

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2093143	<b>(X3) Date Survey Completed</b>  02/21/2019
<b>Name of Provider or Supplier</b>  Kidmed - Stafford	<b>Street Address, City, State</b>  20 Doc Stone Road, Stafford, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at KidMed Stafford on February 21, 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 deficiency cited is as follows:
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, hematology calibration records, and an interview, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) testing according to their policy in calendar year 2017. Findings include: 1. Review of the laboratory's procedure manual revealed a quality assurance policy that stated "hematology calibrations will be completed on the Abbott Emerald analyzer every 6 months and after major maintenance as needed". 2. Review of the laboratory's 2017 and 2018 calibration records revealed one (1) CBC calibration was documented in calendar year 2017 (07/13/17). The lab inspector requested to review additional calibration records for calendar year 2017. No additional calibration documentation was available. 3. In an exit interview with the</p>

technical consultant and project coordinator at approximately 11:30 AM, the above findings were confirmed.