Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2123321	11/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Serenity Pediatrics	71 E Long Lake Road, Bloomfield Hills, MI	

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
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 Testing Personnel #1 (TP1), the laboratory failed to establish a procedure for performing Complete Blood Counts (CBC) for 20 (March 2018 to November 2019) of 20 months reviewed. Findings include: 1. A review of the laboratory's established procedure manual revealed a lack of written procedures to perform CBC testing. 2. An interview on 11/21/19 at 10:20 am with TP1 confirmed the laboratory had not established a CBC procedure to be used by testing personnel.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to establish a control procedure and corrective action procedure to use when control results fail for 20 (March 2018 to November 2019) of 20 months reviewed. Findings include: 1. A record review of the laboratory's established procedure manual revealed a lack of control procedures or corrective action to take when control results fail for Complete Blood Count (CBC) testing. 2. A record review of quality control results revealed the following: a. On 4/5/18, Level L control had "X" flags and was not resolved. b. On 5/21/18, Level H control was out of range for White Blood Cells (WBC), and was not resolved. 3. An interview on 11/21/19 at 11: 07 am with TP1 confirmed the laboratory had not established a control procedure and a corrective action procedure to use when control results fail.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . A. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to provide reference intervals on test reports for 10 (patients #1-10) of 10 patient charts audited. Findings include; 1. A record review of patient charts from the laboratory's electronic medical record system revealed the following tests were entered in Complete Blood Count (CBC) final test reports without a corresponding reference interval for patients #1-10: a. Lymphocyte percentage b. Monocyte percentage c. Granulocyte percentage d. Absolute Lymphocyte count e. Absolute Monocyte count f. Absolute Granulocyte count g. Red Blood Cell count (RBC) h. Mean Corpuscular Hemoglobin (MCH) i. Red Blood Cell Distribution Width (RDW) j. Mean Platelet Volume (MPV) 2. An interview on 11/21/19 at 10:40 am with TP1 confirmed the electronic medical record report CBC results did not contain reference intervals for the analytes listed above. B. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure reference intervals for Complete Blood Count (CBC) testing were consistent between the analyzer reports and the electronic medical record (EMR) reports for 10 (patients #1-10) of 10 patient charts audited. Findings include: 1. A record review of patient charts revealed discrepancies between the scanned analyzer report reference intervals and the EMR reference intervals for patients #1-10 for the following analytes: a. White Blood Cell count i. EMR: 5- 12 x 10/uL ii. Analyzer: 4.5- 10.5 x 10^3/uL b. Hemoglobin (HGB) i. EMR: 11- 15 g/dL ii. Analyzer: 11- 18 g/dL c. Hematocrit (HCT) i. EMR: 34.1- 60.0% ii. Analyzer: 35- 60% d. Mean Corpuscular Volume (MCV) i. EMR: 75- 95 fL ii. Analyzer: 80- 90 fL e. Mean Corpuscular Hemoglobin

	Concentration (MCHC) i. EMR: 30- 35% ii. Analyzer: 33- 37% f. Platelet count i. EMR: 200- 400 x10/uL ii. Analyzer: 150- 450 x 10^3/uL 2. An interview on 11/21/19 at 10:40 am with TP1 revealed providers in the office use the analyzer printout information for their patients, but may fax out the EMR information if requested by an authorized person. 3. An interview on 11/21/19 at 10:40 am with TP1 confirmed the two reports had discrepancies in the reference intervals listed for the analytes listed above.