

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0502642	(X3) Date Survey Completed 02/05/2019
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Form CMS-209 (CLIA Personnel Form), review of laboratory policy, review of personnel records and interview of facility personnel the laboratory did not have a written policy to assess the competency of each of its technical supervisors. The findings included: 1. A review of the laboratory's submitted Form CMS-209, signed by the laboratory director on February 5, 2019, revealed the laboratory identified 5 technical supervisors in addition to himself. 2. A review of the Laboratory Policy and Procedure manual revealed that the manual did not include a policy and procedure to evaluate the competency of each of its technical supervisors. 3. A review of the facility's personnel files, revealed that the technical supervisors did not include evidence that the competency of the technical supervisor had been evaluated. 4. An interview with the Laboratory Director, Laboratory Supervisor, and Administrator on February 5, 2019 at 14:00 hours in the conference room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services CLIA - Clinical Laboratory Improvement Amendments</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of patient results, review of quality control records, and confirmed in interview with facility personnel, the laboratory failed to provide documentation of staining materials for intended reactivity to ensure predictable staining characteristics each time of use for 1 of 5 randomly selected patient charts reviewed. The findings included: 1. Review of patient results found the following patient had results reported for IHC studies. The report (Pathology No. HP-18-04223) stated, " ... Immunohistochemical studies are performed, and these nests stain strongly for p40 and negative for CD 68 ..." 2. Based on review of patient records, the laboratory did not have quality control records for assessing stain acceptability for positive and negative reactivity, when appropriate, for 1 of 5 randomly reviewed patient specimens: Pathology No.: HP-18-04223 Date of Procedure: 09-11/2018 Date Reported: 09-21-2018 IHC stains: p40, CD 68 3. On February 5, 2019 at 13:30 hours the facility attempted to retrieve a scanned copy of the quality control documentation. No documentation was provided. 4. On February 5, 2019 at 13:30 hours the facility attempted to retrieve a paper copy of the quality control documentation. No documentation was provided. 5. According to the CLIA 116 signed by the laboratory director on February 5, 2019, the laboratory reports an estimated annual volume in histopathology of 25,000 tests per year. 6. An interview with the Laboratory Director, Laboratory Supervisor, and Administrator on February 5, 2019 at 14:00 hours in the conference room confirmed the findings. Key: CLIA - Clinical Laboratory Improvement Amendments