Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2088500	01/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dialysis Clinic Inc Donor Services Dba New Mexico	1609 University Blvd Ne, Albuquerque, NM	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	During a recertification survey completed on 01/29/2020 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 493.1250 Analytic Systems 493.1403 Laboratory Director, moderate complexity 493.1409 Technical Consultant, moderate complexity
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on the review of 2018-2019 quality control records, product receipt records, laboratory policies, and interviews with staff the laboratory failed to perform and document 2 levels of quality controls for 3 of 6 shipments of i-Stat Chem 8+ cartridges as required by the manufacturer. The laboratory reported performing 144 Chem 8+ panels (Sodium, Potassium, Chloride, BUN, Creatinine, Glucose, Ionized Calcium, Hematocrit, and Hemoglobin) in a 12 month period. Findings are: A. Review of the manufacturer's instructions, i-STAT 1 Quick Reference Guide for the i-STAT 1 Handheld and i-STAT Chemistry Cartridges for use with a CLIA Certificate of Waiver indicated "Control Testing Frequency Test one cartridge from each lot in each shipment upon receipt. Test a single cartridge from the refrigerator monthly. Select cartridge in the following order: CHEM 8+, 6+, Crea, EC4+, Glucose, E3+" B. Review of the laboratory's iSTAT Testing Work Instruction dated 10/16/2016 indicated: "6.2.7.2 Quality Control(QC) Testing: 6.2.7.2.1 The OR.520.F03 - iSTAT QC Log will be used to document all cartridge QC results. Cartridge QC will be completed with each lot number in the shipment by a designated staff member. 6.2.7.2.1.1 Complete with the cartridge type, lot number, received date, quantity and temperature strip ok section. 6.2.7.2.1.2 Use one sheet for each cartridge 6.2.7.2.1.3

	Document the control name, lot#, level, expiration date and current CLEW for each solution. 6.2.7.2.1.4 Once testing is complete and results determined to be in range, sign and date the Lot/Shipment accepted by line." C. During interview on 01/23/2020 at 01:40 pm, the Quality Compliance Coordinator stated no new lots of cartridges had been received since the last documented external quality controls from the manual quality control log on 06/28/2019. D. During interview on 01/27/2020 at 01:05 pm, the laboratory's former trainer stated: 1. manual quality control record keeping was discontinued in June 2019; 2. he did not verify paper results with the electronic results. E. Review of the laboratory's product receipt records and the external (liquid) quality control records (manual and electronic records) revealed no documentation of external quality controls for the following lots of Chem 8+ cartridges: Lot H18292 expiration date 04/17/2019 2 boxes of 25 cartridges received on 12/11/2018. Lot H19024 expiration date 07/23/2019 2 boxes of 25 cartridges received on 03/27/2019 Lot H192538 expiration date 03/08/2020 3 boxes of 25 cartridges received on 10/18 /2019
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 the review of 2018-2019 quality control records, product receipt records, discard log, laboratory policies, and interviews with staff , the laboratory failed to meet the Condition for Analytic Systems. The laboratory reported performing 167 pH (measure of acidity) tests, 167 pCO2 (partial pressure of carbon dioxide), and 167 pO2 (partial pressure of oxygen) tests in a 12 month period. Findings are: A. The laboratory failed to perform and document 2 levels of quality controls for 3 of 6 shipments of i-Stat Chem G3 cartridges used for blood gas testing. See D5447 B. The laboratory failed to establish and follow an effective quality assessment program. See D5793
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 the review of 2018-2019 quality control records, product receipt records, discard log, laboratory policies, and interviews with staff the laboratory failed to perform and document 2 levels of quality controls for 3 of 6 shipments of i-Stat Chem G3 cartridges used for blood gas testing. The laboratory reported performing 167 pH

	(measure of acidity) tests, 167 pCO2 (partial pressure of carbon dioxide), and 167 pO2 (partial pressure of oxygen) tests in a 12 month period. Findings are: A. Review of the laboratory's iSTAT Testing Work Instruction dated 10/16/2016 indicated: "6.2.7.2 Quality Control(QC) Testing: 6.2.7.2.1 The OR.520.F03 - iSTAT QC Log will be used to document all cartridge QC results. Cartridge QC will be completed with each lot number in the shipment by a designated staff member. 6.2.7.2.1.1 Complete with the cartridge type, lot number, received date, quantity and temperature strip ok section. 6.2.7.2.1.2 Use one sheet for each cartridge 6.2.7.2.1.3 Document the control name, lot#, level, expiration date and current CLEW for each solution. 6.2.7.2.1.4 Once testing is complete and results determined to be in range, sign and date the Lot/Shipment accepted by line." B. During interview on 01/23/2020 at 01:40 pm, the Quality Compliance Coordinator stated no new lots of cartridges had been received since the last documented external quality controls from the manual quality control log on 06/28/2019. C. During interview on 01/27/2020 at 01:05 pm, the laboratory's former Trainer stated: 1. manual quality control record keeping was discontinued in June 2019; 2. he did not verify paper results with the electronic results. D. Review of the laboratory's product receipt records and the external (liquid) quality control records (manual and electronic records) revealed no documentation of external quality controls for the following lots of G3 cartridges upon receipt of the shipments: D19060 expiration date 10/29/2019 1 box of 25 cartridges received on 05 /17/2019 D19171A expiration date 02/17/2020 2 boxes of 25 cartridges received on 08 /01/2019 D19249 expiration date 05/05/2020 2 boxes of 25 cartridges received on 10 /18/2019 3 unused cartridges from this lot were found in the laboratory, available for use, on 01/23/2020 at 01:40 pm.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of 2018-2019 quality control records, product receipt records, discard log, laboratory policies, 2018-2019 proficiency testing records, and interviews with staff, the laboratory failed to establish and follow an effective quality assessment program. Findings are: A. The laboratory failed to perform and document 2 levels of quality controls for 3 of 6 shipments of i-Stat Chem G3 cartridges used for blood gas testing. See D5447 B. The laboratory failed to review and update the quality control policy following a proficiency testing failure. 1. Review of the 2018-3 test event revealed the laboratory received a failing score (40%) for the analyte PCO2. The corrective action, dated 12/03/19, only indicated a possible sample error as the cause of the failure. 2. Review of the laboratory's Individualized Quality Control Program dated 03/27/2016 revealed no reference to proficiency testing failures as part of the overall quality control program and risk assessment. 3. During interview on 01/23 /2020 at 01:14 pm, the Quality Manager stated that policies are reviewed every 2 years so the Quality Control Policy was not due for review until next month (February /March 2020). C. The laboratory did not have an effective system to ensure the accuracy of the quality control data. 1. Review of the electronic and manual quality control records revealed discrepancies between the electronic record and the manual

	record. G3 cartridge lot D17240; test date 02/28/2018 CLEW A35 Level 3 PCO2 manual record = 22.5 mmHg electronic record = 27.2 G3 cartridge lot D18296; test date 12/14/2018 CLEW A37 Level 3 PO2 manual record = 137 mmHg electronic record = 127 2. Review of manual quality control records revealed 2 test dates (03/30 /2018 and 04/16/2018) with identical test results. Electronic records were not available for 03/30/2018 to confirm the reported results. G3 cartridge lot D17295 Quality Control lot (CLEW) A35 pH Level 1 = 7.064 Level 3 = 7.688 PO2 Level 1 = 68 mmHg Level 3 = 131 PCO2 Level 1 = 59.1 mmHg Level 3 = 22.6 D. The laboratory failed to provide corresponding electronic quality control records for the following manual quality control records: G3 cartridge Lot D18056 tested on 07/20 /2018 and 08/24/2018 G3 cartridge Lot D18233A tested on 09/27/2018 and 10/05 /2018 G3 cartridge Lot D18296 tested on 11/16/2018 Requests for all 2018-2019 quality control data were made via email to the Quality Compliance Coordinator on 01 /27/2020 and again on 01/29/2020 but the records for these test dates were not provided. E. . During interview on 01/27/2020 at 01:05 pm, the laboratory's former Trainer stated: 1. Manual quality control record keeping was discontinued in June 2019; 2. He did not verify paper results with the electronic results.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of personnel records, 2018-2019 quality control records, product receipt records, discard log, laboratory policies, 2018-2019 proficiency testing records, and interviews with staff, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: A. The Laboratory Director failed to ensure an effective quality assessment program was established and followed. See D6022 B. The Laboratory Director failed to authorize, in writing, the duties for 2 (TP #1 and TP #3) of 2 new testing personnel reviewed. See D6032
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of 2018-2019 quality control records, product receipt records, discard log, laboratory policies, 2018-2019 proficiency testing records, and interviews with staff, the Laboratory Director failed to ensure an effective quality assessment program was established and followed. Findings are: A. The laboratory failed to perform and document 2 levels of quality controls for 3 of 6 shipments of i-Stat Chem G3 cartridges used for blood gas testing. See D5447 B. The laboratory failed to

	review and update the quality control policy following a proficiency testing failure. 1. Review of the 2018-3 test event revealed the laboratory received a failing score (40%) for the analyte PCO2. The corrective action, dated 12/03/19, only indicated a possible sample error as the cause of the failure. 2. Review of the laboratory's Individualized Quality Control Program dated 03/27/2016 revealed no reference to proficiency testing failures as part of the overall quality control program and risk assessment. 3. During interview on 01/23/2020 at 01:14 pm, the Quality Manager stated that policies are reviewed every 2 years so the Quality Control Policy was not due for review until next month (February/March 2020). C. The laboratory did not have an effective system to ensure the accuracy of the quality control data. See D5793
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of personnel records and interview with laboratory staff, the Laboratory Director failed to authorize, in writing, the duties for 2 (TP #1 and TP #3) of 2 (TP #1 and TP #3)new testing personnel reviewed. Findings are: A. Review of personnel records revealed no documentation that the Laboratory Director had reviewed the training and competency of the new testing personnel (TP #1 and TP #3). 1. The initial training document for TP #1, hired on 07/01/2019, had no documentation of the tasks the testing person had been trained to perform. 2. The initial training document for TP #3, unknown hire date and no longer with the laboratory, had no documentation of the tasks the testing person had been trained to perform. 3. Both training documents were not signed or dated by either the Trainer or the Laboratory Director/designee. B. During interview on 01/23/2020 at 10:42 am, the Quality Compliance Coordinator and the Quality Manager confirmed there were no additional training or authorization records.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the review of personnel files, 2018-2019 quality control records, product receipt records, discard log, laboratory policies, 2018-2019 proficiency testing records, and interviews with staff, the Technical Consultant failed to provide technical

	oversight of the laboratory. Findings are: A. the Technical Consultant failed to establish an effective quality control program. See D6042 B. The Technical Consultant failed to perform individual competency evaluations for 7 (TP #1 - TP #7) of 7 testing personnel for 2019. See D6046
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the review of 2018-2019 quality control records, product receipt records, discard log, laboratory policies, 2018-2019 proficiency testing records, and interviews with staff, the Technical Consultant failed to establish an effective quality control program. Findings are: A. The laboratory failed to perform and document 2 levels of quality controls for 3 of 6 shipments of i-Stat Chem G3 cartridges used for blood gas testing. See D5447 B. The laboratory failed to review and update the quality control policy following a proficiency testing failure. 1. Review of the 2018-3 test event revealed the laboratory received a failing score (40%) for the analyte PCO2. The corrective action, dated 12/03/19, only indicated a possible sample error as the cause of the failure. 2. Review of the laboratory's Individualized Quality Control Program dated 03/27/2016 revealed no reference to proficiency testing failures as part of the overall quality control program. 3. During interview on 01/23/2020 at 01:14 pm, the Quality Manager stated that policies are reviewed every 2 years so the Quality Control Policy was not due for review until next month (February/March 2020). C. The laboratory did not have an effective system to ensure the accuracy of the quality control data. See D5793
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of personnel files, and interview with laboratory staff, the Technical Consultant failed to perform individual competency evaluations for 7 (TP #1 - TP #7) of 7 testing personnel for 2019. Findings are: A. Review of 7 (TP #1 - TP #7) of 7 testing personnel files revealed no documentation of observation, record reviews or blind sample testing to evaluate competency of testing personnel for 2019. The only document found was a sign-in sheet dated 09/03/2019 with the signatures of attendees. B. During interview on 01/23/2020 at 10:42 am, the Quality Compliance Coordinator stated the trainer (a former employee) had staff sign in but there were no individual sign off sheets or training agenda.