

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0312671	<b>(X3) Date Survey Completed</b>  12/12/2023
<b>Name of Provider or Supplier</b>  Robert C Griffith, Iii, Md, Pllc	<b>Street Address, City, State</b>  6311 Kingston Pike Ste 22e, Knoxville, TN	
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>D5475</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package insert, patient Micrographically Oriented Histographic Surgery(MOHS) case, document request, and interview with the laboratory director, the laboratory failed to document positive and negative control reactivity for one of one selected case for use of the Mart-1 immunohistochemistry (IHC) stain in 2023. The findings include: 1. Observation of the laboratory on 12.12.2023 at 8:30 am revealed Mart-1 IHC reagents/stains used in histopathology MOHS procedures stored in the refrigerator. 2. Review of the manufacturer package insert revealed that "Positive and negative controls should be run simultaneously with all patient specimens." 3. Review of randomly selected patient MOHS procedure where the Mart-1 immunohistochemical stain was used revealed patient testing done on the following: Case #23M-975-Performed on 11.09.2023 4. Request on 12.12.2023 at approximately 11:00 a.m. to the laboratory director for documentation of positive and negative control results for the selected case revealed no documentation was present. 5. Interview with the laboratory director on 12.12.2023 at 11:15 a.m. confirmed the laboratory failed to document positive and negative reactivity for Mart-1 IHC stain for one of one selected date/case in 2023.</p>