

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0945914	(X3) Date Survey Completed 02/21/2020
Name of Provider or Supplier James A Coggi, Md, Pc	Street Address, City, State 1031 Office Park Road, Suite 10, West Des Moines, IA	
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION 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 the laboratory's calibration policy, calibration records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 02/21/2020, the laboratory failed to perform and document calibration procedures on the Abbott Cell-Dyn Emerald hematology instrument (complete blood counts) every six months for two out of two time periods in 2019. The findings include: 1. The laboratory's calibration procedure stated that the laboratory would perform a calibration on the Abbott Cell-Dyn Emerald hematology analyzer every six months. 2. Calibration records revealed that the laboratory last calibrated the hematology instrument on 11/30/2018. 3. At the time of the survey, laboratory personnel identifier #2 confirmed that the laboratory had not calibrated the hematology instrument since 11/30/2018 and did not have calibration records for 2019.</p>