

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2037209	<b>(X3) Date Survey Completed</b>  03/11/2022
<b>Name of Provider or Supplier</b>  Sanova Dermatology	<b>Street Address, City, State</b>  12319 N Mopac Expwy Bldg C Ste 100, Austin, TX	
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. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's Instructions for Use (IFU), laboratory's policies and procedures, accession logs, patient reports, quality control records, interview and email, the laboratory failed to document for intended reactivity to ensure predictable staining characteristics for the Mart-1 Immunohistochemical (ihc) stain in dermatopathological specimens in Mohs testing for two of two years of testing. Finding follow. 1. Review of the ihc Direct Mart-1 Anti-human Mart-1 IFU, May 2020, under Quality Control Procedures stated, "Positive and negative controls should be run simultaneously with patient specimens." Under Expected Results stated, "The antibody stains cytoplasm on positive cells, such as melanoma cells and melanocytes in skin tissue. Other types of cells in the same tissue are negative. Interpretations of the staining result is solely the responsibility of the user." 2. Review of the laboratory's Mart-1 Procedure, revised 12/6/2017, under Quality Control stated, "Internal controls are used." 3. Review of the Accession Log showed from 09/14/2021 - 2/24/2022 4 cases with the diagnosis of MMIS (Malignant Melanoma in Situ) (indicating a Mart-1 stain would have been performed): a. M21-446 tested on 09/14/2021 b. M21-486 tested on 09/28/2021 c. M21-553 tested on 11/09/2021 d. M22-027 tested on 01/24/2022 4. Review of 4 of 4 test reports from 09/14/2021 - 02/24/2022 did not include the staining characteristics of the Mart-1 control: a. M21-446 tested on 09/14/2021 b. M21-486 tested on 09/28/2021 c. M21-553 tested on 11/09/2021 d.</p>

M22-027 tested on 01/24/2022 5. Review of the laboratory's quality control records from 2020 - 2022 showed no quality control log for the Mart-1 stain. 6. Interview with testing personnel #4, on the CMS form 209, on March 2, 2022 at 1155 acknowledged the cases diagnosed with MMIS would have a Mart-1 stain and confirmed there was no documentation of the Mart-1 quality control. Interview with the Laboratory Director on March 2, 2022 at 1255 acknowledged they used to have a [quality control] form for that. The form was requested at 1155 but not provided. 7. Email from testing personnel #4 on March 4 at 4:51 PM confirmed they had 22 cases in 2021 with the Mart stain.