

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0976783	(X3) Date Survey Completed 09/19/2018
Name of Provider or Supplier Upc Family Medical Clinic Of Jane Lew	Street Address, City, State 134 Industrial Park Road Ste 200, Jane Lew, WV	
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 calibration records and ABX Micros Hematology Instrument Manual and interview with testing personnel, the laboratory did not have documentation of all calibrations. Findings include: 1. The ABX Micros Hematology Policies stated calibration should be performed at least at a frequency of at least 2 times per year or more frequently if necessary. 2. Calibration records of the ABX Micros demonstrated calibration to be conducted 3X per year for 2016. However, for year 2017, the only record of calibration occurred on 3/17/17. So far for 2018, there was only on calibration conducted on 5/10/18. 3. On 9/19/2018 at approximately 11: 45AM, the Office Manager/TP1 described a process of performing calibration at least several times per year. However, the records were missing from the calibration records.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of personnel competency records and interview with Office Manager /Testing Personnel (TP1), the laboratory did not evaluate the competency of all testing personnel annually. Findings include: 1. The laboratory had a written protocol with accompanying forms to document personnel competency assessment. 2. Personnel competency assessment documentation was documented annually for TP2 for 2016, 2017 and 2018. However, personnel competency assessment documentation was not available for 2016 and 2017 on the Office Manager/ TP1. who's identification was found in testing records. 3. On 9/19/2018 at approximately 12:30 PM, Office Manager /TP1 stated that the competencies were performed but she could not find the documentation within the personnel competency records.