Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1022550	01/14/2020
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 01/14/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to have a written clinical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed personnel records for competency assessments performed during 2019 and to date in 2020. There was no evidence competencies had been performed for the clinical consultant based on their job responsibilities; (2) The surveyor asked the laboratory director if a written policy to evaluate the clinical consultant, based on job responsibilities, was available and if competencies had been performed during the review period. The laboratory director stated to the surveyor, a policy to evaluate the clinical consultant based on job responsibilities had not been written; and competencies had not been performed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

	laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to have quality control procedures that monitored the accuracy and precision of the analytic process for 3 of 3 lot numbers. Findings include: (1) At the beginning of the survey, the laboratory director stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Cell Dyn 1800 analyzer; (b) Three levels of Para 12 Extend (QC) quality control materials were tested each day patient testing was performed on the analyzer; (c) Prior to putting new lot numbers of controls into use, the laboratory established their own means for each analyte and used historic ranges to determine acceptability of control results. (2) The surveyor requested quality control records, to include Levey-Jennings graphs, for three lot numbers of control materials used from 08/07/2019 through 01/06/2020. The laboratory director provided Para 12 Extend peer group reports. The reports did not include the laboratory's established means and ranges for each analyte tested (e.g., White Blood Cell, Hemoglobin, Platelet, etc.), and therefore, the surveyor could not assess the acceptability of the results for the low, normal, and high QC materials over time using laboratory-established ranges, and determine how the laboratory monitored the results for shifts, trends, and/or biases; (3) The surveyor asked the laboratory director if Levey-Jennings graphs had been printed from the analyzer to assess the data using the laboratory-estalished ranges instead of comparing to the peer group. The laboratory director stated to the surveyor the laboratory did not print Levey-Jennings graphs and routinely reviewed the peer data on a monthly basis.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for establishing quality control means for 3 of 6 lot numbers. Findings include: (1) At the beginning of the survey, the laboratory director stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Cell Dyn 1800 analyzer; (b) Three levels of Para 12 Extend quality control materials were tested each day patient testing was performed on the analyzer. (2) The surveyor reviewed the manufacturer's instructions, contained in the operator's manual for the analyzer, which stated: (a) "New control material lots should be analyzed in parallel with current lots prior to their expiration dates" (b) "Run the new controls twice a day for five days" (c)

	"Use the mean of the 10 runs to verify that the new lot yields expected results" (d) "If the calculated mean falls within the range specified on the assay sheet, use it in place of the manufacturer's stated mean" (3) The surveyor reviewed quality control records for 6 lot numbers used from 08/07/19 through the day of the survey. For 3 of the lot numbers, the laboratory did not follow the manufacturer's instructions as follows: (a) For low control lot #91890422, normal control lot #91890423, and high control lot #91890424, the laboratory had established the means for the controls by running them 10 times on one day (07/25/19). (4) The findings were reviewed with the laboratory director, who stated the laboratory had tested the controls 10 times on one day instead of twice a day for five days as required by the manufacturer.