Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0245748	03/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Eastern Nephrology Associates	1302 Medical Center Drive, Wilmington, NC	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of 2020 and 2021 proficiency testing (PT) records, and interview with technical consultant (TC) 3/17/22, the laboratory failed to retain documentation of the processing, reporting and review of PT samples and results for the third hematology event in 2020. Findings: Review of 2020 PT records revealed no documentation of the third hematology PT event in 2020. Review of 2021 PT records revealed the laboratory participated and received a score for the third hematology PT event in 2020. Interview with TC at approximately 11:30 a.m. on 3/17/22, confirmed the third PT event for hematology had been completed and documentation had been reviewed online. She also confirmed the laboratory did not know where the documentation was located.
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 2019, 2020 and 2021 package inserts for TOSOH quality control (QC) reagent and interview with TC 3/17/22, the laboratory failed to retain documentation of lot numbers, expiration dates and assay ranges determined by the manufacturer for the TOSOH QC reagent used for parathyroid hormone (PTH) testing. Findings: Review of 2019, 2020 and 2021 TOSOH QC reagent package inserts revealed the package inserts failed to include the lot numbers, the expiration dates and the assay ranges of Level I and Level II QC determined by the manufacturer. For example: One package insert had the assay ranges written on the package insert but did not include the lot numbers or the expiration date of the QC reagent. Interview with TC at approximately 2:00 p.m. confirmed the package inserts failed to include lot numbers, expiration dates and the assay ranges determined by the manufacturer. She stated they were on the box top of the TOSOH QC reagent. She also confirmed the laboratory was not retaining the box tops of the reagents used.
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 laboratory procedure manual and interview with TC 3/17/22, the laboratory procedure "Daily Procedures for Analyzers" failed to include the type and level of quality control reagent used for the Tacrolimus testing. Findings: Review for laboratory procedure manual revealed "Daily Procedures for Analyzers" procedure. The procedure describes the daily start up of the laboratory analyzers including the type and level of QC reagent used for testing. The procedure failed to include the type and level of QC reagent used for QC of the Tacrolimus testing. Interview with TC at approximately 3:30 p.m. confirmed the procedure for startup, "Daily Procedures for Analyzers", failed to include the type and level of QC reagent used for QC of the Tacrolimus testing.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of package insert, surveyor observation and interview with technical consultant (TC) 3/17/22, the laboratory failed to label quality control (QC) reagent with expiration dates. Findings: Review of package insert for Lyphochek Immunoassay Plus Control revealed "Storage and Stability...Reconstituted and Refrigerated: After reconstituting and storing tightly capped at 2 to 8 degrees celcius (C), this product will be stable as follows: - All analytes 7 days...". At approximately 3:00 p.m. surveyor observed in laboratory refrigerator 3 bottles of reconstituted QC reagent, Lyphochek Immunoassay Plus Control, levels I, II and III, Lot #'s 40411, 40412 and 40413, expiration date of 9/2/24. The 3 bottles of QC reagent were labeled with an "open" date of 3/14/22. They failed to be labeled with an expiration date of 7 days from preparation date. During interview with TC at approximately 3:30 p.m., the TC stated controls that have a 7 day expiration after reconstitution are not normally labeled with the new expiration date because the controls are reconstituted on Monday and are thrown away the following Monday when new controls are made.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation, and testing personnel (TP) interview 3/17/22, the laboratory failed to calibrate the thermometers for the lab refrigerators and freezers used to store reagents, calibrators and controls with the frequency recommended by the manufacturer as required. Findings: Surveyor observation on 3/17/22 thermometer with serial number #150674143 labeled "Calibration due SEP 10, 2017", thermometer with serial number #130434549 labeled "Calibration due "07/30/15", thermometer with serial number #192136056 labeled "Calibration due "26 Apr 2021", During an interview at approximately 4:00 p.m .3/17/22, TP #1 confirmed thermometers with serial numbers #150674143, #130434549 and #192136056 are used to monitor the refrigerators and freezer used for reagent storage and was not aware of the calibration due dates.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and

	specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of calibration reagent package insert, review of the laboratory's 2021 temperature logs, review of 2021 quality assurance (QA) records, and interview with TC 3/17/22, the laboratory failed to ensure and document corrective action when the freezer temperature exceeded acceptable limits for storage of Tacrolimus (TAC) calibrators. Findings: Review of calibration reagent package insert for the TAC assay revealed "Store at: Unopened vials must be stored frozen (-25-15 degrees C)." Review of the 2021 temperature logs revealed freezer temperatures were below the acceptable range of -25-15 degrees C on the following days with no corrective action documented: a. 7 of 22 days in August 2021 - 8/23, 8/24, 8/25, 8/26, 8/27, 8/30, 8/31; b. 9 of 21 days in September 2019 - 9/1, 9/2, 9/3, 9/7, 9/8, 9/9, 9/10, 9/13, 9/14; Review of QA records for the September 2021 review revealed "Reagents are stored and used according to manufacturer's requirements-YES- X. Temperature and humidity documented daily with corrective action if necessary- NO-X ...Corrective Action _ Freezer temperature too cold at the start of the month; adjusted 9/14; after temperature log review." There was no documentation to indicate additional corrective action was taken to ensure patient test results for the TAC assay were not affected when the freezer temperature was below the acceptable range of -25-15 degrees C. Interview with TC at approximately 3:45 p.m. confirmed the temperature was out of range and that 35 patients were tested for TAC assay during the period of 8 /23/21-9/14/21.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records, job descriptions and interview with technical consultant (TC) 3/17/22, laboratory director (LD) failed to specify, in writing, the responsibilities and duties of each testing personnel (TP), that identifies which examinations and procedures each individual is authorized to perform, and whether supervisory or director review is required. Findings: Review of personnel records revealed that TP#1 performed and signed off on the competency evaluation of TC. Review of LD job description revealed under the section "Personnel Management Responsibilities" "Ensure that policies and procedures are established for monitoring individuals ...to verify they maintain competency ...Maintain a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform;" Review of TP job description revealed no delegation of duty to perform competency evaluations. Interview with TC at approximately 9:45 a.m. on 3/17/22, confirmed there is no delegation of duties from the LD for TP#1 to evaluate competency.