

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D0982952	<b>(X3) Date Survey Completed</b> 02/03/2025
<b>Name of Provider or Supplier</b> Semans Dermatopathology Service	<b>Street Address, City, State</b> 101 E Main Street, Rochester, IL	
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>D5601</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director (LD) and laboratory representative, the laboratory failed to document dermatopathology immunohistochemical (IHC) stain positive and negative reactivity for 24 of 24 patients tested from the beginning of 2023 through the date of survey, 02/03/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Immunohistochemical Stain Statement for Offsite Slide Production", which stated, "The Laboratory Director evaluates the immunohistochemical slides made off site. An interpretation of staining results (positive, negative, indeterminate) will be made and recorded in the pathology report and in a log." 2. Review of patient testing logs for IHC staining found no documentation of negative reactivity, only positive reactivity was documented for 24 of 24 patients tested with IHC stains from the beginning of 2023 through the date of survey, 02/03/2025. Report Date: Block #: IHC Stain(s): 01/27/2023 23-264 P63, CK-HMW 02/20/2023 23-594 S100 03/08/2023 23-759 CD34, Sox-10 04/05/2023 23-1321 PGP9.5 04/20/2023 23-1504 CK20, TTF-1, Neurofilament 05/15/2023 23-1925 CK-HMW, P63 06/05/2023 23-1985 ER, PR, Her-2, 06/12/2023 23-2348 Low-Risk HPV, High-Risk HPV 07/21/2023 23-2934 Sox-10, Fontana Masson 08/14/2023 23-3211 CD34 08/17/2023 23-3260 PGP9.5 11/03/2023 23-4667 Ber EP4, CK20, INSM-1, TTF-1 11/09/2023 23-4799 CD45, CK20, Neurofilament, TTF-1 01/24/2024 24-1 ER, PR, Her-2 03/04/2024 24-832 GATA-3,</p>

Her-2, ER, PR 03/08/2024 24-898 ER, PR, Her-2, TTF-1 04/11/2024 24-1568 p63, CK HMW 04/19/2024 24-1763 Sox-10, CK AE1/AE3 05/22/2024 24-2166 Sox-10 06/12/2024 24-2467 p63, CK HMW 07/02/2024 24-2725 Sox-10 01/15/2025 25-45 Sox-10 01/18/2025 25-126 CK7, CK20, TTF-1 01/20/2025 25-241 CD34, Sox-10 3. Interviews with the LD and laboratory representative on 02/03/2025, at 11:20 am, confirmed that the laboratory failed to document dermatopathology IHC stain positive and negative reactivity for 24 of 24 patients tested from the beginning of 2023 through the date of survey, 02/03/2025.