lot number of gram negative identification panels the laboratory must perform QC using: Echerichia coli ATCC 25922, Pseudomonas aeruginosa ATCC 27853, Klebsiella oxytoca ATCC 49131, and Proteus vulgaris ATCC 49132. 5. On 9/9/2024 the laboratory started using lot number 2028-08-23 for gram negative identification panels. The laboratory performed QC using the following organisms: Echerichia coli ATCC 35218, Echerichia coli ATCC 25922, Klebsiella pneumoniae ATCC 700603 and Pseudomonas aeruginosa ATCC 27853. 6. GS2 confirmed the laboratory did not use organisms Klebsiella oxytoca ATCC 49131, and Proteus vulgaris ATCC 49132 for lot number 2028-08-23 for gram negative identification panels.

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:

A. Based on review of the Cobas 8000 Core/ISE maintenance records and confirmed by interview with General Supervisor (GS) #3 at 11:44 am on 10/31/2024, the laboratory failed to perform and document all weekly, monthly, and every 2 month maintenance on the Cobas 8000 Core/ISE instrument for 2 out of 44 weeks, 10 out of 10 months, and 3 out of 5 every 2 month periods from 1/1/2024 - 10/31/2024. The findings include: 1. The Cobas 8000 Core/ISE maintenance log stated the laboratory must perform the following weekly: *Power off analyzer and control unit *Power off data manager *Clean ISE probe rinse stations *Power on data manager *Power on analyzer and control unit *Perform TraceDoc archive 2. Review of the Cobas 8000 Core/ISE maintenance log indicated the laboratory did not perform weekly maintenance activities during the weeks of 04/25/2024 and 07/04/2024. 3. The Cobas 8000 Core/ISE maintenance log stated the laboratory must perform the following monthly: *Check ISE dilution vessels for crystallization and contamination *Clean ISE reagent aspiration filters *Clean water containers *Clean ECO-D aspiration filter 4. Review of the Cobas 8000 Core/ISE maintenance log indicated the laboratory did not perform all monthly maintenance activities during the months of January 2024-October 2024. 5. The Cobas 8000 Core/ISE maintenance log stated the laboratory must perform the following every 2 months: *Replace ISE NA, K, Cl Cartridges 6. Review of the Cobas 8000 Core/ISE maintenance log indicated the laboratory did not perform every 2 month maintenance activities during the months of January 2024, May 2024, and July 2024. 7. At the time of the survey, GS #3 confirmed the laboratory did not perform and document all weekly, monthly or every 2 month maintenance activities listed above from 1/1/2024 - 10/31/2024. B. Based on review of the Cobas c 502 Module maintenance records and confirmed by interview with General Supervisor (GS) #3 at 11:44 am on 10/31/2024, the laboratory failed to perform and document all weekly, monthly, and quarterly maintenance activities on the Cobas c 502 Module for 3 out of 44 weeks, 7 out of 10 months, and 4 out of 4

quarters from 1/1/2024 - 10/31/2024. The findings include: 1. The Cobas c 502 Module maintenance log stated the laboratory must perform the following weekly: *Clean cell covers *Clean rinse stations *Perform weekly pipe 2. Review of the Cobas c 502 Module maintenance log indicated the laboratory did not perform weekly maintenance activities during the weeks of 01/18/2024, 04/25/2024, and 07/04/2024. 3. The Cobas c 502 Module maintenance log stated the laboratory must perform the following monthly: *Clean incubator bath and filter *Clean detergent aspiration filters *Clean circuit board rack filter *Clean power supply filter *Clean radiator filter *Replace reaction cells 4. Review of the Cobas c 502 Module maintenance log indicated the laboratory did not perform all monthly maintenance activities during the months of January 2024, March 2024, April 2024, June 2024, July 2024, September 2024, and October 2024. 5. The Cobas c 502 Module maintenance log stated the laboratory must perform the following quarterly: *Clean ultrasonic mixers 6. Review of the Cobas c 502 Module maintenance log indicated the laboratory did not perform quarterly maintenance activities from 01/01/2024- 10/31/2024. 7. At the time of the survey, GS #3 confirmed the laboratory did not perform and document all weekly, monthly, or quarterly maintenance activities listed above from 1/1/2024 - 10/31/2024.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on observations made during the survey, lack of function check records and procedures, and confirmed by general supervisor identifier #1 (GS1) at approximately 3:00 pm on 10/31/2024, the laboratory failed to define the frequency for performing function check protocols including pipette calibration. In addition, the laboratory failed to perform pipette calibrations from 1/1/2023 - 10/31/2024. The findings include: 1. Observations at the survey revealed the laboratory had in use 8 pipettes. 2. At the time of the survey, GS1 confirmed laboratory did not have a policy defining the frequency for performing pipette calibrations and failed to perform pipette calibrations from 1/1/2023 - 10/31/2024.

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 review of calibration and calibration verification records, chemistry reagent instructions for use (IFU), and confirmed by interview with General Supervisor (GS) #1 at 11:44 am on 10/31/2024, the laboratory failed to perform calibration verification procedures every six months for one out of three time periods from 1/1/2023 - 10/31/2024 for the Roche Cobas 8000 test system. The findings include: 1. Review of the Roche Cobas 8000 instrument reagent IFUs indicated calibration verification must be performed for the following analytes: albumin, alkaline phosphatase, alanine transaminase, ammonia, amylase, aspartate aminotransferase, bicarbonate, direct bilirubin, total bilirubin, calcium, chloride, cholesterol, creatine kinase, creatinine, gamma-glutamyl transferase, glucose, high-density lipoprotein, hemoglobin A1C, beta-hydroxybuterate, iron, lactate, lactate dehydrogenase, lipase, magnesium, phosphorus, potassium, sodium, total protein, triglycerides, uric acid, urea nitrogen, unsaturated iron-binding capacity, urine amylase, urine chloride, urine creatinine, urine potassium, urine sodium, urine glucose, urine microalbumin, alcohol, digoxin, lithium, salicylate, beta human chorionic gonadotropin, carcinoembryonic antigen, creatine kinase- MB, estradiol, ferritin, folate, free thyroxine, free triiodothyronine, follicle stimulating hormone, luteinizing hormone, N-terminal pro-B-type natriuretic, procalcitonin, prostate specific antigen, free prostate specific antigen, total testosterone, total triiodothyronine, troponin-T, c-reactive protein, thyroid stimulating hormone, vitamin B12, and vitamin D. 2. At the time of the survey, GS #1 confirmed the laboratory did not have calibration verification records which included a minimal (zero) value, a mid-point value, and maximum value for the analytes listed above from the time period between 01/01/2024 and 10/31/2024.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Test List & Annual Volume form, the laboratory's

serum human chorionic gonadotropin (HCG) qualitative Individualized Quality Control Plan (IQCP), quality control (QC) records, and confirmed by interview with General Supervisor (GS) #1 at 11:16 am on 10/31/2024, the laboratory failed to perform two levels of QC with each new lot number and shipment of Cardinal Health HCG Combo kits for 10 out of 10 lot numbers of kits used between 01/01/2024- 10/31/2024. The findings include: 1. Review of the Laboratory Test List & Annual Volume form indicated the laboratory used the Cardinal Health HCG Combo kit to perform both urine and serum HCG qualitative testing. 2. The laboratory's IQCP stated that the laboratory would perform 2 levels of QC for each new lot number and shipment of test kits for serum HCG qualitative testing. 3. Review of the HCG QC log indicated the laboratory performed QC for the following dates and lot numbers: *01/10/2024- lot 743958, expiration 06/23/2025 *02/02/2024- lot 743965, expiration 06/23/2025 *02/14/2024- lot 713349, expiration 04/11/2025 *03/21/2024- lot 732424, expiration 05/25/2025 *05/19/2024- lot 766005, expiration 08/02/2025 *06/04/2024- lot 817990, expiration 11/26/2025 *07/25/2024- lot 808393, expiration 11/06/2025 *08/15/2024- lot 844067, expiration 02/02/2026 *09/19/2024- lot 855440, expiration 03/21/2026 *10/11/2024- lot 869294, expiration 04/16/2026 4. At the time of the survey, GS #1 confirmed the laboratory performed urine HCG QC only and did not perform two levels of serum HCG qualitative QC for each of the lot numbers of test kits listed above.

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 review of the laboratory's immunohematology policies, blood bank system alarm check records, and confirmed by interview with General Supervisor (GS) #1 at 2:56 pm on 10/31/2024, the laboratory failed to inspect, perform, and document quarterly alarm system checks for the blood storage refrigerator for four out of eight time periods and the blood bank plasma freezer for eight out of eight time periods from 01/01/2023- 10/31/2024. The findings include: 1. The laboratory's "Testing of Refrigerator Alarms" policy stated that the alarms on the blood storage refrigerator would be checked quarterly. 2. The laboratory's "Testing of Plasma Freezer Alarm" policy stated that the alarms on the plasma freezer would be checked quarterly. 3. At the time of the survey, GS #1 confirmed that the laboratory did not perform quarterly alarm checks on the blood storage refrigerator from 01/01/2024- 10/31/2024. In addition, GS #1 confirmed that the laboratory did not perform quarterly alarm checks on the plasma freezer from 01/01/2023- 10/31/2024.

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 review of the Laboratory Test List and Annual Volume report and confirmed by general supervisor identifier #1 (GS1) at 11:15 am on 10/31/2024, the laboratory failed to perform comparison testing twice annually for four out of four time periods from 1/1/2023 - 10/31/2024 for the analytes: campylobacter antigen, clostridioides difficile toxin A and B, shiga toxin 1 and 2, cryptosporidium antigen, giardia antigen, norovirus 1 and 2, influenza A, influenza B, respiratory syncytial virus, and SARS-CoV-2. The findings include: 1. The laboratory performs the following testing on the BioFire film array: campylobacter antigen, clostridioides difficile toxin A and B, shiga toxin 1 and 2, cryptosporidium antigen, giardia antigen, norovirus 1 and 2, influenza A, influenza B, respiratory syncytial virus, and SARS-CoV-2. 2. The laboratory performs the following testing on the Cepheid GeneXpert: clostridioides difficile toxin A and B, norovirus 1 and 2, influenza A, influenza B, respiratory syncytial virus, and SARS-CoV-2. 3. The laboratory performs campylobacter antigen testing using the Meridian Immunocard STAT test kit. 4. The laboratory performs shiga toxin 1 and 2 testing using the Meridian Immunocard EHEC test kit. 5. The laboratory performs cryptosporidium and giardia antigen testing using the Cardinal Health test kit. 6. At the time of the survey, GS1 confirmed the laboratory had not performed comparison testing for the above analytes from 1/1/2023 - 10/31/2024.

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:

A. Based on review of coagulation lot study documents, prothrombin time (PT) and partial thromboplastin time (PTT) quality control (QC) records, coagulation QC procedures and confirmed by general supervisor identifier #1 (GS1), at 1:30 pm on 10/31/2024 the laboratory failed to document corrective action when PT and PTT QC level 1 and QC level 3 fell outside of the established ranges for 27 out of 30 days from 4/1/2024 - 4/30/2024. The findings include: 1. The coagulation QC procedures stated, "Do not release the results of analytical procedures unless the results of controls are within the determined limits of the procedure." 2. In April 2024 the laboratory used Innovin lot number 564624B, expiration 6/2/2025 to perform PT testing. GS1 confirmed with each new lot of Innovin the laboratory performed coagulation lot studies and also established the QC ranges for PT and PTT. 3. The coagulation lot study revealed the laboratory established the following QC ranges (QC1 lot number 564881A, expiration date 4/4/2026 and QC3 lot number 556581A, expiration date 4/16/2024) for PT and PTT testing: *PT testing QC1 9.8 - 10.4 seconds *PT testing QC3 43.4 - 47.6 seconds *PTT testing QC1 25.3 - 26.6 seconds *PTT testing QC3 54.2 -

57.7 seconds 4. On 4/1/2024 the laboratory accepted the following out of range QC results: 04:11 am 41.1 for PT QC3, 14:33 pm 9.6 for PT QC1, and 14:35 pm 40.5 for PT QC3. 5. On 4/2/2024 the laboratory accepted the following out of range QC results: 14:34 pm 10.5 for PT QC1 and 14:36 pm 41.0 for PT QC3. 6. On 4/3/2024 the laboratory accepted the following out of range QC results: 13:58 pm 42.7 for PT QC3. 7. On 4/4/2024 the laboratory accepted the following out of range QC results: 13:58 pm 43.2 for PT QC3, 04:19 am 58.3 for PTT QC3, and 13:58 pm 58.8 for PTT QC3. 8. On 4/5/2024 the laboratory accepted the following out of range QC results: 04:15 am 43.0 for PT QC3, and 14:18 pm 41.9 for PT QC3. 9. On 4/6/2024 the laboratory accepted the following out of range QC results: 04:21 am 42.7 for PT QC3, and 04:19 am 25.0 for PTT QC1, and 15:40 pm 58.9 for PTT QC3. 10. On 4/8/2024 the laboratory accepted the following out of range QC results: 04:28 am 41.6 for PT QC3, 13:55 pm 9.7 for PT QC1, and 13:57 pm 41.2 for PT QC3. 11. On 4/10/2024 the laboratory accepted the following out of range QC results: 04:04 am 25.2 PTT QC1 and 15:25 pm 58.8 for PTT QC3. 12. On 4/11/2024 the laboratory accepted the following out of range QC results: 14:53 pm 59.3 for PTT QC3. 13. On 4/12/2024 the laboratory accepted the following out of range QC results: 04:11 am 43.1 for PT QC3 and 14:42 pm 42.2 for PT QC3. 14. On 4/13/2024 the laboratory accepted the following out of range QC results: 04:27 am 42.3 for PT QC3, 16:04 pm 9.5 for PT QC1, 16:06 pm 41.8 for PT QC3, and 04:25 am 25.0 for PTT QC1. 15. On 4/14/2024 the laboratory accepted the following out of range QC results: 04:27 am 43.2 for PT QC3, 15:49 pm 9.7 for PT QC1, and 15:51 pm 42.2 for PT QC3. 16. On 4/15/2024 the laboratory accepted the following out of range QC results: 05:31 am 42.4 for PT QC3 and 15:12 pm 42.3 for PT QC3. 17. On 4/16/2024 the laboratory accepted the following out of range QC results: 14:26 pm 43.1 for PT QC3. 18. On 4/17/2024 the laboratory accepted the following out of range QC results: 04:11 am 43.4 for PT QC3 and 15:08 58.6 for PTT QC3. 19. On 4/18/2024 the laboratory accepted the following out of range QC results: 14:58 pm 42.2 for PT QC3 and 14:58 pm 58.3 for PTT QC3. 20. On 4/20/2024 the laboratory accepted the following out of range QC results: 04:14 am 42.5 for PT QC3, 16:28 pm 9.7 for PT QC1, 16:30 41.0 for PT QC3, and 04:12 am 24.7 for PTT QC1. 21. On 4/21/2024 the laboratory accepted the following out of range QC results: 04:15 am 42.3 for PT QC3 and 04:13 am 24.8 for PTT QC1. 22. On 4/22/2024 the laboratory accepted the following out of range QC results: 04:20 am 58.0 for PTT QC3 and 14:41 pm 57.9 for PTT QC3. 23. On 4/23/2024 the laboratory accepted the following out of range QC results: 14:15 am 58.1 for PTT QC3. 24. On 4/24/2024 the laboratory accepted the following out of range QC results: 04:04 am 41.7 for PT QC3 and 14:18 pm 58.6 for PTT QC3. 25. On 4/25/2024 the laboratory accepted the following out of range QC results: 14:34 pm 58.8 for PTT QC3. 26. On 4/26/2024 the laboratory accepted the following out of range QC results: 22:40 pm 11.0 for PT QC3, 03:28 am 24.7 for PTT QC1 and 22:40 pm 26.7 for PTT QC1. 27. On 4/27/2024 the laboratory accepted the following out of range QC results: 04:31 am 25.1 for PTT QC1. 28. On 4/28/24 the laboratory accepted the following out of range QC results: 15:50 pm 9.6 for PT QC1 and 15:52 pm 58.3 for PTT QC3. 29. On 4/29/2024 the laboratory accepted the following out of range QC results: 14:43 pm 9.5 for PT QC1 and 14:45 pm 58.6 for PTT QC3. 30. On 4/30/2024 the laboratory accepted the following out of range QC results: 04:06 am 43.2 for PT QC3 and 15:12 pm 40.4 for PT QC3. 31. The laboratory performed PT testing on 114 patients and PTT testing on 31 patients on the days the above QC fell outside the established range. 32. At the time of the survey, GS1 confirmed the laboratory did not have corrective action for the 27 days that QC fell outside the established range. B. Based on review of coagulation lot study documents, prothrombin time (PT) and partial thromboplastin time (PTT) quality control (QC) records, coagulation QC procedures and confirmed by general supervisor identifier #1 (GS1), at 1:30 pm on 10/31/2024 the laboratory

failed to evaluate patient results when the laboratory accepted QC outside of the established ranges for 27 out of 30 days from 4/1/2024 - 4/30 /2024. For findings refer to D5783 A. THIS IS A REPEAT DEFICIENCY FROM THE SURVEY ON 12/15 /2022.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of coagulation lot study documents, prothrombin time (PT) and partial thromboplastin time (PTT) quality control (QC) records, coagulation QC procedures, the 12/15/2022 survey plan of correction and confirmed by general supervisor identifier #1 (GS1), at 1:30 pm on 10 /31/2024 the laboratory failed take effective corrective action to resolve coagulation QC problems when PT and PTT QC level 1 and level 3 fell outside of the established ranges for 27 out of 30 days from 4/1 /2024 - 4/30 /2024. The findings include: 1. At the 12/15/2022 CLIA survey the laboratory had been cited for D5783 for coagulations QC being outside the established range. 2. On 1/04/2023 the laboratory submitted a plan of correction that stated, "Upon review of testing records multiple techs were involved with the days that results for coag level 3 were out of range.... Believe problem to be not waiting long enough after reconstitution before running QC material... Lab manager discussed this deficiency with staff at a December lab meeting. Reminded staff that QC must be in before reporting patient results. Primary operator of CA-660 will review results monthly to make sure values are in range. Will also inservice all techs on proper reconstitution of QC material. 3. The laboratory did not take effective corrective action, refer to D5783 A and B.

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 review of laboratory policies and procedures, Individualized Quality Control Plans, quality control records and MicroScan Dried Gram Positive and MicroScan Dried Gram Negative instructions for use, coagulation lot study documents, the 12/15 /2022 survey plan of correction, and lack of training records, and confirmed by interview with general supervisor identifier #1 and general supervisor identifier #2 the laboratory director failed to meet the responsibilities to ensure quality control programs are established and maintained as specified in the standard D6093; to ensure quality assessment programs are established and maintained as specified in the standard D6094; to ensure all testing personnel received the appropriate training prior to reporting patient test results as specified in the standard D6101; and to ensure that

an approved procedure is available for all aspects of the testing process as specified in D6106.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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:

A. Based on review of bacteriology quality control (QC) records and MicroScan Dried Gram Positive and MicroScan Dried Gram Negative instructions for use (IFU), and confirmed by interview with general supervisor identifier #2 (GS2) at 9:38 am on 10/31/2024, the laboratory director failed to ensure the laboratory established a QC program that included following the manufacturer's instructions for performing gram positive and gram negative substrate (biochemical) QC for two out of two lot numbers of identification panels used from 9/9/2024 - 10/31/2024. For findings refer to D5411. B. Based on review of coagulation lot study documents, prothrombin time (PT) and partial thromboplastin time (PTT) quality control (QC) records, coagulation QC procedures and confirmed by general supervisor identifier #1 (GS1), at 1:30 pm on 10/31/2024 the laboratory director failed to ensure the laboratory maintained an acceptable QC program when PT and PTT QC level 1 and level 3 fell outside of the established ranges for 27 out of 30 days from 4/1/2024 - 4/30/2024. For findings refer to D5783. C. Based on review of the Annual Volume and Test List, the laboratory's serum human chorionic gonadotropin (HCG) qualitative Individualized Quality Control Plan (IQCP), quality control (QC) records, and confirmed by interview with General Supervisor (GS) #1 at 11:16 am on 10/31/2024, the laboratory director failed to ensure the laboratory performed two levels of QC with each new lot number and shipment of Cardinal Health HCG Combo kits for 10 out of 10 lot number of kits used between 01/01/2024 - 10/31/2024. For findings refer to D5445.

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:

A. Based on lack of a quality assessment policy and confirmed by general supervisor identifier #1 (GS1) at approximately 3:00 pm on 10/31/2024, the laboratory director failed to ensure that laboratory established a written quality assessment policy. The findings include: 1. At the time of the survey, the laboratory did not have a written quality assessment policy. 2. GS1 confirmed the laboratory did not have a written quality assessment policy. B. Based on review of coagulation lot study documents, prothrombin time (PT) and partial thromboplastin time (PTT) quality control (QC) records, coagulation QC procedures, the 12/15/2022 survey plan of correction and confirmed by general supervisor identifier #1 (GS1), at 1:30 pm on 10/31/2024 the laboratory director failed to ensure the laboratory maintained an effective quality assessment policy to resolve coagulation QC problems when PT and PTT QC level 1

and level 3 fell outside of the established ranges for 27 out of 30 days from 4/1/2024 - 4/30 /2024. For findings refer to D5793.

D6101

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on review of personnel records and the Laboratory Personnel Report Form CMS-209 and confirmed by interview with the general supervisor, identifier #1 (GS1), at 8:38 am on 10/31/2024, the laboratory director failed to ensure that all testing personnel received the appropriate training prior to reporting patient results for one of out seven testing personnel hired since the last survey on 12/15/2022. The findings include: 1. The Laboratory Personnel Report Form CMS-209 revealed that the laboratory employed testing personnel indenter #4 (TP4) after the last survey performed on 12/15/2022. 2. GS1 confirmed that TP4 routinely performed both moderate and high complexity patient testing. 3. At the time of the survey, the laboratory director failed to ensure the laboratory documented training for TP4.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and confirmed by interview with the general supervisor, identifier #2 (GS2) at 9:38 am on 10/31/2024, the laboratory director failed to ensure the laboratory had procedures for three out of eight microbiology test systems. For findings refer to D5401.