Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473055	09/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine Associates	3100 S Elm Place, Suite A, Broken Arrow, 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 09/18,19,20/19 The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director, senior partner, office manager, and laboratory supervisor during an exit conference performed at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to ensure attestation statements were signed by the analyst(s) and failed to maintain a copy of all proficiency testing records for a minimum of two years for 5 of 18 events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records, with the following identified: (a) First 2018 Chemistry Miscellaneous Event (i) The attestation statement had not been signed by the analyst(s); (ii) Copies of instrument printouts could not be located; (ii) A copy of the results form submitted to the proficiency testing program could not be

	located. (b) First 2018 Microbiology Event (i) The attestation statement had not been signed by the analyst(s). (c) Second 2018 Chemistry Core Event (i) The attestation statement had not been signed by the analyst(s); (ii) Copies of instrument printouts could not be located; (ii) A copy of the results form submitted to the proficiency testing program could not be located. (d) Second 2018 Microbiology Event (i) The attestation statement had not been signed by the analyst(s). (e) Third 2018 Chemistry Core Event (i) A copy of the results form submitted to the proficiency testing program could not be located. (2) The surveyor reviewed the records with the laboratory supervisor, who stated the attestation statements had not been signed by the the analyst (s) and the copies had not been maintained, as indicated above.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to take corrective action for an unacceptable proficiency testing score. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. The following was identified: (a) Second 2018 Chemistry Core Event (i) Potassium - The laboratory failed the result for 2 of 5 samples (CH-06 and CH-08) and attained a 60% score. (2) The records were then reviewed further by the surveyor. There was no evidence corrective action had been taken for the above failures; (3) The surveyor reviewed the records with the laboratory supervisor, and asked if corrective action had been taken and documented for the failures. The laboratory supervisor stated corrective action had not been taken.
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and office manager, the laboratory failed to participate in 1 of 5 proficiency testing events for the analytes TSH and Free T4. Findings include: (1) On the first day of the survey, the

	surveyor reviewed proficiency testing records for 2018 and 2019 and identified the laboratory attained a 0% score for the analytes TSH (Thyroid Stimulating Hormone) and Free T4 (Thyroxine) for the first 2018 Chemistry Core Event, due to a failure to participate; (2) There was no documentation in the laboratory records to indicate what occurred for the laboratory to not participate, and the date that the proficiency testing samples were received in the laboratory. The surveyor reviewed the shipping schedule for the proficiency testing program which showed the first proficiency testing event was mailed to the laboratory on 01/23/18 and the results were due back to the proficiency testing program by 02/09/18; (3) The surveyor reviewed the records with the laboratory supervisor and office manager and asked them to explain why the laboratory did not participate in the event and if patient testing had been suspended during that time for TSH and Free T4. The laboratory supervisor and the office manager stated the following: (a) They did not know what occurred for the laboratory to not participate in the event; (b) The individual who was the laboratory supervisor at that time was no longer an employee; (c) Testing had not been suspended. (3) Since the laboratory failed to participate in the proficiency testing event, it resulted in a 0% score for the analytes TSH and Free T4. The following were examples of patient TSH and Free T4 testing performed when the laboratory failed to participate in proficiency testing: (a) Patient #1 - TSH testing performed on 02/08/18 (b) Patient #5 - Free T4 testing performed on 02/08/18 (c) Patient #6 - Free T4 testing performed on 02/12/18 (d) Patient #2 - TSH testing performed on 02/16/18 (e) Patient #7 - Free T4 testing performed on 02/20/18 (f) Patient #3 - TSH testing performed on 02/21/18 (d) Patient #4 - TSH testing performed on 02/27/18 (e) Patient #8 - Free T4 testing performed on 02/27/18 (f) Patient #9 - TSH testing performed on 03/16/18 (g) Patient #10 TSH and Free T4 testing performed on 03/19/18 (h) Patient #11 - Free T4 testing performed on 03/19/18 (i) Patient #12 - Free T4 testing performed on 03/21/18 (j) Patient #13 - Free T4 testing performed on 03/27/18 (k) Patient #14 - TSH testing performed on 03/29 /18 (l) Patient #15- TSH and Free T4 testing performed on 04/09/18 (m) Patient #16 - TSH and Free T4 testing performed on 04/11/18 (n) Patient #17 - TSH and Free T4 testing performed on 04/18/18 (o) Patient #18 - TSH and Free T4 testing performed on 04/25/18
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 supervisor the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following failures: (a) First 2018 Chemistry Miscellaneous Event (i) Folate - The laboratory failed the result for 1 of 3 samples (IA-01) and attained a 67% score. (b) Second 2018 Chemistry Core Event (i) Total Bilirubin - The laboratory failed the results for 1 of 5 samples (CH-06) and attained an 80% score. (2) The records were then reviewed further by the surveyor. There was no evidence corrective action had been taken for the above failures; (3) The surveyor reviewed the records with the laboratory supervisor, and asked if corrective action had been taken and documented for the failures. The laboratory supervisor stated corrective action had not been taken.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to verify the accuracy of Hemoglobin A1c testing at least twice annually. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor Hemoglobin A1c testing was performed using the Cobas Pentra 400 analyzer; (2) The surveyor reviewed proficiency testing records for 2018 and 2019 and identified the laboratory was not enrolled for the analyte Hemoglobin A1c (enrollment and participation in a proficiency testing program is not required for Hemoglobin A1c; it is not a regulated analyte), The surveyor asked the laboratory supervisor if the laboratory had a method to verify the testing for accuracy in lieu of proficiency testing. The laboratory supervisor stated to the surveyor Hemoglobin A1c testing had not been verified for accuracy in 2018 and to date in 2019; (3) The following were examples of patient Hemoglobin A1c testing performed when the testing had not been verified for accuracy: (a) Patient #19 - testing performed on 02/07/18 (b) Patient #20 - testing performed on 02/16/18 (c) Patient #21 - testing performed on 02/23/18 (d) Patient #22 - testing performed on 02/27/18 (e) Patient #23 - testing performed on 05/02/18 (f) Patient #24 - testing performed on 05 /11/18 (g) Patient #25 - testing performed on 05/14/18 (h) Patient #26 - testing performed on 05/21/18 (i) Patient #27 - testing performed on 05/24/18 (j) Patient #28 - testing performed on 05/30/18 (k) Patient #29 - testing performed on 10/29/18 (l) Patient #30 - testing performed on 10/31/18 (m) Patient #31 - testing performed on 11 /05/18 (n) Patient #32 - testing performed on 11/13/18 (o) Patient #33 - testing performed on 11/19/18 (p) Patient #34 - testing performed on 11/26/18 (q) Patient #35 - testing performed on 11/30/18 (r) Patient #36 - testing performed on 12/28/18 (s) Patient #37 - testing performed on 01/04/19 (t) Patient #38 - testing performed on 01 /11/19 (u) Patient #39 - testing performed on 01/17/19 (v) Patient #40 - testing performed on 01/23/19 (w) Patient #41 - testing performed on 01/28/19 (x) Patient #42 - testing performed on 04/29/19 (y) Patient #43 - testing performed on 05/08/19 (z) Patient #44 - testing performed on 05/13/19 (aa) Patient #45 - testing performed on 05/20/19 (bb) Patient #46 - testing performed on 05/29/19 (cc) Patient #47 - testing performed on 08/01/19 (dd) Patient #48 - testing performed on 08/12/19 (ee) Patient #49 - testing performed on 08/16/19 (ff) Patient #50 - testing performed on 08/21/19 (gg) Patient #51 - testing performed on 08/29/19
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, written policies and procedures, manufacturer's instructions, and interview with the laboratory supervisor and office manager, 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. Findings include: (1) The laboratory failed to have a written urine microscopic procedure; and failed to have a written procedure that explained the current practices and procedures being performed in the laboratory. Refer to D5401; (2) The laboratory failed to have complete written policies and procedures. Refer to D5403; (3) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (4) The laboratory failed to follow the manufacturer's instructions for performing calibrations. Refer to D5437; (5) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (6) The laboratory failed to follow the manufacturer's quality control specification. Refer to D5479; (7) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with the laboratory supervisor and office manager, the laboratory failed to have a written urine microscopic procedure; and failed to have a written procedure that explained the current practices and procedures being performed in the laboratory. Findings include: URINE MICROSCOPIC PROCEDURE (1) On the first day of the survey, the laboratory supervisor stated to the surveyor Urine Microscopic testing was performed in the laboratory; (2) On the second day of the survey, the surveyor reviewed written policies and procedures contained in the manual titled, "General Laboratory Procedures". A urine microscopic procedure could not be located; (3) The surveyor asked the laboratory supervisor and office manager if a written procedure for performing urine microscopic testing existed. Both stated a procedure had not been written. CURRENT PRACTICES (1) On the first day of the survey, the laboratory supervisor stated to the surveyor Mononucleosis testing was performed in the laboratory using whole blood specimens (as a waived procedure); (2) On the second day of the survey, the surveyor reviewed written policies and procedures contained in the manual titled, "General Laboratory Procedures". The procedure titled, "Mono Test Procedure" allowed for the use of serum and plasma samples (which would make this a non-waived test system) and stated, "The OSOM Mono test is intended for the qualitative detection of infectious mononucleosis heterophile antibodies in serum, plasma, or whole blood as an aid in the diagnosis of infectious mononucleosis"; (3) The surveyor reviewed the findings with the laboratory supervisor who stated the laboratory did not use serum or plasma samples and the procedure in the manual did not reflect the laboratory's current method of performing Mononucleosis testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on a review of the policy and procedure manual, and interview with the laboratory supervisor, the laboratory failed to have complete written policies and procedures. Findings include: MEDONIC M-SERIES ANALYZER (1) On the first day of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) On the third day of the survey, the surveyor reviewed the laboratory policy and procedure manual. The following could not be located: (a) The reportable range for test results for the test system as established or verified in 493.1253; (b) Reference Intervals (normal values); (c) Imminently life-threatening test results, or panic or alert values; (d) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (3) The surveyor reviewed the findings with the laboratory supervisor, who stated the procedures had not been written. HORIBA PENTRA C-400 ANALYZER (1) On the first day of the survey, the laboratory supervisor stated to the surveyor Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Hemoglobin A1c, Potassium, Sodium, Total Bilirubin, Total Protein, Cholesterol, HDL Cholesterol, Triglyceride, and CK (Creatine Kinase) testing were performed on the ABX Pentra 400 analyzer; (2) On the third day of the survey, the surveyor reviewed the laboratory policy and procedure manual. The following could not be located: (a) The reportable range for test results for the test system as established or verified in 493.1253; (b) Quality Control Procedures including: (i) Type of control (e.g., manufacturer or in-house, electronic); (ii) Identity (e.g., normal, abnormal, level I,II, patient or a control); (iii) Criteria to determine acceptable control results. (c) Reference Intervals (normal values); (d) Imminently life-threatening test results, or panic or alert values; (e) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (3) The surveyor reviewed the findings with the laboratory supervisor, who stated the procedures had not been written. BECKMAN COULTER ACCESS 2 ANALYZER (1) On the first day of the survey, the laboratory supervisor stated to the surveyor Vitamin D, Vitamin B12, Folate, Ferritin, TSH (Thyroid Stimulating Hormone), Free T3 (Triiodothyronine), Free T4,

	PSA (Prostate Specific Antigen), SHBG (Sex Hormone Binding Globulin), and Testosterone testing were performed on the Beckman Coulter Access 2 analyzer; (2) On the third day of the survey, the surveyor reviewed the laboratory policy and procedure manual. The following could not be located: (a) The reportable range for test results for the test system as established or verified in 493.1253; (b) Quality Control Procedures including: (i) Type of control (e.g., manufacturer or in-house, electronic); (ii) Identity (e.g., normal, abnormal, level I,II, patient or a control); (iii) Criteria to determine acceptable control results. (c) Reference Intervals (normal values); (d) Imminently life-threatening test results, or panic or alert values; (e) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (3) The surveyor reviewed the findings with the laboratory supervisor, who stated the procedures had not been written.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 2 of 3 analyzers. Findings include: MEDONIC M SERIES (1) On the first day of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic M series analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions contained in Section 8 of the operator's manual. The following maintenance was required on a monthly basis: (a) Cleaning with Hypochlorite and Enzymatic Cleaner (3) The surveyor then reviewed maintenance records for 11 months (October 2018 through August 2019). The monthly maintenance had not been documented as performed: (a) Between 10/26/18 and 01/31/19 (b) Between 01/31/19 and 03/01/19 (c) Between 04/26/19 and 06/19/19 (4) The surveyor reviewed the records with the laboratory supervisor who stated the monthly maintenance had not been performed as indicated above. ABX PENTRA 400 (1) On the first day of the survey, the laboratory supervisor stated to the surveyor Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, Cholesterol, HDL Cholesterol, Triglyceride, CK (Creatine Kinase), and Hemoglobin A1c were performed on the ABX Pentra 400 analyzer; (2) On the third day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer, which required the following: (a) Weekly (i) ISE cleaning with the kit + global initialization (ii) Shut down with Deproteinizer (with mixer) (b) Bi-Monthly (i) Filter Lee replacement (ii) Glycol level check (3) The surveyor then reviewed maintenance records for 8 months (January through August 2019). The maintenance had not been documented as performed as follows: (a) Weekly (i) Between 03/22/19 and 04/05/19 (ii) Between 05/31/19 and 06 /17/19 (iii) Between 07/26/19 and 08/05/19 (b) Bi-Monthly (i) Between 02/05/19 and 06/28/19 (4) The surveyor reviewed the records with the laboratory supervisor who stated the maintenance had not been performed as indicated above.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing calibrations. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic M Series analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions, contained in the operator's manual. Section 7 titled, "Calibration" stated, "This section describes the step-by-step procedure for calibration of the Medonic M-Series. The instrument has been calibrated by Boule prior to shipment. Good laboratory practice, however, requires regular checks and calibration of the measured parameters. It is recommended to calibrate the instrument every 6 months"; (3) The surveyor then reviewed maintenance and calibration records for 2018 and 2019. There was no documentation to prove the analyzer had been calibrated after 10/01/18 (due 04/2019); (4) The surveyor asked the laboratory supervisor if the analyzer had been calibrated after 10/01/18. The laboratory supervisor reviewed the records and stated the analyzer had not been calibrated since 10/01/18; (5) The following were examples of patient CBC testing performed when the analyzer had not been calibrated every six months as recommended by the manufacturer: (a) Patient #52 - testing performed on 04/08/19 (b) Patient #53 - testing performed on 04/11/19 (c) Patient #54 - testing performed on 04/19/19 (d) Patient #55 - testing performed on 04/30/19 (e) Patient #56 - testing performed on 05/02/19 (f) Patient #57 - testing performed on 05/15/19 (g) Patient #58 - testing performed on 05/28/19 (h) Patient #59 - testing performed on 06/03/19 (i) Patient #60 - testing performed on 06/13/19 (j) Patient #61 - testing performed on 06/20/19 (k) Patient #62 - testing performed on 06/28/19 (l) Patient #63 - testing performed on 07/03/19 (m) Patient #64 - testing performed on 07/15/19 (n) Patient #65 - testing performed on 07/23/19 (o) Patient #66 - testing performed on 07/30/19 (p) Patient #67 - testing performed on 08/02/19 (q) Patient #68 - testing performed on 08/12/19 (r) Patient #69 - testing performed on 08/22/19 (s) Patient #70 - testing performed on 08/30/19 (t) Patient #71 - testing performed on 09/06/19 (u) Patient #72 - testing performed on 09/10/19
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, Cholesterol, HDL Cholesterol, Triglyceride, and CK (Creatine Kinase) testing were performed on the ABX Pentra 400 analyzer; (2) On the second day of the survey, the surveyor reviewed 2017, 2018, and 2019 calibration records and identified that calibration procedures for the above analytes had been performed with one or two levels of calibrators. Since the calibration procedures included only one or two levels, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) The surveyor reviewed calibration verification records, with the following identified: (a) For Creatinine, there was no documentation to prove calibration verification had been performed after 09/13/17 (due 03/2018); (b) For Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, Cholesterol, HDL Cholesterol, Triglyceride, and CK, there was no documentation to proveand calibration verification had been performed after 04/18/18 (due 10/2018). (4) The surveyor reviewed the records with the laboratory supervisor and asked if calibration verification procedures had been performed since the above dates. The laboratory supervisor stated calibration verification procedures had not been performed; (5) The following were examples of patient testing performed when calibration verification procedures had not been performed (NOTE: CMP testing includes the analytes Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein; Lipid Profile testing includes the analytes Cholesterol, HDL Cholesterol, and Triglyceride); (a) CMP Patient Testing (i) Patient #73 - testing performed on 01/02/19 (ii) Patient #74 - testing performed on 01/11/19 (iii) Patient #75 - testing performed on 01/23/19 (iv) Patient #76 - testing performed on 02/06/19 (v) Patient #77 - testing performed on 02/13/19 (vi) Patient #78 - testing performed on 02/28/19 (vii) Patient #79 - testing performed on 03/06/19 (viii) Patient #80 - testing performed on 03/13/19 (ix) Patient #81 - testing performed on 03/21/19 (x) Patient #82 - testing performed on 04/03/19 (xi) Patient #83 - testing performed on 04/12/19 (xii) Patient #84 - testing

	performed on 04/24/19 (xiii) Patient #85 -testing performed on 08/02/19 (xiv) Patient #86 - testing performed on 08/12/19 (xv) Patient #87 - testing performed on 08/30/19 (b) Lipid Profile Patient Testing (i) Patient #89 - testing performed on 01/09/19 (ii) Patient #90 - testing performed on 01/18/19 (iii) Patient #91 - testing performed on 01 /23/19 (iv) Patient #92 - testing performed on 01/31/19 (v) Patient #93 - testing performed on 08/02/19 (vi) Patient #94 - testing performed on 08/09/19 (vii) Patient #95 - testing performed on 08/16/19 (viii) Patient #96 - testing performed on 08/30/19 (c) CK Patient Testing (i) Patient #97 - testing performed on 01/04/19 (ii) Patient #98 - testing performed on 01/11/19 (iii) Patient #99 - testing performed on 01/21/19 (iv) Patient #100 - testing performed on 08/05/19 (v) Patient #101 - testing performed on 08/20/19 (vi) Patient #102 - testing performed on 08/28/19
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's quality control specifications. Findings include: (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyor: (a) Ferritin, TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), SHBG (Sex Hormone Binding Globulin), and Vitamin D testing were performed on the Beckman Coulter Access 2 analyzer; (c) Two levels of Bio-Rad Immunoassay Premium Control quality control (QC) materials were performed each day of patient Ferritin, TSH, and PSA testing; (d) Two levels of Bio-Rad Lyphochek Specialty Immunoassay Control QC materials were performed each day of patient SHBG and Vitamin D testing. (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions for the QC materials which stated, "The mean values and the corresponding +/-3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (3) The surveyor reviewed records for testing performed from 04/01/19 through the third day of the survey. For 4 of 8 lot numbers, it was identified the laboratory had used the package insert guideline ranges instead of laboratory established ranges for each analyte tested to determine acceptability of QC results. The package insert ranges had been used from 04/01/19 through 06/30/19 as follows: (a) Bio-Rad Immunoassay Premium Control (level 1 lot #27331 and level 3 lot #27333) (i) Ferritin - The laboratory used the manufacturer's range of 13.2-26.2 for level 1 and 230-330 for level 3 (ii) TSH - The laboratory used the manufacturer's range of 0.52-0.76 for level 1 and 23.8-35.7 for level 3 (iii) PSA - The laboratory used the manufacturer's range of 0.36-0.78 for level 1 and 17.2-32.3 for level 3 (b) Bio-Rad Lyphochek Specialty Immunoassay Control (level 1 lot #25281 and level 2 lot #25282) (i) SHBG - The laboratory used the manufacturer's range of 8.2-12.3 for level 1 and 31.0-46.0 for level 2 (ii) Vitamin D - The laboratory used the manufacturer's range of 6.3-21.5 for

	level 1 and 16.1-45.4 for level 2 (4) The surveyor reviewed the findings with the laboratory supervisor who stated the laboratory had used the manufacturer's provided ranges for determining acceptability of the results, as indicated above, and did not establish their own ranges; (5) The following were examples of patient testing performed: (a) Ferritin Patient Testing (i) Patient #103 - testing performed on 04/19 /19 (ii) Patient #104 - testing performed on 04/20/19 (iii) Patient #105 - testing performed on 04/23/19 (iv) Patient #106 - testing performed on 04/27/19 (v) Patient #107 - testing performed on 05/08/19 (vi) Patient #108 - testing performed on 05/20 /19 (vii) Patient #109 - testing performed on 05/30/19 (viii) Patient #110 - testing performed on 06/03/19 (ix) Patient #111 - testing performed on 06/10/19 (x) Patient #112 - testing performed on 06/21/19 (xi) Patient #113 - testing performed on 06/28 /19 (b) TSH Patient Testing (i) Patient #114 - testing performed on 04/02/19 (ii) Patient #115 - testing performed on 04/15/19 (iii) Patient #116 - testing performed on 04/23/19 (iv) Patient #117 - testing performed on 04/29/19 (v) Patient #118 - testing performed on 05/01/19 (vi) Patient #119 - testing performed on 05/13/19 (vii) Patient #120 - testing performed on 05/22/19 (viii) Patient #121 - testing performed on 05/31 /19 (ix) Patient #122 - testing performed on 06/06/19 (x) Patient #123 - testing performed on 06/11/19 (xi) Patient #124 - testing performed on 06/20/19 (xii) Patient #125 - testing performed on 06/27/19 (c) PSA Patient Testing (i) Patient #126 - testing performed on 04/03/19 (ii) Patient #127 - testing performed on 04/17/19 (iii) Patient #128 - testing performed on 04/30/19 (iv) Patient #129 - testing performed on 05/06 /19 (v) Patient #130 - testing performed on 05/13/19 (vi) Patient #131 - testing performed on 05/22/19 (vii) Patient #132 - testing performed on 06/03/19 (viii) Patient #133 - testing performed on 06/17/19 (ix) Patient #134 - testing performed on 06/20/19 (x) Patient #135 - testing performed on 06/28/19 (d) SHBG Patient Testing (i) Patient #136 - testing performed on 04/05/19 (ii) Patient #137 - testing performed on 04/15/19 (iii) Patient #138 - testing performed on 04/30/19 (iv) Patient #139 - testing performed on 05/02/19 (v) Patient #140 - testing performed on 05/14/19 (vi) Patient #141- testing performed on 05/28/19 (vii) Patient #142 - testing performed on 06/11/19 (viii) Patient #143 - testing performed on 06/20/19 (ix) Patient #144 - testing performed on 06/28/19 (e) Vitamin D Patient Testing (i) Patient #145 - testing performed on 04/02/19 (ii) Patient #146 - testing performed on 04/12/19 (iii) Patient #147 - testing performed on 04/22/19 (iv) Patient #148 - testing performed on 04/24 /19 (v) Patient #149 - testing performed on 05/01/19 (vi) Patient #150 - testing performed on 05/06/19 (vii) Patient #151 - testing performed on 05/15/19 (viii) Patient #152 - testing performed on 05/24/19 (ix) Patient #153 - testing performed on 05/29/19 (x) Patient #154 - testing performed on 06/04/19 (xi) Patient #155 - testing performed on 06/12/19 (xii) Patient #156 - testing performed on 06/19/19 (xiii) Patient #157 - testing performed on 06/25/19 (xiv) Patient #158 - testing performed on 06/30/19
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, manufacturer's instructions, and interview with the laboratory supervisor and office manager, the

	laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. 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 a written urine microscopic procedure; and failed to have a written procedure that explained the current practices and procedures being performed in the laboratory. Refer to D5401; (b) The laboratory failed to have complete written policies and procedures. Refer to D5403; (c) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (d) The laboratory failed to follow the manufacturer's instructions for performing calibrations. Refer to D5437; (e) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (f) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479.
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, written policies and procedures, manufacturer's instructions, and interview with the laboratory supervisor and office manager, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Refer to D6016; (3) The laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018; (4) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (5) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (6) The laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training. Refer to D6029; (7) The laboratory director failed to ensure policies and procedures had been written, and were current. Refer to D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the

	laboratory supervisor, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (2) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions for performing calibrations. Refer to D5437; (3) The laboratory director failed to ensure the laboratory followed the manufacturer's quality control specifications. Refer to D5479.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and office manager, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Findings include: (1) The laboratory director failed to ensure attestation statements were signed by the analyst(s) and failed to ensure the laboratory maintained a copy of all proficiency testing records for a minimum of two years. Refer to D2015; (2) The laboratory director failed to ensure the laboratory participated in 1 of 5 proficiency testing events for the analytes TSH and Free T4. Refer to D2100.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings include: (1) The laboratory director failed to ensure corrective action was taken for an unacceptable proficiency testing score. Refer to D2094; (2) The laboratory director failed to ensure proficiency testing results were thoroughly reviewed and evaluated. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the laboratory verified the accuracy of Hemoglobin A1c testing at least twice annually. Refer to D5217; (2) The laboratory director failed to ensure the accuracy of Hemoglobin A1c testing had been verified at least twice annually. Refer to D5217; (3) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months. Refer to D5439.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, manufacturer's instructions, and interview with the laboratory supervisor and office manager, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and office

	manager, the laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #16 - This person was hired to perform patient testing on 07/11/17. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 11/09/18. (2) The surveyor reviewed the findings with the laboratory supervisor and office manager. Both stated there was no additional documentation to prove the above person had been initially trained to perform moderate complexity testing.
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 a review of written policies and procedures and interview with the laboratory supervisor and office manager, the laboratory director failed to ensure policies and procedures had been written, and were current. Findings include: (1) The laboratory director failed to ensure the laboratory had a written urine microscopic procedure; and failed to ensure a written procedure explained the current practices and procedures being performed in the laboratory. Refer to D5401; (2) The laboratory director failed to ensure the laboratory had complete written policies and procedures. Refer to D5403.
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 a review of records, manufacturer's instructions, and interview with the laboratory supervisor and office manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. 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 the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (3) The technical consultant failed to ensure persons were evaluated at least semiannually during the first year of performing moderate complexity testing. Refer to D6053; (4) The technical consultant failed to ensure persons were evaluated at least annually after the first year of performing moderate complexity testing. 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 possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor and office manager, the laboratory failed to ensure the individual who performed competencies met the educational qualifications of a technical consultant for 8 of 9 testing persons. Findings include: (1) On the first day of the survey, the surveyor reviewed records for 9 persons performing moderate complexity testing in 2018 and 2019. The records indicated the evaluations for 8 of 9 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #3 - The competency evaluations had been performed on 10/12/18 and 08/30/19 by the laboratory supervisor (this person had earned an associate degree in applied science); (b) Testing Person #4 - The competency evaluation had been performed on 09/06/19 by the laboratory supervisor; (c) Testing Person #5 - The competency evaluation had been performed on 10/22/19 by the laboratory supervisor; (d) Testing Person #6 - The competency evaluation had been performed on 08/14/19 by the laboratory supervisor; (e) Testing Person #13 - The competency evaluation had been performed on 09/28/19 by the laboratory supervisor; (f) Testing Person #14 - The competency evaluation had been performed on 12/13/18 by the laboratory supervisor; (g) Testing Person #15 - The competency evaluations had been performed

	on 09/02/18 and 09/09/19 by the laboratory supervisor; (h) Testing Person #16 - The competency evaluations had been performed on 11/09/18 and 09/05/19 by the laboratory supervisor. (2) The surveyor explained to the laboratory supervisor and office manager that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).
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 a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (2) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions for performing calibrations. Refer to D5437; (3) The technical consultant failed to ensure calibration verification procedures had been performed at least once every 6 months. Refer to D5439; (4) The technical consultant failed to ensure the laboratory followed the manufacturer's quality control specifications. Refer to D5479.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and office manager, the technical consultant failed to ensure persons were evaluated at least semiannually during the first year of performing moderate complexity testing. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records. The following was identified for 4 of 11 persons hired after the previous recertification survey: (a) Laboratory Supervisor - This person was hired on 03/08/17. There was no evidence a semiannual evaluation had been performed (initial training was completed on 03/24/17 and a competency evaluation had been performed on 07 /05/19); (b) Testing Person #8 - This person was hired on 04/18/18. There was no evidence that a semiannual evaluation had been performed (initial training was completed on 10/19/18 and additional competency evaluations had not been performed to date); (c) Testing Person #14 - This person was hired on 05/30/17. There

	was no evidence that a semiannual evaluation had been performed (initial training was completed on 08/04/17 and a competency evaluation was performed on 12/03/18); (d) Testing Person #16 - This person was hired on 07/11/17. There was no evidence that a semiannual evaluation had been performed (a competency evaluation had not been documented as performed until 11/09/18). (2) The surveyor reviewed the findings with the laboratory supervisor and office manager. Both verified semiannual evaluations had not been performed as indicated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory supervisor and office manager, the technical consultant failed to ensure persons were evaluated at least annually after the first year of performing moderate complexity testing. Findings include: (1) On the first day of the survey, the surveyor reviewed records for 8 persons who performed moderate complexity testing in the main laboratory. For 1 of the persons, there was no evidence a competency evaluation had been performed annually: (a) Laboratory Supervisor - There was no documentation a competency evaluation had been performed between 03/24/17 (inital training completed) and 07/09 /19. (2) Surveyor #1 reviewed the findings with the laboratory supervisor and office manager. Both stated an annual competency evaluation had not been performed in 2018.