Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1022550	05/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
South Pointe Pediatrics	1615 S Eucalyptus Ave Suite 210, Broken Arrow, OK	

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	The recertification survey was performed on 05/06/2022. The findings were reviewed with the laboratory director at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written procedures, and interview with the laboratory director, the laboratory failed to ensure two levels of quality control testing had been performed at least once a day when patient specimens were tested for one of six days. Findings include: (1) On 05/06/2022 at 10:45 am, the laboratory director stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Abbott Cell-Dyn 1800 analyzer; (b) Three levels (Low, Normal, and High) of Streck Para 12 Extend QC (Quality Control) material were performed each day of patient testing. (2) A review of the laboratory's written CBC procedure manual titled, "Policy: Procedure Manual" under the "Cell-Dyn Quality Control Corrective Action" stated: (a) "Anytime at least 2 levels of control are not within range for any analyte, patient results are not to be reported until the problem is corrected.". (3) A review of QC and patient records for testing performed between 01/07/2021 through 02/08/2021 revealed two of three levels of QC failed for one of six days of patient testing: (a) Hematocrit - Normal control failed QC on 01/07/2021 at 10:07 am (b) Hematocrit - High control failed QC on 01/07/2021 at 10:08 am (c) Patient #3127 was reported on

	01/07/2021 at 12:16 pm (4) The records were reviewed with the laboratory director who stated on 05/06/2022 at 12:57 pm, a patient was reported when two levels of control for Hematocrit were not within the acceptable range.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the technical consultant failed to ensure a semiannual evaluation for moderate complexity testing was performed for one of one testing persons. Findings include: (1) On 05/06/2022 at 10:45 am, the laboratory director stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Abbott Cell-Dyn 1800 analyzer. (2) A review of 2021 and 2022 personnel records for one person requiring a semiannual competency for the above testing, revealed the following: (a) Testing Person #1 - The initial training had been documented as performed on 04/01/2020. There was no evidence the semiannual competency had been performed (due 10/2020); (3) The findings were reviewed with the laboratory director who stated on 05/06/2022 at 11: 30 am the semiannual competency had not been performed as indicated above.