Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0019516	04/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kci Laboratory	4344 Broad River Rd, Columbia, SC	

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	An announced CLIA recertification survey was conducted at KCI on 04/19/2024 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 DEFICIENCES were found to be out of compliance:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of policies and procedures, review of testing records and staff interview, the laboratory failed to sign proficiency testing reports from College of American Pathologist (CAP) for 2022 and 2024. In 2022 3 of 13 attestation sheets were not signed. In 2024 1 of 13 PT performance sheets were not signed. Findings included: 1. A review of the laboratory's policy titled "Quality Assurance Plan" dated 2-94 revealed that the labortatory would reviewed results and grades, provide corrective action for unaceptable/unsatisfactory results discussed monthly. 2. A review of CAP 2022 3rd Event: a. The laboratory received an unsatisfactory score of 60% for Hemoglobin A1C attestation. Not signed by laboratory director. b. Hematology, Blood Cell Identification the laboratory received a satisfactory score of 80%. 3. A review of CAP 2024-1st Event the laboratory failed to document testing personnel on the following attestation sheets: a. Microbiology, 1st Event: The laoratory received an satisfactory score of 100% for FLu A, Flu B,SARS-COV-2,and KOH. b. General Chemistry and Therapeutic Drugs, Kit # C-A-2024 3. In an interview on 04/19/2024 at 1:05 pm in the laboratory office, the laboratory director confirmed the above findings.

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 policies and procedures, testing personnel records, and staff interview, the laboratory did not follow their procedure for competency assessments for 4 of 4 testing personnel. Findings included: 1. The laboratory's policy for competency evaluation for personnel performing clinical testing states, "Initial training and competency must be documented prior to the reporting of any patient results. Six months following the initial competency assessment. Twelve months following the initial competency assessment. Annually thereafter." 2. In a review of 2022 and 2023 records, competencies for TP1, TP2, TP3 and TC did not indicate initial, six months, or annual competency on the forms; thus, the surveyor was unable to determine the type of competency performed. 3. In an interview on 04/19/2024 at 1 : 05 pm in the laboratory office, the Laboratory Director confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: I. Based on review of policies and procedures, review of records and staff interview, the laboratory failed to assess proficiency testing performance from the College of American Pathologist (CAP) for 2022 and 2024. 4 of 13 Surveys in 2022 and 1 of 13 in 2024 there was no documentation of review or evaluation of results by the laboratory director. Findings included: 1. A review of policy titled "Quality Assurance Plan" dated 2-94 revealed the laboratory required a review of proficiency testing grades, corrective action for unacceptable/unsatisfactory results discussed monthly. 2. A review of CAP 2022 reports revealed the following results; the laboratory failed to review or evaluate the results of: a. General Chemistry/ Therapeutic Drugs 2022 2nd Event: The laboratory received an unsatisfactory score of 60% for ALT. b. Chemistry for subspeciality Troponin 2022 2nd Event: The laboratory received 100% score. c. Urine Chemistry, 2022 2nd Event d. Chemistry for subspeciality Troponin 2022 3rd Event: The laboratory received 100% score. 3. In an interview on 04/19/2024 at 12:45 pm in the laboratory office, the Laboratory Director confirmed the findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: I. Based on review of policies and procedures, records reviewed and staff interview, the laboratory failed to establish and follow written policies and procedures for optimum integrity of patient's specimen from the time of collection or receipt of specimen through completion of testing and reporting of results for 2 of 2 years reviewed. Kirkland Correctional Institute (KCI) receives specimens from all around the state of South Carolina (SC). Findings included: 1. A review of policies revealed the laboratory did not have a policy to address how to maintain a system that ensures specimen integrity from the time of collection at remote locations to KCI through completion of testing and reporting of results. 2. A review of the laboratory records revealed there was no documentation of records of specimens transported from other prisons throughout the state of SC. 3. A review of the laboratory records revealed there was no documentation of records of specimens transported at proper temperatures as instructed by manufacturer to ensure specimen(s) has been preserved and analyzed within the limitations of the test methodology. 4. In an interview on 04 /19/2024 at 2:32pm in the conference room, the laboratory director was asked to provide documentation. Laboratory confirmed above findings. No documents available. II. Based on review of policies and procedures, records review and staff interview, the laboratory failed to establish and follow written polices for an ongoing mechanism to monitor and assess, when indicated, problems identified in the preanalytical systems. Findings included: 1. A review of the laboratory's policies titled "Quality Assurance Plan" revealed the laboratory is required "to monitor and evaluate the ongoing overall quality of the total process; identify and correct problems; assure accurate, reliable, and prompt reporting of test results". 2. A review of policies titled "Patient Test Management Plan" revealed the laboratory is required to follow the plan for "all rejected specimens will be logged in the Recollect Logbook". 3. A review of records revealed there was no documentation of monitoring, assessing, or identifying problems in preanalytical systems. There was no corrective action documentation for identified problems available to review. 4. In an interview on 04/19/2024 at 2:32pm in the conference room, the Laboratory Director confirmed there was no documentation of corrective action logs?
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: Based on review of direct observation, review of manufacturer's instructions, of environmental records, and confirmed in staff interview, the laboratory failed to monitor storage room temperature for 12 of 12 months reviewed. Findings included: 1. During a 2nd tour of the laboratory on 4/19/2024 at 2:27 pm, the surveyor observed the following in the storage room: a. BD Gold top blood collection tubes, Lot #4032524, 7 packages b. BD Purple top blood collection tubes, Lot #331881903, 7 packages c. BD Navy top blood collection tubes, Lot #3222778, 0.5 package. d. BD Green top blood collection tubes, Lot #3163689, 1 package. e. BD Red top blood

	collection tubes, Lot #3194571, 3 packages f. BD Blue top blood collection tubes,1.5 packages Lot #3289138, and 3 packages Lot # 4011406 2. A review of the manufacturer's instructions label on the box of the BD blood collection tubes revealed a room temperature requirement of 4-25C/39.2-77F. 3. A review of the laboratory environmental records revealed no documentation of room temperature monitoring of the storage room. The laboratory was asked to provide documentation, and none was available. 4. During the interview on 04/19/2024 at 2:30pm, the laboratory director confirmed the above findings. Word Key: C=Celsius F=Fahrenheit
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of policies and procedures, records reviewed and staff interview, the laboratory failed to follow written policies for concurrent testing of reagents or acceptable chemistry quality control results from Lot-to-Lot for 2 of 2 years reviewed. Findings included: 1. A review of the laboratory's policies titled "Quality Assurance Plan" revealed the laboratory is required "to monitor and evaluate the ongoing overall quality of the total process". 2. A review of the laboratory records revealed there was no documentation of chemistry quality control assessments of Lot-to-Lot verification for chemistry. 3. In an interview on 04/19/2024 at 2:32 pm in the conference room, the laboratory director confirmed there was no documentation of chemistry Lot-to-Lot assessment.