

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2311219	<b>(X3) Date Survey Completed</b>  04/29/2026
<b>Name of Provider or Supplier</b>  Carolyn Sok Dermatopathology	<b>Street Address, City, State</b>  7000 Woodlands Ln, Solon, OH	
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>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to ensure final laboratory test reports indicated the name and address of the laboratory location where the tissue biopsy slide interpretations (professional component) were conducted in the subspecialty of Histopathology for five out of five final test reports reviewed between 02/07/2026 through 04/20/2026, of a total 2,186 patient tissue biopsy slide interpretations performed. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 04/12/2026 and provided on the date of the inspection revealed the laboratory performed tissue biopsy slide interpretation testing procedures. 2. Review of five out of five patient tissue biopsy slide interpretation final test reports performed on 02/07/2026, 02/18/2026, 02/23/2026 and two reports on 04/20/2026 revealed only the CLIA certificate number of the laboratory where the tissue biopsy slide interpretations (professional component) were performed with no name and address indicated. 3. The Laboratory Director, on 04/29/2026 at 10:35 AM, confirmed the laboratory's final test reports did not indicate the name and address of the laboratory</p>

location where patient tissue biopsy slide interpretations (professional component) were performed. 4. Review of patient final test reports from 01/10/2025 through 04/29/2026 found 2,186 patient tissue biopsy slide interpretations were performed.