Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2159614	02/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cgt Global	1230 Soldiers Field Rd, Suite 2, Boston, MA	

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 CLIA recertification survey was conducted for the CGT Global laboratory on 02/16/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Operations Manager (LOM) on 2/16/24, the laboratory failed to perform calibration verifications every six

	months or, as appropriate, as evidenced by the following: The surveyor reviewed the quality control records on 2/16/24 for the calendar years 2022 and 2023. The review revealed that calibration verifications of at least three points were not performed once every six months for four (4) out of four (4) analytes requiring calibration verification on the Sysmex pocHi-100i analyzer. The six-month calibration verifications for erythrocyte count (RBC), hemoglobin, leukocyte count (WBC), and platelets were performed on 1/12/24 and 10/14/22. The calibration verifications were not performed every six months; none performed in 2023. The LOM confirmed in an interview on 2 /16/24 at 2:09 P.M. that calibration verifications had not been performed every six months for four (4) out of four (4) hematology analytes requiring calibration verification. The laboratory performs 5,000 hematology tests annually.
D9999	493.51 NOTIFICATION REQUIREMENTS FOR LABORATORIES ISSUED A CERTIFICATE OF COMPLIANCE Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. Based on record review and interview, the laboratory failed to notify HHS or its designee within 30 days of a change in name and a change in location as evidenced by the following: A CMS-116 indicating a change in name effective July 1, 2023 and a change in location effective October 3, 2022 was received at the State Agency on February 9, 2024. The State Agency was not notified within 30 days of change in name and location.