Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0663184	03/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Physicians To Children Llc	6920 Nervia St, Coral Gables, FL	

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	An announced CLIA recertification survey was conducted at Physician to Children LLC on 03/17/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 Analytic Systems 493.1250
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Testing Person, the laboratory failed to use positive and negative controls each day of use for ABO Group and Rh testing and Throat culture testing for 2 (2018-2020) out of 2 years reviewed (See D5449).
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and interview with the Testing Person, the laboratory failed to use positive and negative controls each day of use for ABO Group and Rh testing and Throat culture testing for 2 (2018-2020) out of 2 years reviewed. Findings Included: 1. Review of the manufacturer's instruction for ABO Group and Rh manual slide testing controls revealed that "It is recommended that these reagents be tested on each day of use with appropriate positive and negative controls. Positive control-redblood cells known to possess the antigen toward which the reagent is directed. Group A, B red blood cells are considered an appropriate control. Negative control-red blood cells known to lack the antigen toward which the reagent is directed." The policy (last signed by the Laboratory Director on 03/03/20) stated that each day of testing "Personnel with known blood type/Rh will be used as fresh controls." Each day of testing only 1 Personnel's blood was used for controls, this does not meet the requirement of a positive and negative each day of testing as each Personnel only has 1 type of blood (for example A negative, A positive, O negative, etc.). Review of Patient logs from 08/31/18 revealed that each day of patient testing only 1 Personnel's blood was used for controls. Interview on 03/17/19 at 1:00 PM the Testing Person confirmed that 2 levels of control were not performed each day of patient testing. The laboratory does 25 patient test a year. 2. Review of the manufacturer's instruction for Throat cultures revealed that "Recommended organism strain for User Quality Control" is to plate 1 plate with "Streptococcus pyogens" and it will have heavy growth, and "Staphylococcus aureus" which will have complete inhibition. Review of Quality Control records revealed no positive or negative controls done for the plates used for Throat cultures. Interview on 03/17/20 at 2:45 PM the Testing Person revealed that they did not do a positive and negative control each day of testing and no IQCP had been performed.