

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1027665	<b>(X3) Date Survey Completed</b>  06/15/2022
<b>Name of Provider or Supplier</b>  Woodruff Institute Llc,The	<b>Street Address, City, State</b>  2235 Venetian Ct Ste 1, Naples, FL	
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>D0000</b>	An announced recertification survey was conducted on 6/15/22 at The Woodruff Institute LLC, a clinical laboratory in Naples, Florida. The Woodruff Institute LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is description of the Standard-level deficiencies.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of employee competency records, and interview with the Office Manager, the Laboratory Director failed to perform competency evaluations on one Testing Personnel (#B) out of two Testing Personnel (#A and #B) who perform histopathology testing for two out of two years (2020 - 2021). The findings included: Record review of the CMS 209 signed by the Laboratory Director on 6/13/22 revealed two testing personnel (#A and #B). Review of employee competency records found no competency evaluations performed on Testing Person #B who performed histopathology testing for two out of two years (2020 - 2022). Record review of the "Quality Assurance Components" revealed, "Personal are evaluated semiannually during the first year of employment... Thereafter, evaluations are performed yearly in the month of July." On 06/15/22 at 11:00 a.m., the Office Manager stated she was unaware that Testing Personnel #B needed competency evaluations since she was the Laboratory Director at another office.</p>