Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2201457	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Samaritan Family Care	713 N Broadway Street, Ste 301a, Paintsville, KY	

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	An initial certification survey was conducted on 10/20/2022, and the facility was found not to be in compliance with the laboratory requirements at 42 CFR, Part 493.
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 observation, document review, and interview, the laboratory failed to ensure its procedure manual included the course of action to take if test systems became inoperable for one (1) of one (1) nonwaived test performed. The findings include: A review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116)," completed and signed by the laboratory director and

	dated 10/20/2022, indicated the laboratory performed approximately seven (7) complete blood counts (CBCs) per year. A review of the laboratory's procedure manual, dated 07/28/2020, revealed it did not include written instructions for staff to follow if the CBC analyzer was inoperable. Observation during a laboratory tour, on 10/20/2022 at 9:10 AM, revealed a Sysmex XP-300 analyzer [an automated hematology (study of blood and blood disorders) analyzer]. The Laboratory Supervisor stated CBC testing was performed on the analyzer, and the laboratory began CBC testing in 01/2021. Interview with the Laboratory Supervisor, on 10/20 /2022 at 12:00 PM, revealed that a phlebotomist would collect and send samples to the hospital laboratory if systems or instruments became inoperable. The Laboratory Supervisor further stated this policy was not a written policy, and it was not included in the laboratory's procedure manual.
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 interview and document review, the laboratory failed to verify new lot numbers of EightCheck 3WP X-tra (the commercial name of the quality control material used by the laboratory) complete blood count (CBC) controls for six (6) of six (6) lots reviewed in 2021 and 2022. The findings include: A review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116)," completed and signed by the laboratory director and dated 10/20 /2022, revealed the laboratory performed approximately seven (7) CBCs per year. A review of the laboratory's procedure manual, dated 7/28/2020, revealed "Parallel test new controls by analyzing the three (3) levels of control a minimum of twice a day for five (5) days prior to expiration of the previous lot. After a minimum of ten (10) data points are accumulated and values are running within assay ranges, the lot may be placed into production. The new lot will be validated prior to the current lot expiration. A review of CBC quality control records revealed parallel testing was not performed for the six (6) lots listed: a. Lot number 113807, expiration date 08/25 /2021; put into use on 06/09/2021 b. Lot number 122207, expiration date 11/17/2021; put into use on 08/23/2021 c. Lot number 130607, expiration date 02/09/2022; put into use on 11/18/2021 d. Lot number 202507, expiration date 05/04/2022; put into use on 02/07/2022 e. Lot number 210907, expiration date 07/27/2022; put into use on 05/06/2022 f. Lot number 219307, expiration date 10/19/2022; put into use on 07/26 /2022 Interview with the Laboratory Supervisor, on 10/20/2022 at 10:35 AM, revealed the parallel testing to verify a new lot of CBC controls was not performed.

D6006	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(d) 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. (d) Each individual may direct no more than five laboratories. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to ensure the laboratory director was not the director of more than five (5) nonwaived certified laboratories. The findings include: A review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116)," completed and signed by the laboratory director and dated 10/20/2022, revealed the laboratory director also served as the laboratory director for five (5) additional laboratories, each with their own separate certification. Interview with the Laboratory Supervisor, on 10 /20/2022 at 11:30 AM, revealed the laboratory director was the laboratory director at six (6) locations, which was more than the five (5) allowed per the regulation.