

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2096856	<b>(X3) Date Survey Completed</b>  02/24/2023
<b>Name of Provider or Supplier</b>  Individx	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6107</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records of personnel training, competency evaluation, laboratory policies and procedures, random patient testing records, and interview with the laboratory 's technical supervisor (TS) and testing personnel (TP); the laboratory failed to provide records showing that the laboratory director (LD) has authorized, delegated, and approved lab personnel of any responsibilities and duties in writing. The findings include: 1. The laboratory did not have any records of written delegation and authorization of responsibilities and duties by the LD for the laboratory's technical supervisor and testing personnel. 2. On February 24, 2023, at approximately 2:00 p.m. the TS and TP affirmed that the LD did not assign, delegated, and authorized in writing duties and responsibilities to the laboratory personnel including the TS and TP. 3. The laboratory testing declaration form, signed by the LD on 2/23/23 stated that the laboratory performs 20,500 tests annually.</p>