Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2096856	03/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Individx	9600 Center Ave, Ste 100, Rancho Cucamonga, 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 review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed 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. The findings included: a. The laboratory performed routine chemistry testing including, but not limited to, the following tests: Albumin (Alb), Amylase (Amy), Creatine (Cre), and total Iron. b. In order to meet the CLIA requirements and to verify the accuracy of the routine chemistry testing system annually , the laboratory elected to enroll its routine chemistry proficiency testing (PT) with American Association of Biocatalysts (AAB) PT provider. c. The laboratory attained a score of 60% for the analyze of Alb in the 3rd 2017 PT event which was unsatisfactory performance PT event. d. The laboratory attained scores of 60% and 0% for the analyte of Cre, Amy and Iron, respectively in the 3rd 2016 PT event which were unsatisfactory performance PT event e. The failures of Alb, Cre and Iron in PT events' scores showed as follow: Event Analyte Score (%) 3rd 2017 Alb 60 3rd 2016 Amy 60 3rd 2016 Cre 60 3rd 2016 Iron 0 f. The laboratory performed Alb, Cre, and Iron in approximately 110 each for patient samples per month. g. The laboratory staff affirmed (3/20/2018 @ 12: 15 PM) that the laboratory failed to attain at least 80% of the acceptable responses for the analyte of Cre, Amy and Iron in the 3rd 2016 PT event, which was unsatisfactory performance event. h. The laboratory staff affirmed (3/20/2018) that the laboratory failed to attain at least 80% of the acceptable responses for the analyte of Alb in the 3rd 2017 PT event, which were unsatisfactory performance event.

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 review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed 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. The findings included: a. The laboratory performed endocrinology testing including, but not limited to, the following tests: Free T4 (FT4), Triiodothyronine (T3), and Ty (T4). b. In order to meet the CLIA requirements and to verify the accuracy of the endocrinology testing system annually , the laboratory elected to enroll its endocrinology proficiency testing (PT) with American Association of Biocatalysts (AAB) PT provider. c. The laboratory failed to attain scores of at least 80 % of the acceptable responses for the analyte of FT4, T3 and Ty in the 3rd 2016 PT event, which were unsatisfactory performance event. d. Prior to this routine re-certification survey, this laboratory had received and completed the responses to a PT Desk review, CMS 2567 report (10/24 /2016), for the failure to achieve satisfactory performance for FT4 testing in two out of three consecutive PT events. The laboratory attained scores of 0% for FT4 in both the 1st and the 3rd 2016 PT events. e. The failures of the 3rd 2016 endocrinology PT scores showed as follow: Analyte Score (%) FT4 0 T3 0 Ty 0 f. The laboratory performed T3 and Ty in approximately 100 each patient samples per month. g. The laboratory staff affirmed (3/20/2018 @ 12:20 PM) that the laboratory failed to attain at least 80% of the acceptable responses for the analyte of T3 and Ty in the 3rd 2016 PT event, which were unsatisfactory performance events.
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 laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed 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. The findings included: a. The laboratory performed Complete Blood Cell counts (CBC) and reported the following parameters including, but not limited to, the followings: White blood cells (WBC) with cell differentials , Red blood cell (RBC), Hemoglobin (Hgb), Hemotocrit (Hct) and Platelets count (Plt) for the patient samples. b. In order to meet the CLIA requirements, and to verify the accuracy of the CBC testing system annually, the laboratory elected to enroll its hematology proficiency testing (PT) with American Association of Biocatalysts (AAB) PT provider. c. The laboratory failed to attain a score of at least 80 % of the acceptable responses for its CBC parameters in the 1st 2017 for Cell differentials, Hgb, WBC, Platelet counts, which were unsatisfactory performance event. d. The 1st 2017 hematology PT scores showed as follow: Analyte Score (%) Cell diff 12 Hgb 60 WBC 0 Plt 60% e. The laboratory

	performed CBC in approximately 560 patient samples per month. f. The laboratory staff affirmed (3/20/2018 @ 12:10 PM) that the laboratory failed to attain at least 80% of the acceptable responses for its CBC parameters in the 1st 2017 for Cell differentials, Hgb, WBC, Platelet counts, which were unsatisfactory performance event.
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 interview with the laboratory staff, it was determined that the laboratory failed to perform specifications comparable to those established by the manufacturer for the following performance characteristics, 1) Accuracy, 2) Precision, 3) Reportable range of test results for the test system, and 4) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The findings included: a. The laboratory had moved from previous location to the current location in La Verne, CA. b. The laboratory re-installed the following equipments when they moved to the new location: 1) Celldyn 3700 for Complete Blood Cell Counts (CBC), Beckman Olympus 680 for routine chemistry tests. c. At the time of this survey (3/20/2018), based on interview with the laboratory staff that the laboratory had not completed its verification of the testing system performances for Celldyn 3750 and Olympus AU6800 and to ensure the accuracy of the testing system.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2087, D-2098, and D-2121
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff, 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. The findings included: See D-5421
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 the laboratory records, and interview with the laboratory staff, 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. The findings included: See D-6016 and D-5421