Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0252422	11/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kendall & Kemmerlin Pa (Drs)	1817 Woodruff Road, Greenville, 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 onsite announced CLIA recertification survey was conducted on November 18, 2024, at the clinical laboratory in the office of Kendall and Kemmerlin, PA by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following ia a list of standard level deficiencies found during the survey at the cite:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the review of the College of American Pathologist (CAP) survey evaluation forms and staff interview, the laboratory failed to document the laboratory director (LD) and testing personnel (TP) review and approval of attestation forms for proficiency testing (PT) performed for 2 years reviewed. (2023and 2024). Findings included: 1. Review of the PT documentation reveals a lack of signed attestation forms for events listed below: a. CAP CM-A 2023 b. CAP HE-A 2023 c. CAP FH1-B

	2023 d. CAP FH1-C 2023 e. CAP CM-B 2023 f. CAP CM-A 2024 g. CAP FH1-A 2024 2. In an interview on November 18, 2024, in the laboratory office at 1:30 pm with the office manager (OM) and TP1, the 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 the review of the laboratory's policy and procedures and staff interview, the laboratory failed to produce a written policy for the assessment personnel competency. Findings included: 1. Review of the laboratory's policy and procedure manual reveals a lack of a written policy and procedure for establiehing competency assessment of testing personnel. 2. In an interview on November 18, 2024, in the laboratory office at 1:30 pm with the OM and TP1, the 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 the review of CAP PT documentation and staff interview, the laboratory failed to provide evidence of review and evaluation of the laboratory's PT performance. Findings included: 1. Review of CAP PT documentation reveals a lack of evidence of performance review and evaluation for each of the following PT events: a. CAP CM-A 2023 b. CAP HE-A 2023 c. CAP FH1-B 2023 d. CAP FH1-C 2023 e. CAP CM-B 2023 f. CAP CM-A 2024 g. CAP FH1-A 2024 2. The events listed above lack the signatures of the LD or TP1 to verify review and evaluation. 3. In an interview on November 18, 2024, in the laboratory office at 1:30 pm with the OM and TP1, the findings were confirmed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of CAP PT documentation review and staff interview, the laboratory failed to review and document corrective action for failures of PT results. Findings included: 1. Review of the following CAP PT events reveals a lack of documentation for review and corrective action taken for unsuccessful PT performance: a. CM-A 2023 1. CMP-06 urine sediment ID lab result = fat droplet Good response = Erythrocyte 2. CMP-07 CSF & Body Fluid lab result = Basophil, Mast Cell Good response = Mesothelial Cell b. FH1-A 2024 1. FH1-04 MPV lab result = 6.5 fl Acceptable range = 6.6 to 8.0 2. FH1-05 MPV lab result = 6.1fl

	Acceoptable range = 6.8 to 8.0 c. CM-A 2024 1. CMP-05 urine sediment ID lab result = Starch granule Good response = Leucine Crystals 2. CMP-06 urine sediment ID lab result = RBC Cast Good response = Granular cast 3. CMMP-26 Vaginal Wet Prep lab result = Clue Cell(s) Present Intended response = Epithel Cells Present 4. USP-01 urine sediment ID lab result = Eyrthrocyte Good response = RBC Cast 2. In an interview on November 18, 2024, in the laboratory office at 1:30 pm with thw OM and TP1, the findings were confirmed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of CAP PT documentation and staff interview, the LD failed to ensure evaluation of the laboratory's performance and to identify any problems that require corrective action. Findings included: 1. The following PT events lack evidence of review and evaluation by the LD or other appropriate staff: a. CAP CM-A 2023 b. CAP HE-A 2023 c. CAP FH-B 2023 d. CAP FH1-C 2023 e. CAP CM_B 2023 f. CAP CM-A 2024 g. CAP FH1-A 2024 2. The PT events listed above lack the signature of the LD or TP1 to verify review and evaluation. 3. In an interview on November 18, 2024, in the laboratory office at 1:30 pm with the OM and TP1, the findings were confirmed.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of laboratory documentation, employee personnel files, and staff interview, the LD failed to ensure that prior to testing patient's specimens that the employees receive appropriate training for the complexity of the services provided to demonstrate they can perform all testing operations reliably and report accurate results. Findings included: 1. Review of the laboratory's policy and procedure manual reveals a lack of a written policy and procedure for assessment of employee competency. 2. Review of the employee personnel files reveals a lack of initial competency assessment for two of two TP. 3. In an interview on November 18, 2024,

	in the laboratory office at 1:30 pm with the OM and TP1, the findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of laboratory documentation, employee personnel files, and staff interview, the TC failed to ensure that the evaluation and documenting of performance of individuals responsible for moderate complexity testing is done at least semiannually during the first year of patient testing. Findings included: 1. Review of the laboratory's policy and procedure manual reveals a lack of a written policy and procedure for assessment of employee competency. 2. Review of the employee personnel files reveals a lack of semiannual competency assessment for two of two TP. 3. In an interview on November 18, 2024, in the laboratory office at 1:30 pm with the OM and TP1, the findings were confirmed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of laboratory documentation, employee personnel files and staff interview, the TC failed to ensure that the evaluation and documentation of employee competency is performed annually after the first year of employment. Findings included: 1. Review of the laboratory's policy and procedure manual reveals a lack of a written policy and procedure for assessment of employee competency. 2. Review of the employee personnel files reveals a lack of annual competency assessment for two of two TP. 3. In an interview on November 18, 2024, in the laboratory office at 1:30 pm with the OM and TP1, the findings were confirmed.