

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0714044	(X3) Date Survey Completed 10/22/2024
Name of Provider or Supplier Cmg, Nationwide	Street Address, City, State 125 Nationwide Drive, Lynchburg, VA	
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	An announced CLIA recertification survey was conducted at CMG, Nationwide on October 22, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to document review/evaluation for seven (7) ungraded challenge samples reported from two (2) of 2 PT events in calendar year 2024 . Findings include: 1. Review of the laboratory's 2024 American Proficiency Institute (API) Events 1-2 revealed no documentation of review/evaluation for the following 7 challenge samples: API Chemistry Event 1- BNP samples PSC-01 and PSC-02, reported performance as "Not Graded; API Chemistry Event 1 - Troponin samples PSC-01 and PSC-02, reported performance as "Not Graded; API Hematology Event 1 - Platelet HEM-03 reported performance as "Not Graded; API Microscopy Event 2 -Vaginal Wet Preparation VA-02, performance reported "Not Graded, See Data Summary"; API Urinalysis Event 2 - Urobilinogen UA-04, performance reported as "Not Graded, See Data Summary". 2. The inspector requested to review the evaluation documentation for the ungraded PT challenges outlined above. No documentation of review/evaluation was available. 3. An exit interview with the two primary testing personnel on 10/22/24 at 3:30 PM confirmed the above findings.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</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.

This STANDARD is not met as evidenced by:

Based on review of procedures, instrument calibration records, lack of documentation, and interview, the laboratory failed to perform every six month instrument calibration procedures for Complete Blood Count (CBC) patient testing during one of two calendar years reviewed (review timeframe September 7, 2022 to October 22, 2024). Findings include: 1. Review of the laboratory's procedures revealed a hematology calibration protocol that outlined to calibrate CBC testing at a frequency of every 6 months. 2. Review of the laboratory's Abbott Emerald instrument calibration documentation during the review timeframe of September 2022 to 10/22/24 revealed that calibration procedures were recorded on the following dates: 10/18/22, 4/14/23, 8/22/23, 1/26/24, 10/11/24, and 10/24/24. The inspector noted a nine month lapse in CBC calibration occurred in 2024. The inspector requested to review additional calibration records for the Abbott Emerald analyzer during the calibration lapse outlined above in calendar year 2024. No additional calibration documentation was available for review. 3. An exit interview with the two primary testing personnel on 10/22/24 at 3:30 PM confirmed the above findings.