Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1082218	02/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
East Lake Pediatrics Pa	2137 Little Rd, Trinity, FL	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing record review and interview with Testing Personnel #A, the laboratory failed to retain proficiency testing documentation for one (3rd testing event 2017) event out of three events (1st, 2nd, 3rd testing events for 2016 and 2017) for two years (2016-2017). Findings include: During record review of hematology proficiency testing for 2016-2017, the documentation for the API proficiency testing 3rd Event for hematology for 2017 was missing from the API proficiency testing binder. During an interview on 02/26/18 at 11:55 a.m., the Testing Personnel #A was asked about the missing API proficiency testing 3rd Event in hematology for 2017 and stated they would look for missing documentation. Documentation was not provided by time of exit.
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 calibration record review and interview with the Laboratory Director and Testing Personnel #A, the laboratory failed to follow manufacturer's instructions for the calibration process for two out of two years (2016-2017). Findings include: During record review of calibration records, the records for MCV (Mean Cell Volume) - Calibration 04/20/16, WBC (White Blood Cell) and HgB (Hemoglobin) - Calibration 01/19/16, WBC and RBC (Red Blood Cell)- Calibration 04/12/17, and HgB, MCV, and Plt (Platelet)- Calibration 11/20/17 showed analyte's that the old calibration factor needed to be replaced with the new calibration factor per manufacturer's instructions. During an interview on 02/26/18 at 11:55 a.m., the Laboratory Director and Testing Personnel #A stated that they did not know the procedure for calibration.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with Laboratory Director and Testing Personnel #A, the laboratory failed to perform quality control lot to lot comparison and to monitor quality control for shift and trends for two out of two years (2016-2017). Findings included: Quality control lot to lot comparison documentation was not available at the time of survey. During an interview on 02/26/18 at 11:55 a.m., the Laboratory Director and Testing Personnel #A stated they did not perform Quality control lot to lot comparison.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with Laboratory Director and Testing Personnel #A, the laboratory failed to monitor quality control for shift and trends for two out of

	two years (2016-2017). Findings included: Record review of the Levey-Jennings Chart report for Lot# 088700,Level High and WBC (White Blood Cell) analyte, Lot# 078700, Level Normal and RBC (Red Blood Cell) analyte, Lot#069500, Level High, and Lymphocyte number analyte showed a shift but documentation was not available that a corrective action occurred due to the shift. The laboratory's procedure manual for reviewing quality control over time stated "If upon review of the Levey-Jenning Chart report, there are errors found (meaning cell controls did not pass the required parameters)." During an interview on 02/26/18 at 11:55 a.m., the Laboratory Director stated they did not know to look for shifts and trends. The laboratory only looked for acceptable quality control.