

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0913782	(X3) Date Survey Completed 05/24/2024
Name of Provider or Supplier South Texas Dermatology	Street Address, City, State 4141 South Staples #300, Corpus Christi, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5601	<p>HISTOPATHOLOGY 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 a review of laboratory policies, a review of quality control records, patient test records, and confirmed in an interview with laboratory personnel, the laboratory failed to check the NovodiAx immunohistochemistry (IHC) stain for positive and negative reactivity each time of use for 10 of 10 patients reviewed from March 2024 to May 2024. The findings included: 1. Based on a review of the laboratory's policy titled "Histopathology" signed by the laboratory director on May 20, 2024, under "Frequency and Record of Quality Control Analyses" it stated, "Each day that this procedure is performed, a positive and negative control sample will be analyzed in exactly the same manner as patient samples. The results obtained with control materials will be recorded on a sheet that contains the following information: name of procedure, description and source of positive control, results expected for the positive control, description and source of negative control, results expected for the negative control, date of test, an identifier such as initials indicating who performed the test, results obtained with the positive control, and results obtained with the negative control." 2. A review of the laboratory's quality control records from March 2024 to May 2024 found no documentation that the laboratory performed positive and negative reactivity each time it performed a NovodiAx IHC stain for patient testing. 3. A random review of patient test records from March 2024 to May 2024 found the laboratory performed a NovodiAx IHC on the following 10 of 10 patients when no</p>

quality control testing was documented (see patient alias list). 4. In an interview at 10:35 hours on 05/24/2024, the Laboratory Manager confirmed the laboratory did not perform quality control testing on the Novodiya IHC.