Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2015652	01/23/2019
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, PLLC on January 23, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of analyzer validation records, user guide, patient test logs, and an interview, the laboratory director (LD) failed to verify the normal values (reference ranges) for Complete Blood Count (CBC) testing prior to reporting eight hundred sixty-six (866) patient CBC panels from September 27, 2017 to the date of the survey, January 23, 2019. Findings include: 1. Review of hematology analyzer records revealed a new instrument installation, by a Horiba field service technical specialist, occurred on 9/27/17. The inspector noted that the validation documentation contained no verification of the CBC patient normal values by the LD for the new Horiba Micro 60 instrument (Serial Number 702CS96721). No normal value verification documentation was available for review upon request. 2. Review of the Micro 60 Users Guide for new instrument installation revealed the instruction: "The patient reference range must be validated by the Lab Director". 3. Review of the patient test

	log from the laboratory's electronic medical record, DOCUTAP, and Project Coordinator's notes revealed that the laboratory had reported 866 CBC reports from 9 /27/17 to the date of the survey on 1/23/19. 4. An interview with the Lab Coordinator, Project Coordinator, and Technical Consultant, at approximately 3:00 PM, confirmed that the laboratory director failed to validate patient CBC reference ranges prior to reporting patient results as outlined above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's analyzer validation records, patient test logs, Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel files, and an interview, the laboratory director (LD) failed to perform competency assessments for one (1) of two (2) technical consultants in calendar years 2017 and 2018 (Cross Reference D6030 -REPEAT DEFICIENCY).
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel files, and interview, the laboratory director (LD) did not perform competency assessments for one (1) of two (2) technical consultants in calendar years 2017 and 2018. **REPEAT DEFICIENCY Findings: 1. Review of the laboratory's CMS 209 form revealed that the LD identified two technical consultants (TC). (See Personnel Code Sheet.) 2. Review of the laboratory's available personnel files revealed no competency assessment documentation for TC B in 2017 and 2018. The documentation was not available for review upon request. 3. In an interview with the Lab Coordinator, Project Coordinator, and TC A at approximately 3:00 PM, it was confirmed that the LD failed to document competency assessments for TC B as outlined above.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a tour, review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), analyzer installation validation records, users guide, personnel files, and an interview, a technical consultant (TC) failed to document training and competency evaluations for one (1) of seven (7) testing personnel after a hematology instrument change on September 27, 2017. Findings include: 1. During a laboratory tour, at approximately 1:00 PM, the inspector noted a Horiba Micros 60 hematology analyzer in use for Complete Blood Count (CBC) testing. The Project Coordinator stated: "we replaced our Abbott Emerald with the Micros 60 in 2017". 2. Review of the laboratory's CMS 209 revealed that the LD identified two technical consultants (TC) and seven (7) hematology testing personnel (TP). 3. Review of the laboratory's instrument validation records revealed the Micros 60 analyzer installation (Serial Number 702CS96721) was performed by a Horiba field service technical specialist on 9/27/17. 4. Review of the Horiba User's Guide revealed manufacturer's instructions that the "Training Checklist is to be completed prior to patient testing for operators". 5. Review of the laboratory's personnel files revealed no Horiba operator training checklist for TP A. No TP A competency was available for review when requested by the inspector. The Project Coordinator stated: "I am not able to provide the documentation that the initial training checklist was completed". (See Personnel Code Sheet.) 6. An interview with the Lab Coordinator, Project Coordinator, and TC A, at approximately 3:00 PM, confirmed that the TC failed to document training competency evaluations for TP A as outlined above.