

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0502642	(X3) Date Survey Completed 05/06/2021
Name of Provider or Supplier Histopath Inc	Street Address, City, State 4455 S Padre Island Drive, Suite 39, 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 review of the laboratory's slide quality control records from June 2020 and September 2020 (as of the day of the survey), review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of evaluating immunohistochemical stains for positive and negative reactivity each time of use for 4 of 4 events. The findings were: 1. Random review of quality control records from June 2020 and September 2020 found the following dates when patients were tested and a positive and negative quality control reactivity was not documented: June 2, 2020 June 22, 2020 September 2, 2020 September 18, 2020 2. A review of patient test records revealed the following patients were tested on the identified days: Pathology No: ST-20-01488 June 2, 2020 CD56 Chromogranin Ki67 Synaptophysin Pathology No: HP-20-02343 June 22, 2020 ER PR HER2 P53 Ki67 Pathology No: HP-20-03359 September 2, 2020 P16 Pathology No: ST-20-02804 September 18, 2020 Pankeratin 3. An interview with the laboratory director at the exit conference on May 6, 2021 confirmed the findings.</p>