Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2130154	09/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Global Diagnostic Labs, Llc	4960 Peachtree Industrial Boulevard Suite 220, Norcross, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on September 25, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 hematology calibration review and staff interview, the laboratory failed to perform instrument calibrations every six months as required. Findings include: 1. Beckman Coulter AcT5 Diff (hematology analyzer) calibration document review revealed the laboratory did not perform required instrument calibration between 10/24 /17 and 9/10/18. 2. An interview with Staff #2 (CMS 209) on 9/25/18 in a conference room at approximately 3:00 p.m. confirmed the aforementioned hematology analyzer calibration was not performed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on reference laboratory test report review and staff interview, the laboratory failed to properly identify the reference laboratory performing patient testing. Findings include: 1. Reference laboratory test report review revealed the report did not contain the name, address, or laboratory director (LD) of the reference laboratory where the test was performed. 2. The reference laboratory report contained the name, address, and LD of the survey facility only. 3. An interview with Staff #4 (CMS 209) on 9/25/2018 at approximately 3:00 p.m. in a conference room confirmed the reference laboratory report did not contain the name or address of the reference laboratory nor the name of the reference laboratory LD.