Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1087292	05/12/2021
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 on-site survey was conducted at the Kidmed West End on May 12, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on April 19, 2021 with off-site record review of documentation on May 6, 2021 and a follow-up phone conference on May 10, 2021. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and in compliance with the applicable COVID-19 reporting requirements.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and an interview, the laboratory failed to participate in one (1) of 7 Complete Blood Count (CBC) events reviewed. Record review included all three events in 2019, 2020 and the first event in 2021. Findings include: 1. Review of the CASPER 0155D Individual Laboratory Profile Report and the American Proficiency Institute (API) PT records for the third event in 2020 revealed the laboratory received a score of 0%. 2020 Event C- 0%- for the CBC module (Notation by API-failure to participate). 2. An exit interview with

	the technical consultant on 05/12/21 at approximately 10:30 AM confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of policy and procedures (P&P), Abbott Emerald calibration records, and interviews, the laboratory failed to document Abbott Emerald calibration procedures for hematology Complete Blood Count (CBC) testing according to their written policy in the calendar year 2020. Findings include: 1. Review of the P&P revealed a calibration policy (signed by the lab director 1/11/17) that outlined to calibrate CBC testing on the Abbott Emerald at a frequency of every six (6) months. 2. Review of the laboratory's 2020 and 2021 (up to the date of survey) calibration records revealed calibrations were performed on the Abbott Emerald on 08/07/2019, 05/13/2020 and 01/21/2021. The surveyor requested additional documentation for calendar year of 2020 demonstrating calibration for the Abbott Emerald every 6 months. The laboratory provided no additional calibration documentation between 05/13/2020 to 01/21/21. 3. An exit interview with the technical consultant at approximately 10:30 AM on 5/12/21 confirmed the findings.