Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1076170	06/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Amc Laboratory	1600 West 21st Street Suite B, Clovis, NM	

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	During a complaint/addition of specialties survey completed on 06/14/18 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR part 493.801 Proficiency Testing, Enrollment and Testing of Samples 42 CFR part 493.1403 Laboratory director, moderate complexity 42 CFR part 493.1411 Technical Consultant, moderate complexity 42 CFR part 493.1463 General Supervisor, high complexity
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the review of proficiency test reports, patient records, quality control records, and interviews with laboratory staff, the laboratory failed to enroll in proficiency testing for regulated analytes performed as part of a Complete Metabolic Profile (CMP) and Basic Metabolic Profile (BMP). 646 patients were tested January through April 2018. Findings are: A. Review of 2018 proficiency test records including the 2018 enrollment form revealed the laboratory failed to enroll and participate in proficiency testing for routine chemistry. The records indicated enrollment and testing for the following regulated analytes: CK (Creatinine incase), Magnesium, and TSH (Thyroid Stimulating Hormone) as part of the Comprehensive Chemistry and Immunochemistry modules. B. Interview with a technical

	representative of the proficiency testing agency on 06/15/2018 at 10:13 am revealed the laboratory should have enrolled in the Basic Chemistry module. 1. The Basic Chemistry module included the following regulated analytes: ALT (Alanine Aminotransferase), AST (Asparate Aminotransferase), ALB (Albumin), ALKP (Alkaline Phospatase), CO2 (Bicarbonate), TBili (Total Bilirubin), Ca (Calcium), Chloride, Total Cholesterol, Creatinine, Glucose, Phosphorus, Potassium, Sodium, Total Protein, Triglyceride, BUN (Urea Nitrogen), and UA (Uric Acid). 2. The technical representative also stated the owner of the laboratory called the agency on 06 /13/2018 to enroll in the Basic Chemistry module. C. Review of the patient collection logs for January - May 2018 revealed the laboratory collected CMP and BMP samples for testing in the laboratory. 646 patients were tested January - April 2018. 1. January 2018 153 patients, #J1-153, were tested by the laboratory. The test report for patient #J2 was printed to verify testing by the laboratory on 01/02/2018. The report contained results for the following regulated analytes: Glucose, BUN, Creatinine, Sodium, Potassium, Chloride, Calcium, Total Protein, Albumin, Globulin, TBili, ALKP, AST, and ALT. 2. February 2018 175 patients, #F1-175, were tested by the laboratory. The test report for patient #F1 was printed to verify testing by the laboratory on 02/06/2018. The report contained results for the following regulated analytes: Glucose, BUN, Creatinine, Sodium, Potassium, Chloride, Calcium, Total Protein, Albumin, Globulin, TBili, ALKP, AST, and ALT. 3. March 2018 184 patients, #M1-184, were tested by the laboratory. The test report for patient #M1 was printed to verify testing by the laboratory on 03/07/2018. The report contained results for the following regulated analytes: Glucose, BUN, Creatinine, Sodium, Potassium, Chloride, Calcium, Total Protein, Albumin, Globulin, TBili, ALKP, AST, and ALT. 4. April 2018 134 patients, #A1-134, were tested by the laboratory. The test reports for two (2) patients, #A3 & A4, were printed to verify testing by the laboratory in April on 04/04/2018. The reports contained results for the following regulated analytes: Glucose, BUN, Creatinine, Sodium, Potassium, Chloride, Calcium, Total Protein, Albumin, Globulin, TBili, ALKP, AST, and ALT. D. During the exit interview on 06/14/2018 at 11:00 am, the laboratory director indicated he was not aware of this deficient practice.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on the review of proficiency test reports, patient records, quality control records, and interviews with laboratory staff, the laboratory failed have a system to evaluate non-regulated analytes (Bicarbonate and C-Reactive Protein) twice per year. Findings are: A. Review of 2018 proficiency test records revealed the laboratory failed to enroll and participate in proficiency testing for routine chemistry. The records indicated enrollment and testing for the following non-regulated analytes: GGT (Gamma-Glutamyltransferase) and Vitamin D. B. Review of the 2018 enrollment form indicated the laboratory was enrolled in proficiency testing for Comprehensive Chemistry and Immunochemistry. C. Interview with a technical representative of the proficiency testing agency on 06/15/2018 at 10:13 am revealed the laboratory should have enrolled in the Basic Chemistry module which included the CO2 (Bicarbonate). The technical representative also stated the owner of the

	laboratory called the agency on 06/13/2018 to enroll in the Basic Chemistry module. D. There was no evidence that the laboratory used an alternate method to evaluate CO2 and C-Reactive Proteins twice per year. E. Review of the patient collection logs for January - April 2018 revealed the laboratory collected 646 CMP and BMP samples for testing in the laboratory. 1. January 2018 153 patients were tested by the laboratory. The test report for patient CMP #2J was printed from the electronic medical record system (EMR) to verify testing by the laboratory on 01/02/2018. The report contained results for the following non-regulated analytes: CO2 and CRP (C-Reactive Protein). 2. February 2018 175 patients were tested by the laboratory. The test report for patient CMP #1F was printed from the EMR to verify testing by the laboratory on 02/06/2018. The report contained results for the following non-regulated analytes: CO2 and CRP (C-Reactive Protein). 3. March 2018 184 patients were tested by the laboratory. The test report for patient CMP #1M was printed from the EMR to verify testing by the laboratory on 03/07/2018. The report contained results for the following non-regulated analytes: CO2 and CRP (C-Reactive Protein). 4. April 2018 134 patients were tested by the laboratory. The test reports for two (2) patients, CMP #3A & #4A, were printed from the EMR to verify testing by the laboratory in April on 04/04/2018. The reports contained results for the following non-regulated analytes: CO2 and CRP (C-Reactive Protein). F. During the exit interview on 06/14/2018 at 11:00 am, the laboratory director indicated he was not aware of this deficient practice.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer instructions, laboratory temperature records and interviews with laboratory staff, the laboratory failed to have a system to monitor the temperature of Refrigerator/Freezer #2 used to store chemistry reagents and samples. Findings are: A. Review of 2018 temperature logs for Refrigerator /Freezer #2 on 06/12/2018 (located near the new Theratest reader) revealed no documentation of temperatures since 05/02/2018. B. Review of the manufacturer's instructions for the use of the Radiance Industrial Company Min-Max Time Stamp thermometer located in Refrigerator/Freezer #2 indicated the sensor should be placed away from the refrigerator wall. C. Observation of the contents of Refrigerator /Freezer #2 on 06/12/2018 at 2:56 pm revealed the laboratory had placed the thermometer sensor on the top rack against the refrigerator wall. D. Observation of the contents of the refrigerator on 06/12/2018 at 3:00 pm and 6/13/2018 at 9:15 am revealed the laboratory stored the following reagents/supplies: 2 boxes Theratest EL-RF/3 IgM, IgG, IgA lot 03182753 expiration date 03/20/2019; received on 04/24 /2018. 1 box Theratest El Anti-CCP/2 lot 04182766 expiration date 03/27/2019 received on 04/24/2018. Vitros ECO2, Chloride, Total Bilirubin, Albumin, Alkaline Phosphatase, Alanine Transferase, and Calcium slides. The manufacturer's storage requirement was 2-8 degrees Celsius or colder 17 degrees Celsius. Vitros Immuno

	Wash Vitros ERF (Electrolyte Reference Fluid) The following vials were observed in the door of the refrigerator. The protective seal was removed from each vial but there was no indication when the vials were opened leaving only the stopper. Vitros Cal kit 2 (1) lot 062671 expiration date 05/22/2019 1 vial. Vitros PV II lot A6016 expiration date 10/31/2019 1 vial Vitros Cal Kit 2 (2) lot 02672B1 expiration date 05/22/2019 1 vial Vitros PV I lot W5904 expiration date 06/26/2019 1 vial Vitros Cal Kit 2 (3) lot 02674B1 expiration date 05/22/2019 1 vial Vitros Cal Kit 2 (4) lot 02674B1 expiration date 05/22/2019 1 vial E. Observation of the contents of the freezer on 06 /12/2018 at 3:00 pm and 06/13/2018 at 9:15 am revealed the laboratory stored the following reagents/supplies: Patient serum samples Vitros calibrators for sodium, cholesterol (lot 0839-1348-4943 expiration date 04/01/2019), Creatinine (lot 1507-1473-5450 expiration date 05/01/2019), Triglyceride, and C-reactive Protein. Vitros CRP PV1 lot L6276 expiration date 11/28/2018, no received date and in a blue bag Vitro CRP PV1 lot L6276 expiration date 11/28/2018, opened on 04/22/2018 at 14:00 pm Vitros calibrator kit lot 0757 expiration date 09/18/2018, received on 03/20/2018 F. During interview on 06/12/2018 at 10:15 am, the laboratory owner stated that Testing Person (TP) #3 had been ill and no patient testing had been performed on the Theratest system. The laboratory owner was not aware that no one was documenting the temperatures and instructed TP #2 to do it. G. During interview on 06/12/2018 at 1: 30 pm TP #1 stated she recorded the temperature of Refrigerator/Freezer #1 on the days she worked but did not monitor Refrigerator/Freezer #2. H. A second review of the Refrigerator/Freezer #2 logs on 06/13/2018 at 5:10 pm revealed no documentation of the freezer or refrigerator temperatures. A third review of the logs on 06/14/18 at 10:43 am revealed documentation of the freezer temperature (-20 degrees Celsius) but none for the refrigerator.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control records and interviews with laboratory personnel and [consulting agency] representative, the laboratory failed to establish acceptable ranges for chemistry quality control materials. Findings are: A. Review of the quality control records indicated the laboratory started patient testing using the Vitros 350 on 12/13/2017. However, there was no evidence of any quality control studies performed for the following lots of quality control materials: Performance Verifier (PV) I lot N5113 expiration date 08/08/2018 PV II lot 3905 expiration date 06 /04/2018 PV I lot W5904 expiration date 06/26/2019 PV II lot A6016 expiration date 10/31/2019 B. Review of quality control printouts in December 2017 and June 2018

	revealed handwritten documentation by testing personnel of quality control ranges. The preprinted ranges appeared to be normal patient reference ranges. D. During interview on 06/13/2018 at 1:45 pm, Testing Person (TP) #1 stated that she would print copies of the manufacturer's instructions for each lot and use the manufacturer ranges to determine acceptability of the results. She also stated that she did not use the Vitros quality control software in the laboratory she normally works at and could not access the quality control files in the analyzer. E. During interview on 06/13/2018 at 12:00 pm, the former technical consultant stated that neither he nor TP #1 could access the analyzer's quality control files because they had not received training on the software. He further stated "I know everything was done" in reference to the quality control studies. However, he was unable to locate the missing records. F. During interview on 06/14/2018 at 10:07 am, TP #3 also indicated he used the ranges from the manufacturer's instructions to assess the acceptability of the quality control results. G. During interview on 06/14/2018 at 9:00 am, the laboratory owner stated that TP #3 (hired April 2018) had not received training on how to update the quality control ranges on the Vitros 350 and that was why he and TP #1 were writing the ranges on the printouts. H. During interview on 06/14/2018 at 10:17 am, a representative from Vitros stated that it was not the responsibility of the manufacturer to establish quality control ranges for their customers. The representative also stated that the quality control ranges do not print on the report. She confirmed that the ranges printed are the patient reference ranges. I. Review of the manufacturer's instructions indicated that the ranges provided by the manufacturer were "Range of Means" which is defined as a range determined by the means from different analyzers. It is not specific to the analyzer used by the laboratory. The manufacturer stated in the instructions, "Each laboratory should establish its own analyte-specific mean. Each laboratory should evaluate and, if necessary, update the mean after each reagent lot change. The within-lab standard deviation (SD) published on the assay sheet for a given analyte may be used as the laboratory's baseline SD for any slide lot."
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 the review of laboratory history, CMS Personnel Report Form 209, personnel records and interviews with laboratory staff and manufacturer/contractor representative, the laboratory director failed to provide overall management and direction of the laboratory. Findings are: A. Review of laboratory record history indicated the following: On 1/12/12018, the New Mexico Department of Health received a request from [consulting agency] on behalf of the laboratory to update the laboratory director and to add high complexity tests to the test menu. These changes were approved on 04/20/2018 after the [consulting agency] provided documentation showing the laboratory director was no longer directing 5 active non-waived laboratories. B. The laboratory failed to enroll in proficiency testing for regulated analytes performed as part of a Complete Metabolic Profile (CMP) and Basic Metabolic Profile (BMP). See D6015 C. During interview on 06/12/2018 at 11:00 am, the [consulting agency] representative stated the laboratory director also served as the technical supervisor of the laboratory. Review of an unsigned CMS Personnel Report Form 209 faxed by the [consulting agency] representative on 06/12/2018 at 01:19 pm

	indicated no Technical Consultant for the laboratory, only technical supervisor, high complexity. D. Review of laboratory records revealed no documentation that the laboratory director had visited the laboratory in-person. During interview on 06/12 /2018 at 1:45 pm, the laboratory owner (former laboratory director) stated the laboratory director had planned on being present for the inspection. E. Review of the laboratory director's contract (1 page) dated December 21, 2017 revealed no requirement for the director to perform site visits other than during inspections (certification). There was also no documentation of specific duties and responsibilities of the laboratory director in this document. F. Review of laboratory policies revealed the new laboratory director had not reviewed and approved the policies and procedures for moderate complexity testing. See D6031 G. There was no documentation of the highest level of education for 2 (TP #1 and TP#3) of 4 testing personnel, performing non-waived testing. See D6028
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the review of proficiency test reports, patient records, quality control records, and interviews with laboratory staff, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for regulated analytes. Findings are: The laboratory failed to enroll in proficiency testing for regulated analytes performed as part of a Complete Metabolic Profile (CMP) and Basic Metabolic Profile (BMP). See D2000
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) 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 the review of personnel records and interviews with laboratory staff, the laboratory director failed to ensure that documentation of the highest level of education was maintained in the laboratory for 2 (TP #1 and TP #3) of 4 testing personnel. Findings are: A. Review of personnel records revealed no documentation of the education of Testing Person #1, a temporary employee performing moderate complexity testing on the Vitros 350 chemistry analyzer. 1. During interview on 06/12

	/2018 at 1:30 pm, Testing Person #1 stated the laboratory owner had not requested a copy of her college diploma or transcript since she began working for the laboratory in May 2018. 2. During interview on 06/12/2018 at 1:45 pm, the laboratory owner confirmed that she did not have a copy of a transcript or diploma on file for Testing Person #1. The laboratory owner provided a copy on the following morning, 06/13 /2018. B. Review of personnel records revealed no documentation of the education of TP #3. The laboratory owner contacted TP#3 for this information during the survey on 06/12/2018. A representative from [consulting agency], was able to fax a copy of TP#3's education to the laboratory on the same day.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 the review of laboratory policies, laboratory history and interview with the laboratory director, the laboratory director failed to review and approve the laboratory policies and procedures. Findings are: A. Review of laboratory record history indicated the following: On 1/12/12018, the New Mexico Department of Health received a request from [consulting agency] on behalf of the laboratory to change the laboratory director and to add high complexity tests to the test menu. These changes were approved on 04/20/2018 after the [consulting agency] provided documentation showing the laboratory director was no longer directing 5 active non-waived laboratories. B. Review of laboratory policies for moderate complexity testing revealed no documentation that the laboratory had reviewed and approved the test methods. C. During interview on 06/14/2018 at 2:55 pm, the laboratory director confirmed this finding.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY 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 the review of facility history records, CMS Personnel Report Form 209, electronic text messages and interviews with laboratory staff and [consulting agency] the laboratory failed to have qualified technical consultant that provided technical oversight of the laboratory. Findings are: A. On 4/27/2018, the former technical consultant notified the New Mexico Department of Health via text message that he was no longer the technical consultant for the laboratory. 1. During interview on 06/12 /2018 at 11:00 am, the [consulting agency] representative stated the laboratory director also served as the technical supervisor of the laboratory. 2. Review of the CMS Personnel Report Form 209 completed by the [consulting agency] representative

	on 06/12/2018 at 01:19 pm indicated no Technical Consultant for the laboratory, only technical supervisor, high complexity. B. The technical consultant failed to establish and maintain documentation of chemistry quality control ranges for the Vitros 350 chemistry analyzer. See D6042 C. Based on the review of facility history records, CMS Personnel Report Form 209, laboratory personnel records and interview with laboratory staff, the technical consultant failed to perform and document competency evaluations for 2 (TP #2 and TP #4) of 4 testing personnel. See D6046
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the review of quality control records and interviews with laboratory personnel and [consulting agency] representative, the technical consultant failed to establish and maintain documentation of chemistry quality control ranges for the Vitros 350 chemistry analyzer. Findings are: There was no documentation of laboratory established ranges for chemistry quality control materials. See D5469
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of facility history records, CMS Personnel Report Form 209, laboratory personnel records and interview with laboratory staff, the technical consultant failed to perform and document competency evaluations for 2 (TP #2 and TP #4) of 4 testing personnel. Findings are: A. Review of personnel records revealed no documentation of competency evaluations for 2 (TP #2, #4) #of 4 testing personnel. 1. TP #2 was trained on the Cell Dyne 1700 Hematology analyzer in December 2014. 2. TP #4 had no documentation of training or competency in the personnel file. B. During interview on 06/12/208 at 11:17 am, the laboratory owner stated that TP #2 and #4 were 'still testing." The laboratory owner also stated at 2:42 pm that TP #4 started testing after the primary testing person left the laboratory [at the end of April 2018]. C. Review of historical survey records indicated neither TP #2 nor TP #4 were listed as testing personnel during the survey in August 2016.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).

	This STANDARD is not met as evidenced by: Based on the review of laboratory history and CMS Personnel Report Form 209, the laboratory director failed to ensure the laboratory employed a qualified general supervisor. Findings are: A. Review of the CMS Personnel Report Form 209 signed by the laboratory director on 06/12/2018 indicated the laboratory owner was the general supervisor of the laboratory. B. Review of the delegation of authority dated and signed by the laboratory director on May 23, 2018 indicated the laboratory owner was designated as the General Supervisor for "proficiency testing documents." C. There was no documentation, such as previous hands-on laboratory training /experience, provided during the survey to establish the laboratory owner's qualifications as general supervisor of a high complexity laboratory. D. Review of previous surveys and application packets indicated that prior to 04/20/2018 the laboratory owner's only laboratory experience was as director of a moderately complexity laboratory after completing the 20 CME (Continuing Medical Education) courses for moderate complexity laboratory director in 2013. There was no documentation indicating previous laboratory training or experience.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratory history, CMS Personnel Report Form 209 and interviews with laboratory staff and manufacturer/contractor representative, the laboratory failed to employ a qualified general supervisor. Findings are: Review of the CMS Personnel Report Form 209 and Delegation of Responsibilities revealed the laboratory delegated responsibilities of "proficiency testing documents" to an unqualified individual. See D6143
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(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 or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii)

Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on the review of laboratory history and CMS Personnel Report Form 209 and interview with staff, the laboratory failed to employ a qualified general supervisor. Findings are: A. Review of the CMS Personnel Report Form 209 signed by the laboratory director on 06/12/2018 indicated the laboratory owner was the general supervisor of the laboratory. B. Review of the delegation of authority dated and signed by the laboratory director on May 23, 2018 indicated the laboratory owner was designated as the General Supervisor for "proficiency testing documents." C. There was no documentation, such as previous hands-on laboratory training/experience, provided during the survey to establish the laboratory owner's qualifications as general supervisor of a high complexity laboratory. D. Review of previous surveys and application packets indicated that prior to 04/20/2018 the laboratory owner's only laboratory experience was as director of a moderately complexity laboratory after completing the 20 CME (Continuing Medical Education) course for moderate complexity laboratory director in 2013. There was no documentation indicating previous laboratory training or experience. E. During interview on 06/12/2018 at 11: 30 am, the laboratory owner confirmed that she was the general supervisor of the

	laboratory.
D9999	The CMP includes the following tests: Glucose - energy source for the body; a steady supply must be available for use, and a relatively constant level of glucose must be maintained in the blood. Calcium - one of the most important minerals in the body; it is essential for the proper functioning of muscles, nerves, and the heart and is required in blood clotting and in the formation of bones. Proteins Albumin - a small protein produced in the liver; the major protein in serum Total Protein - measures albumin as well as all other proteins in serum Electrolytes Sodium - vital to normal body processes, including nerve and muscle function Potassium - vital to cell metabolism and muscle function CO2 (carbon dioxide, bicarbonate) - helps to maintain the body's acid-base balance (pH) Chloride - helps to regulate the amount of fluid in the body and maintain the acid-base balance Kidney Tests BUN (blood urea nitrogen) - waste product filtered out of the blood by the kidneys; conditions that affect the kidney have the potential to affect the amount of urea in the blood. Creatinine - waste product produced in the muscles; it is filtered out of the blood by the kidneys so blood levels are a good indication of how well the kidneys are working. Liver Tests ALP (alkaline phosphatase) - enzyme found in the liver and other tissues, bone; elevated levels of ALP in the blood are most commonly caused by liver disease or bone disorders. ALT (alanine amino transferase, also called SGPT) - enzyme found mostly in the cells of the liver and kidney; a useful test for detecting liver damage AST (aspartate amino transferase, also called SGOT) - enzyme found especially in cells in the heart and liver; also a useful test for detecting liver damage Bilirubin - waste product produced by the liver as it breaks down and recycles aged red blood cells The basic metabolic panel (BMP) is a frequently ordered panel of 8 tests that gives a health practitioner important information about the current status of a person's metabolism, including health of the kidneys, blood glucose level, and electrolyte and acid/base balance. Abnormal results, and especially combinations of abnormal results, can indicate a problem that needs to be addressed. The CMP is made up of 14 tests; the basic metabolic panel (BMP) is a subset of those and has 8 tests. It does not include the liver (ALP, ALT, AST, and bilirubin) and protein (albumin and total protein) tests. A healthcare provider may order a CMP rather than a BMP if he or she wants to get a more complete picture of the status of a person's organ function or to check for specific conditions, such as diabetes or liver or kidney disease.