Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2015652	03/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kidmed Southside	5021 Craig Rath Boulevard Building - Iv, Midlothian, 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 Southside 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. 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. Review of the provided laboratory documentation revealed a Lab Tech job responsibility document that included "Obtain lab samples" with capillary samples included in the sample types listed. The technical consultant (TC) confirmed that CBC samples were collected by fingersticks (capillary samples). Review of the available lab policies revealed a lack of an acceptability or rejection policy for fingerstick CBC samples. 3. In an exit interview with the TC and lab coordinator at 4:58 pm, 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 available laboratory policies, lack of documentation and interviews, the laboratory failed to retain policies and procedures approved by the Laboratory director at the time of the survey on March 13, 2025. Findings include: 1. At approximately 1:45 pm, the surveyor reviewed the provided laboratory documentation which lacked a laboratory procedure manual. The Technical Consultant (TC) stated that a procedure manual was not available for review at that time but that individual policies were available in the respective manuals. The surveyor asked to see evidence of the lab director's review and approval of a current policy for Hematology Quality Control statistical review (refer to D6042), and specimen rejection (refer to D5403). The TC confirmed that the approved policies were not currently available for review 2. In an exit interview at 4:58 pm with the TC and lab coordinator, the lack of a Laboratory director approved Policy and 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, laboratory Policy and Procedures, and interviews, the technical consultant (TC) failed to ensure a Quality Control program was established and maintained for three (3) of 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 3 months in 2024: April, June, and August. 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 2024 QA review documentation lacked a "performed/reviewed by" name, signature and date. 3. Review of the laboratory Policy and Procedures revealed no policy for Hematology QC statistical evaluation performance and frequency. 4. The findings above were confirmed during an exit interview at 4:58 pm with the TC and lab coordinator.