Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0478993	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Nephrology Associates	3604 Live Oak Street Suite 100, Dallas, TX	

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 Laboratory Director and Technical Supervisor were at the entrance conference conducted 06/04/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Laboratory Director and Technical Supervisor on 06/06/2019. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of CMS 155 reports, the laboratory failed to attain a score of at least 80 percent for the hematocrit (HCT) Hematology analyte for 1 of 1 proficiency testing events in 2019 (Hematology-1st Event). Findings included: 1. Review of CMS 155 Dallas Nephrology Associates (45D0478993) report for proficiency testing 2019 (1st event) revealed the following unsatisfactory score: HCT 2019 1st Event 60% The laboratory failed to attain a score of at least 80% for HCT analyte.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) policy, BIO-RAD control material manufacturer's instructions, expected value sheets, Architect c4000 QC data, and in interview with staff, the laboratory failed to retain all data used for establishing statistical parameters (standard deviation [SD]) of control material put into use 04 /2017 on the Architect c4000. Findings included: 1. Review of the laboratory's DTILAB GENERAL QUALITY CONTROL PLAN pages 14-15 stated: "XI. ESTABLISHING QC PRODUCT DATA RANGES: (QC) Quality Control on all methods at DTILAB involves a standard process of evaluation of QC data prior to installation of a new QC lot. Assay/QC Verification Procedure ... 3. Verify all levels of the new control lot by initially running each level of control a minimum of, 3 times in its perspective file to ensure that the mean of all 3 runs are within the range shown on the original MFG assay sheet. 4. Run the new control levels a minimum of twice a day for 10 days. 5. Use the mean of, at least 20 runs, minimum to verify that the new lot yields means falling within the range specified by the manufacturer in the package insert. 6. If the calculated mean falls within the range specified on the assay sheet, use it in place of the manufacturer's stated mean. 7. If parallel testing for immunoassays is not possible, assayed controls are used and manufacturer limits are posted until the target mean and SD of the new assayed lot is obtained." The policy did not include instructions for unassayed control material used by the laboratory. 2. Review of BIO-RAD Liquid Unassayed Multiqual manufacturer's instructions (package insert) stated, "The values listed are approximate and are provided only for your convenience. The actual observed value will vary depending upon lot number, temperature, analyzer, reagent, method, and calibrator." During a telephone interview on 06/06/2019 at 11:50 am, the Biorad technical representative stated that for unassayed quality control material every laboratory should establish their own mean and SD. He also stated that statistically for every 20 data points there should be 1 outlier in a QC program. 3. Review of Biorad control material Level 1 (Lot #47941), Level 2 (Lot #47942), and Level 3 (Lot #47943) used on the Architect c4000 revealed the lot numbers were put into use 04/2017 (expiration date 10/31/2019). The laboratory provided spreadsheets of SD's and means for all analytes, which were consistent with what was entered in the QC program for ranges used for day-to-day acceptability. Data used to establish those SD's and means were not available. The ranges, which are determined by SD and mean calculation, did not detect immediate error (refer to D5441). 4. During an interview on 06/06/2019 at 11:50 am, when asked how the ranges and SD's were established the Technical Supervisor (TS) stated she changed the mean. The TS was asked again how the SD's were established and she stated she changed the mean. The surveyor explained to the TS that the SD's made the ranges wide and were unable to detect immediate error, the TS stated if she made the SD's any smaller there would be many QC issues. The laboratory was unable to provide the documentation for establishing the SD for the above lot number set.
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 review of verification studies for Architect c4000 chemistry analyzer, and confirmed in interview, the laboratory failed to ensure their policy included reportable ranges for the Architect c4000 as established/verified when the analyzer was implemented in 12/2017. Findings included: 1. According to verification studies, the Architect c4000 analyzer was installed 12/2017. 2. Review of verification studies for Architect c4000 analyzer revealed the laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies for chemistry analytes as required by 493.1253. The following is a random sampling of chemistry analytes: Reportable range from verification study Albumin 0.6-9.5 g/dL Laboratory reportable range: Albumin 0.4-10.5 g/dL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study alanine aminotransferase (ALT) 7.5-3598.0 U/L Laboratory reportable range: ALT 6-4113 U/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study Amylase 6.3-5938.0 U/L Laboratory reportable range: Amylase 3-6554 U/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study Sodium 107.1-189.6 mmol/L Laboratory reportable range: Sodium 100-200 mmol/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study Cholesterol 9.5-657.9 mg/dL Laboratory reportable range: Cholesterol 7-705 mg/dL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. 3. During an interview on 06/05/2019 at 10:00 am, the Technical Supervisor stated that the defined reportable ranges were based on the manufacturer's reportable range and she was using an "allowable 10%." This confirmed that the laboratory did not implement the reportable ranges for each analyte obtained in the verification studies.
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:
I. Based on review of Cobra II Auto Gamma Counting System operator's manual (Publication number 169-4087 Rev. G), laboratory environmental records (01/2017 - 05/2019), and confirmed in interview, the laboratory failed to ensure humidity levels were within operating specifications for the Cobra II Gamma Counter for 29 of 29 months. Findings included: 1. Review of the Cobra II Auto Gamma Counting System operator's manual) stated the following in the section titled "Environmental Requirements": "Relative Humidity: 30-85 percent (noncondensing)" 2. Review of the laboratory environmental logs (01/2017 - 05/2019) titled "Room Humidity Record; Location Hot Lab" revealed the laboratory utilized a humidity range of greater than 19% and less than 81% for the Hot Lab. The humidity range used by the laboratory did not correspond to manufacturer's specified acceptable humidity range of 30-85%. 3. Review of laboratory environmental records (01/2017 - 05/2019) revealed the following days when the humidity levels were NOT within manufacturer's operating specifications: 01/04/2017; 29% 01/05/2017; 28% 01/06/2017; 28% 01/09/2017; 29% 01/18/2017; 29% 01/26/2017; 26% 01/27/2017; 26% 01/31/2017; 28% 02/02/2017; 21% 02/04/2017; 25% 02/03/2017; 29% 02/09/2017; 23% 02/10/2017; 25% 02/16 /2017; 27% 02/23/2017; 29% 03/01/2017; 26% 03/02/2017; 26% 03/03/2017; 25% 03 /08/2017; 26% 03/14/2017; 25% 04/05/2017; 26% 04/07/2017; 26% 04/13/2017; 29% 01/02/2018; 22% 01/03/2018; 23% 01/04/2018; 25% 01/05/2018; 24% 01/12/2018; 26% 01/16/2018; 24% 01/17/2018; 24% 01/18/2018; 23% 01/23/2018; 25% 01/24 /2018; 26% 01/25/2018; 27% 01/30/2018; 27% 01/31/2018; 26% 02/01/2018; 29% 02 /07/2018; 27% 02/08/2018; 29% 02/12/2018; 25% 02/13/2018; 26% 02/14/2018; 23% 02/15/2018; 27% 02/16/2018; 29% 02/19/2018; 26% 02/20/2018; 23% 02/21/2018; 25% 02/22/2018; 28% 02/23/2018; 29% 02/26/2018; 25% 02/27/2018; 28% 02/28 /2018; 28% 03/01/2018; 28% 03/02/2018; 27% 03/05/2018; 27% 03/06/2018; 28% 03 /07/2018; 29% 03/08/2018; 27% 03/09/2018; 28% 03/15/2018; 23% 03/16/2018; 23% 03/19/2018; 27% 03/20/2018; 28% 03/21/2018; 29% 06/04/2018; 24% 3. In an interview on 06/04/2019 at 1145 hours in the laboratory, the laboratory manager was asked if the Cobra II Gamma Counter was stored in the Hot Lab. She stated that the Gamma Counter was stored in the Hot Lab. The laboratory manager stated she was not aware of the manufacturer's humidity requirements for the Gamma Counter. This confirmed the above findings. 40420 II. Based on direct observation, review of manufacturer's instructions, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for the storage of calibration verification material. Findings: 1. Review of Validate Calibration Verification/Linearity Test Kit for calibrators GC4, GC1, GC3, LP instructions for use stated: "STORAGE AND STABILITY ... Test Kits are stored at -10C to -25C. Do NOT store in a frost-free freezer. Test kits are stable until the expiration date printed on the bottle and storage container when handled according to instructions. A maximum of four (4) freeze-thaw cycles is recommended." 2. During a tour of the laboratory on 06/05/19 at 2:30 pm, the surveyor observed calibration verification material stored in the "Frigidaire" kitchen frost-free freezer. GC1 Calibration Verification/Linearity Test Kit Lot #11AK20118, Expiration Date: 10/31/2019 Received date: 11/07/18, Open date: 11/12 /18 GC3 Calibration Verification/Linearity Test Kit Lot #13AN24018, Expiration Date: 09/06/2019 Received date: 11/07/18, Open date: 11/13/18 GC4 Calibration Verification/Linearity Test Kit Lot #14A26718, Expiration Date: 10/04/2019 Received date: 11/28/18, Open date: 11/12/18 LP Calibration Verification/Linearity Test Kit Lot #50AM20118, Expiration Date: 09/26/2019 Received date: 11/07/18, Open date: 11/12/18 The laboratory failed to ensure the proper storage of calibration verification material. The laboratory did not ensure storage of calibration verification material was in a non-frost-free freezer. 3. During an interview on 06/06/19 at 9:

	30am, the technical supervisor stated that the day the calibration material arrives it is used. Then after usage it is stored in the frost-freezer and not used again. Review of calibration verification data revealed the following lot numbers used were consistent with the lot numbers of material stored in the frost-free freezer as mentioned above: GC1 Calibration Verification/Linearity Test Kit, Lot #11AK20118, Expiration Date: 10/31/2019 was calibrated on 05/14/2019 for the following analytes: albumin, BUN (blood urea nitrogen), calcium, cholesterol, chloride, creatinine, glucose, potassium, magnesium, sodium, phosphorus, total protein, triglyceride GC3 Calibration Verification/Linearity Test Kit, Lot #13AN24018, Expiration Date: 09/06/2019 was calibrated on 05/20/2019 for the following analytes: Alkaline phosphatase (ALP), Alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), Gamma-glutamyl transferase (GGT), lipase GC4 Calibration Verification/Linearity Test Kit, Lot #14A26718, Expiration Date: 10/04/2019 was calibrated on 05/14/2019 for the following analyte: total bilirubin LP Calibration Verification/Linearity Test Kit, Lot #50AM20118, Expiration Date: 09/26/2019 was calibrated on 05/14/2019 for the following analyte: high-density lipoprotein (HDL) III. Based on direct observation, manufacturer's instructions, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for the proper storage of opened reagents on the Architect c4000 analyzer for 3 of 3 reagents (Hemoglobin A1c, lipase, creatinine). Findings: 1. During a tour of the laboratory on 06/06/2019 at 1:55 pm, the surveyor observed a paper taped onto the Abbot c4000 analyzer that stated: "Remove LIPASE & (word blacked out) everyday Leave MACHINE on RUN MODE every day Remove A1C on Wednesdays & Fridays Remove CREATININE on Fridays" 2. Review of Hemoglobin A1c manufacturer's instructions (package insert) revealed the following: "REAGENT HANDLING AND STORAGE ... Reagent Storage Unopened reagents are stable until the expiration date when stored at 2 to 8C. Reagent stability is 50 days (1,200 hours) if the reagent is uncapped and on board." Review of creatinine manufacturer's instructions (package insert) revealed the following: "Reagent Storage ... On board Storage Temperature System temperature Maximum Storage Time 5 days Additional Storage Instructions After 5 days, the reagent kit must be discarded." Review of Lipase manufacturer's instructions (package insert) revealed the following: "REAGENT HANDLING AND STORAGE ... Reagent Storage Unopened reagents are stable until the expiration date when stored at 2 to 8C. Reagent stability is 11 days if the reagent is uncapped and onboard." The manufacturer included stability of various conditions and separate conditions of opened/closed reagents but did not state the conditions were accumulative. The laboratory's practice was not consistent with the manufacturer's instructions. 3. During a tour of the laboratory on 06/06/2019 at 1: 55 pm, the surveyor observed in the reagent refrigerator the following: A1c reagent Lot#53747UQ09, expiration date 12-06-2019, open date "5-15." Testing Person-5 confirmed the reagent had been opened and loaded onto the analyzer and then removed and placed back in the refrigerator. 4. During an interview on 06/06/2019 at 1:55 pm, the Technical Supervisor stated that she made the decision to remove the reagents off of the analyzer to extend the stabilities. She also stated that on Fridays creatinine is taken off because "sometimes it is a holiday." This confirmed the laboratory failed to follow manufacturer's instructions for the storage of opened chemistry reagents used on the Architect c4000.
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 review of laboratory's quality control (QC) policy, BIO-RAD control material manufacturer's instructions, expected value sheets, Architect c4000 QC data, and in interview with staff, the laboratory failed to ensure their control procedures detected immediate error for 1 of 1 set of current lot numbers. Findings: 1. Review of the laboratory's DTILAB GENERAL QUALITY CONTROL PLAN pages 14-15 stated: "XI. ESTABLISHING QC PRODUCT DATA RANGES: (QC) Quality Control on all methods at DTILAB involves a standard process of evaluation of QC data prior to installation of a new QC lot. Assay/QC Verification Procedure ... 3. Verify all levels of the new control lot by initially running each level of control a minimum of, 3 times in its perspective file to ensure that the mean of all 3 runs are within the range shown on the original MFG assay sheet. 4. Run the new control levels a minimum of twice a day for 10 days. 5. Use the mean of, at least 20 runs, minimum to verify that the new lot yields means falling within the range specified by the manufacturer in the package insert. 6. If the calculated mean falls within the range specified on the assay sheet, use it in place of the manufacturer's stated mean. 7. If parallel testing for immunoassays is not possible, assayed controls are used and manufacturer limits are posted until the target mean and SD of the new assayed lot is obtained." The laboratory policy did not state how unassayed control material would be established. The quality control material being used by the laboratory was unassayed. 2. Review of BIO-RAD Liquid Unassayed Multiqual manufacturer's instructions (package insert) stated, "The values listed are approximate and are provided only for your convenience. The actual observed value will vary depending upon lot number, temperature, analyzer, reagent, method, and calibrator." During a phone interview on 06/06/2019 at 11:50 am, a technical representative from Bio-Rad stated that for unassayed quality control material every laboratory should establish their own mean and SD. He also stated that statistically for every 20 data points there should be 1 outlier in a QC program. 3. Review of Architect c4000 chemistry analyzer QC data (random review 12/2017 through 05/2019) revealed the ranges used did not detect immediate error, as follows (random sampling of analytes): Liquid Unassayed Multiqual control (put into use 04/01/2017): Laboratory Chloride QC ranges used for day-to-day acceptability: Level 1 (Lot #47941, Expiration date: 10/31/2019) - Expected Mean 76.750; Expected SD 2.00 (1SD); Range 72.750-80.750 mmol/L Level 2 (Lot #47942, Expiration date: 10/31/2019)- Expected Mean 99.370; Expected SD 3.000 (1SD); Range 93.370-105.370 mmol/L Level 3 (Lot #47943, Expiration date: 10/31/2019) - Expected Mean 117.890; Expected SD 4.000 (1SD); Range 109.890-125.890 mmol/L The laboratory's QC ranges were too wide to detect immediate error. Review of chloride QC from May 2019 revealed 22 QC data points with no QC failures. Laboratory Magnesium QC ranges used for day-to-day acceptability: Level 1 (Lot #47941, Expiration date: 10/31/2019) - Expected Mean 0.960; Expected SD 0.080 (1SD); Range 0.800-1.120 mg/dL Level 2 (Lot #47942, Expiration date: 10/31/2019)- Expected Mean 2.560; Expected SD 0.080 (1SD); Range 2.400-2.720 mg/dL Level 3 (Lot #47943, Expiration date: 10/31/2019) - Expected Mean 4.010; Expected SD 0.200 (1SD); Range 3.610-4.410 mg/dL The

	laboratory's QC ranges were too wide to detect immediate error. Review of magnesium QC from May 2019 revealed 28 QC data points with no QC failures. Laboratory Albumin QC ranges used for day-to-day acceptability: Level 1 (Lot #47941, Expiration date: 10/31/2019) - Expected Mean 2.490; Expected SD 0.100 (1SD); Range 2.290-2.690 g/dL Level 2 (Lot #47942, Expiration date: 10/31/2019)- Expected Mean 3.540; Expected SD 0.100 (1SD); Range 3.340-3.740 g/dL Level 3 (Lot #47943, Expiration date: 10/31/2019) - Expected Mean 4.300; Expected SD 0.100 (1SD); Range 4.100-4.500 g/dL The laboratory's QC ranges were too wide to detect immediate error. Review of albumin QC from May 2019 revealed 22 QC data points with no QC failures. Laboratory Sodium QC ranges used for day-to-day acceptability: Level 1 (Lot #47941, Expiration date: 10/31/2019) - Expected Mean 112.160; Expected SD 2.000 (1SD); Range 108.160-116.160 mmol/L Level 2 (Lot #47942, Expiration date: 10/31/2019)- Expected Mean 143.360; Expected SD 3.000 (1SD); Range 137.360-149.360 mmol/L Level 3 (Lot #47943, Expiration date: 10/31 /2019) - Expected Mean 162.060; Expected SD 4.00 (1SD); Range 154.060-170.060 mmol/L The laboratory's QC ranges were too wide to detect immediate error. Review of sodium QC from May 2019 revealed 21 data points with no QC failures. 3. During an interview on 06/06/2019 at 11:50 am, when asked how the ranges and SD's were established the Technical Supervisor (TS) stated she changed the mean. The TS was asked again how the SD's were established and she stated she changed the mean. The surveyor explained to the TS that the SD's made the ranges wide and were unable to detect immediate error, the TS stated if she made the SD's any smaller there would be many QC issues. The laboratory was unable to provide the documentation for establishing the ranges for the above lot number.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) policy, BIO-RAD control material manufacturer's instructions, expected value sheets, Architect c4000 QC data, and in interview with staff, the laboratory failed to document established and defined statistical parameters (standard deviation [SD]) for unassayed control material used on the Architect c4000 for day-to-day acceptability since 04/2017. Findings: 1. Review of the laboratory's DTILAB GENERAL QUALITY CONTROL PLAN pages 14-15 stated: "XI. ESTABLISHING QC PRODUCT DATA RANGES: (QC) Quality Control on all methods at DTILAB involves a standard process of evaluation of QC data prior to installation of a new QC lot. Assay/QC Verification Procedure ... 3. Verify all levels of the new control lot by initially running each level of control a

minimum of, 3 times in its perspective file to ensure that the mean of all 3 runs are within the range shown on the original MFG assay sheet. 4. Run the new control levels a minimum of twice a day for 10 days. 5. Use the mean of, at least 20 runs, minimum to verify that the new lot yields means falling within the range specified by the manufacturer in the package insert. 6. If the calculated mean falls within the range specified on the assay sheet, use it in place of the manufacturer's stated mean. 7. If parallel testing for immunoassays is not possible, assayed controls are used and manufacturer limits are posted until the target mean and SD of the new assayed lot is obtained." The policy did not include instructions for unassayed control material used by the laboratory. 2. Review of BIO-RAD Liquid Unassayed Multiqual manufacturer's instructions (package insert) stated, "The values listed are approximate and are provided only for your convenience. The actual observed value will vary depending upon lot number, temperature, analyzer, reagent, method, and calibrator." During a telephone interview on 06/06/2019 at 11:50 am, the Biorad technical representative stated that for unassayed quality control material every laboratory should establish their own mean and SD. He also stated that statistically for every 20 data points there should be 1 outlier in a QC program. 3. Review of Biorad control material Level 1 (Lot #47941), Level 2 (Lot #47942), and Level 3 (Lot #47943) used on the Architect c4000 revealed the lot numbers were put into use 04/2017 (expiration date 10/31/2019). The laboratory provided spreadsheets of SD's and means for all analytes, which were consistent with what was entered in the QC program for ranges used for day-to-day acceptability. Data used to establish those SD's and means were not available. The ranges, which are determined by SD and mean calculation, did not detect immediate error (refer to D5441). 4. Review of Architect c4000 QC data from 12/2017 through 05/2019 revealed statistical parameters used for day-to-day acceptability (random sampling of analytes): Laboratory Chloride QC: Level 1- Expected Mean 76.750; Expected SD 2.00 (1SD); Range 72.750-80.750 mmol/L Level 2- Expected Mean 99.370; Expected SD 3.000 (1SD); Range 93.370-105.370 mmol/L Level 3- Expected Mean 117.890; Expected SD 4.000 (1SD); Range 109.890-125.890 mmol/L Laboratory Magnesium QC: Level 1- Expected Mean 0.960; Expected SD 0.080 (1SD); Range 0.800-1.120 mg/dL Level 2- Expected Mean 2.560; Expected SD 0.080 (1SD); Range 2.400-2.720 mg/dL Level 3- Expected Mean 4.010; Expected SD 0.200 (1SD); Range 3.610-4.410 mg/dL Laboratory Albumin QC: Level 1- Expected Mean 2.490; Expected SD 0.100 (1SD); Range 2.290-2.690 g/dL Level 2- Expected Mean 3.540; Expected SD 0.100 (1SD); Range 3.340-3.740 g/dL Level 3- Expected Mean 4.300; Expected SD 0.100 (1SD); Range 4.100-4.500 g/dL Laboratory Sodium QC: Level 1- Expected Mean 112.160; Expected SD 2.000 (1SD); Range 108.160-116.160 mmol/L Level 2- Expected Mean 143.360; Expected SD 3.000 (1SD); Range 137.360-149.360 mmol/L Level 3- Expected Mean 162.060; Expected SD 4.00 (1SD); Range 154.060-170.060 mmol/L Review of the QC data from May 2019 did not include QC outliers. Biorad's instructions were for the laboratory to establish their own SD and mean for each lot number. Biorad representative instructed that ranges should be based on a 95% confidence interval, meaning that 1 of 20 QC points should be a statistical outlier, in order to detect immediate error. The ranges used did not detect immediate error and the laboratory did not document control procedures including data used for defined SD. 5. During an interview on 06/06/2019 at 11:50 am, when asked how the ranges and SD's were established the Technical Supervisor (TS) stated she changed the mean. The TS was asked again how the SD's were established and she stated she changed the mean. The surveyor explained to the TS that the SD's made the ranges wide and were unable to detect immediate error, the TS stated if she made the SD's any smaller there would be many QC issues. The laboratory was unable to provide the documentation for establishing the ranges for the above lot number.