Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0558190	09/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Boris Ratiner Md Inc	18386 Ventura Blvd, Tarzana, CA	

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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 the survey on September 19, 2024, a review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the technical consultant (TC), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for alanine aminotransferase (ALT) analyte in 2023. The findings include: 1. Based on review of PT records for the first event of 2023 (Q1-2023), API reported an unsatisfactory score report as follows: ALT PT Q1-2023 Overall score: 60% Specimen Reported Expected CHM-01 *26 13 - 21 CHM-02 *27 10 - 17 CHM-03 247 199 - 300 CHM-04 93 69 - 104 CHM-05 182 144 - 218 2. The TC affirmed by interview on September 19, 2024, at approximately 10:30 a.m. that the laboratory obtained the PT scores mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 15,470 Routine Chemistry test samples, including ALT analyte, during the time the laboratory had unsatisfactory proficiency testing results.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the lack of the laboratory's verification of performance documentation for moderate complexity testing for Cell Blood Count (CBC), interviews with the technical consultant (TC) and testing personnel (TP), and review of nine (9) randomly selected patient test records, the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings include: 1. Based on the review of laboratory records on September 19, 2024, the laboratory had no documentation to show for the verification of performance for CBC using the Cell-dyn instrument when it was acquired in 2022. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics and those to be approved by the laboratory director before starting testing patients' samples: (A) Accuracy (B) Precision (C) Reportable range (D) Reference Range 2. Based on the interviews with the TC and TP, no method correlation was performed for Horiba, the old Hematology instrument, as it was unusable. The facility acquired Cell-dyn as a replacement in 2022 but was unable to find the documentation during the survey. 3. Based on the review of two out of nine patient test records, the CBC results reported couldn't be assured due to the missing documentation for the verification of performance for the Hematology analyzer, Cell-dyn. 4. The TC and TP affirmed at the time of the survey on September 19, 2024, at approximately 10:45 a.m. that no binder or documents could be retrieved to show that performance specifications were performed prior to reporting patient test results when the laboratory went live testing and reporting CBC tests. 5. Based on the laboratory testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 14,200 CBC tests. Thus, the precision and accuracy of the reported test results could not be assured.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on survey findings on September 19, 2024, review of proficiency testing records, and interview with the technical consultant, the laboratory director is herein cited for the deficient practice in providing overall technical oversight for ALT testing. See D2087.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the deficiency cited (D5421), the laboratory director is herein cited for deficient practice in ensuring test system verification procedures were compliant with the regulations at 493.1253(b)(1) before the laboratory personnel was allowed to test patients' samples without confirming the manufacturer's performance specifications.