

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0019516	(X3) Date Survey Completed 08/25/2026
Name of Provider or Supplier Kci Laboratory	Street Address, City, State 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 onsite CLIA recertification survey was conducted on August 25, 2026 at the laboratory of the Kirkland Correctional Institution (KCI) by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with conditions of participation for the Clinical Laboratory Improvement Amendments (CLIA) of 1988 requirements found at 42 CFR Part 493. The following is a list of deficiencies cited as a result of the August 25, 2026 recertification survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to follow manufacturer's instructions for samples and supplies kept at room temperature for 2 out 2 years (2025 and 2026). Findings included: 1. During a tour of the laboratory on August 25, 2026, at 2:10 pm the surveyor observed Abbott ID NOW COVID 19 2.0, Lot # 000x007477 0001008721, Ref 192-000 kits being stored at room temperature. Review of package insert reveals proper sample collection, storage and transport are essential for correct results. Under Storage and Stability, store Kit at 2-30C. 2. The surveyor requested but the laboratory failed to provide documented function checks of room and refrigerated thermometers used to measure the temperature of the room and refrigerator(s). 3. In an interview on August 25, 2026, at 3:00 pm with the laboratory director (LD) the above findings were confirmed.
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 record review Centers of Medicare and Medicaid Services (CMS) 116, lack of documentation, and staff interview, the laboratory failed to establish and/or follow written policies and procedures to assess employee(s) consistency in slide review (manual differential, urine sediment) for 3 out of 3 testing personnel. Findings included: 1. Review of South Carolina Department of Corrections Laboratory Policy and Procedure Scope: Competency reveals no written criteria to evaluate slide review between testing personnel performing moderately complex testing of Complete Blood Cell Count (CBC) with differential. The following are identified on the CMS 209 as testing personnel (TP): a. TP1 b. TP2 c. TP3 2. The surveyor requested but the laboratory failed to provide documentation of evaluation of testing personnel for consistency in slide review of manual differential and/or urine sediment. 3. In an interview on August 25, 2026, at 3:00 pm with the laboratory director (LD) the above findings were confirmed.

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:

Based on record review (College of American Pathology (CAP) PT) results, lack of documentation, and staff interview, the laboratory failed to document its review and follow up actions for unsatisfactory PT performance. Findings included: 1. Review of laboratory policy and procedure reveals the requirement of investigation and follow up for unsuccessful PT performance. 2. Review of CAP PT results 2025 Chemistry 2nd event reveals a score of 20% for analyte valporic acid. 3. In an interview on August 25, 2026, at 2:10 pm with LD in the office the above findings were confirmed.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on records review, lack of documentation, and staff interview the laboratory failed to document the twice annual verification of the laboratory information system (LIS). Findings included: 1. Review of laboratory records reveals a lack of requirement for twice annual verification of the LIS. 2. The surveyor requested but the laboratory failed to provide documentation of twice annual verification of the LIS.0 3. In an interview on August 25, 2026 at 11:00am in the laboratory office with the technical consultant (TC), the findings were confirmed.

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 records review, lack of documentation, and staff interview, the current laboratory director failed to approve, sign, and date procedures and/or changes in procedures for the 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. Review of (CMS 116 and CMS 209 Personnel Report form) records reveal: a. 1 Laboratory Director (LD) 2. Review of the policies and procedures for South Carolina Department of Corrections reveals lack of signature and dates documenting LD approval. The following policies and procedures were reviewed: a. South Carolina Department of Corrections Laboratory Policy and Procedure Scope: Competency, effective date: January 01, 2017 b. Patient Test Management Plan, last revised 10-02. c. Beckman Coulter DxH 690T Automated Hematology Analyzer, Standard Operating Procedures, no effective date. d. Kirkland Correctional Institution Laboratory RPR-Charcoal Flocculation last revised 06-01; new procedure "RPR Card Test For Syphilis" no effective date or dates of use. e. Preparation of Differential Blood Smear, last reviewed date 8-99 3. In an interview on August 25, 2026, at 3:00 pm with the LD4 the above findings were confirmed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation and staff interview the laboratory failed to ensure equipment has not exceeded their expiration date, has not deteriorated, or is of substandard quality in 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. During a laboratory tour on August 25, 2026, at 2:10 pm the surveyor observed the following equipment in the laboratory: a. Zeiss Primo Star Microscope Nikon; last sticker MSR, Inc. 312 600 4788, 9-22-9/2023, oil b. LW Scientific Digital Rotator c. Benchmark Centrifuge, LC-8 series, Model Lab Cen, C31000 110061174, d. Fisherband Centrifuge SN 220709AD017 e. Centrifuge Model Horizon 24 Fisher SN 220709AD016 f. C5 LW Scientific Ultra Centrifuge, Model C5 5000RPM, Serial number: S106821, tested 12/2/10 g. Acurite Timer, no information h. Thermometers for refrigerator and freezer: i. Thermofisher, Serial Numbers: 230294641, expiration 26 Apr. 2025 ii. Thermofisher, Serial Number, Serial Number: 230192634, expiration 21 Mar. 2025 and room (no information) None of the equipment had current documentation of maintenance on the day of survey. 2. The surveyor requested and the laboratory failed to provide documentation for current performance verification of equipment. 3. In an interview on August 25, 2026, at 3:00 pm with the LD the above findings were confirmed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on policy and procedures, lack of documentation, and staff interview, the laboratory failed to establish and/or follow procedures for performing function checks in each piece of equipment/instrument it uses, in patient testing as required 493.1254 (b)(2)(i)-(b)(2)(ii). Findings included: 1. Review of policy and procedures (Beckman Coulter DxH 690T Automated Hematology Analyzer and RPR Card Test For Syphilis) for moderately complex testing reveals the following equipment is needed: I. Beckman Coulter DxH 690T Automated Hematology Analyzer a. Thermometer and humidity monitoring device to ensure the analyzer is kept between "(16-32C or 60-90F) with a humidity between 0 to 95% without condensation". b. Centrifuge at 2500 RPMS for 10 minutes for Lipemic/Icteric specimens II. RPR Card Test For Syphilis a. Thermometer to ensure the "temperature of the reagents and samples is crucial to test outcome; it should be between 20-30C". b. Mechanical rotator set at 100+-5 rpm and circumscribing inch diameter c. Timing device, minute and second capability d. MLA Pipets-10 ml, 50ml, 100ml, 200ml, and 1,000ml 2. The surveyor requested but the laboratory failed to provide function checks for each type of device or instrument to ensure that it is functioning correctly and is properly calibrated. 3. In an interview on August 25, 2026, at 3:00 pm with the laboratory director (LD) the above findings were confirmed. Celsius (C) Fahrenheit (F)