Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0957619	(X3) Date Survey Completed 04/15/2024
Name of Provider or Supplier William H Freeman, Md, Pa	**Street Address, City, State** 600 Club Lane, Conway, AR	

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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Through a review of patient final reports and through interviews with laboratory staff, it was determined the laboratory failed to document the time it receives a specimen in the laboratory. Survey findings include: A. Through a review of patient final reports it was determined that three of three patient complete blood count final reports failed to include the date or time the laboratory collected or received the patient specimen. B. A review of the patient final report January 2022 through March 2024 revealed that the final reports did not include the time of collection or receipt of the specimen into the laboratory. C. In an interview, at 2:10 p.m. on 4/15/2024, testing personel #1 (as listed on the form CMS-209) confirmed the laboratory failed to document the time of collection of laboratory specimens.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, lack of documentation, as well as interview with staff, it was determined the laboratory's procedure manual failed to include a procedure for anomalies and or abnormal

	distributions signaled by the instrument for Hematology tests performed in the laboratory. As evidenced by: A. A review of the laboratory policy and procedure manual revealed in Section 9 titled Parameter and System Information Message, Section Abnormalities states "Follow your laboratory's protocol for verification on all samples with anomalies and / or abnormal distributions signaled by the instrument. Pathological cells may vary in the stability towards lysing of their cytoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments." B. The surveyor requested the laboratory's protocol or policy for verification on all samples with anomalies and or abnormal distributions signaled by the instrument none was provided. C. In an interview on 4/15/2024 at 11:23 a.m., the testing personnel #1 (as listed on form CMS-209), confirmed the Policy and Procedure Manual did not include a procedure for anomalies and or abnormal distributions signaled by the instrument for Complete Blood Counts.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through review of package inserts, observation, and interview it was determined that the laboratory did not change expiration dates on control materials after opening as required by manufacturer. Finding follow: A) Review of the package insert for Boule Con-Diff Trilevel hematology controls revealed that the product expires in fourteen days after vial is opened and the expiration dates should be changed as required after opening. B) On 4/15/24 at 2:10 p.m. the surveyor observed three vials of Boule Con-Diff Trilevel hematology controls lot numbers 22312-31, 22312-32, and 22312-33 with expiration date 5/14/2024 in current use without a date of when the controls were opened or amended expiration written on the vials. C.) In an interview on 4/15/2024 at 2:25 p.m. laboratory testing personnel #1 on form CMS 209, confirmed that no dates were written on the vials when the controls were put into use and, when asked when the control material was put into use, stated that she most always forgets to put open /use date on the hematology controls.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

	review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Base on review of the CMS-209 form presented at the time of the survey, a review of personnel records for three personnel listed on the form CMS-209, and through interviews with laboratory staff, it was determined three of three testing personnel failed to have written authorization to perform testing without direct supervision. Survey findings include: A. Through a review of the CMS- 209 form, it was determined that three persons was designated as testing personnel. B. A review of personnel records for three personnel listed on the form CMS-209 revealed that three of three testing personnel failed to have written authorization to perform testing without direct supervision. Laboratory testing personnel (TP) # 1, TP #2, and TP #3 did not have a written authorization to perform testing without direct supervision. C. In an interview at 10:10 a.m. on 4/15/2024, Testing Personnel #1 (listed on the form CMS-209) confirmed that the laboratory did not have documented authorization for testing for employees performing testing.