

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2133426	(X3) Date Survey Completed 07/05/2023
Name of Provider or Supplier Usa Mobile Diagnostic Center	Street Address, City, State 6304 Usa Health Blvd, Mobile, AL	
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 a review of Policies and Procedures, a review of Sysmex XN 1000 calibration records, and an interview with the Technical Consultant, the laboratory failed to perform and document one of two calibrations on the Sysmex XN 1000 in 2022. The findings include: 1. A review of Policies and Procedures revealed the following under "Sysmex XN-1000 Hematology Analyzer", "...The laboratory must verify calibration every six months...". 2. A review of Sysmex XN-1000 calibration records revealed calibrations on the instrument were performed on 4/28/2022 and 5/24/2023. No evidence of a calibration performed in the second half of 2022 was available for review. 3. During an interview on 7/5/2023 at 12:00 PM, the Technical Consultant confirmed the above findings.</p>