Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2047655	03/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Amerathon Health Llc Dba American Health	10204 Lantern Road, Fishers, IN	

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	A complaint survey was completed on 3/5/26 and it was determined that Immediate Jeopardy exists for the following condition level deficiencies: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director 50583
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to enroll and participate in a proficiency testing program for the Specialities Chemistry and Hematology for 2 of 3 events (event 1 and event 2) in 2025. Findings include: 1. Review of the CASPER report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system indicated the laboratory had no proficiency testing scores for the testing events 1 and 2 for the Specialties of Chemistry and Hematology for 2025: a) Hematology: WBC Diff, RBC, HGB, WBC Count, PLT, PTT, PT. b) Routine Chemistry: ALT; ALB; ALK Phos; AST; T-Bili; CA, Total; CO2; CL; CHOL, HDL, CREA, GLU, MG, PHOS, K+, NA+, TP, TRIG, BUN. c) Toxicology: VANCO 2. Policy and Procedure titled "Proficiency Testing" policy number 6-102.18 MWR, signed and dated on 12-31-2024 by the laboratory director, states on page 1 of 9, "Participation in a CLIA (clinical laboratory Improvement amendment) approved proficiency testing program is required for all analytes tested." 3. In an interview on 3-5-2026 at 9:15 am, SP-01 (Technical Consultant) confirmed the laboratory had not

	enrolled in a proficiency testing program for event 1 and event 2 in 2025 and did not perform proficiency testing for those events. 4. Review of the Clincial Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS 116 states the annual testing volume for Chemistry and Hematology is 1,080,130. Legend: WBC Diff= White Blood Cells Differential RBC= Red Blood Cells HGB= Hemoglobin HCT= Hematocrit WBC= White Blood Cells PLT= Platelet PTT= Partial Thromboplastin Time PT= Prothrombin Time ALB= Albumin ALP= Alkaline Phosphatase ALT= Alanine Transaminase AST= Aspartate Aminotransferase BUN= Blood Urea Nitrogen CA= Calcium, total CHOL= Cholesterol, total CL= Chloride CO2= Carbon dioxide CREA= Creatinine GLU= Glucose PHOS= Phosphorus K+= Potassium MG= Magnesium NA+= Sodium TP= Total Protein T-BILI= Bilirubin, total TRIG= Triglycerides HDL= High Density Lipoprotein VANCO= Vancomycin-toxicology
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) (2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1). This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to enroll and participate in a proficiency testing program as required by their policy for tests not included in subpart I under the Speciality of Chemistry for 2 of 3 events (event 1 and event 2) in 2025. Findings include: 1. Policy and Procedure titled "Proficiency Testing" policy number 6-102.18MWR, signed and dated on 12-31-2024 by the laboratory director, states on page 1 of 9, "Participation in a CLIA (clinical laboratory Improvement amendment) approved proficiency testing program is required for all analytes tested." 2. The "Enclosure I Test Methodology and Annual Test Volume Log", signed by the laboratory director on 3/3/2026, listed the following analytes not included under subpart I as being testing at this laboratory: D-BILI, and NH3. The annual test volume was listed as 18,886 for NH3 and 22,053 for D-BILLI . 3. In an interview on 3-5-2026 at 9:15 am, SP-01 (Technical Consultant) confirmed the laboratory had not enrolled in a proficiency testing program for event 1 and event 2 in 2025 and did not perform proficiency testing for those events. Legend: D-BILI= Direct Bilirubin NH3= Ammonia
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the preanalytic processes where patient specimens for testing

	were not received within four hours of the collection time as defined by their policy for 4 of 17 patients reviewed. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to process patient specimens for testing within four hours of the collection time as defined by their policy for 4 of 17 patients reviewed. Findings include: 1) Policy titled, "Barcode Labeling of Specimens," policy #=17-116.5MDW, dated and signed by the LD on 6/17 /22, read on page 4 of 5, "...*Serum samples should be spun within 4 hour of collection..." 2) Review of patient results reports indicated the following patient specimens for testing were received outside of the laboratory's four hour requirement from the time of collection and/or the timeframe was "unknown": Patient Date/Time Date/Time Result(s) Collected Received pt #1 11/4/25 11/4/25 Urea Nitrogen 02:15 am 7:32 am 15 (no units) pt #2 12/9/25 12/10/25 Potassium Unknown 5:25 pm 3.7 (no units) pt #3 1/31/26 2/2/26 Calcium 1:22 pm 2:49 pm 10.3 (no units) pt #4 3/2/26 3/2 /26 Carbon Dioxide 07:03 am 1:51 pm 25 (no units) 3) In interview on 3/2/26 at 10:08 am, SP-1 (Laboratory Consultant) confirmed the laboratory was recieving and processing patient specimens for testing beyond the four hour timeframe once collected for the above patient test results. 4) Review of the Clincial Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS 116 states the annual testing volume for Chemistry is 776,461. Legend: SP=staff person, LD= Laboratory Director
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, document review, lack of documentation, and interview, the laboratory failed to meet the following analytic system requirements: 1. To follow the manufacturer's instructions to complete calculation and reference range verification at least biannually and each change of lot and update the International Sensitivity Index (ISI) each change of lot for the test Prothrombin Time from 1-12-26 to the date of survey (Refer to D5411); 2. To ensure quality control materials were not expired for 1 of 1 Chemistry analyzer (Beckman Coulter AU Series 5822 serial number 2018013)

	from 11-1-2025 to 12-12-25 (Refer to D5417); 3. To ensure quality control materials were not expired for 2 of 2 Hematology analyzers (Beckman Coulter DxH 800, serial numbers 80171963(1) and 68775173(2) from 11-23-25 to 11-28-25 (Refer to D5417); 4. To ensure tachometer and timer checks were performed on 6 of 6 centrifuges observed and used for processing samples from 9-9-2022 to the date of the survey. (refer to D5431); and 5. To perform lot number verification for unassayed controls for the establishment of new means and ranges for 20 of 20 tests on one of one Chemistry analyzer from 11-1-2025 to 12-12-2025. (Refer to D5469).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 observation, document review and interview, the laboratory failed to follow the manufacturer's instructions to complete calculation and reference range verification at least biannually and each change of lot and failed to update the International Sensitivity Index (ISI) each change of lot for the test PT from 1-12-2026 to the date of survey and for 3 of 3 PT patients reviewed. Findings include: 1. During a tour of the laboratory on 3-3-2026 at 12:30 PM, a Sysmex CS-2500 coagulation analyzer serial number 24252 was in use for patient testing for the test PT. The following was observed on the instrument: a. The analyzer's INR calibration curve had a calibration update of 10-6-2025 with a Dade Innovin reagent lot number 564643. The calibration curve expired on 1-12-2026. The ISI value listed on the calibration curve was 1.10. b. The Dade Innovin reagent in use on the analyzer was lot number 564650 with an expiration date of 3-30-2026. 2. A review of a package inserts from an open box of Innovin had a lot number of 564650 and an expiration date of 3-30-2026 with an ISI listed as 1.09. The current lot ISI did not match the ISI in the analyzer. 3. Policy and Procedure titled "Sysmex CS Series Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT)", dated and signed by the LD on 10-15-2025, states on page 8 of 15, "INR calculation and reference range verification is required with 1. A change in lot number or type of PT reagent, 2. An analyzer change, 3. A new PT reference range, 4. A change in the INR calculation, 5. At least biennially." 4. Policy and procedure attachment "Attachment D: Homeostasis Laboratory Reagent Lot Rollover Studies for CS-2500" policy number 10-110m CS dated 1-12-16, signed by the LD on 10-15-2025, states on page 1 of 14, " The following recommendations should be used as a guideline when converting to new lot of reagents for Homeostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use ... Verification of Reference Range ... Calculate mean and 2 SD range. MNPT for INR Calculations must be the geometric mean ... Lot to Lot Method Correlation 40 samples: 20 Normal, 20 Abnormal ..." 5. Document titled "Coagulation QC Control Ranges Log Sheet" confirmed the last lot rollover for Innovin was performed on 8-29-2025 on lot 564632. 6. In interview on 3-5-2026 at 10:10 am, SP-01 (Technical Consultant) confirmed the last Innovin rollover, INR Calculation, and reference range verification was 8-29-2025. SP-01 confirmed that the ISI value in the analyzer is different than the current lot package insert. 7. The following patients had testing for PT without a valid ISI or an Innovin rollover, INR Calculation, and reference range verification being performed. Patient

	Date Result(s) pt#5 1-19-2026 18.7 seconds INR 1.8 pt#6 1-30-2026 16.8 seconds INR 1.6 pt#7 2-2-2026 15.4 seconds INR 1.4 Legend: SP= Staff Person, QC= Quality control, PT= Prothrombin Time, ISI= International Sensitivity Index, INR= International Normalized Ratio, pt= Patient.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A. Based on observation, document review and interview, the laboratory failed to ensure QC materials had not been used beyond the expiration dates for 15 of 15 tests under the assay CBC with differential (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NE, LY, MO, EO and BA) from 11-23-2025 to 11-28-2025 for 2 of 17 patients reviewed. Findings include: 1. On a tour of the laboratory on 3-3-2026 at 1:00 pm with SP-01, the following was observed: a. 2 Beckman Coulter DxH 800 analyzers serial numbers 80171963 Analyzer 1 and serial number 68775173 Analyzer 2 were in use for patient testing. b. QC runs were reviewed on both analyzers for the dates of 11-26-2025 through 11-28-2025: 1) Analyzer #1 QC: Level 1 expired on 11-22-2025 Level 2 expired on 11-22-2025 2) Analyzer #2 QC: Level 1 expired on 11-22-2025 Level 2 expired on 11-22-2025 Level 3 expired on 11-30-2025 2. Document titled "Beckman Coulter Unicell DxH Quality Control Protocol with moving averages", signed by the LD effective on 10-4-2019, states on page 2 of 9, "stable until expiration date on vial stored at 2-30 degrees Celsius." 3. An e-mail from SP-04 (Laboratory Manager) to SP-06 (Testing Personnel) and SP-01 (Technical Consultant) on 10-30-2025 at 2:52 pm, stated "Until we hear back from you will need to keep using the expired QC unfortunately". 4. In an e-mail from SP-03 (Clinical Consultant) to SP-04 (Laboratory Manager) on 1-5-2026 at 5:07 pm, stated "You can use expired QC. We need to pay close attention to trend/bias-the '10x' rule." 5. Document titled "Coulter 6C Cell Control" states on page 2 of 108, "It is not recommended to use the reagent after shelf-life expiration indicated on the label". 6. In an interview on 3-2-2026 at 10:08 am, SP-01 (Technical Consultant) confirmed the laboratory had notified management regarding the 6C QC expiring. SP-01 confirmed the facility was to use expired controls per SP-04 (Laboratory Manager). 7. In an interview on 3-3-2026 at 1:15 pm, SP-06 (Testing Personnel) confirmed they were told to run expired QC materials. 8. A review of patient results reported indicated 2 patient samples were run on the Beckman DxH series SN 80171963 and SN 68775173 between 11-23-2025 and 11-28-2025 with expired QC. a. pt#1 on 11-26-2025 at 4:49 pm - WBC=4.3 K/cmm, RBC=3.02 M/cmm, HGB=9.6 g/dl, HCT= 30.1%, MCV=99.7 fl, MCH=31.9pg, MCHC=32.0 g/dl, RDW=18.4 %, PLT=148 K /cmm, MPV=8.1 fl., NE=81.3 %, LY= 8.5%, MO=9.9%, EO= 0.0%, BA=0.3 %. b. pt#2 on 11-28-2025 at 4:39 pm- WBC=4.6 K/cmm, RBC=2.69 M/cmm, HGB=9.0 g /dl, HCT=26.8 %, MCV=99.5 fl, MCH=33.3 pg, MCHC= 33.5 g/dl, RDW=16.9 %, PLT=158 K/cmm, MPV=8.0 fl., NE=72.8 %, LY= 13.8%, MO=9.9 %, EO=3.1%, BA=0.4 %. B. Based observation, document review, lack of documentation, and interview, the laboratory failed to ensure QC materials had not been used beyond the expiration dates for 20 of 20 tests (ALB, ALP, ALT, AST, BUN, CA, CHOL, CL, CO2, CREA, GLU, PHOS, K+, NA+, TP, T-BILI, TRIG, VANCO, DBILI, HDL) run on one of one Chemistry analyzer from 11-1-2025 to 12-12-2025 for 2 of 17 patients

reviewed. Findings include: 1. On a tour of the laboratory on 3-3-2026 at 2:00 pm, a Beckman AU 5800 SN number 46593457 was in use for patient testing. 2. An e-mail from SP-06 (Testing Personnel) dated 10-30-2025 at 12:39 pm to SP-04 (Laboratory Manager), states that the "Unassayed Chemistry Control (Human)- Quality Control Level 1 and Level 2 will expire on October 31, 2025." 3. An e-mail on 10-31-2025 at 10:25 am, from SP-06 (Testing Personnel) to the facility staff, states the laboratory information system "SLAB will not show AU QC results because the expiration date. We can not tell if QC passed through SLAB." SP-06 requests "please change the expiration date for us." 4. An e-mail dated 11-3-2025 at 10:59 am, from SP-01 to the previous LD, states "We were told to use expired until new came in." 5. An e-mail dated 12-2-2025 at 4:05 pm, from SP-04 (Laboratory Manager) to SP-02 (LD) and SP-01 (Technical Consultant), states "This has been going on for 3 weeks and it all started because the BC rep reported we were using expired QC, not the tech. If we had not used expired QC, this would not have been brought up as an issue but we had no choice since we had no other QC to run, all labs expired." 6. Policy and Procedure titled "Quality Control Protocol for Chemistry with Beckman Coulter AU Series", Policy 8-102.13IND, signed and dated by the Laboratory Director on 1-13-2025 states on page 3 of 6 "E-1", "Verify that the materials are not expired". 7. In an interview on 3-2-2026 at 10:08 am, SP-01 confirmed that management had directed the laboratory staff to run expired controls for Hematology and Chemistry departments. 8. In an interview on 3-3-2026 at 1:15 pm, SP-06 confirmed administration told the laboratory staff to run expired QC. SP-06 confirmed this has happened multiple times. 7. In an interview on 3-3-2026 at 2:00 pm, SP-01 (Technical Consultant) confirmed the laboratory does not keep a log of current lot numbers. SP-01 confirmed the new lot verification dates were entered into the laboratory information system on 12-1-2025 and completed on 12-12-2026. 8. Upon request for QC documentation on the laboratory information system data or Bio-Rad QC package inserts for lot number 92991 and 92992, on 3/3/2026 at 2 pm, SP-01 (Technical Consultant) indicated they do not have documentation for these lot numbers. SP-1 confirmed they do not keep a log of current lot numbers in use. 8. Two patients were tested without valid QC: a) Pt. 3 was tested on 12-1-2025 at 6:59 pm, GLU= 141mg/dl, NA= 141 mEq/L, K= 4.0 mEq/L, CL= 103mEq/L, CO2=25 mEq/L, BUN= 18 mg/dl, CREA=1.4 mg/dl, CA= 7.9 mg/dl, TP= 6.2 g/dl, ALB=3.9 g/dl, ALP= 78 IU/L, AST= 13 IU/L, ALT=13 IU /L, T-BILI=0.3 mg/dl, CHOL=158 mg/dl, TRIG= 132 mg/dl, HDL=42 mg/dl. b) Pt #4 was tested on 12-2-2025 at 7:52 pm, GLU= 95mg/dl, NA= 140 mEq/L, K= 4.9 mEq /L, CL= 103 mEq/L, CL=103 mEq/L, CO2=29 mEq/L, BUN= 26 mg/dl, CREA=0.9 mg/dl, CA= 7.7 mg/dl, TP=6.2 g/dl, ALB= 3.1 mg/dl, ALP= 119 IU/L, AST= 14 IU /L, ALT= 15 IU/L, T-BILI= 0.4 mg/dl, CHOL= 98 mg/dl, TRIG= 129 mg/dl, HDL=32 mg/dl Legend: RDW= Red cell distribution Width WBC= White Blood Cells PLT= Platelet RBC= Red Blood Cells MO= Monocytes HGB= Hemoglobin NE= Neutrophils HCT= Hematocrit LY= Lymphocytes MCV= Mean Corpuscular Volume MCH= Mean Corpuscular Hemoglobin MCHC= Mean Corpuscular Hemoglobin Content MO= Monocytes EO= Eosinophil BA= Basophil MPV= Mean Corpuscular volume mg/dl=milligrams per deciliter mEq/L= milliequivalents per liter IU/L= international units per liter %= percent g/dl= grams per deciliter K/cmm= thousands of cells per cubic millimeter M/cmm= millions per cubic millimeter Fl= femtoliter ALB= Albumin ALP= Alkaline Phosphatase ALT= Alanine Transaminase AST= Aspartate Aminotransferase BUN= Blood Urea Nitrogen CA= Calcium, total CBC= Complete Blood Count CHOL= Cholesterol, total CL= Chloride CO2- Carbon dioxide CREA= Creatinine GLU= Glucose PHOS= Phosphorus K+= Potassium NA+= Sodium TP= Total Protein T-BILI= Bilirubin, total TRIG= Triglycerides VANCO= Vancomycin D-BILI= Direct Bilirubin HDL= High Density Lipoprotein LDL= Low Density Lipoprotein SP= Staff Person, QC= Quality Control, Pt= Patient,

	LD= Laboratory Director, SN= Serial Number,
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following: This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure tachometer and timer checks were performed on 6 of 6 centrifuges observed and used for processing samples from 9-9-2022 to the date of the survey on 6 of 17 patient test reports reviewed. Findings include: 1) During a tour of the laboratory, on 3/4/26 at 10: 16 am with SP-5 (Phlebotomist), the following centrifuges were observed to have expired tachometer and timer checks: 1) Rotina 38/Ser=385-01/Exp=12/20/25 2) Rotina 380/Ser=00190/Exp=12/20/25 3) Labsco 614B/Ser=Unknown/Exp=9/9/22 4) Labsco 614B/Ser=Unknown/Exp=9/9/22 5) Rotina 38/Ser=308-01/Exp=12/1/23 6) Horizon 614B/Ser=230600AB578/ Exp=06/06/23 (Located in SP5's vehicle) 2) Review of policy titled, "Centrifuge Operation and Maintenance," policy#=16-130.6 M, dated and signed by the LD on 7/21/23, read on page 1 of 8, "...Improper speed or force or shortened spin times, will cause faulty separation of the serum/plasma from the cellular components thereby causing a pre-analytical error. Procedural directions must be followed to prevent this." The policy continues to read on page 3 of 8, "... Quality Control A. Laboratory centrifuges are checked annually with a Photo Electronic tachometer in order to assure proper rotational speed, measured in revolutions per minute (RPM's)...The timer is also checked against a stopwatch..." 3) Patient results reports indicated the following patient specimens were processed using the above centrifuges with expired tachometer and timer checks: Patient Date reported Analyte pt#12 1/8/26 BUN=45 mg/dL pt#13 2/19/26 BUN=42 mg/dL pt#14 3/4/26 BUN=13 mg/dL pt#15 3/2/26 NH3=50 umol/L pt#16 2/27/26 NH3=48 umol/L pt#17 1/8/26 NH3=69 umol/L 4) In interview on 3/4/26 at 9:45 am, SP-1 (Technical Consultant) confirmed the centrifuges used in the laboratory (five in production at the time of survey) and the ones located in the phlebotomists' vehicles (approximately 12-15) are all expired for tachometer and timer checks (see above). 5) In interview on 3/4 /26 at 10:28 am, SP-5 (Phlebotomist) confirmed the centrifuge in their vehicle was past due (expired on 6/6/23) for its tachometer and timer check. 6) Review of the Clincial Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS 116 states the annual testing volume for Chemistry and Hematology is 1,080,130. Legend: SP=staff person Pt=patient NH3=ammonia BUN=urea nitrogen mg/dL=miligram per deciliter umol/L=micromoles per liter ser= serial number exp= expiration date
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 document review and interview, the laboratory failed to perform lot number verification for unassayed controls for the establishment of new means and ranges for 20 of 20 tests (ALB, ALP, ALT, AST, BUN, CA, CHOL, CL, CO2, CREA, GLU, PHOS, K+, NA+, TP, T-BILI, TRIG, VANCO, DBILI, HDL) from 11-1-2025 to 12-12-2025 for 2 of 17 patients reviewed. Findings include: 1. The laboratory used expired Chemistry QC from 11/1/2025 to 12-12-2025 until verification of the new QC lot was completed (refer to D5417). 2. Policy and Procedure titled "Quality Control Protocol for Chemistry with Beckman AU Series" policy number 8-102.12IND, signed and dated by the LD on 1-13-2025, states on page 2 of 6 that "A lot number verification of the new QC must be performed to create new QC means and ranges." 3. Levy Jennings charts for 3 of 20 tests (cholesterol, glucose and calcium) indicated new lot numbers 93041 and 93042 for Chemistry QC was effective on 11-21-2025. 4. The data sheet (no title) attached to the Levy Jennings charts (cholesterol, glucose and calcium), did not document lot numbers or analytes associated with the graph, but indicated new ranges for lot numbers 93041 and 93042 were entered into the laboratory information system between 12-1-25 and 12-12-25. 5. In an interview on 3-3-2026 at 2:00 pm, SP-01 (Technical Consultant) confirmed the laboratory does not keep a log of current lot numbers. SP-01 confirmed the new lot verification dates were entered into the laboratory information system on 12-1-2025 and completed on 12-12-2026. 6. In an interview on 3-4-2026 at 12:00, SP-06 (Testing Personnel) confirmed they could not remember the date the new lot verification started; however, they were running 2 different lots at the same time for a while. 7. The following patients were tested without verification of unassayed controls: a) Pt# 3 was tested on 12-1-2025 at 6:59 pm, GLU= 141mg/dl, NA= 141 mEq/L, K= 4.0 mEq/L, CL= 103mEq/L, CO2=25 mEq/L, BUN= 18 mg/dl, CREA=1.4 mg/dl, CA= 7.9 mg/dl, TP= 6.2 g/dl, ALB=3.9 g/dl, ALP= 78 IU/L, AST= 13 IU/L, ALT=13 IU/L, T-BILI=0.3 mg/dl, CHOL=158 mg/dl, TRIG= 132 mg/dl, HDL=42 mg/dl. b) Pt #4 was tested on 12-2-2025 at 7:52 pm, GLU= 95mg/dl, NA= 140 mEq/L, K= 4.9 mEq/L, CL= 103 mEq/L, CL=103 mEq/L, CO2=29 mEq/L, BUN= 26 mg/dl, CREA=0.9 mg/dl, CA= 7.7 mg /dl, TP=6.2 g/dl, ALB= 3.1 mg/dl, ALP= 119 IU/L, AST= 14 IU/L, ALT= 15 IU/L, T-BILI= 0.4 mg/dl, CHOL= 98 mg/dl, TRIG= 129 mg/dl, HDL=32 mg/dl
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, document review, lack of documentation, and interview, the LD failed to ensure that the laboratory complied with regulations for preanalytic testing, analytic testing and proficiency testing. The LD failed to: 1. Ensure the

	laboratory processed patient specimens for testing within four hours of the collection time as defined by their policy for 4 of 17 patients reviewed. (Refer to D6007); 2. Ensure the laboratory performed lot number verification for unassayed controls for the establishment of new means and ranges for 20 of 20 tests on one of one Chemistry analyzer from 11-1-2025 to 12-12-2025. (Refer to D6007); 3. Ensure coagulation ISI and INR calibration was accurate and not expired for PT testing from 1-12-26 to the date of survey. (Refer to D6007); 4. Ensure the laboratory was enrolled and participated in proficiency testing for two of three events (event 1 and 2) in 2025 for the Specialties of Hematology and Chemistry. (Refer to D6015); 5. Ensure control material(s) had not been used beyond the expiration dates for 2 of 2 Hematology analyzers from 11-23-25 to 11-28-25 and 1 of 1 Chemistry analyzers from 11/1/2025 to 12-12-25. (Refer to D6020); and 6. Ensure tachometer and timer checks were performed on 6 of 6 centrifuges observed from 9-9-2022 to the date of the survey. (Refer to D6023).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation, document review and interview, the LD failed to ensure tests systems for the Specialties of Chemistry and Hematology provide quality laboratory services for preanalytic and analytic testing. The LD failed to: 1. Ensure the laboratory processed patient specimens for testing within four hours of the collection time as defined by their policy for 4 of 17 patients reviewed (refer to D5311); 2. Ensure the laboratory established unassayed control ranges for one of one Chemistry analyzer (refer to D5469); and 3. Ensure coagulation ISI and INR calibration was not expired. (refer to D5411).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on document review and interview, the LD failed to ensure the laboratory was enrolled and participated in a proficiency testing program for the Specialities of Chemistry and Hematology for 2 of 3 events (event 1 and event 2) in 2025. (Refer to D2001 and D2003)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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, document review, lack of documentation, and interview, the LD failed to ensure control material(s) had not been used beyond the expiration dates for for analytes and tests in the Specialties of Hematology and Chemistry. (Refer to D5417).
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the LD failed to ensure tachometer and timer checks were performed on 6 of 6 centrifuges observed in use for processing patient specimens from 9-9-2022 to the date of the survey on 6 of 17 patient test reports reviewed (Refer to D5431).