Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2285228	05/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Agatha Bogard, Md	7940 W N Avenue, Kalamazoo, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to enroll in a proficiency testing program for cell identification and leukocyte differential for 11 (June 2023 to May 2023) of 11 months since the laboratory started performing cell identification and leukocyte differential patient testing. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of enrollment in a proficiency testing program for its cell identification and leukocyte differential testing in the specialty of hematology. 2. An interview on 5/29/24 at 9:14 am with the Laboratory Director confirmed the laboratory was not enrolled in proficiency testing for cell identification and leukocyte differential.
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 Laboratory Director, the laboratory failed to establish a competency assessment policy for testing personnel for 11 (June 2023 to May 2023) of 11 months since the laboratory started performing testing. Findings include: 1. A review of the laboratory's personnel records revealed a lack of competency assessment performed for Testing Personnel #1 performing high complexity cell identification and leukocyte differential testing. 2. A review of the laboratory's "Qualifications" policy revealed a lack of competency assessment policy for testing personnel. 3. An interview on 5/29/24 at 10:50 am with the Laboratory Director confirmed a competency assessment policy was not established for testing personnel.
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 record review and interview with Laboratory Director, the laboratory failed to ensure procedure manuals were signed and dated by the laboratory director prior to testing patients for 11 (June 2023 to May 2023) of 11 months since the laboratory started performing testing. Findings include: 1. A review of the laboratory's procedure manual revealed that a laboratory director signature or date was not present for all procedures. 2. An interview on 05/29/2024 at 9:21 am with Laboratory Director confirmed the policies and procedures had not been approved, signed, and dated.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with Laboratory Director, the laboratory failed to include the laboratory address on the test report for 1 (Patient 1) of 6 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed a lack of the laboratory name on the test report for Patient 1 receiving testing on 8/3/23. 2. An interview on 5/29/24 at 9:36 am with the Laboratory Director confirmed that the laboratory address was missing from test report.