

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2273426	(X3) Date Survey Completed 07/15/2026
Name of Provider or Supplier Alpha Medical Laboratory, Llc	Street Address, City, State 1404 S Fretz, Ste 100, Edmond, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 07/15/2026. The laboratory was found out of compliance with the following CLIA Conditions: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant 493.1415; D6056: Clinical Consultant
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records and interview with the laboratory director, the laboratory failed to retain two of two years of PT records from 2025 to 2026. Finding Included: (1) A review of Chemistry Core and Hematology PT records from January 2025 through the current date revealed the following documents had not been maintained and could not be provided: (a) 2025 Chemistry Core 1st event - attestation statement, copy of the results submitted to the PT program, instrument printouts, and graded evaluation; (b) 2025 American Proficiency Institute Chemistry Core 2nd event - attestation statement; (c) 2025 American Proficiency Institute Chemistry Core 3rd event - attestation statement, copy of the results submitted to the PT program, instrument printouts, and graded evaluation; (d) 2026 American Proficiency Institute Chemistry Core 1st event - attestation statement, copy of the results submitted to the PT program, instrument printouts, and graded evaluation; (e) 2025 American Proficiency Institute Hematology/Coagulation 2nd event - attestation statement; (f) 2025 American Proficiency Institute Hematology/Coagulation 3rd event - attestation statement and graded evaluation; (g) 2026 American Proficiency Institute Hematology/Coagulation 1st event - attestation statement and graded evaluation. (2) Interview with the laboratory director on 07/15/2026 at 3:30 pm confirmed the laboratory had not retained the PT

	records for at least two years, therefore they were not available for review at the time of survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to review and evaluate proficiency testing results for one of four Hematology Proficiency Testing events reviewed in 2025 and 2026. Findings include: (1) On 07/15 /2026, a review of American Proficiency Institute (API) Hematology Proficiency Testing (PT) records for four events (First 2025, Second 2025, Third 2025, and First 2026) identified the following failures with no evidence that corrective actions had been documented as performed: (a) Second 2025 Event, Sample DXH 06 - The laboratory attained a score of 80% for hematocrit (HCT) and white blood cells (WBC), with no documentation of corrective action(s) taken. (2) Interview with the laboratory director on 07/15/2026 at 02:30 pm confirmed corrective action had not been documented for the failure.
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 a review of records and interview with the laboratory director and testing person #1, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed using the Abaxis Piccolo Express and Biosite Triage Meter Pro analyzers during the review period of January 2026 through the current date. Findings include: (1) The laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for six of six months reviewed during 2026. Refer to D5441; (2) The laboratory failed to perform two levels of quality control (QC) materials each day of patient testing. Refer to D5447; (3) The laboratory failed to verify the stated ranges of control materials before they were put into use. Refer to D5469; (4) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for six of six months reviewed during 2026. Findings include (1) On 07/15/2026 at 10:00 am, the laboratory director stated the following: (a) Complete Blood Count (CBC) testing was performed using the Beckman Coulter DxH 560 analyzer; (b) Three levels of DxH 800 Series Control materials (abnormal low, normal, abnormal high) quality control (QC) materials were performed each day of patient testing; (2) A review of quality control (QC) from January through June 2026 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (I.e., biases, shifts, trends) for 12 of 12 lot numbers of control materials used during the timeframe; (3) Interview with the laboratory director on 07/15/2026 at 02:10 pm confirmed there was no documentation that QC data to include Levey-Jennings graphs and cumulative statistical data had been reviewed and evaluated during the review period.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director and testing person #1, the laboratory failed to perform two levels of quality control (QC) materials for 44 of 49 days of patient testing during the review period of January 2026 through the current date. Findings include: I. TROPONIN I AND CKMB TESTING (1) On 07/15/2026 at 10:20 am, testing person #1 stated the following: (a) Troponin I and Creatine Kinase Isoenzyme (CKMB) testing were performed using the Biosite Triage Meter Pro analyzer and plasma specimens; (b) It was the policy of the laboratory to perform two levels of QC materials each day of patient testing. (2) A review of QC and patient test records for testing performed from January 2026 through the current date identified at least two levels of QC materials had not been performed each day of patient testing reviewed for 21 of 25 days; (3) The records were reviewed with the laboratory director who stated on 07/15/2026 at 03:15 pm, the laboratory had not performed two levels of QC testing each day of patient testing; (4) The following were the days of patient Troponin I and CKMB testing performed when two levels of QC had not been performed: (a) Patient #2601050564 - testing performed on 01/06/2026 (b) Patient #2601200272 - testing performed on 01/20/2026 (c) Patient #2601220066 - testing performed on 01/22/2026 (d) Patient #2601220243 - testing performed on 01/23/2026 (e) Patient #2601290214 - testing performed on 01/29/2026 (f) Patient #2601310301 - testing performed on 01/31/2026 (g) Patient #2602040290 - testing performed on 02/04/2026 (h) Patient #2602050242 - testing

performed on 02/05/2026 (i) Patient #2602060222 - testing performed on 02/06/2026 (j) Patient #2602090274 - testing performed on 02/09/2026 (k) Patient #2602110165 - testing performed on 02/11/2026 (l) Patient #2602210150 - testing performed on 02/21/2026 (m) Patient #2602220009 - testing performed on 02/22/2026 (n) Patient #2605020238 - testing performed on 05/02/2026 (o) Patient #2605040489 - testing performed on 05/09/2026 (p) Patient #2605190155 - testing performed on 05/23/2026 (q) Patient #2605140144 - testing performed on 05/27/2026 (r) Patient #2605160081 - testing performed on 05/29/2026 (s) Patient #2606020639 - testing performed on 06/06/2026 (t) Patient #2606110192 - testing performed on 06/13/2026 (u) Patient #2606160056 - testing performed on 06/19/2026 II. COMPLETE METABOLIC TESTING (CMP) (1) On 07/15/2026 at 10:20 am, testing person #1 stated the following: (a) CMP testing (included the analytes Sodium, Potassium, Total CO₂, Chloride, Glucose Calcium, BUN, Creatinine, Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Total Bilirubin, Albumin, and Total Protein) was performed using the Abaxis Piccolo Xpress analyzer and plasma specimens; (b) It was the policy of the laboratory to perform two levels of QC materials each month. (2) A review of QC and patient test records for testing performed from January 2026 through the current date identified at least two levels of QC materials had not been performed each day of patient testing reviewed for 18 of 19 days; (3) The records were reviewed with the laboratory director who stated on 07/15/2026 at 03:15 pm, the laboratory had not performed two levels of QC testing each day of patient testing because they believed the test system was waived; (4) The following were the days of patient CMP testing performed when two levels of QC had not been performed: (a) Patient #2601020004 - testing performed on 01/02/2026 (b) Patient #2601150192 - testing performed on 01/15/2026 (c) Patient #2601300624 - testing performed on 01/30/2026 (d) Patient #2602030585 - testing performed on 02/03/2026 (e) Patient #2602140158 - testing performed on 02/14/2026 (f) Patient #2602270288 - testing performed on 02/27/2026 (g) Patient #2603020018 - testing performed on 03/02/2026 (h) Patient #2603150010 - testing performed on 03/15/2026 (i) Patient #2603310420 - testing performed on 03/31/2026 (j) Patient #2604020394 - testing performed on 04/02/2026 (k) Patient #2604280412 - testing performed on 04/28/2026 (l) Patient #2605050214 - testing performed on 05/05/2026 (m) Patient #2605140811 - testing performed on 05/14/2026 (n) Patient #2605160405 - testing performed on 06/15/2026 (o) Patient #2606300754 - testing performed on 06/30/2026 (p) Patient #2607020874 - testing performed on 07/02/2026 (q) Patient #2607030256 - testing performed on 07/03/2026 (r) Patient #2607090546 - testing performed on 07/09/2026 III. LACTATE TESTING (1) On 07/15/2026 at 10:20 am, testing person #1 stated the following: (a) Lactate testing was performed using the Abaxis Piccolo Xpress analyzer and plasma specimens; (b) It was the policy of the laboratory to perform two levels of QC materials each month. (2) A review of QC and patient test records for testing performed from January 2026 through the current date identified at least two levels of QC materials had not been performed each day of patient testing reviewed for five of five days; (3) The records were reviewed with the laboratory director who stated on 07/15/2026 at 03:15 pm, the laboratory had not performed two levels of QC testing each day of patient testing because they believed the test system was waived; (4) The following were the days of patient Lactate testing performed when two levels of QC had not been performed: (a) Patient #2605290527 - testing performed on 05/30/2026 (b) Patient #2607010756 - testing performed on 07/01/2026 (c) Patient #2607090401 - testing performed on 07/09/2026 (d) Patient #2607100301 - testing performed on 07/10/2026 (e) Patient #2607130089 - testing performed on 07/13/2026 48517 Based on a review of records and interview with the laboratory director and testing person #1, the laboratory failed to perform two levels of quality control (QC) materials for 31 of 31 days of patient testing during the review period of

January 2026 through the current date. Findings include: I. BNP TESTING (1) On 07/15/2026 at 10:20 am, testing person #1 stated the following: (a) Beta natriuretic peptide (BNP) testint was performed using the Biosite Triage Meter Pro analyzer and plasma specimens; (b) It was the policy of the laboratory to perform two levels of QC materials each day of patient testing. (2) A review of QC and patient test records for testing performed from January 2026 through the current date identified at least two levels of QC materials had not been performed each day of patient testing reviewed for 27 of 27 days; (3) The records were reviewed with the laboratory director who stated on 07/15/2026 at 03:15 pm, the laboratory had not performed two levels of QC testing each day of patient testing; (4) The following were the days of patient BNP testing performed when two levels of QC had not been performed: (a) Patient #260110216 - testing performed on 01/10/2026 (b) Patient #2601120227 - testing performed on 01/12/2026 (c) Patient #2601220294 - testing performed on 01/22/2026 (d) Patient #2601220332 - testing performed on 01/22/2026 (e) Patient #2601220334 - testing performed on 01/22/2026 (f) Patient #2601290436 - testing performed on 01/29/2026 (g) Patient #2601310379 - testing performed on 01/31/2026 (h) Patient #2602020380 - testing performed on 02/02/2026 (i) Patient #2602020380- testing performed on 02/02/2026 (j) Patient #2602030585 - testing performed on 02/03/2026 (k) Patient #2602040625 - testing performed on 02/04/2026 (l) Patient #2602080013 - testing performed on 02/08/2026 (m) Patient #260209274 - testing performed on 02/09/2026 (n) Patient #2602100814 - testing performed on 02/10/2026 (o) Patient #2602230244 - testing performed on 02/23/2026 (p) Patient #2602240647 - testing performed on 02/24/2026 (q) Patient #2603040181 - testing performed on 03/04/2026 (r) Patient #2603050269 - testing performed on 03/05/2026 (s) Patient #2603050463 - testing performed on 03/05/2026 (t) Patient #2603280037 - testing performed on 03/28/2026 (u) Patient #2603300019 - testing performed on 03/30/2026 (v) Patient #2603310419 - testing performed on 03/31/2026 (w) Patient #2603310420 - testing performed on 03/31/2026 (x) Patient #26004090636 - testing performed on 04/09/2026 (y) Patient #2604160280 - testing performed on 04/16/2026 (aa) Patient #2604160448 - testing performed on 04/16/2026 (bb) Patient #2604160454 - testing performed on 04/16/2026 (cc) Patient #2604160457 - testing performed on 04/16/2026 (dd) Patient #2604160458 - testing performed on 04/16/2026 (ee) Patient #2604160460 - testing performed on 04/16/2026 (ff) Patient #2604160462 - testing performed on 04/16/2026 (gg) Patient #2604160463 - testing performed on 04/16/2026 (hh) Patient #2604160468 - testing performed on 04/16/2026 (ii) Patient #2604160471 - testing performed on 04/16/2026 (jj) Patient #2604160486 - testing performed on 04/16/2026 (kk) Patient #2604160491 - testing performed on 04/16/2026 (ll) Patient #2604160495 - testing performed on 04/16/2026 (mm) Patient #2604160496 - testing performed on 04/16/2026 (nn) Patient #2604160497 - testing performed on 04/16/2026 (oo) Patient #2604160505 - testing performed on 04/16/2026 (pp) Patient #2604160465 - testing performed on 04/16/2026 (qq) Patient #2604170378 - testing performed on 04/17/2026 (rr) Patient #2604200261 - testing performed on 04/20/2026 (ss) Patient #2604230522 - testing performed on 04/23/2026 (tt) Patient #2604230551 - testing performed on 04/23/2026 (uu) Patient #2604230416 - testing performed on 04/24/2026 (vv) Patient #2604230591 - testing performed on 04/24/2026 (ww) Patient #2604230418 - testing performed on 04/24/2026 (xx) Patient #2604230422 - testing performed on 04/24/2026 (yy) Patient #2604230420 - testing performed on 04/24/2026 (zz) Patient #2604230564 - testing performed on 04/24/2026 (aaa) Patient #260230682 - testing performed on 04/24/2026 (bbb) Patient #260230684 - testing performed on 04/24/2026 (ccc) Patient #260230688 - testing performed on 04/24/2026 (ddd) Patient #260230662 - testing performed on 04/24/2026 (eee) Patient #2604160374 - testing performed on 04/25/2026 (fff) Patient #2604250231 - testing performed on 04/25/2026 (ggg) Patient #2604250231 - testing

performed on 04/25/2026 (hhh) Patient #2604160679 - testing performed on 04/26/2026 (iii) Patient #2604150674 - testing performed on 04/26/2026 (jjj) Patient #2604160679 - testing performed on 04/26/2026 (kkk) Patient #2604150534 - testing performed on 04/26/2026 (lll) Patient #2604200030 - testing performed on 04/26/2026 (mmm) Patient #2604160622 - testing performed on 04/26/2026 (nnn) Patient #2604160370 - testing performed on 04/26/2026 (ooo) Patient #2604170239 - testing performed on 04/26/2026 (ppp) Patient #2604160010 - testing performed on 04/26/2026 (qqq) Patient #2604160321 - testing performed on 04/26/2026 (rrr) Patient #2604200345 - testing performed on 04/26/2026 (sss) Patient #260420010 - testing performed on 04/26/2026 (ttt) Patient #2604170260 - testing performed on 04/26/2026 (uuu) Patient #2604160136 - testing performed on 04/26/2026 (vvv) Patient #2604150701 - testing performed on 04/26/2026 (www) Patient #2604170396 - testing performed on 04/26/2026 (xxx) Patient #204160474 - testing performed on 04/26/2026 (yyy) Patient #2604160367 - testing performed on 04/26/2026 (zzz) Patient #2604160661 - testing performed on 04/26/2026 (aaaa) Patient #2604150737 - testing performed on 04/26/2026 (bbbb) Patient #2604150739 - testing performed on 04/26/2026 (cccc) Patient #2604150672 - testing performed on 04/26/2026 (dddd) Patient #2604170521 - testing performed on 04/26/2026 (eeee) Patient #2604170397 - testing performed on 04/26/2026 (ffff) Patient #2604150692 - testing performed on 04/26/2026 (gggg) Patient #2604160372 - testing performed on 04/26/2026 (hhhh) Patient #2604150673 - testing performed on 04/26/2026 (iiii) Patient #2604180038 - testing performed on 04/26/2026 (jjjj) Patient #2604150676 - testing performed on 04/26/2026 (kkkk) Patient #2604200436 - testing performed on 04/26/2026 (llll) Patient #2604170261 - testing performed on 04/26/2026 (mmmm) Patient #2604160315 - testing performed on 04/29/2026 (nnnn) Patient #2604160013 - testing performed on 04/29/2026 (oooo) Patient #2604170290 - testing performed on 04/29/2026 (pppp) Patient #260410666 - testing performed on 04/29/2026 (qqqq) Patient #2604210018 - testing performed on 04/29/2026 (rrrr) Patient #2604170271 - testing performed on 04/29/2026 (ssss) Patient #2604160671 - testing performed on 04/29/2026 (tttt) Patient #2604160671 - testing performed on 04/29/2026 (uuuu) Patient #2604200421 - testing performed on 04/29/2026 (vvvv) Patient #2604210026 - testing performed on 04/29/2026 (wwww) Patient #2604160047 - testing performed on 04/29/2026 (xxxx) Patient #2604160314 - testing performed on 04/29/2026 II. D-Dimer Testing (1) On 07/15/2026 at 10:20 am, testing person #1 stated the following: (a) D-Dimer testing was performed using the Alere Triage Meter Pro analyzer and plasma specimens; (b) It was the policy of the laboratory to perform two levels of QC materials each month. (2) A review of QC and patient test records for testing performed from January 2026 through the current date identified at least two levels of QC materials had not been performed each day of patient testing reviewed for 4 of 4 days; (3) The records were reviewed with the laboratory director who stated on 07/15/2026 at 03:15 pm, the laboratory had not performed two levels of QC testing each day of patient testing because they believed the test system was waived; (4) The following were the days of patient D-Dimer testing performed when two levels of QC had not been performed: (a) Patient #2601090487 - testing performed on 02/03/2026 (b) Patient #260203585 - testing performed on 01/16/2026 (c) Patient #2604160455 - testing performed on 04/25/2026 (d) Patient #2604250230 - testing performed on 04/25/2026 (e) Patient #2604250230 - testing performed on 05/21/2026

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 a review of records and interview with the laboratory director, the laboratory failed to verify the stated ranges of control materials before they were put into use for 12 of 12 lot numbers reviewed during the review period of January 2026 through the current date. Findings include: (1) On 07/15/2026 at 10:00 am, the laboratory director stated the following: (a) Complete Blood Count (CBC) testing was performed using the Beckman Coulter DxH 560 analyzer; (b) Three levels of DxH 800 Series Control materials (abnormal low, normal, abnormal high) quality control (QC) materials were performed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of QC results. (2) A review of records for 12 lot numbers of QC materials put into use from January 2026 through the current date identified no evidence the provided ranges had been verified before the lot numbers had been put into use for 12 or 12 lot numbers as follows: (a) Abnormal Low lot# 352518011, Normal lot #362518012, and Abnormal High lot #372518013 put into use on 01/01/2026; (b) Abnormal Low lot# 352618211, Normal lot #36218212, and Abnormal High lot #372618213 put into use on 03/05/2026; (c) Abnormal Low lot# 352618411, Normal lot #362618412 and Abnormal High lot #372618413 put into use on 05/07/2026; (d) Abnormal Low lot# 352618511, Normal lot #362618512, and Abnormal High lot #372618513 put into use on 06/04/2026 and was currently in use. (3) The findings were reviewed with the laboratory director who stated on 07/15/2026 at 01:45 pm, the manufacturer's ranged had not been verified before the above lot numbers had been put into use.

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 a review of records and interview with the laboratory director and testing person #1, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of January 2026 through the current date. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process. Refer to D5441; (b) The laboratory failed to perform two levels of quality control (QC) materials each day of patient testing. Refer to D5447; (c) The laboratory failed to verify the stated ranges of control materials before they were put into use. Refer to D5469.

D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure test reports reflected the address of where the testing was performed for five of five reports reviewed. Findings include: (1) On 07/15/2026 at 02:00 pm, the laboratory director stated the laboratory performed lactic acid and troponin I testing; (2) A review of patient reports identified the address of the laboratory on the reports (224 N 6th Street, Jenks, OK 74037) did not match the address on the CLIA certificate (1404 S Fretz, STE 100, Edmond, OK 73003) for the following: (a) Patient sample # 312933 testing performed on 03/26/2026; (b) Patient sample # 227140 testing performed on 03/26/2026; (c) Patient sample # 228123 testing performed on 04/07/2026; (d) Patient sample # 330980 testing performed on 04/14/2026; (e) Patient sample # 241686 testing performed on 05/01/2026; (3) The findings were reviewed with the laboratory director who stated on 07/15/2026 at 02:00 pm, the correct laboratory address had not been included in the patient test reports.
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 a review of records and interview with the laboratory director and testing person #1, the laboratory director failed to provide overall management and direction during the review period of January 2026 through the current date. Findings include: (1) The laboratory director failed to ensure enrollment and participation in a proficiency testing program for Routine Chemistry and D-dimer testing for one of three events in 2025. Refer to D6015; (2) The laboratory director failed to ensure quality control and quality assessment programs were established and maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026.
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 a review of records and interview with the laboratory director and testing person #1, the laboratory director failed to ensure enrollment and participation in a proficiency testing program for Routine Chemistry and D-dimer testing for one of three events in 2025. Findings include: (1) On 07/15/2026 at 10:20 am, testing person #1 stated the following: (a) CMP (included the analytes Sodium, Potassium, Total CO2, Chloride, Glucose Calcium, BUN, Creatinine, Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Total Bilirubin, Albumin, and Total Protein) and Lactate testing were performed using the Abaxis Piccolo Xpress analyzer and plasma specimens; (b) Troponin I, Creatine Kinase Isoenzyme (CKMB), Beta natriuretic peptide (BNP), and D-Dimer testing were performed using the Alere Triage Meter Pro analyzer and plasma specimens. (2) A review of proficiency testing records for 2025 identified no evidence the laboratory had enrolled in proficiency testing until 02/14/2025; (3) The findings were reviewed with the laboratory director, who confirmed on 07/15/2026 at 11:15 am, the laboratory failed to enroll in the first 2025 proficiency testing event.
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 a review of records and interview with the laboratory director testing person #1, the laboratory director failed to ensure quality control and quality assessment programs were established and maintained to ensure the quality of laboratory services during the review period of January 2026 through the current date. Findings include: (1) The laboratory director failed to ensure control procedures monitored the accuracy and precision of the complete analytic process. Refer to D5441; (2) The laboratory director failed to ensure at least two levels of quality control (QC) materials had been performed each day of patient testing. Refer to D5447; (3) The laboratory director failed to ensure the laboratory verified the stated ranges of control materials before they were put into use. Refer to D5469; (4) The laboratory director failed to ensure a method was in place to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory director failed to ensure test reports included pertinent information required for interpretation for five of five reports reviewed. Findings include: (1) The laboratory

	director failed to ensure test reports reflected the address of where the testing was performed. Refer to D5805.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director, the technical consultant failed to provide technical supervision in accordance with 493.1413 of this subpart for one of two competency evaluations performed in 2025 and 2026. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually. Refer to D6054.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this

	section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b) (7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for one of two competency evaluations reviewed during 2025 and to date in 2026. Findings include: (1) A review of records for two persons performing moderate complexity testing during 2025 and to date in 2026 identified the 2025 annual competency evaluation for one of two testing persons had been performed by an individual who did not meet the regulatory requirements of a technical consultant as follows: (a) Testing Person #2 - Performed on 05/20/2025 (2) The records were reviewed with the laboratory director who stated on 07/15/2026 at 11:10 am, the annual evaluation had been performed by an individual who did not meet the regulatory qualifications of a technical consultant.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of two testing persons during the review period of January 2025 through the current date. Findings include: (1) A review of personnel records for two persons performing moderate complexity testing during 2025 and to date in 2026 identified no evidence an annual competency evaluation had been performed for one of two testing persons as follows: (a) Testing Person #1 - Not documented as performed during the review period. (2) The records were reviewed with the laboratory director who stated on 07/15/2026 at 11:10 am, the annual evaluation had not been documented as performed during the review period.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to have a clinical consultant to provide clinical consultation in accordance with 493.1419 during the review period of January 2025 through the current date. Findings

	include: (1) The laboratory failed to ensure the position of Clinical Consultant was filled by an individual who met the qualification requirements of 493.1417. Refer to D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure the position of Clinical Consultant was filled by an individual who met the qualification requirements of 493.1417 during the review period of January 2025 through the current date. Findings include: (1) A review of the Form CMS-209 (Laboratory Personnel Report) identified one individual listed as the Clinical Consultant; and records were requested to confirm the qualifications of the individual; (2) Interview with the laboratory director on 07/15/2026 at 04:20 pm confirmed the individual that had been listed on Form CMS-209 was not serving as the Clinical Consultant and the position had not been filled during the review period.