Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1040912	04/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oxford Nephrology Associates	1790 Barron St, Oxford, MS	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's Standard Operating Procedure Manual and confirmation with the staff at 12:30 pm on 4/12/18, the laboratory failed to establish a written policy for specimen labeling, to include a unique patient identifier, in order to distinguish between patients with the same first and last name or birth date.
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 the laboratory procedure manual and confirmation with staff at 12: 30 pm on the day of survey, 4/12/18, the laboratory did not have available on the day of survey, written approved procedures that included the following when applicable to the test procedure: Findings include: 1. Requirements for patient preparation, storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection. 2. Written centrifuge policy including schedule of function checks (RPM checks, timer) and who will perform them.
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 surveyor review of written quality assessment (QA) policies and procedures, the laboratory director failed to ensure that a comprehensive QA program designed to monitor and evaluate the overall quality of the total testing process (general laboratory, preanalytic, analytic and postanalytic systems) was maintained and followed to assure the quality of the laboratory services provided. Findings include: The laboratory director had not ensured that the following parts of the written laboratory QA program was being followed: QA - Periodic site visits -review and sign all laboratory logs such as temperature, maintenance logs, daily & monthly QC (quality control), proficiency testing and calibration - a. Periodic visits by the technical consultant need to be defined--Weekly, Monthly, Quarterly b. Temperature logs from December 2017 through 4/9/18 were signed as reviewed on 4/9/18, not monthly as stated in the QA policy c. Review of Controls for the Vitros 350 and AcT Diff 2 analyzers from 11/9/17 through 3/29/18 were signed as reviewed on 2/8/18 and 4/9/18, not monthly as stated on the QA checklist.