Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0663184	06/09/2022
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	A recertification survey conducted from 06/01/2022 to 06/09/2022 found the PHYSICIANS TO CHILDREN LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition was cited: - D3000 FACILITY ADMINISTRATION.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain copies of the testing results (instrument printouts) and attestation from the proficiency testing (PT) for one out of six events for the specialty of Hematology (2020-2022). Findings include: -Review of American Academy of Family Physicians (AAFP) PT records for Hematology specialty in 2020 (second and third event), 2021 (first, second and third event) and first event of 2022 revealed that: -The laboratory failed to have an attestation signed by testing personnel (TP) and laboratory director (LD) and failed to have the instrument printouts for the first event of 2022. During an interview on 06/01 /2022 at 01:30 PM, the LD confirmed that the laboratory failed to have the documents listed above for the event of reference.

D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on records review and interview with Laboratory Director (LD), the laboratory failed to report SARS-COV-2 Antigen test results as required to Florida Department of Health (FDOH) since testing began on 02/07/2021. Findings include: -Review of Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS- 116) signed by the Laboratory Director on 05/31/2022, revealed that the laboratory performed Status COVID-19 Antigen/Flu A/B test to detect SARS CoV-2 Antigen. -Review of SARS CoV Antigen testing records revealed that the laboratory started testing with Care Start COVID-19 Antigen test on 02/07/2021, Quidel QuickVue on 09/09/2021 and Status COVID-19 Antigen/Flu A/B test from 01/04 /2022. The laboratory performed 600 tests with 72 tests results positive from 02/07 /2021 to 06/01/2022 -The laboratory had no records of reporting test results to the FDOH. During an interview on 06/01/2022 at 1:30 PM, the LD confirmed the laboratory was not reporting results to FDOH for SARS CoV-2 test results from 02/07 /2021 to 06/01/2022 and the testing volume for this period was as listed above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of records and testing personnel (TP) # B interview, the laboratory failed to document all required maintenance performed to the Sysmex XP-300 analyzer from 03/18/2020 to present. Findings include: Based on Sysmex XP-300 analyzer user manual, the laboratory had to perform daily, weekly, monthly and every three months maintenance actions. The laboratory had no records to document the maintenance actions required as per manufacturer instruction from 03/18/2020 to 06 /01/2022. During an interview on 06/01/2022 at 01:00 PM, the TP # B confirmed that there was no documentation of all required maintenance for the period of reference.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform

	test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with Laboratory Director /Technical Consultant revealed that he failed to perform initial competency evaluation for testing personnel (TP) # B. Findings include: - Review of the CMS-209 form Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 06 /01/2022 revealed that the laboratory had two TP (A and B). -TP B started in December 2021, the laboratory had no records of the initial competency evaluation completed for the staff. During an interview on 06/01/2022 at 12:30 PM, with LD, he confirmed that there was no initial competency evaluation for TP B.