Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1087292	03/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kidmed West End	4687 Pouncey Tract Road, Glen Allen, VA	

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 Kidmed West End on March 13, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Kidmed West End was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 the survey Centers for Medicare and Medicaid Services CLIA Application for Certification (CMS116), policies and procedures, lack of documentation, and interviews, the laboratory failed to establish a policy for specimen acceptability and rejection for Hematology Complete Blood Count (CBC) samples at the time of the survey on March 13, 2025. Findings include: 1. Review of the survey CMS116 revealed the laboratory performs moderate complexity CBC testing on the Horiba Micros 60 Hematology analyzer. 2. During an interview at 9:20 am, the technical consultant (TC) stated that CBC samples were collected by fingersticks (capillary samples). 3. Review of the available laboratory policies and procedures (P&Ps) revealed a Lab Tech job responsibility document that included "Obtain lab samples" with capillary samples included in the sample types listed. Review of lab's P&Ps revealed a lack of an acceptability or rejection policy of CBC samples. 4. In an exit interview with the Technical consultant and lab coordinator at 12:15pm, it was confirmed that the laboratory lacked a specimen acceptance and rejection policy.
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 laboratory proficiency testing documentation, lack of documentation and interviews, the laboratory failed to retain policies and procedures approved by the Lab director at the time of the survey on March 13, 2025. Findings include: 1. Review of the laboratory's proficiency testing documentation revealed a Proficiency Testing policy written by the Technical Consultant (TC) dated July 2022. The policy lacked evidence of the lab director's review and approval. 2. At approximately 10:00 am, the surveyor requested to review the laboratory's procedure manual . The TC indicated the manual was under construction and being updated. The surveyor asked to see evidence of the lab director's review and approval of the current policies and procedures, to which the TC said there was none When asked at 11:35 am about a policy for Hematology Quality Control statistical evaluations, and at 11:54 am about a policy for changing patient reports (revised results), the TC stated there were no policies. 3. In an exit interview at 12:15 pm with the TC and lab coordinator, the lack of approved laboratory procedure manual was confirmed.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of the laboratory's hematology Quality Control (QC) records, Quality Assurance (QA) Manual, and interviews, the technical consultant (TC) failed to ensure a Quality Control program was established and maintained for five (5) of the 12 months in calendar year 2024. 1. Review of the laboratory's Hematology QC

	documentation included monthly Horiba QC and Levy Jennings (statistical) Reports with QC review documentation signed by the TC. Review of the 2024 QC summary reports revealed no documentation of TC review, as evidenced by signature, for the following 5 months: April, June, July, August, and September. The 2024 Hematology QC documentation lacked QC results for November 1 - 4, 2024. (When asked, the lab coordinator printed the acceptable QC results from the Hematology analyzer.) 2. Review of the laboratory's QA Manual revealed a Delegation of Responsibility memo, dated 3/14/17 and signed by the lab director, that delegated Quality Control and Quality Assessment to the Technical Consultant. The QA Manual incorporated hand written monthly QA summaries that included documentation of Hematology quality control review. The QA summary for November 2024 lacked notation and corrective action for the lack of QC retention for November 1 - 4, 2024. The 2024 QA review documentation lacked a "performed/reviewed by" name, signature and date. 3. When asked, at approximately 11:35 am, about a policy for Hematology QC statistical evaluation performance and frequency, the TC stated that there was no policy. 4. The findings above were confirmed during an exit interview at 12:15 pm with the TC and lab coordinator.