Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0919208	05/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Kidney Specialists Of Central Oklahoma Pc	3366 Nw Expressway Suite 550, Oklahoma City, 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 initial survey was performed on 05/06,07,08/2026. Standard-level deficiencies were cited.
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 review of policy and procedure and interview with the director of operations and general supervisor, the written policy for assessing the clinical consultant and general supervisor based on the position responsibilities did not define the frequency of assessments to be performed. Findings include: (1) On 05/06/2026, a review of the competency assessment policy for assessing the clinical consultant and general supervisor titled, "Laboratory Policy - Personnel" identified it did not define the frequency of assessments; (2) Interview with the director of operations and general supervisor on 05/06/2026 at 01:22 pm confirmed that although the competencies based on the position responsibilities for the clinical consultant and the general supervisor had been performed annually, the policy did not define the frequency of assessments.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manuals and interview with the general supervisor, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the laboratory for three of three policies reviewed. Findings include: I. Standard Operating Procedures (1) On 5/7/2026 at 1:00 pm, the general supervisor stated urine Beta-hydroxybutyrate, Creatinine, Glucose, Hemoglobin, Microalbumin, Nitrate, pH, Specific Gravity, Total Bilirubin, Urobilinogen, and Leukocyte esterase testing were performed on the Diazyme c270 DZ-Lite analyzer; (2) The procedure titled, "Standard Operating Procedures" indicated that the laboratory performed urine drug screen testing and not urine chemistry testing; (3) The findings were reviewed with the general supervisor who stated on 05/7/2026 at 1:00 pm the laboratory did not perform urine drug screen testing and the procedure in the manual did not reflect the laboratory's current method of urine chemistries. II. Instruments (1) On 5/7/2026 at 1:00 pm, the general supervisor stated urine Beta-hydroxybutyrate, Creatinine, Glucose, Hemoglobin, Microalbumin, Nitrate, pH, Specific Gravity, Total Bilirubin, Urobilinogen, and Leukocyte esterase testing were performed on the Diazyme c270 DZ-Lite analyzer; (2) The procedure titled, "Instruments" indicated that the laboratory performed testing on the Indiko IA and Diazyme c270 DZ-Lite analyzers; (3) The general supervisor stated on 05/7/2026 at 1:00 pm the procedure manual did not reflect the laboratory's current sample stability for urine chemistry testing. III. Specimen Transport (1) On 5/7 /2026 at 1:00 pm, the general supervisor stated urine chemistry testing on the Diazyme c270 DZ-Lite analyzer was performed on fresh samples within 4 hours of collection or within 24 hours if refrigerated; (2) The procedure titled, "Specimen Transport" indicated that the laboratory performed urine chemistry testing as follows: (i) Room Temperature - 0-12 hours; (ii) Refrigerated - 12 hours-10 days; (iii) Frozen - 10-180 days. (3) The findings were reviewed with the general supervisor who stated on 05/7/2026 at 1:00 pm the laboratory did not perform urine drug screen as stated in the procedure manual and it did not reflect the laboratory's current procedure for urine chemistry testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of policy and procedure and interview with the general supervisor and director of operations, the laboratory failed to have a complete written policy and procedure for quality control for one of one test system reviewed. Findings include: (1) On 05/06/2026 at 02:04 pm, the general supervisor and director of operations stated the laboratory began performing urinalysis testing which included the analytes Nitrite, Glucose, Beta-Hydroxybutyrate, Bilirubin, Microalbumin, Microprotein, Hemoglobin, pH, Specific Gravity, Creatinine, Urobilinogen, and Leukocyte Esterase on 02/19/2026 using urine specimens and Diazyme DS-Lite c270 analyzer; (2) On 05 /07/2026, a review of the policy and procedure titled "Laboratory Policy - Quality Control" for the test system identified no evidence of the following: (a) Type and identity of controls (e.g., Manufacturer, or in-house, electronic, level 1, 2, normal, abnormal, etc.); (b) Number and frequency of testing controls; (c) Method for establishing means and ranges for new lot numbers of QC materials; (d) Criteria to determine acceptable control results; (e) Corrective action to take when control results fail to meet criteria for acceptability. (f) Procedures describing the method for establishing means and ranges for new lot of QC materials. (3) The findings were reviewed with the general supervisor and director of operations who stated on 05/07 /2026 at 01:44 pm, the laboratory did not have a complete written policy and procedure for QC as stated above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the standard operating procedure and interview with the general supervisor and the director of operations, the laboratory failed to ensure one of one procedure manual had been approved, signed, and dated by the current laboratory director. Findings include: (1) On 05/06/2026 at 09:45 am, the general supervisor stated the following were performed in the laboratory: (a) Urine Beta-hydroxybutyrate, Creatinine, Glucose, Hemoglobin, Microalbumin, Nitrate, pH, Specific Gravity, Total Bilirubin, Urobilinogen, and Leukocyte esterase testing on the Diazyme c270 DZ-Lite analyzer. (2) A review of the manual titled, "Standard Operating Procedures" identified no evidence the manual had been approved signed, and dated by the current laboratory director; (3) The manual was reviewed with the general supervisor who stated on 05/06/2026 at 12:15 pm, the manual had not been signed and dated as approved by the current laboratory director.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3)

	Humidity. (b)(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 general supervisor and director of operations, the laboratory failed to ensure the relative humidity was documented or maintained as required by the manufacturer of the Diazyme DS-Lite c270 analyzer for 15 of 54 days reviewed from February 19, 2026 through the current date. Findings include: (1) On 05/06/2026 at 02:04 pm, the general supervisor stated urinalysis testing was performed using the Diazyme DZ-Lite c270 analyzer; (2) A review of the operator's manual for the analyzer required the relative humidity be maintained at 35-80% with no condensation; (3) A review of laboratory humidity records from February 19, 2026 through the current date identified the following: (a) February 2026 - the relative humidity readings were undocumented for seven of seven days (specific days were February 19, 20, 23, 24, 25, 26, 27 of 2026); (b) March 2026 - the relative humidity readings were documented as less than 35% for eight of 21 days (specific days were March 2, 12, 13, 17, 18, 19, 23, 24 of 2026). (4) The records were reviewed with the general supervisor and director of operations who stated on 05/06/2026 at 02:25 pm, the laboratory humidity had not been maintained as required by the manufacturer as stated above.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the general supervisor and director of operations, the laboratory failed to validate specimen integrity for the urinalysis testing. Findings include: (1) On 05/06/2026, the general supervisor and director of operations stated the following: (a) The laboratory began testing Nitrite, Glucose, Beta-Hydroxybutyrate, Bilirubin, Microalbumin, Microprotein, Hemoglobin, pH, Specific Gravity, Creatinine, Urobilinogen, and Leukocyte Esterase on 02/19/2026 using urine specimens and Diazyme DS-Lite c270 analyzer; (b) The specimens were collected Monday through Friday in plastic urine cups and typically tested on the same day as sample collection if time allowed; (c) The urine sample cups were good for 4 hours at room temperature; (d) If testing could not be performed on the day of collection, the specimen(s) would be refrigerated at 2-8 degrees C (Centigrade) up to 24 hours and tested following storage in the laboratory refrigerator. (2) An interview with the general supervisor and director of operations on 05/07/2026 at 02:21 pm confirmed a validation study had not been performed to ensure urine specimens tested

	on the Diazyme DS-Lite c270 analyzer maintained their integrity from the point of collection through the day of testing.
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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor and director of operations, the laboratory failed to have control procedures that monitored accuracy and precision of the complete analytic process for one of three analytes reviewed from 02/19/2026 through the current date. Findings include: (1) On 05/06/2026 at 02:04 pm, the general supervisor and director of operations stated the following: (a) The laboratory began performing urinalysis testing which included the analyte Urobilinogen on 02/19/2026 using the Diazyme DS-Lite c270 analyzer; (b) Two levels of Serocare Urobilinogen QC (Quality Control) materials were performed each day of patient testing; (c) Laboratory-established ranges were used for determining acceptability of QC results; (d) Urobilinogen QC level 1 lot #RA232603 and Urobilinogen QC level 2 Lot #RA232604 had been put into use 04/23/2026 and were currently in use. (2) On 05/07/2026 at 11:44 am, a review of the QC file on the analyzer showed the following for Urobilinogen testing: (a) Level 1 - The lot number was listed as RA052602 with a range 0.550 - 1.450; (b) Level 2 - The lot number was listed as RA052603 with a range 4.390 - 8.170. (3) A review of records identified no documentation to show how the ranges had been established for the above lot numbers prior to putting into use for patient testing; (4) Interview with the general supervisor and director of operations on 05/07/2026 at 03:25 pm confirmed the following: (a) The new lot numbers had not been entered into the analyzer QC file which continued to reflect the previous lot numbers; (b) The laboratory had not established ranges for the new QC lot numbers and were using the ranges that had been established for the previous lot numbers.