Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2096856	12/09/2020
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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 second quarter (Q2-2018) event of the America Association of Bioanalysts (AAB) proficiency testing records and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for General Immunology. The findings included: 1. For Q2-2018, AAB reported an overall score of 66.0 % for General Immunology: Analyte Score Reported Antistreptolysin O 100% Infectious mononucleosis 0 Rheumatoid Factor 100% 2. Based on the laboratory's annual testing declaration for 2018-2020 the laboratory analyzed and reported approximately 500 General Immunology tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed 12/9/2020 at approximately 1:00 p.m. that the laboratory received the above unsatisfactory proficiency testing score.
D2082	GENERAL IMMUNOLOGY CFR(s): 493.837(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 review on the proficiency testing (PT) performance records, corrective actions records for the years of 2018, and interview with the laboratory technical supervisor (TS) on December 9, 2020; the laboratory failed to undertake any remedial actions or training for unsatisfactory Infectious Mononucleosis (IM) analyte PT performance. The findings include: 1. The laboratory participated in the American Association of Bioanalysts (AAB) PT program for the year 2018, obtaining an unsatisfactory analyte performance for the analyte Infectious Mononucleosis (IM); however, the laboratory fail to take any remedial actions or training for unsatisfactory analyte performance. 2. The TS on December 9, 2020 at approximately 1:25 p.m., affirmed that the laboratory received an unsatisfactory score for the analyte IM for the Q-2 2018 event and did not take any remedial actions or training for the unsatisfactory performance. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/09/2020, stated that the laboratory performs approximately 500 General Immunology test annually .
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 American Association of Bioanalysts (AAB) proficiency testing records and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for HDL Cholesterol for the first event of 2020 (Q1-2020). The finding included: 1. Based on review of PT records for Q1-2020, AAB reported an unsatisfactory score of 40% for HDL Cholesterol test. The laboratory failed to report an acceptable test value for three (3) out of five (5) tested samples: Sample # Reported Intended range 1 27 19-34 2 52 50-94 3 98 9-17 4 78 5-8 5 115 27-49 2. Based on the laboratory testing declaration submitted at the time of the survey on 12/09/2020 the laboratory analyzed and reported approximately 2,500 Routine Chemistry tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed 12/09/2020 at approximately 1:15 p.m. that the laboratory received the above unsatisfactory proficiency testing score.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS Cumulative Scores - Regulated Analytes proficiency testing (PT) report results and interview with the technical supervisor (TS); it was determined that the laboratory failed to return PT results for Routine Chemistry subspecialty for the second quarter PT event (Q2-2020) to the proficiency testing program within the time frame specified by the program which is unsatisfactory

	performance and results in a score of zero (0). The findings included: 1. The American Association of Bioanalysts (AAB) proficiency reported for Q2-2020 an unsatisfactory score of 0% for Routine Chemistry for analytes Iron and Magnesium for failure to submit results within the time frame specified by the program. 2. The TS affirmed 12/09/2020 at approximately 1:35 p.m. that the laboratory received the above unsatisfactory proficiency testing scores. 3. Based on the laboratory's annual test volume declaration CMS 116 submitted 12/9/2020 the laboratory analyzed and reported approximately 2,500 Routine Chemistry tests which included Iron and Magnesium.
D2105	ENDOCRINOLOGY CFR(s): 493.843(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 review on the proficiency testing (PT) performance records, corrective actions records for the years of 2018, and interview with the laboratory technical supervisor (TS) on December 9, 2020; the laboratory failed to undertake any remedial actions or training for unsatisfactory Pregnancy Serum, Triiodothyronine, Total (TT3), Thyroid Stimulating Hormone (TSH), Thyroxine, Total (TT4), and Thyroxine Total regulated analytes PT performance. The findings include: 1. The laboratory participated in the American Association of Bioanalysts (AAB) PT program for the year 2018, obtaining an unsatisfactory analyte performance for Pregnancy Serum, Triiodothyronine, Total (TT3), Thyroid Stimulating Hormone (TSH), Thyroxine, Total (TT4), and Thyroxine Total analytes; however; the laboratory fail to take any remedial actions or training for unsatisfactory analyte performance. 2. The TS on December 9, 2020 at approximately 1:25 p.m., affirmed that the laboratory received an unsatisfactory score for Pregnancy Serum, Triiodothyronine, Total (TT3), Thyroid Stimulating Hormone (TSH), Thyroxine, Total (TT4), and Thyroxine Total analytes for the Q-2 2018 event and did not take any remedial actions or training for the unsatisfactory performance. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/09/2020, stated that the laboratory performs approximately 500 endocrinology test annually.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review the laboratory's policies & procedures, proficiency testing performance records, lack of corrective action records and documentation, and interview with the technical supervisor, the laboratory director failed to ensure that an

	approved corrective action plan policy exists and is followed when any proficiency testing result is found to be unsatisfactory performance. The findings include: See D2082 and D2105.