Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1100997	(X3) Date Survey Completed 02/08/2018
Name of Provider or Supplier Legacy Point Family Medicine	**Street Address, City, State** 81 North 2000 West, Ste F2, West Point, UT	

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
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 procedure manual review, lack of documentation, and interview with the director, the procedure manual for 1 of 1 non-waived tests performed (complete blood count {CBC} testing performed on the Horiba Micros 60) failed to include 7 required elements. The laboratory began testing in August of 2017 and performs approximately 60 CBCs a month. Findings include: 1. The laboratory lacked a written CBC procedure manual and used the manufacturer's instructions for use as their test reference material. 2. The manual supplied by the manufacturer did not include: the requirements for specimen collection, labeling, storage, and referral; control

	procedures; corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; the laboratory's normal value ranges; panic or alert values; the laboratory's system for entering results in the patient record, including the protocol for reporting imminently life-threatening results (panic values); and the course of action to take if a test system becomes inoperable. 3. The director stated on 02/07/2018 at approximately 12:00 p.m. the laboratory didn't have a laboratory specific procedure manual and their only reference material was the manufacture's instructions for use.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of Horiba Micros 60 instructions for use and interview with the director, the laboratory director failed to sign and date as approved the procedure manual for 1 of 1 non-waived tests performed (complete blood count {CBC} testing on the Micros 60). Findings include: 1. The laboratory director stated on 02/07/2018 at approximately 12:00 p.m. the laboratory used the manufacturer's instructions for use as their procedure manual for CBC testing on the Micros 60 and did not have a laboratory specific manual. 2. The director failed to sign and date as approved the manufacturer's instructions for use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for use for the Horiba Micros 60, maintenance record review, and interview with the director, the laboratory failed to perform and document 2 of 2 manufacturer's required daily maintenance procedures (Start Up and Shut Down) each day of testing for 6 of 6 days of testing reviewed. Finding include: 1. The manufacturer's instructions for the Micros 60 used for complete blood count testing states to perform daily Start Up and Shut Down procedures. 2. Maintenance records failed to include documentation of Start Up performance for 2 of 6 days of testing reviewed (11/22/2017 and 12/07/2017). 3. Maintenance records failed to include documentation of Shut Down procedures for 6 of 6 days of testing reviewed (09/15/2017, 10/23/2017, 11/22/2017, 12/07/2017, 12/20/2017, and 02/06/2018). 4. The director stated on 02/07/2018 at approximately 1:00 p.m. the laboratory did not document Shut Down procedures and staff were not consistent about documenting daily instrument Start Up procedures.