

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0693402	(X3) Date Survey Completed 03/21/2023
Name of Provider or Supplier Cornerstone Medical Group	Street Address, City, State 914 Vista Drive, Dalton, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 21, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 the review of the Sysmex XP-300 (serial number A5095) calibration documents and testing personnel interview, the laboratory failed to calibrate the analyzer at the frequency required by the manufacturer. Findings: 1. Review of the available calibration documents revealed calibration was performed : June 2020, December 2020, January 2022, June 2022. 2. No calibration was performed in 2021 or December 2022. The over due calibration has not been performed to date. 3. Letter from the manufacturer field service representative stated : "The calibration was due June 22, 2021 but was not completed until January 2022". 4. Interview with testing personnel #1 (CMS 209) in the lab on 3/21/23 at 2 PM, confirmed the findings.</p>

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on the review of the Sysmex XP-300 (serial number A5095) calibration documents and testing personnel interview, the laboratory technical consultant failed to ensure the calibrations were performed on the analyzer at the frequency required by the manufacturer. Refer to D 5437