

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2064164	<b>(X3) Date Survey Completed</b>  04/03/2019
<b>Name of Provider or Supplier</b>  Priority Medical Clinic, Llc	<b>Street Address, City, State</b>  601 North 15th Avenue, Laurel, MS	
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>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 manufacturer's instructions for calibration in the Beckman Coulter AcT diff hematology analyzer operator's guide, calibration records since the last survey on 10-4-17, and patient complete blood count (CBC) reports, the laboratory failed to follow manufacturer's instructions when the calibration of white blood cell (WBC) count, red blood cell (RBC) count, and hemoglobin failed on 9-20-18. A total of 691 patient CBC results were reported from 9-20-18 through 4-3-19. Findings include: Review of calibration records for the Beckman Coulter AcT diff hematology analyzer since 10-4-17 revealed the calibration of WBC, RBC, and hemoglobin failed on 9-20-18. Manufacturer's instructions for calibration in the Beckman Coulter AcT diff hematology analyzer operator's guide state for failed calibration results, call your Beckman Coulter Service Representative for assistance. On the day of the survey, 4-3-19, there was no documentation of corrective action performed for the failed calibration. Review of patient test reports revealed a total of 691 patient CBC results, which include WBC, RBC, and hemoglobin, were reported from 9-20-18 through 4-3-19.</p>

**D6073**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1425(b)(4)

Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions for calibration in the Beckman Coulter AcT diff hematology analyzer operator's guide, calibration records since the last survey on 10-4-17, and patient complete blood count (CBC) reports, testing personnel failed to follow the laboratory's established corrective action policies and procedures whenever calibration failed for white blood cell (WBC) count, red blood cell (RBC) count, and hemoglobin on 9-20-18. A total of 691 patient CBC results were reported from 9-20-18 through 4-3-19. Refer to D5437 (Failure to follow manufacturer's instructions for failed calibration).