Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0707888	(X3) Date Survey Completed 12/17/2020
Name of Provider or Supplier Alfred B Rosenstein Md	**Street Address, City, State** 4000 Old Court Road Suite 205, Baltimore, MD	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the federal proficiency testing (PT) data report and review of the comparative evaluation summary from the American Association of Bioanalysts (AAB) PT program, the laboratory failed to successfully participate in the AAB PT program for hematology testing, in which the laboratory is certified under CLIA (D2130).
D2121	HEMATOLOGY CFR(s): 493.851(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing (PT) data report and review of the comparative evaluation summary from the American Association of Bioanalysts (AAB) PT program, the laboratory failed to attain a score of 80% for each analyte in the AAB PT program for hematology testing. The following analyte was noted as failed in the 2020 1st event. Findings: 1. AAB 2020 1st event White Blood Cells 60%
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing (PT) data report and review of the comparative evaluation summary from the American Association of Bioanalysts (AAB) PT program, the laboratory failed to achieve satisfactory performance for the same analyte in 2 consecutive hematology testing events. The following analyte was noted as failed in the 2020 2nd and 3rd events. Findings: 1. AAB 2020 2nd event Cell Identification or White Blood Cell Differential 60% 2. AAB 2020 3rd event Cell Identification or White Blood Cell Differential 73%
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the federal proficiency testing (PT) data report and review of the comparative evaluation summary from the American Association of Bioanalysts (AAB) PT program, the laboratory director failed to ensure that the laboratory successfully participated in the AAB PT program for hematology testing, in which the laboratory is certified under CLIA (D6019).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing (PT) data report and review of the comparative evaluation summary from the American Association of Bioanalysts (AAB) PT program, the laboratory director failed to ensure that an approved corrective action plan was followed when PT results in hematology were found to be unsatisfactory. Refer to D2121 and D2130. Findings: 1. AAB 2020 1st event White Blood Cells 60% 2. AAB 2020 2nd event Cell Identification or White Blood Cell Differential 60% 3. AAB 2020 3rd event Cell Identification or White Blood Cell Differential 73%