Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0558190	01/14/2019
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
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 third quarter (Q3-2017) American Proficiency Institute (API)) proficiency testing records and interview with the technical consultant, it was determined that the laboratory failed attain a score of at least 80 percent of acceptable responses for Red Blood Cell (RBC) count. The findings included: a. Q3-2017, API reported an unsatisfactory score of 60% for RBC analyte. b. For fourteen (14) out of fourteen (14) random patient test results reviewed covering period from 12/15/2016 to 8/15/2018 the laboratory analyzed and reported these patients for Complete Blood Count (CBC) tests during the approximate time the laboratory received an unsatisfactory proficiency testing score for RBC. c. The testing personnel confirmed (1 /14/2019, 1300) that the laboratory received the above unsatisfactory proficiency testing score.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records and interview with the technical consultant, it was determined that the laboratory failed to at least twice annually, the laboratory must verify the accuracy of

	any test or procedure it performs that is not included in subpart I of this part. The findings included: a. API reported the following unsatisfactory scores. Analyte: Score: Event/Year: CRP Quant 0% Q3-2016 CRP Quant 50% Q2-2017 CRP Quant 0% Q3-2017 PTH 0 Q2-2017 25 OH Vit D 0% Q2-2017 b. For thirteen (13) out of fourteen (14) random patient test results reviewed covering period from 12/15/2016 to 8/15/2018, the laboratory analyzed and reported these patients for C-Reactive Protein (CRP) tests during the approximate time the laboratory received an unsatisfactory proficiency testing scores for CRP. For six (6) out of fourteen (14) random patient test results reviewed covering period from 12/15/2016 to 8/15/2018, the laboratory analyzed and reported these patients for Parathyroid Hormone (PTH) tests during the approximate time the laboratory received an unsatisfactory proficiency testing score for PTH. For five (5) out of fourteen (14) random patient test results reviewed covering period from 12/15/2016 to 8/15/2018, the laboratory analyzed and reported these patients for 25-Hydroxy Vitamin D tests during the approximate time the laboratory received an unsatisfactory proficiency testing score for 25-Hydroxy Vitamin D. c. The technical consultant confirmed (1/14/2019, 1300) that the laboratory received the above unsatisfactory proficiency testing scores.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of random patient test results and interview with the technical consultant, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. The findings incuded: a. Based on review of the following random patient test results: Patient #1 EL-ANA Screen (Collection Date: 11/16/2017 18:22, Status: Final) Results entered four (4) times. EL-ANA9C Elisa Method, IgG (Collection Date: 11/16/2017 18; 22, Status: Final) Results entered three (3) times. Patient #2 Rheumatoid Factor /3 IgM IgG, IgA (Collection date 6/8/2018, Status: Final) Results were entered two (2) times. 25-Hydroxy Vitamin D (Collection Date: 6/8/2018, Status: Final) Results were entered two (2) times. Patient #3 Quantiferon-TB Gold IT (Collection Date: 6/13/2018 09:22, Status: Final) Results were entered two (2) times. Patient #4 Cyclic Citrullinated Peptide-4P (Collection Date: 8/15/2018 09:30, Status: Final) Results entered three (3) times. Patient #5 Cyclic Citrullinated Peptide-4P (Collection Date: 8/15/2018 09:30, Status: Final) Results entered three (3) times. b. The technical consultant confirmed (1/14/2019, 1300) that the above patient test results are entered on the final test reports multiple times.
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 American Proficiency Institute (API) proficiency testing records and interview with the technical consultant, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 5217, and D 2121.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of random patient test results and interview with the technical consultant, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5891 and D 6040.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of random patient test results and interview with the technical consultant, it was determined that the technical consultant failed to ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. The findings included: a. Based on review of the following random patient test results: Patient #1 EL-ANA Screen (Collection Date: 11 /16/2017 18:22, Status: Final) Results entered four (4) times. EL-ANA9C Elisa Method, IgG (Collection Date: 11/16/2017 18; 22, Status: Final) Results entered three (3) times. Patient #2 Rheumatoid Factor /3 IgM IgG, IgA (Collection date 6/8/2018, Status: Final) Results were entered two (2) times. 25-Hydroxy Vitamin D (Collection Date: 6/8/2018, Status: Final) Results were entered two (2) times. Patient #3 Quantiferon-TB Gold IT (Collection Date: 6/13/2018 09:22, Status: Final) Results were entered two (2) times. Patient #4 Cyclic Citrullinated Peptide-4P (Collection Date: 8/15/2018 09:30, Status: Final) Results entered three (3) times. Patient #5 Cyclic Citrullinated Peptide-4P (Collection Date: 8/15/2018 09:30, Status: Final) Results entered three (3) times. b. The technical consultant confirmed (1/14/2019, 1300) that the above patient test results are entered on the final test reports multiple times.