Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0680711	05/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Nicklaus Children's At Galloway	7800 Sw 87th Ave Ste C350, Miami, 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 was conducted on May 17, 2022. South Florida Pediatrics Partners clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have all testing personnel rotate through performance of proficiency testing (PT) samples for four (2020 2nd, 2021 1st, 3rd, 2022 1st) of six events (2020 2nd, 3rd, 2021 1st, 2nd, 3rd, 2022 1st) for the specialty of hematology. Findings: Review of the American Academy of Family Physicians (AAFP) PT attestations for hematology showed Testing Personnel B performed the PT for the 2020 2nd event, 2021 1st and 3rd events, and 2022 1st event. Review of the AAFP PT records for hematology testing listed the following submission deadlines: 2020 2nd event 06/24/2020 2020 3rd event 10/28/2020 2021 1st event 04/02/2021 2021 2nd event 06/30/2021 2021 3rd event 10 /27/2021 2022 1st event 03/30/2022 Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 08/17/2020 for the survey on 08/18 /2020, listed four Testing Personnel (A, B, C, D). Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 05/10/2022 for the survey on 05/17/2022, listed two Testing Personnel (A, B). Testing Personnel A and B were currently employed at the laboratory and had competency evaluations performed on 09 /15/2020, 03/20/2021, 09/20/21, and 03/21/2022. Testing Personnel C and D are no longer employed by the laboratory and had competency evaluations performed on 09 /15/2020, 03/20/2021, and 09/20/21. On 05/17/2022 at 11:17 AM, Testing Personnel

	B acknowledged she had performed four of the six proficiency testing. On 05/17/2022 at 1:40 PM, Testing Personnel B stated Testing Personnel C left in February 2022 and Testing Personnel D left in October 2021.
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 interview, the laboratory failed to have maintain copies of the testing results (instrument printouts) from the proficiency testing (PT) for four (2020 2nd, 3rd, & 2021 2nd, 3rd) of six (2020 2nd, 3rd, 2021 1st, 2nd, 3rd, & 2022 1st) events for the specialty of hematology. Findings: Review of the American Academy of Family Physicians (AAFP) PT records showed the instrument printouts from the Beckman Coulter ACT diff 2 hematology analyzer for the 2020 2nd and 3rd events, and the 2021 2nd and 3rd events were missing. On 05/17/2022 at 11:15 AM, Testing Personnel B stated she did not know they needed to keep the instrument printouts.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain Quality Control (QC) documents (background counts and daily controls) for six of six patient (#1, #2, #3, #4, #5, #6) testing dates reviewed. Findings: Review of QC for the background checks and daily controls (low, normal, high) run on the Beckman Coulter AcT diff 2 hematology analyzer revealed the background counts and/or daily controls were missing. Patient #1 had a complete blood count (CBC) on 03/01/2021, no background counts or daily controls were available for review. Patient #2 had a complete blood count (CBC) on 04/07/2021, no background counts were available for review. Patient #3 had a complete blood count (CBC) on 09/17/2021, no background counts or the low and high daily controls were available for review. Patient #4 had a complete blood count (CBC) on 01/28/2022, no background counts or daily controls were available for review. Patient #5 had a complete blood count (CBC) on 02/23/2022, no background counts or daily controls were available for review. Patient #6 had a complete blood count (CBC) on 03/02/2022, no background counts or daily controls

	were available for review. On 05/17/2022 at 1:30 PM Testing Personnel B stated she did not know where the missing background counts and daily controls were located.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to perform calibration on the Beckman Coulter AcT diff 2 hematology analyzer at least once every 6 months from 06/17/2021 to 05/17/2022. Findings: Review of the operations manual for the Beckman Coulter AcT diff 2 hematology analyzer noted "Coulter recommends that you calibrate your instrument according to the regulations required by your inspecting agency." Review of the laboratory's calibration documentation on the hematology analyzer showed the last calibration was completed on 06/16/2021. No other documentation of calibrations performed after 6/16/2022 were available for review. On 05/17/2022 at 12:20 PM, Testing Personnel B stated a calibration was performed in December of 2021 and that she was unable to find the calibration documentation.