Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0898079	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cpn, Inc Dba Ah Levine Children's Arboretum	7800 Providence Road, Suite 203, Charlotte, NC	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of Centers for Medicare & Medicaid Services (CMS)-209, and review of College of American Pathologists (CAP) proficiency testing (PT) records for 2019, 2020 and 2021 8/17/21, the laboratory failed to ensure PT was performed by testing personnel (TP) who routinely perform hematology testing. Findings: Review of CMS-209 submitted at time of survey revealed 12 TP routinely perform hematology testing. Review of laboratory procedure "Proficiency Testing" revealed "Proficiency Testing Participation:...Proficiency Testing is required for every moderately complex test. 1. For moderately complex tests, you receive five samples three times a year. That means you will receive 15 samples over a year's time....3. Per CLIA, 11-07, one person must run all five samples in that shipment." The procedure fails to ensure all TP who routinely perform hematology testing have the opportunity to participate in PT as required. Review of 2019, 2020 and 2021 CAP PT records revealed 1 TP (5 of 12 TP) participated in each of 5 PT events; the 3rd event of 2019, the 1st, 2nd and 3rd events of 2020 and the 1st event of 2021. 7 of 12 TP did not participate in the 5 PT events.
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 review of 2020 hematology quality control (QC) records 8/17/21 and email correspondence with technical consultant (TC) 8/19/21, the laboratory failed to use the manufacturer's established QC values for the ActDiff hematology analyzer from 5 /1/20 until 8/8/20, a period of approximately 3 months. Findings: Review of 2020 hematology QC records revealed the laboratory began using Lot #067500, 077500 and 087500 on 5/1/20. Review of QC records for Lot #067500, 077500 and 087500 revealed the laboratory entered the QC values established for the ActDiff2 hematology analyzer. Email correspondence with TC at approximately 3:30 p.m. confirmed incorrect QC values were entered. She also confirmed the laboratory uses an ActDiff hematology analyzer to perform testing.