Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0680711	10/03/2018
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to follow manufacturer's instructions of performing quality control. There is no documented record of quality control for the following waived tests: 10SG Urine Reagent Strips (URS), respiratory syncytial virus (RSV) in nasal swabs, human chorionic gonadotropin (hCG) in urine, Streptococcus (Strep) A antigen for throat swabs, Infectious Mononucleosis (IM) in whole blood test from 2016 to 2018. Findings include: Record review from 2016 to 10/2/2018 showed that the laboratory was not following manufacturer instructions of performing quality control for the following waived tests: - URS test, manufacturer instructions stated that user should do confirmation of performance of reagent strips by testing known positive and negative specimen with each new lot, each new shipment of strips, when new bottle opened, when strips stored for more than a month, training of new staff. -RSV test, manufacturer instructions stated to record daily quality control and to test external positive and negative control for each new shipment received. -Urine hCG test, as per manufacturer instructions it is recommended that a positive and negative control tested to verify a proper test performance with each new lot, each new shipment, monthly as a check to storage, each new untrained operator. -IM test, as per manufacturer instruction recommends the periodic use of external control materials to ensure proper kit performance -Strep A test, as per manufacturer instructions it is recomended that a positive and negative external control be run per kit During an

	interview on 10/02/2018 at 12:30 pm, the office manager confirmed that the laboratory was not documenting quality control on the waived tests listed above for the period of reference.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of AAFP (American Academy of Family Physicians) proficiency testing records and interview with laboratory director, the laboratory failed to have a passing score for 2 out of 8 event for the specialty of hematology. Findings include: Review of AAFP proficiency records revealed that the laboratory failed second event of 2016 with 0 % score due to failure to report and second event of 2018 with 27 % score. During an interview on 10/02/2018 at 12:30 PM, the laboratory director confirmed that the laboratory failed the 2 events of reference.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with Office Manager (OM), the laboratory failed to perform the annual competency assessment on 3 out of 3 testing personnel since at least 2016. Findings include: Review of employee documentation found no competency evaluations on testing person #A to #C for the year 2016 to 2018. During an interview on 10/02/2018 at 12:30 PM, the OM confirmed that there were no competencies performed on the employees listed above for the years of reference.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of quality assurance policy, laboratory records from 2016 to 2018 and interview with Office Manager (OM), the laboratory failed to document the quality assurance (QA) activity during the years 2016, 2017, 2018. Findings include: Review of quality control records revealed that there was no documentation of the QA

	activity during the years 2016 to10/2/ 2018. During an interview on 10/02/2018 at 12: 30 PM, the OM confirmed there were no records of QA activity records for the years of reference.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality assurance policy and laboratory records from 2016 to 2018 and interview with Laboratory Director (LD), the laboratory director failed to document the quality assurance (QA) activity during the years 2016, 2017 and 2018. Findings include: Review of quality control records revealed that there was no documentation of the QA activity during the years 2016 to 2018. During an interview on 10/02/2018 at 12:30 PM with the LD, he confirmed that there were no records of QA activity for the years of reference. Refer to 5293
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 from 2016 to 2018 and interview with Office Manager (OM), revealed that the technical consultant failed to perform annual competency assessment for the testing personnel during for 2016, 2017 and 2018. Findings include: Review of personnel records revealed that there were no annual competency evaluations for 3 out of 3 testing person during the years 2016 to 2018. During an interview on 10/028/2018 at 12:30 PM the OM confirmed there were no records of annual competency evaluation for the 3 testing person for the years of reference. Refer to 5209