Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050835	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wah-Zha-Zhi Health Center	715 Grandview, Pawhuska, 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 survey was performed on 6/19,20/2018. The findings were reviewed with the chief medical officer and laboratory supervisor/testing person #1 during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: Analytic Systems 493.1405; D6000: Laboratory Director, Moderate Complexity 493.1409; D6033: Technical Consultant, Moderate Complexity
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with laboratory supervisor /testing person #1, the laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, surveyor #2 reviewed the policy titled "Staff Competency Assessment". It did not include guidance for assessing the competency of the technical consultant; (2) Surveyor #2 then reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence a technical consultant competency, based on their job responsibilities, had been performed; (3) Surveyor #2 asked the laboratory supervisor/testing person #1 if a written policy to evaluate the technical consultant based on job responsibilities was available. The laboratory supervisor/testing person#1 stated a policy to evaluate the technical consultant based on job responsibilities had not been written or performed.
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/testing person #1, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2017 and 2018 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) First 2018 Chemistry Core Event (i) BUN (Blood Urea Nitrogen) - 4 of 5 results exhibited a positive bias (aa) CH-02 - SDI 3.0 (bb) CH-03 - SDI 2.6 (cc) CH-04 - SDI 3.4 (dd) CH-05 - SDI 2.3 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) Surveyor #2 reviewed the above findings with the laboratory supervisor /testing person #1 who stated the biases had not been addressed.
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, manufacturer's instructions, and interview with the laboratory supervisor/testing person #1, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to ensure an analyzer was stored as required by the manufacturer. Refer to D5413; (2) The laboratory failed to demonstrate the performance specifications for a new test method. Refer to 5421; (3) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and would detect immediate errors that would occur due to test system failure, adverse environmental conditions. Refer to D5441; (4) The laboratory failed to perform a negative and positive control each day of Urine Microalbumin/Creatinine testing. Refer to D5447; (5) The laboratory failed to perform a negative and positive control each day of patient Serum HCG (Human Chorionic Gonadotropin) screen testing. Refer to D5449; (6) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479; (7) The laboratory failed to have a system that evaluated and defined the relationship between two analyzers at least twice a year. Refer to D5775.
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 a review of records, manufacturer's instructions, and interview with the laboratory supervisor/testing person #1, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) On the first day of the survey, the laboratory supervisor/testing person #1 stated the following to the surveyors: (a) CBC (Complete Blood Count) testing was performed on the Sysmex 1000i analyzer. (2) On the second day of the survey, surveyor #2 reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) Surveyor #2 reviewed laboratory humidity records from May 2017 through May 2018 which verified the humidity readings were less than 30% for 7 of 13 months as follows: (a) October 2017 - 1 of 31 humidity readings were documented as less than 30% (day 31); (b) November 2017 - 6 of 30 humidity readings was documented as less than 30% (days 1,2,21,22,23,30); (c) December 2017 - 11 of 31 humidity readings was documented as less than 30% (days 6,7,8,11,12,13,14,15,27,28,29); (d) January 2018 - 18 of 31 humidity readings were documented as less than 30% (days 3,4,5,8,9,11,12,16,17,18,19,23,24,25,26,29,30,31); (e) February 2018 - 10 of 28 humidity readings were documented as less than 30% (days 1,2,5,6,7,8,9,12,13,16); (f) March 2018 - 9 of 31 humidity readings were documented as less than 30% (days 2,6,7,8,9,12,13,14,15); (g) April 2018 - 3 of 30 humidity readings were documented as less than 30% (days 3,4,9); (4) Surveyor #2 reviewed the records with the laboratory supervisor/testing person #1 who stated the humidity of the laboratory had been maintained below 30% as indicated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor/testing person #1, the laboratory failed to demonstrate the performance specifications for a new test method. Findings include: (1) On the first day of the survey, the laboratory supervisor/testing person #1 stated to surveyor #1 the laboratory began performing Urine Microalbumin/Creatinine testing using two Siemens DCA Vantage analyzers (Serial numbers S059404 and S059406) on 01/19/17; (2) Surveyor #1 reviewed the validation records for the analyzers with the following identified: (a) Analyzer Serial Number S059404 (i) There was no evidence the precision and reportable ranges had been demonstrated; (ii) There was no evidence the reference ranges (normal ranges) had been verified. (b) Analyzer Serial Number S059406 (i) There was no evidence the accuracy, precision, and reportable ranges had been demonstrated; (ii) There was no

	evidence the reference ranges (normal ranges) had been verified. (3) Surveyor #1 reviewed the records with the laboratory supervisor/testing person #1 who verified the performance specifications had not been demonstrated for each analyzer as indicated above because it was believed the test system was classified as waived; (4) The following were examples of patient Urine Microalbumin/Creatinine testing performed: (a) Patient #1 - testing performed on 01/18/17 (b) Patient #2 - testing performed on 01/31/17 (c) Patient #3 - testing performed on 05/03/17 (d) Patient #4 - testing performed on 05/08/17 (e) Patient #5 - testing performed on 05/23/17 (f) Patient #6 - testing performed on 06/12/17 (g) Patient #7 - testing performed on 06/29 /17 (h) Patient #8 - testing performed on 07/10/17 (i) Patient #9 - testing performed on 07/26/17 (j) Patient #10 - testing performed on 08/08/17 (k) Patient #11 - testing performed on 08/31/17 (l) Patient #12 - testing performed on 09/11/17 (m) Patient #13 - testing performed on 09/26/17 (n) Patient #14 - testing performed on 10/10/17 (o) Patient #15 - testing performed on 10/31/17 (p) Patient #16 - testing performed on 11 /06/17 (q) Patient #17 - testing performed on 11/27/17 (r) Patient #18 - testing performed on 12/07/17 (s) Patient #19 - testing performed on 12/21/17 (t) Patient #20 - testing performed on 01/30/18 (u) Patient #21 - testing performed on 02/06/18 (v) Patient #22 - testing performed on 02/26/18 (w) Patient #23 - testing performed on 03 /12/18 (x) Patient #24 - testing performed on 04/05/18 (y) Patient #25 - testing performed on 04/27/18 (z) Patient #26 - testing performed on 05/03/18 (aa) Patient #27 - testing performed on 05/25/18 (bb) Patient #28 - testing performed on 06/04/18 (cc) Patient #29 - testing performed on 06/07/18 (dd) Patient #30 - testing performed on 06/15/18 (ee) Patient #31 - testing performed on 06/18/18
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor/testing person #1, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and would detect immediate errors that would occur due to test system failure, adverse environmental conditions. Findings include: HEMATOLOGY (1) On the first day of the survey, the laboratory supervisor /testing person #1 verified the following to the surveyors: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (b) Three levels (low, normal, and high) of Sysmex e-check XS quality control (QC) materials were tested each day patient testing was performed; (c) The laboratory established their own means and ranges before new lot numbers of QC materials were put into use. (2) On the second day of the survey, surveyor #1 reviewed quality control records for 24 lot numbers of control materials used from 02/27/17 through the second day of the survey. The following was identified: (a) For 12 of 24 lot numbers, there were no

records (i.e., Levey-Jennings data) proving the control results had been monitored for variances. The QC lot numbers were as follows: (i) Low control lot #70450804, normal control lot #70450805, and high control lot #70450806 - Used from 02/27/17 through 05/05/17; (ii) Low control lot #71010804, normal control lot #71010805, and high control lot #71010806 - Used from 05/08/17 through 06/30/17; (iii) Low control lot #71570804, normal control lot #71570805, and high control lot #71570806 - Used from 07/03/17 through 08/25/17; (iv) Low control lot #72130804, normal control lot #72130805, and high control lot #72130806 - Used from 08/28/17 through 10/22/17. (b) For 6 of 24 lot numbers, the laboratory had failed to utilize an established target value for the lower limit of acceptability and utilized the low default setting of 0.0. In addition, the upper limit that had been entered was beyond the manufacturer's expected guideline ranges as follows: (i) Low control lot #80160804, normal control lot #80160805, and high control lot #80160806 - Used from 02/12/18 through 04/06 /18 (aa) For the analyte RBC for the low control, a target value of 2.33 and a control range of 0.0-4.66 was used. The manufacturer's guideline range was 2.23-2.47; (bb) For the analyte Hemoglobin for the low control, a target value of 5.5 and a control range of 0.0-11.0 was used. The manufacturer's guideline range was 5.3-5.9; (cc) For the analyte Hematocrit for the low control, a target value of 17.1 and a control range of 0.0-34.2 was used. The manufacturer's guideline range was 16.0-18.4; (dd) For the analyte Platelet for the low control, a target value of 53 and a control range of 0.0-106 was used. The manufacturer's guideline range was 40-74; (ee) For the analyte RBC for the normal control, a target value of 4.34 and a control range of 0.0-8.68 was used. The manufacturer's guideline range was 4.17-4.51; (ff) For the analyte Hemoglobin for the normal control, a target value of 11.8 and a control range of 0.0-23.6 was used. The manufacturer's guideline range was 11.4-12.4; (gg) For the analyte Hematocrit for the normal control, a target value of 35.4 and a control range of 0.0-70.8 was used. The manufacturer's guideline range was 33.1-37.3; (hh) For the analyte Platelet for the normal control, a target value of 227 and a control range of 0.0-454 was used. The manufacturer's guideline range was 201-255; (ii) For the analyte RBC for the high control, a target value of 5.27 and a control range of 0.0-10.54 was used. The manufacturer's guideline range was 5.09-5.51; (jj) For the analyte Hemoglobin for the high control, a target value of 16.4 and a control range of 0.0-32.8 was used. The manufacturer's guideline range was 15.8-17.2; (kk) For the analyte Hematocrit for the high control, a target value of 47.9 and a control range of 0.0-95.8 was used. The manufacturer's guideline range was 44.8-50.6; (ll) For the analyte Platelet for the high control, a target value of 550 and a control range of 0.0-1100 was used. The manufacturer's guideline range was 488-596. (ii) Low control lot #81280804, normal control lot #81280805, and high control lot #81280806 - Put into use on 06/04/18 and was currently in use (the ranges were adjusted by the laboratory supervisor on 06/19 /18 at 05:50 pm when surveyor #1 had identified the default setting of 0.0 had been used for the lower limits) (aa) For the analyte RBC for the low control, a target value of 2.29 and a control range of 0.0-4.58 was used. The manufacturer's guideline range was 2.18-2.40; (bb) For the analyte Hemoglobin for the low control, a target value of 5.5 and a control range of 0.0-11.0 was used. The manufacturer's guideline range was 5.2-5.5; (cc) For the analyte Hematocrit for the low control, a target value of 17.0 and a control range of 0.0-34.0 was used. The manufacturer's guideline range was 15.8-18.2; (dd) For the analyte Platelet for the low control, a target value of 57 and a control range of 0.0-114 was used. The manufacturer's guideline range was 43-77; (ee) For the analyte RBC for the normal control, a target value of 4.25 and a control range of 0.0-8.50 was used. The manufacturer's guideline range was 4.09-4.43; (ff) For the analyte Hemoglobin for the normal control, a target value of 11.8 and a control range of 0.0-23.6 was used. The manufacturer's guideline range was 11.2-12.2; (gg) For the analyte Hematocrit for the normal control, a target value of 34.7 and a

control range of 0.0-69.4 was used. The manufacturer's guideline range was 32.3-36.5; (hh) For the analyte Platelet for the normal control, a target value of 221 and a control range of 0.0-442 was used. The manufacturer's guideline range was 198-252; (ii) For the analyte RBC for the high control, a target value of 5.18 and a control range of 0.0-10.36 was used. The manufacturer's guideline range was 4.97-5.39; (jj) For the analyte Hemoglobin for the high control, a target value of 16.2 and a control range of 0.0-32.4 was used. The manufacturer's guideline range was 15.6-16.8; (kk) For the analyte Hematocrit for the high control, a target value of 47.1 and a control range of 0.0-94.2 was used. The manufacturer's guideline range was 43.8-49.4; (ll) For the analyte Platelet for the high control, a target value of 533 and a control range of 0.0-1066 was used. The manufacturer's guideline range was 482-590. (c) For 4 of 24 lot numbers, the package insert guideline ranges (instead of laboratory established ranges) had been used to determine acceptability of results as follows: (i) Low control lot #73250804 - Used from 11/29/17 through 02/11/18 (aa) For the analyte Hemoglobin, the package insert mean of 5.6 and range of 5.3-5.9 had been used to evaluate QC results. (ii) Low control lot #80720804 and normal control lot #80720805 - Used from 04/07/18 through 06/01/18 (aa) For the analyte Hemoglobin for the low control, the package insert mean of 5.7 and range of 5.4-6.0 had been used to evaluate QC results; (bb) For the analyte RBC (red blood cell) for the normal control, the package insert mean of 4.35 and range of 4.18-4.52 had been used to evaluate QC results. (iii) Low control lot #81280804 and normal control lot #81280805 - Put into use on 06/04/18 and was currently in use (aa) For the analyte Hemoglobin for the low control, the package insert mean of 5.5 and range of 5.2-5.8 was being used to evaluate QC results (the mean and range had been inadvertently adjusted to the package insert ranges by the laboratory supervisor on 06/19/18 at 05: 50 pm when surveyor #1 had identified the default setting of 0.0 had been used for the lower limits (see b above); (bb) For the analyte RBC for the normal control, the package insert mean of 4.26 and range of 4.09-4.43 was being used to evaluate QC results (the mean and range had been inadvertently adjusted to the package insert ranges by the laboratory supervisor on 06/19/18 at 05:50 pm when surveyor #1 had identified the default setting of 0.0 had been used for the lower limits (see b above). (3) The records were reviewed with the laboratory supervisor. The laboratory supervisor stated the following: (a) The laboratory did not monitor QC results for variances, as indicated in (a) above, from 02/27/17 through 10/22/17; (b) The QC ranges, as indicated in (b) above, would not detect immediate error, but could not explain where the ranges came from; (c) The package insert ranges had inadvertently been used, as indicated in (c) above, but could not explain how those ranges had been entered into the analyzer. (4) The following were examples of patient CBC testing performed when the laboratory did not have control procedures that monitored the accuracy and precision of the complete analytic process; and/or detect immediate errors: (a) Patient #101 - testing performed on 02/27/17 (b) Patient #102 - testing performed on 03/07/17 (c) Patient #103 - testing performed on 03/15/17 (d) Patient #104 - testing performed on 03/28/17 (e) Patient #105 - testing performed on 04/06/17 (f) Patient #106 - testing performed on 04/17/17 (g) Patient #107 - testing performed on 04/25/17 (h) Patient #108 - testing performed on 05/09/17 (i) Patient #109 - testing performed on 05/16/17 (j) Patient #110 - testing performed on 05/30/17 (k) Patient #111 - testing performed on 06/07/17 (l) Patient #43 - testing performed on 06/19/17 (m) Patient #44 - testing performed on 06/23/17 (n) Patient #45 - testing performed on 07/06/17 (o) Patient #46 - testing performed on 07/14/17 (p) Patient #47 - testing performed on 07/31/17 (q) Patient #48 - testing performed on 08/08/17 (r) Patient #49 - testing performed on 08/17/17 (s) Patient #50 - testing performed on 08/25/17 (t) Patient #51 - testing performed on 09/07/17 (u) Patient #52 - testing performed on 09 /19/17 (v) Patient #53 - testing performed on 09/28/17 (w) Patient #54 - testing

performed on 10/10/17 (x) Patient #55 - testing performed on 10/20/17 (y) Patient #56 - testing performed on 12/04/17 (z) Patient #57 - testing performed on 12/19/17 (aa) Patient #58 - testing performed on 12/29/17 (bb) Patient #59 - testing performed on 01 /08/18 (cc) Patient #60 - testing performed on 01/17/18 (dd) Patient #61 - testing performed on 01/29/18 (ee) Patient #62 - testing performed on 02/08/18 (ff) Patient #63 - testing performed on 02/20/18 (gg) Patient #64 - testing performed on 02/28/18 (hh) Patient #65 - testing performed on 03/12/18 (ii) Patient #66 - testing performed on 03/26/18 (jj) Patient #67 - testing performed on 03/29/18 (kk) Patient #68 - testing performed on 04/03/18 (ll) Patient #69 - testing performed on 04/06/18 (mm) Patient #70 - testing performed on 06/04/18 (nn) Patient #71 - testing performed on 06/11/18 (oo) Patient #72 - testing performed on 06/15/18 (pp) Patient #73 - testing performed on 06/18/18 CHEMISTRY (1) On the first day of the survey, the laboratory supervisor /testing person #1 verified the following to the surveyors: (a) Albumin, Total Bilirubin, Calcium, CO2, Chloride, Creatinine, Glucose, ALP (Alkaline Phosphatase), Potassium, Total Protein, Sodium, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Triglycerides, BUN (Blood Urea Nitrogen), Cholesterol and HDL (High Density Lipoprotein) testing were performed using the EliTech Envoy 500 Plus analyzer; (b) Two levels of ELITech Clinical Systems Serum Control kit (level 1 and level 2) were tested each day patient testing was performed. (2) On the second day of the survey, the surveyors reviewed QC records for the following: (a) Serum Control Kit Level 1 and Level 2 (lot #6151) - Used from 08/15/17 through 05/31/18. (3) It was identified that, although Levey-Jennings graphs had been printed each month, the graphs were not a true representation of the QC ranges that had been used to evaluate daily QC acceptability. The laboratory supervisor/testing person #1 stated the following to the surveyors: (a) For new lot numbers of QC materials, the manufacturer's package insert ranges were entered into the analyzer and utilized for evaluating the QC on a daily basis (refer to D5479 for not following the manufacturer's specifications); (b) QC results were not interfaced with the LIS (Laboratory Information System); (c) The cumulative data displayed on the Levey-Jennings graphs were generated from the LIS using the monthly cumulative calculated ranges and not reflective of the actual ranges (i.e., package insert ranges) that were entered into the analyzer and used to determine daily QC acceptability. Examples were as follows: (i) Serum Control Kit Lot #6151 (aa) AST (Aspartate Aminotransferase) level 1 - The Levey-Jennings graph reflected a range of 19.0-39.0 when a package insert range of 24-44 had been used to evaluate QC results; (bb) AST level 2 - The Levey-Jennings graph reflected a range of 109-165 when a package insert range of 126-180 had been used to evaluate QC results; (cc) Cholesterol level 1 - The Levey-Jennings graph reflected a range of 138-166 when a package insert range of 134-174 had been used to evaluate QC results; (dd) Cholesterol level 2 - The Levey-Jennings graph reflected a range of 234-274 when a package insert range of 230-280 had been used to evaluate QC results; (ee) Glucose level 1 - The Levey-Jennings graph (which displayed the cumulative calculated data from the LIS) reflected a range of 91.0-113.0 when a package insert range of 85.3-123.3 had been used to evaluate QC results; (ff) Glucose level 2 - The Levey-Jennings graph reflected a range of 266.0-326.0 when a package insert range of 235.6-332.6 had been used to evaluate QC results; (gg) Potassium level 1 - The Levey-Jennings graph reflected a range of 3.8-4.4 when a package insert range of 3.48-4.70 had been used to evaluate QC results; (hh) Potassium level 2 - The Levey-Jennings graph reflected a range of 6.4-7.2 when a package insert range of 6.0-7.5 had been used to evaluate QC results; (ii) Total Protein level 1 - The Levey-Jennings graph reflected a range of 5.8-6.8 when a package insert range of 5.55-7.07 had been used to evaluate QC results; (jj) Triglycerides level 2 - The Levey-Jennings graph reflected a range of 4.3-5.3 when a package insert range of 4.22-5.36 had been used to evaluate QC results. (4) Therefore, the surveyors

	determined the laboratory did not have a method to monitor the accuracy and precision of the testing process; (5) Refer to D5479 for examples of patient testing performed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor/testing person #1, the laboratory failed to perform a negative and positive control each day of Urine Microalbumin/Creatinine testing. Findings include: (1) On the first day of the survey, the laboratory supervisor/testing person #1 stated the following to surveyor #1: (a) The laboratory began performing Urine Microalbumin/Creatinine testing using two Siemens DCA Vantage analyzers (Serial numbers S059404 and S059406) on 01 /19/17; (b) Two levels of quality control (QC) materials were performed weekly (each Wednesday) on both analyzers. (2) Surveyor #1 asked the laboratory supervisor /testing person #1 if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory supervisor/testing person #1 stated the laboratory had not developed an IQCP. Therefore, surveyor #1 determined two levels of QC testing must be performed each day of patient testing; (3) Surveyor #1 reviewed QC and patient testing records from January through June 2018. The review verified two levels of QC testing had not been performed each day of patient testing for 12 of 13 days of patient testing reviewed; (4) Surveyor #1 reviewed the records with the laboratory supervisor/testing person #1 who stated two levels of QC materials had not been performed each day of patient Urine Microalbumin/Creatinine testing because it was believed the testing was classified as waived; (5) The following were examples of patient Urine Microalbumin/Creatinine testing performed on the analyzers when two levels of QC materials had not been tested (The laboratory supervisor/testing person #1 stated the two analyzers were used interchangeably and it could not be determined which analyzer was used for the patients tested): (a) Patient #20 - testing performed on 01/30/18 (b) Patient #21 - testing performed on 02/06/18 (c) Patient #22 - testing performed on 02/26/18 (d) Patient #23 - testing performed on 03/12/18 (e) Patient #24 - testing performed on 04/05/18 (f) Patient #25 - testing performed on 04/27/18 (g) Patient #26 - testing performed on 05/03/18 (h) Patient #27 - testing performed on 05/25/18 (i) Patient #28 - testing performed on 06/04/18 (j) Patient #29 - testing performed on 06/07/18 (k) Patient #30 - testing performed on 06 /15/18 (l) Patient #31 - testing performed on 06/18/18
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor/testing person #1, the laboratory failed to perform a negative and positive control each day of patient Serum HCG (Human Chorionic Gonadotropin) screen testing. Findings include: (1) On the first day of the survey, the laboratory supervisor/testing person #1 stated to the surveyors the laboratory performed HCG screen testing using the Quidel HCG Combo test kit (a non-waived test kit); (2) On the second day of the survey, surveyor #2 reviewed records of patient testing from January 2017 through May 2018 and identified the following during 3 of the 17 months: (a) Negative and positive quality control testing had not been perform 3 days of the review period: (a) Patient #98 - Testing performed on 07/25/17 (b) Patient #99 - Testing performed on 08/15/17 (c) Patient #100 - Testing performed on 02/15/18 (3) The surveyor reviewed the records with the laboratory supervisor/testing person #1, who believed the control testing had been performed, but had not been documented.
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/testing person #1, the laboratory failed to follow the manufacturer's quality control specifications. Findings include: (1) On the first day of the survey, the laboratory supervisor/testing person #1 stated the following to the surveyors: (a) Albumin, Total Bilirubin, Calcium, CO2, Chloride, Creatinine, Glucose, ALP (Alkaline Phosphatase), Potassium, Total Protein, Sodium, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Triglycerides, BUN (Blood Urea Nitrogen), Cholesterol and HDL (High Density Lipoprotein) testing were performed using the EliTech Envoy 500 Plus analyzer; (b) Two levels of ELITech Clinical Systems Serum Control kit (level 1 and level 2) were tested each day patient testing was performed. (2) On the second day of the survey, the surveyors reviewed the manufacturer's instructions for the control materials. They stated, "For routine use it is recommended that each laboratory establishes its own means and acceptable ranges and use the published ranges as a guide"; (3) The surveyors then reviewed quality control records for the current and previous lot numbers of control materials used for patient testing from 08/15/17 through the second day of the survey with the laboratory supervisor/testing person #1. The laboratory supervisor/testing person #1 stated the laboratory had used the package insert means and limits for each level of control instead of establishing their own means and limits as stated in the manufacturer's package insert: (a) Serum Control Kit Level 1 and Level 2 (lot #6151) - Used from 08/15/17 through 05/31/18; (b) Serum Control Kit Level 1 and Level 2 (lot #7118) - Put into use on 06/01/18 and was currently in use. (4) The surveyors reviewed the findings with the laboratory supervisor/testing person #1 who stated the laboratory had not established their own means and limits of acceptability, but instead used the manufacturer's package insert limits; (5) The following were examples of patient BMP*, CMP* and Lipid Profile* testing when the laboratory failed to

	establish quality control means and limits: (a) Patient #74 - BMP and Lipid Profile testing performed on 08/18/17 (b) Patient #75 - BMP and Lipid Profile testing performed on 08/29/17 (c) Patient #76 - BMP and Lipid Profile testing performed on 09/05/17 (d) Patient #77 - BMP and Lipid Profile testing performed on 09/18/17 (e) Patient #78 - BMP and Lipid Profile testing performed on 09/29/17 (f) Patient #79 - BMP and Lipid Profile testing performed on 10/12/17 (g) Patient #80 - BMP and Lipid Profile testing performed on 10/24/17 (h) Patient #81 - BMP and Lipid Profile testing performed on 11/06/17 (i) Patient #82 - CMP and Lipid Profile testing performed on 11/20/17 (j) Patient #83 - CMP and Lipid Profile testing performed on 12/11/17 (k) Patient #84 - CMP and Lipid Profile testing performed on 12/28/17 (l) Patient #85 - CMP and Lipid Profile testing performed on 01/16/18 (m) Patient #86 - BMP and Lipid Profile testing performed on 01/26/18 (n) Patient #87 - BMP and Lipid Profile testing performed on 02/06/18 (o) Patient #88 - CMP and Lipid Profile testing performed on 02/20/18 (p) Patient #89 - CMP and Lipid Profile testing performed on 03/05/18 (q) Patient #90 - CMP and Lipid Profile testing performed on 03/26/18 (r) Patient #91 - BMP and Lipid Profile testing performed on 04/06/18 (s) Patient #92 - CMP and Lipid Profile testing performed on 04/26/18 (t) Patient #93 - CMP and Lipid Profile testing performed on 05/01/18 (u) Patient #94 - CMP and Lipid Profile testing performed on 05/11/18 (v) Patient #95 - BMP and Lipid Profile testing performed on 05/29/18 (w) Patient #96 - CMP and Lipid Profile testing performed on 06/07/18 (x) Patient #97 - CMP and Lipid Profile testing performed on 06/18/18 *BMP (Basic Metabolic Panel) - BUN, Calcium, Creatinine, Glucose, Chloride, CO2, Potassium, and Sodium *CMP (Comprehensive Metabolic Panel) - BUN, Calcium, Creatinine, Glucose, Chloride, CO2, Potassium, Sodium, Albumin, ALT, AST, Alkaline Phosphatase, Total Bilirubin, and Total Protein *Lipid Profile - Cholesterol, HDL Cholesterol, Triglyceride
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor/testing person #1, the laboratory failed to have a system that evaluated and defined the relationship between two analyzers at least twice a year. Findings include: (1) On the first day of the survey, the laboratory supervisor/testing person #1 stated to surveyor #1 the laboratory began performing Urine Microalbumin/Creatinine testing using two Siemens DCA Vantage analyzers (Serial numbers S059404 and S059406) on 01/19 /17; (2) Surveyor #1 asked the laboratory supervisor/testing person #1 if the relationship between the test results using the two analyzers had been evaluated at least twice annually during 2017 through the current date. The laboratory supervisor /testing person #1 stated the relationship between the analyzers had not been evaluated; (3) Refer to D5421 for examples of patient testing.
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, manufacturer's instructions, and interview with the laboratory supervisor/testing person #1, 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 ensure an analyzer was stored as required by the manufacturer. Refer to D5413; (b) The laboratory failed to demonstrate the performance specifications for a new test method. Refer to D5421; (c) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and would detect immediate errors that would occur due to test system failure, adverse environmental conditions. Refer to D5441; (d) The laboratory failed to perform a negative and positive control each day of Urine Microalbumin /Creatinine testing. Refer to D5447; (e) The laboratory failed to perform a negative and positive control each day of patient Serum HCG (Human Chorionic Gonadotropin) screen testing. Refer to D5449; (f) The laboratory failed to have a system that evaluated and defined the relationship between two analyzers at least twice a year. Refer to D5775.
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 procedures, observation, manufacturer's instructions, and interview with the laboratory supervisor/testing person #1, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for a new test system were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure urine sediment examinations were being performed using a standardized method; and failed to ensure test methods were performed as required for accurate and reliable results. Refer to D6014; (3) The laboratory director or designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer to D6016; (4) The laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify problems requiring corrective action. Refer to D6018; (5) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (6) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (7) The laboratory director failed to ensure policies and procedures were complete. Refer to D6031.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor/testing person #1, the laboratory director failed to ensure verification procedures for a new test system were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications were demonstrated for a new test method. Refer to D5421. .
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, written procedure, observation, manufacturer's instructions, and interview with the laboratory supervisor/testing person #1, the laboratory director failed to ensure urine sediment examinations were being performed using a standardized method; and failed to ensure test methods were performed as required for accurate and reliable results. Findings include: URINE SEDIMENT EXAMINATIONS (1) On the second day of the survey, the laboratory supervisor/testing person #1 stated the following to surveyor #1: (a) The laboratory performed microscopic urine sediment examinations; (b) Prior to 06/07/18, urine specimens were processed in the Drucker Horizon Mini B centrifuge, which was not a variable speed centrifuge (the speed could not be adjusted, but the timer could be adjusted); (c) Beginning 06/07/18, urine specimens were processed in the Cardinal Health Benchtop Centrifuge 6F centrifuge (surveyor #1 observed that the centrifuge was not a variable speed and timer centrifuge (i.e., the speed and timer could not be adjusted). (2) Surveyor #1 reviewed function check records for the centrifuges with the following identified: (a) Drucker Horizon Mini B centrifuge (i) 03/11/16 - The speed had been checked at 3399 rpm; (ii) 12/21/17 - The speed had been checked at 3385 rpm. (b) Cardinal Health Benchtop Centrifuge 6Fcentrifuge (i) 06/18/18 - The speed had been checked at 3360 rpm (revolutions per minute) and the timer had been checked at 10 minutes. (3) Surveyor #1 then reviewed the laboratory's procedure manual. The policy titled, "Urinalysis Microscope Procedure" required that urine specimens be processed at a speed of 2000 rpm. The policy did not specify the time that urines were to be processed in the centrifuge; (4) Surveyor #1 had previously

	reviewed textbooks (during surveys and at the state agency) to reference the proper centrifugation for urine specimens for performing microscopic urinalysis testing, which was 1500-2000 rpm for 5 minutes; (5) Surveyor #1 determined the laboratory was not centrifuging urine specimens appropriately for ensuring the accurate recovery of all components because of the following: (a) Drucker Horizon Mini B centrifuge (i) The centrifuge was processing at a speed that was too fast. (b) Cardinal Health Benchtop Centrifuge 6Fcentrifuge (i) The centrifuge was processing at a speed that was too fast; (ii) The centrifuge was processing at a time that was too long. (6) The following were examples of patient urine microscopic testing performed when the samples were not being processed in a standardized manner: (a) Using the Drucker Horizon Mini B centrifuge (i) Patient #32 - testing performed on 01/09/18 (ii) Patient #33 - testing performed on 01/29/18 (iii) Patient #34 - testing performed on 02/22/18 (iv) Patient #35 - testing performed on 03/23/18 (v) Patient #36 - testing performed on 04/26/18 (vi) Patient #37 - testing performed on 05/15/18 (vii) Patient #38 - testing performed on 05/30/18 (b) Using the Cardinal Health Benchtop Centrifuge 6Fcentrifuge (i) Patient #39 - testing performed on 06/12/18 (ii) Patient #40 - testing performed on 06/14/18 (iii) Patient #41 - testing performed on 06/15/18 (iv) Patient #42 - testing performed on 06/18/18 NOTE: The following is a reference obtained by the surveyor following the survey which verifies the facility was not centrifuging patient urine specimens at a standardized speed and time to ensure the accurate recovery of all components: (a) The textbook "A Handbook of Routine Urinalysis" by Sister Laurine Graff (J.B. Lippincott Company), states "In an attempt to standardize the microscopic examination, the laboratory should adopt a regulated speed, time, and amount for the centrifugation of the urine specimens. Mix the specimen and then place approximately 10-15 ml of urine into a centrifuge tube, and centrifuge at 2000 rpm for about 5 minutes". ACCURATE AND RELIABLE RESULTS (1) The laboratory director failed to ensure the manufacturer's specifications were followed for establishing quality control ranges. 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/testing person #1, the laboratory director or designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2017 and 2018 proficiency testing records. It was identified for 10 of 18 events, the attestation statements had been signed approximately 1-4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2018 Chemistry Miscellaneous Event - The samples had been tested on 05/07/18 and the attestation statement had not been signed by the laboratory director or designee until 06/08/18; (b) First 2018 Chemistry Core Event - The samples had been tested on 02/08/18/18 and the attestation statement had

	not been signed by the laboratory director or designee until 03/08/18; (c) First 2018 Immunology Event - The samples had been tested on 04/13/18 and the attestation statement had not been signed by the laboratory director or designee until 06/08/18; (d) First 2017 Chemistry Core Event - The samples had been tested on 02/08/19 and the attestation statement had not been signed by the laboratory director or designee until 06/29/17; (e) First 2017 Chemistry Miscellaneous Event - The samples had been tested on 05/11/17 and the attestation statement had not been signed by the laboratory director or designee until 06/29/17; (f) First 2017 Hematology Event - The samples had been tested on 03/30/17 and the attestation statement had not been signed by the laboratory director or designee until 06/29/17; (g) Second 2017 Hematology Event - The samples had been tested on 07/28/17 and the attestation statement had not been signed by the laboratory director or designee until 09/21/17; (h) First 2017 Microbiology Event - The samples had been tested on 03/03/17 and the attestation statement had not been signed by the laboratory director or designee until 06/29/17; (i) First 2017 Immunology Event - The samples had been tested on 04/11/17 and the attestation statement had not been signed by the laboratory director or designee until 06/29/17; (j) Second 2017 Immunology Event - The samples had been tested on 08/21 /17 and the attestation statement had not been signed by the laboratory director or designee until 09/21/17. (2) Surveyor #2 reviewed the findings with the laboratory supervisor/testing person #1 and explained that the attestation statement must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
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/testing person #1, 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 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, manufacturer's instructions, and interview with the laboratory supervisor/testing person #1, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory failed to ensure an analyzer was stored as required by the manufacturer. Refer to D5413; (2) The laboratory director failed to ensure control procedures monitored the accuracy and precision of the testing process; and detect immediate errors that would occur due to test system failure, adverse environmental conditions. Refer to D5441; (3) The laboratory director failed to ensure a negative and positive control was performed each day of Urine Microalbumin /Creatinine testing. Refer to D5447; (4) The laboratory director failed to ensure a negative and positive control was performed each day of patient Serum HCG (Human Chorionic Gonadotropin) screen testing. Refer to D5449.
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, manufacturer's instructions, and interview with the laboratory supervisor/testing person #1, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 policy and interview with the laboratory supervisor /testing person #1, the laboratory director failed to ensure policies and procedures were complete. Findings include: (1) The laboratory director failed to ensure Based on a review of records, written policy, and interview with laboratory supervisor/testing person #1, the laboratory failed to have a written technical consultant competency policy, based on the position responsibilities, as listed in Subpart M. Refer to D5209.
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/testing person #1, 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 that verification procedures were adequate to determine the performance characteristics. Refer to D6040; (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 evaluate testing persons performing moderate complexity testing at least annually. Refer to D6054.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor/testing person #1, the technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the performance specifications were demonstrated for a new test method. Refer to D5421.
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/testing person #1, 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 an analyzer was stored as required by the manufacturer. Refer to D5413; (2) The technical consultant failed to ensure control procedures monitored the accuracy and precision of the testing process; and detect immediate errors that would occur due to test system failure, adverse environmental conditions. Refer to D5441; (3) The technical consultant failed to ensure a negative and positive control had been performed each day of Urine Microalbumin/Creatinine testing. Refer to D5447; (4) The laboratory failed to

	perform a negative and positive control each day of patient Serum HCG (Human Chorionic Gonadotropin) screen testing. Refer to D5449; (5) The technical consultant failed to ensure the manufacturer's quality control specifications were followed. Refer to D5479; (6) The technical consultant failed to have a system that evaluated and defined the relationship between two analyzers at least twice a year. Refer to D5775.
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 the laboratory supervisor/testing person #1, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) On the first day of the survey, the laboratory supervisor/testing person #1 stated the following to the surveyors: (a) CBC (Complete Blood Count) was performed on the Sysmex XS 1000i analyzer; (b) Urine Microalbumin/Creatinine testing were performed on two Siemens DCA Vantage analyzers (Serial numbers S059404 and S059406); (c) Albumin, Total Bilirubin, Calcium, CO2, Chloride, Creatinine, Glucose, ALP (Alkaline Phosphatase), Potassium, Total Protein, Sodium, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Triglycerides and BUN (Blood Urea Nitrogen), Cholesterol and HDL (High Density Lipoprotein) testing were performed on the Envoy 500 Plus analyzer; (d) Microscopic Urinalysis, Manual Differentials, Wet Prep, Pinworm, and KOH Prep procedures were performed in the laboratory; (e) Serum HCG (Human Chorionic Gonadotropin) testing was performed using the Quidel HCG Combo Test Kit. (2) Surveyor #2 reviewed personnel records for 3 persons who performed testing in 2017 and 2018 and identified the following for 1 of 3 persons: (a) Testing Person #1 (i) Although evaluations had been performed on 12/20/16 and 03/15/18, there was no evidence an annual evaluation had been documented as performed in 2017; (3) Surveyor #2 reviewed the findings with laboratory supervisor/testing person #1, who stated the annual evaluation had not been documented as performed by the technical consultant in 2017 for testing person #1.