Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2089215	12/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Robyn Jacobson Pediatrics Pllc	3910 Northdale Blvd Ste 204, Tampa, 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
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 the Office Manager, the laboratory failed to perform competency assessments on 2 (#A and #B) out of 2 Testing Personnel. Findings Included: Review of the policy and procedure (last reviewed by the Laboratory Director on 09/21/15) states that "After initial competency assessment at the completion of orientation and training, competency assessments will occur at 6 months, 12 months and annually thereafter." Review of Testing Personnel #A and #B revealed no competency assessment in their personnel files. During an interview on 12 /06/18 at 11:30 AM the Office Manager confirmed that there was no documentation of competency assessments on Testing Personnel #A and #B.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #A the laboratory failed to document the temperature of the refrigerator that the controls are kept in and the room humidity for 2 (2017-2018) out of 2 years reviewed. Findings Included: Review of the manufacturers instructions for the hematology analyzer revealed that the controls should be between 2-8 degrees Celsius and the humidity of the room where the hematology analyzer is should be between 30%- 85%. Review of temperature charts revealed no temperature chart for the refrigerator that the controls were kept in and no humidity charts. During an interview on 12/06/18 at 12:20 PM Testing Personnel confirmed that it was not documented.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #A the laboratory failed to monitor their quality control over time for shifts and trends for 2 (2017-2018) out of 2 years reviewed. Findings Included: Review of the policy and procedures (last reviewed by the Laboratory Director on 09/21/15) stated under Quality Control Graphs and Shifts and Trends that "These graphs illustrate a method's accuracy and precision over time." It also states "it is necessary to evaluate a trend to eliminate the possibility of reporting erroneous result." During an interview on 12/06/18 at 12:30 PM Testing Person #A revealed that even though it is looked at daily, quality control is not looked at over time for shifts and trends.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #A the laboratory failed to verify new lot numbers of quality control material when in use for 2 (2017-2018) out of 2 years reviewed. Findings Included: Review of policy and procedure (last reviewed by the Laboratory Director 09/21/2015) states that when changing lot numbers of quality controls "The established means must be verified and adjusted to facility specific data, as necessary: Each level of the new control material must be evaluated 5 times, with alternating personnel and on multiple days when possible, to verify that control results fall within manufacturer stated 2SD ranges. Results may be compared against those found with in the package insert and filed in the quality control binder, or documented on the chart template, to show acceptability of new lot control material." During an interview on 12/06/18 at 12:30 PM Testing Person#A confirmed that this procedure was not being performed.