Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2147391	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Purohit Pediatric Clinic Grandview	3686 Grandview Parkway, Birmingham, AL	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, a review of an IQCP (Individualized Quality Control Plan), quality control and installation records, patient logs, and an interview with Testing Personnel (TP) #1(also the Clinic Manager), the surveyor determined the laboratory failed to ensure an IQCP was established and implemented for this laboratory to include risk factors and mitigation of risks associated with this laboratory. The laboratory utilized its sister laboratory's IQCP, which was developed prior to the opening of this laboratory and prior to the establishment of any historical data related to factors, which may affect this laboratory. The findings include: 1. The initial certification survey was conducted on 10/24/2018. 2. A review of the installation records revealed the Reichert Unistat Bilirubinometer (Routine Chemistry testing) was installed in June of 2018. The laboratory's first patient specimen was tested in mid-July. 3. A review of the policy and procedure manual revealed quality control testing for the Bilirubinometer (Bilirubin) included two manufacturer cuvettes for high and low levels were tested daily. Two external liquid controls were tested at least once per month, based on an IQCP plan (see paragraph 4). 4. A review of the IQCP for Bilirubins revealed a page which referenced the use of the plan at two sister facilities. Further review revealed

	the Laboratory Director signed the plan, dated 10/01/2017, one year prior to this laboratory's opening. 5. At 11:06 AM on 10/24/2018, the surveyor asked TP #1 if the same exact plan was utilized at the other two facilities. TP #1 answered yes the plan was the same one. When asked, TP #1 stated no historical data had been established for this laboratory at the time of opening to develop an IQCP. Thus, the elements of risk (Testing Personnel, Environment, Reagents, Test System and Specimen) were considered in general terms, and not unique to this laboratory. The surveyor discussed with the testing personnel the possibility of these elements being affected differently by factors which may be unique to this site, or at least different (such as ability of testing personnel to perform, environmental factors, the test system, etc. 6. A review of the quality control records revealed the external controls, two levels, were being tested once per month. 7. The patient logs revealed 9-10 patients had been tested from July - October 24, 2018. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor