Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1085773	10/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Abraham Ishaaya, Md, Inc	5901 W Olympic Blvd, Ste 203, Los Angeles, 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 Surveyor review of laboratory's policy & procedure, random patient, quality control (QC) and proficiency testing (PT) records for the years of 2019 and 2020, and interview with the laboratory technical consultant (TC) on October 9, 2020 at 12:30 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for ALT, AST, Alkaline Phosphatase, Homocysteine, Total Billirubin, Total Cholesterol and UIBC at 1 testing event out of 4 events, reviewed. The findings include: 1. The laboratory participated in the API PT program for the years of 2019 and 2020. However, it failed to attain a score of at least 80 percent of acceptable responses for some analytes in 2019 and/or 2020. a. The laboratory received a zero score for the analyte ALT at the 2nd event in 2019. b. The laboratory received a zero score for the analyte AST at the 2nd event in 2019. c. The laboratory received a zero score for the analyte Alkaline Phosphatase at the 1st event in 2020. d. The laboratory received a zero score for the analyte Homocysteine at the 1st event in 2020. e. The laboratory received a score of 50% for the analyte Homocysteine at the 2nd event in 2020. f. The laboratory received a score of 60% for the analytes Total Billirubin and Total Cholesterol, and 40% for the analyte UIBC at the 2nd event in 2020. 2. The laboratory TC on October 9, 2020 at 12:30 pm, affirmed that the laboratory did not receive at least 80% score for some analytes in 2019 and/or 2020. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/8/2020, stated that the laboratory performs 70,000 routine chemistry tests, annually.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, proficiency testing (PT) performance review and corrective actions records for the years of 2019 and 2020, and interview with the laboratory technical consultant (TC) on October 9, 2020 at 1:25 pm, the laboratory failed to undertake any remedial actions or training for unsatisfactory analyte performance for 2 events out of 4 events, reviewed. The findings include: 1. The laboratory participated in the API PT program for the years of 2019 and 2020, and obtained an unsatisfactory analyte performance for the analytes ALT, AST, Alkaline Phosphatase and Homocysteine. However, it did not take any remedial actions or training for unsatisfactory analyte performance. a. The laboratory received a zero score for the analyte ALT at the 2nd event in 2019 which is an unsatisfactory analyte performance. b. The laboratory received a zero score for the analyte AST at the 2nd event in 2019 which is an unsatisfactory analyte performance. c. The laboratory received a zero score for the analyte Alkaline Phosphatase at the 1st event in 2020 which is an unsatisfactory analyte performance. d. The laboratory received a zero score for the analyte Homocysteine at the 1st event in 2020 which is an unsatisfactory analyte performance. e. The laboratory received a score of 50% for the analyte Homocysteine at the 2nd event in 2020 which is an unsatisfactory analyte performance. 2. The laboratory TC on October 9, 2020 at 1:25 pm, affirmed that the laboratory received an unsatisfactory analyte performance at 2 PT events and did not take any remedial actions or training for the unsatisfactory analyte performances in 2019 and 2020. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/8/2020, stated that the laboratory performs 70,000 routine chemistry tests, annually.
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 Surveyor review of laboratory's policy & procedure, random patient, quality control (QC) and proficiency testing (PT) records for the years of 2019 and 2020, and interview with the laboratory technical consultant (TC) on October 9, 2020 at 12:40 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Thyroid Stimulating Hormone at 1 testing event out of 4 events, reviewed. The findings include: 1. The laboratory participated in the API PT program for the years of 2019 and 2020. It received a score of 40% for the analyte Thyroid Stimulating Hormone at the 2nd event in 2020. 2. The laboratory TC on October 9, 2020 at 12:45 pm, affirmed that the laboratory did not receive at least 80% score for Thyroid Stimulating Hormone in 2020. 3. The laboratory's testing declaration form,

	signed by the laboratory Director on 10/8/2020, stated that the laboratory performs 1,000 Thyroid Stimulating Hormone tests, annually.
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 Surveyor review of laboratory's policy & procedure, random patient, QC and PT testing records for the years of 2019 and 2020, and interview with the laboratory technical consultant (TC) on October 9, 2020 at 12:30 pm, it was determined that the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D2087, D2094, D2098, D6018, D6019, D6023 and D6032.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, PT records for the years of 2019 and 2020, and interview with the laboratory technical consultant on October 9, 2020 at 1:25 pm, the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for 2 PT events out of 4 events, reviewed. The findings include: The laboratory director did not review the received API PT reports on 2 occasions that required corrective actions. 1. The laboratory received a zero score for the analyte AST at the 2nd event in 2019. The laboratory director signed a form named PT discrepancies investigation and corrective action work-up document on 9/19/19 however, did not investigate or take any corrective actions for the failure. 2. The laboratory received a zero score for the analyte Homocysteine at the 1st event in 2020. The laboratory director signed (undated) a performance review and corrective action form from API but did not take any corrective action to the problem.

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 Surveyor review of laboratory's policy and procedure, PT records for the years of 2019 and 2020, and interview with the laboratory technical consultant on October 9, 2020 at 1:25 pm, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when AST and Homocysteine proficiency testing results were unacceptable or unsatisfactory. The findings include: See D2087, D2094 and D6018.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient, quality control (QC) and proficiency testing (PT) records for the years of 2019 and 2020, and interview with the laboratory technical consultant (TC) on October 9, 2020 at 12:40 pm, it was determined that the laboratory director failed to ensure the maintenance of an acceptable levels of analytical performance for AST, Homocysteine, Thyroid Stimulating Hormone, Total Billirubin and Total Cholesterol. The findings include: See D2087 and D2098.
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: Based on Surveyor review of laboratory's policy and procedure, and interview with the laboratory technical consultant on October 9, 2020 at 11:15 am, it was determined that the laboratory director failed to 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. The findings include: 1. In the beginning of October, 2020 the laboratory hired a new technical consultant who also works as a testing person however, the laboratory did not have any documents showing that the laboratory director had specified any responsibilities and duties. 2. The laboratory TC on October 9, 2020 at 11:15 am, affirmed that the laboratory director did not specify the responsibilities and duties in writing.