

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>42D0687782</p>	<p>(X3) Date Survey Completed</p> <p>05/24/2024</p>
<p>Name of Provider or Supplier</p> <p>Columbia Nephrology Associates, Pa</p>	<p>Street Address, City, State</p> <p>121 Park Central Drive, Suite 200, Columbia, SC</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>An announced CLIA initial survey was conducted at Columbia Nephrology Associates, PA on 05/24/2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCIES were found to be out of compliance:</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations and staff interview, the laboratory failed to ensure thermometers were consistent with the manufacturer's instructions. 5 out of 5 thermometers were expired. Findings included: 1. During a tour of the laboratory on 05/24/2024 at 2:32 pm with TP1, the following was revealed: a. Room thermometer expired (exp) M1 5/2020, traceable.com, 281482-1714 b. Wall thermometer, S/N 181277433, S66279, exp. Oct 2021 c. Wall thermometer, S/N 192585437, exp. 5/15 /2021, traceable.com, 14-64823311705863 d. Refrigerator thermometer, Probe 1, 6441, exp. 02/24/2022, S/N 200133033 Probe 2, 6441, exp. 02/24/2022, S/N 200133033 e. No thermometer in the storage room. Blood collection tubes were kept with no temperature monitoring. The following was revealed: a. 7 packs of Red Top, Vacuette, Lot#B240238S, exp. 08/03/2025, label 4C to 25C. b. 3 packs of Red Top,</p>

BD Vacutainer Tubes, Lot#2217105, exp. 07/31/2024, Ref#367820, label 4C to 25C. c. 2 packs of Tiger Top, BD Vacutainer Tubes, Lot#4004398, exp.12/31/2024, Ref#367988, label 4C to 25 C. d. 12 packs of Purple Top, BD Vacutainer Tubes, Lot#4045176, exp. 06/30/2025, Ref#367367, label 4C to 25C. e. 5 packs of Yellow Top, BD Vacutainer Tubes, Lot 4068601, exp. 02/28/2025, Ref#367986, label 4C to 25C. f. No thermometer in phlebotomy draw room, the following was revealed: a. 1 pack of purple top, BD Vacutainer Tubes, label 4C to 25C b. pack of red top, BD Vacutainer Tubes, label 4C to 25C c. 1 pack of gold top, BD Vacutainer Tubes, label 4C to 25C

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 direct observation, review policies and procedures, review of package inserts and staff interview, the laboratory failed to label urine and chemistry controls with open and expiration dates. Findings included: 1. During a tour of the laboratory on 05/24/2024 2:32 pm with testing personnel, the surveyor directly observed the following quality controls: a. Bio-Rad Liquichek Urine Level 1, Chemistry Control, Lot#97421, exp. 12/31/2024 b. Bio-Rad Liquichek Urine Level 2, Chemistry Control, Lot#97422, exp. 12/31/2024 c. Bio-Rad Liquid Specialty Immunoassay Control, Lot#65001, exp. 09/30/2026 d. Bio-Rad Liquid Specialty Immunoassay Control, Lot#65002, exp. 09/30/2026 e. Bio-Rad Liquid Assayed Multiqual Control, Level 3, Lot#45963, exp.10/31/2025 f. Bio-Rad Liquid Assayed Multiqual Control, Level 1, Lot#45961, exp. 10/31/2025 g. Boule Con-Diff Tri-Level Control, Lot#22403-03, exp. 07/31/2024 h. Boule Con-Diff Tri-Level Control, Lot#22403-02, exp. 07/29/2024 i. Boule Con-Diff Tri-Level Control, Lot#22403-01, exp. 07/29/2024 No documentation of open and or expiration dates written on bottle. 2. A review of policy and procedures titled "QA 002.01 Quality Control Program Overview revealed under section 2.0 Guidelines 2.2.4 "as required by manufacturer". 3. A review of package inserts, revealed quality controls expire within a specified amount of time: a. Bio-Rad Liquichek Urine Chemistry Controls Level 1 and 2, "once opened store tightly capped at 2 to 8 C stable 30 days" b. Bio-Rad Liquichek Specialty Immunoassay Control Levels 1, 2, and 3, "once thawed, opened, and stored tightly capped at 2 to 8 C stable 30 days, Except-PTH(Intact): 7 days" c. Bio-Rad Liquid Assay Multiqual Levels 1, 2, and 3, "once thawed opened, and stored tightly capped at 2 to 8 C, stable 14 days, Except-Alkaline Phosphate, AST/SGOT, Bilirubin (Neonatal) and Bilirubin (Total): 9 days-Bilirubin (Direct), Cholesterol (HDL), Cholinesterase, Creatine Kinase (CK), Phosphorus and Triglycerides: 7 days"-LAP Arylamidase: 3 days" d. Boule Con-Diff Tri-Level Hematology Control "open vial stability 14 days after opening". 4. In an interview on 05/24/2024 at 3:00 pm in the conference room with testing personnel, the above findings were confirmed.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on review of policy and procedures, lack of documentation, and staff interview, the laboratory failed to verify that calculations performed by the laboratory information system (LIS) are correct. Findings included: 1. A review of policy LIS 008.02 LIS Validation, 3.0 Calculations/Formulas revealed: a. "Verify that calculations performed by the LIS are correct. b. Obtain at least 1 printout of each result that was calculated by the LIS and verify their accuracy by manually calculating them. c. If there are any discrepancies, document comments and notify LIS Customer Support for help in correcting the formula. d. Attach the reports to the worksheet." 2. A review of records revealed the laboratory failed to follow the LIS 008.02 Validation policy. No documentation available on 05/24/2024. Page 2 of LIS 008.02 is a worksheet to be used. 3. In an interview with testing personnel on 05/24/2024, confirmed the above findings.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
 Based on record review, review of policies and procedures and staff interview, the technical consultant failed to ensure that policies and procedures were followed for competency. Findings included: 1. Review of CMS 209 laboratory personnel report form revealed one technical consultant (TC). 2. Review of policy titled "Job Summary and Specifications" GP 006.01 revealed on pg. 8 under job responsibilities "evaluates the competencies of all personnel on a regular basis". 3. Review of testing personnel's files revealed the following: I. TP1 missing competencies for 2021. II. TP2 competency records a. Titled "Ortho Clinical Diagnostics" Dated January 10, 2022 Signed by: TP1 b. Titled "CDS Medonic M Series" Dated May 8, 2024 Signed by: TP1 c. Titled "Ortho Clinical Diagnostics" Dated February 1, 2024 Signed by: TP1 III. TP3 competency records a. Titled "CDS Medonic M Series" Dated November 22, 2021 Signed by: TP1 b. Titled "Ortho Clinical Diagnostics" Dated November 22, 2021 Signed by: TP1 c. Titled "CDS Medonic M Series" Dated May 16, 2022 Signed by: TP1 d. Titled "Ortho Clinical Diagnostics" Dated May 16, 2022 Signed by: TP1 e. Titled "CDS Medonic M Series" Dated May 22, 2023 Signed by: TP1 f. Titled "Ortho Clinical Diagnostics" Dated July 10, 2023 Signed by: TP1 4. In an interview with testing personnel on 05/24/2024 at 3:00pm in the conference room, the above findings were confirmed.

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:

During an onsite initial survey on 05/24/2024, facility documentation, record review (CMS 209), and staff interview, the Laboratory Director/Technical Consultant failed to ensure competency was signed for 2 out 3 testing personnel (TP). Findings included: 1. A review of laboratory's competency records revealed the following. a. TP-1, missing 2021 competencies Date of competency: 2020 Date of competency: 2022 Date of competency: 2024 Assessor: TC b. TP-2, missing 2023 competencies Date of competency: 05/02/2022 CDS Medonic M Series, Assessor TC. Date of competency: 01/10/2022 for Ortho Diagnostics Date of competency: 2/01/2024 for Ortho Diagnostics Date of competency: 05/08/2024 for CDS Medonic M Series Assessor: TP-1 c. TP-3, missing competencies for CDS Medonic M Series (2021,2022) Date of competency: 11/22/2021 for Ortho Diagnostics Date of competency: 05/16/2022 for Otho Diagnostics Date of competency: 05/22/2023 for CDS Medonic M Series Date of competency: 07/10/2023 for Ortho Diagnostics Assessor: TP-1 2. A review of laboratory personnel report form CMS 209 on 05/24 /2024 revealed one laboratory director (LD)/ Technical Consultant (TC). 3. A review of General Procedures, GP 006.01, page 8, JOB SUMMARY AND SPECIFICATIONS for "Technical Consultant", under job responsibilities revealed that "evaluates the competencies of all personnel on a regular basis (initial, 6 months, and annually thereafter)". 4. In an interview 05/24/2024 at 11:45 am with testing personnel (TP1), the above findings were confirmed.