Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0930979	08/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southpoint Pediatrics	9071 S 1300 W #301, W Jordan, UT	

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**
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 Individual Quality Control Plan, (IQCP) review, lack of documentation, and interview with staff, the laboratory failed to document the director reviewed the IQCP to determine the IQCP (to perform quality control per lot number of Piccolo basic metabolic profile and hepatic function test cartridges received and once per month) was adequate quality control for detection of problems in the analytic system from 2017 to 2019. The laboratory performed approximately two hepatic function tests per day and one basic metabolic profile test per two weeks. Findings include: 1. The laboratory IQCP reviewed failed to include documentation the director reviewed the IQCP in conjunction with the monthly quality assessment review, proficiency testing records, and quality control records to ensure the reduced frequency of quality control (two level of quality control performed per lot number and monthly) was sufficient to identify basic metabolic profile and hepatic function test cartridge testing problems. 2. In an interview with the laboratory manager on 08/13/2019 at approximately 4:50 P. M. staff confirmed the laboratory director failed to document a review of the IQCP for 2017 and 2018.