

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2129713	(X3) Date Survey Completed 03/14/2022
Name of Provider or Supplier Indigobridge Laboratories, Llc	Street Address, City, State 3000 Kent Ave Ste 2962, West Lafayette, IN	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow established competency policies and procedures for one of five personnel reviewed (SP1, General Supervisor). Findings include: 1. The "Competency Assessment Policy" (approved on 2/18/2020) stated that "Competency assessments must be conducted six months after hire, annually thereafter." 2. The "Competency Assessment Log" for SP1 indicated the following competency evaluations had not been performed: six-month, and annual for 2020 or 2021. 3. On 03/14/2022 at 11:45 am, SP1 indicated that their hire date as General Supervisor was 9/30/2019. 4. On 03/14/2022 at 11:55 am, SP1 acknowledged that they did not have a competency assessment six months after their hire date. SP1 added that they also did not have a competency assessment for 2020 or 2021. 5. Review of patient records indicated that SP1 performed Epigallocatechin gallate (EGCg) testing on patient #1 (PT1) on 5/15/2020 and patient #2 (PT2) on 9/16/2020.</p>