Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1009099	12/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Apex Diagnostic Laboratories	2702 Triana Blvd, Huntsville, 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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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 a review of the Hematology calibration records and an interview with the current Technical Consultant (TC), the laboratory failed to ensure one of two 2018 calibrations on the Horiba ABx Micros 60 Hematology analyzer was performed and documented. The findings include: 1. A review of calibration records for the Horiba Hematology analyzer revealed documentation of calibrations performed on 8/4/2017 and 8/28/2018. 2. During an interview on 12/5/2018 at 5:20 PM, the current TC was asked for documentation of the Horiba calibration from the first half of 2018. The TC explained the usual procedure in the laboratory was to have the Horiba Service Technician perform a calibration during the "PM" (Preventative Maintenance) service call, and the laboratory staff performed the other calibration in August each year. 3. As the interview on 12/5/2018 continued, the TC provided the surveyor with a copy of the "Service Report" from February 2018, however the "Calibration" box on the report was not checked; the report documented the technician had run QC (quality controls), but there was no indication he had performed a calibration. The TC further stated the Horiba Technician always performed a calibration during the PM service, however the

	laboratory had been unable to obtain a copy of the calibration for their records. Thus the above noted findings were confirmed. .
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 a review of the calibration verification (C/V) records for the Roche Cobas e411 Immunochemistry analyzer, and an interview with the current Technical Consultant (TC), the surveyor determined the laboratory failed to perform and/or document one of two 2018 calibration verifications every six months as required by laboratory policy. The findings include: 1. A review of the calibration verification (C /V) records for the Roche Cobas e411 Immunochemistry analyzer (for Vitamin B12, Folate, Prolactin, Thyroid Stimulating Hormone [TSH], and Free T4 testing) revealed the laboratory performed and documented calibration verification (C/V) on 9/15/2017 and 8/22/2018. 2. During an interview on 12/5/2018 at 5:15 PM, the TC confirmed all the above tests are calibrated with only one or two calibrators. [Analytes calibrated with less than three calibrators must have a C/V performed every six months.] However, the TC stated the personnel had been unable to find the missing C/V documentation from early 2018. Thus, the above noted findings were confirmed. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on a review of installation and validation documentation for the Hitachi CLA-1 analyzer for Allergy testing and interviews with the Technical Consultant and Testing Personnel #1, the Laboratory Director failed to document review and approval of the initial validation procedures as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the documentation under the Validation Section for the Hitachi CLA-1 analyzer revealed correlations on three split samples were used to establish accuracy and precision for the Food panel (used for qualitative allergy testing). A validation page in this section was signed by the previous Technical Consultant "for Dr. [Name of Laboratory Director]" and dated "12/10/2016". Also included in this section was a faxed page to Testing Personnel #2 from Hitachi technical support. At the bottom of the fax was a handwritten note, "Validation Approved", signed by the Laboratory Director; the notation was not dated. 2. In a separate section of the binder with a small pink "Correlation" tab were the correlations on three split samples dated 11/10/2016 used to establish accuracy and precision for the South East (SE) Inhalant Panel on the Hitachi CLA-1. There was no documentation of review by the Technical Consultant or the Laboratory Director. 3. During an interview and review of these records on 12/7 /2018 at 2:30 PM, the surveyor asked the current Technical Consultant (TC) if he knew when the Laboratory Director (LD) had approved the validation procedure; the TC stated he had the LD sign on the faxed sheet included with the Food Panel data "yesterday" (12/4/2018), and was not sure if the Laboratory Director had reviewed the SE Inhalant Panel data since it was in a separate section. The surveyor then asked when patient testing began on the Hitachi; Testing Personnel #1 checked the patient worksheets and stated 4/11/2017. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor