Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0668450	11/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Willow Creek Pediatrics	7138 S 2000 E Ste 106, Salt Lake City, 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 patient test records review, quality control (QC) records review, lack of documentation, procedure manual review, and interview with the laboratory manager, the laboratory failed to follow their procedure to perform two levels of quality control each month and new lot number of test cartridges received for one of eleven tests reviewed. Findings include: 1. Patient test records review include the instrument print out for patient Number 536872 tested for total and direct bilirubin concentrations on 03/02/2019 using Piccolo cartridge lot number 8301AC3. 2. Q C records review failed to include documentation lot number 8301AC3 was checked using two levels of control prior to use. QC for February 2019 was performed using reagent cartridge lot number 8222BA3 and QC for March 2019 was performed using lot number 8222BA3. 3. Procedure manual review Individualized Quality Control Plan (IQCP) stated the laboratory performed reagent cartridge quality control monthly and with each new lot number of cartridges prior to testing patient samples. 4. In an interview with the laboratory manager on 11/05/2019 at approximately 3:45 P.M. the laboratory manager confirmed the lot number on the instrument printout did not have documentation qualify control was performed prior to performing patient testing.