Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1002868	03/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Preferred Pediatrics Llc	142 Rue Marguerite, Thibodaux, LA	

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 Certification Survey was performed on March 13, 2019 at Preferred Pediatrics, LLC, CLIA ID # 19D1002868. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to follow their established policy for Complete Blood Count (CBC) flags. Findings: 1. Review of the laboratory's "Patient Flag" policy for CBC testing revealed the following: a) "1, 2, 3, 4, M: Action: 1. Wait 10-20 minutes mix/rerun" b) " *: Action: 1. Wait 10-20 minutes mix/rerun" 2. Review of random selection of final test reports with CBC flags from February 28, 2019 through March 4, 2019 revealed the laboratory did not have documentation that the following five (5) of five (5) patient samples were retested: February 28, 2019: Patient 1 with the following flags: LY: *L, MO: *, GR: *H, LY #: *, MO#: *H, GR#: *H March 1, 2019: Patient 2 with the following flags:MO: 3, GR: 3, MO#: 3, GR#: 3 March 1, 2019: Patient 3 with the following flags: LY:2, MO:2, GR: M, LY#: 2, MO#:2, GR#: M March 4, 2019: Patient 4 with the following flags: MO: M, GR: M, MO#: M, GR#: M March 4, 2019: Patient 5 with the following flags: MO: M, GR: M, MO#: M, GR#: M 3. In interview on March 13, 2019 at 10:46 am, Personnel 2 stated the laboratory did not have documentation that the identified samples were retested. Personnel 2 further stated the laboratory repeats any patient sample that has a CBC flag and maintains the retested results in the patient's chart. Personnel 2 stated if flags remain, the laboratory writes the action taken on the report.

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 observation, record review, and interview with personnel, the laboratory failed to monitor the temperature of the room where laboratory reagents are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on March 13, 2019 revealed the laboratory did not monitor the temperature of the room where the following laboratory reagents are stored: a) Osom Ultra Flu A and B test, Lot # 448M21A, Quantity: six (6) boxes b) Quickvue RSV, Lot # 704491, Quantity: ten (10) boxes c) One Step Plus Strep A Dipstick, Lot # STA810032, Quantity: fourteen (14) boxes 2. Review of the manufacturer requirements for the identified items revealed the following: a) Osum Ultra Flu A and B: storage requirement 2-30 degrees Celsius b) Quickvue RSV: storage requirement 15-30 degrees Celsius c) One Step Plus Strep A Dipstick: storage requirement 2-30 degrees Celsius 3. In interview on March 13, 2019 at approximately 10:20 am, Personnel 2 stated the laboratory does not monitor the temperature of the area where the identified supplies are stored.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to follow their established policy for Complete Blood Count flags. Refer to D5401. 2. The laboratory failed to monitor the temperature of the room where laboratory reagents are stored per manufacturer requirements. Refer to D5413.