Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1087292	01/24/2019
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 January 24, 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:
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and interview, the laboratory failed to attain a testing event score of at least eighty (80) percent (%) for one (1) of six (6) Hematology testing events reviewed. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT records, a total of 6 events, revealed unsatisfactory performance for the following event: 2017 API 3rd Event - Hematology overall score of sixty-five (65) %-with Red Blood Cell count scored sixty (60) %, Hematocrit scored 60%, Hemoglobin scored 60%, White Blood Cell count scored 60%, Platelet count scored 60%. 2. In an interview with the Lab Coordinator, Project Coordinator, and Technical Consultant at approximately 12:30 PM, it was confirmed that the laboratory failed to attain a satisfactory score for the PT event listed above.
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, patient test logs, and interviews, the laboratory failed to evaluate and verify operational performance of the relocated Abbott Emerald Hematology analyzer prior to reporting six hundred sixty-seven (667) patient Complete Blood Count (CBC) panels from October 1, 2017 to the date of the survey, January 24, 2019. Findings include: 1. Review of the laboratory's hematology analyzer records revealed an instrument installation occurred on 10/1/17. The inspector noted no records of accuracy, precision, reportable and reference range verification documented for the Abbott Emerald (SN 032211-002733) after the installation and prior to patient testing. The inspector requested to review performance specifications. No documentation was available for review. The Project Coordinator stated: "we moved the Emerald from another office location and we were not aware that the system had to be revalidated after moving". 2. 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 667 patient CBC reports from 10/1/17 to the date of the survey on 1/24/19 utilizing the Emerald (SN 032211-002733). 3. In an interview with the Lab Coordinator, Project Coordinator, and Technical Consultant at approximately 12:30 PM, it was confirmed that the laboratory failed to evaluate performance specifications 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 laboratory's 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 inspector requested to review competency assessment documentation for TC B. The documentation was not available for review. 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.