

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1043494	(X3) Date Survey Completed 07/19/2018
Name of Provider or Supplier K Wade Foster Md Pa	Street Address, City, State 6020 Park Blvd, Pinellas Park, FL	
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 record review and interview with the Histology Supervisor, the facility failed to perform competency assessments on the one of one Clinical Consultant /Testing Person. Findings Included: Review of the CMS-209 Laboratory Personnel Report dated 7/18/18 revealed the laboratory has one Clinical Consultant who also serves as the one Testing Person. A review of this employee's record revealed no documentation of competency assessments. Phone interview on 07/24/2018 at 11:00 am with the Histology Supervisor confirmed that the laboratory did not have competency evaluations for the Clinical Consultant/Testing Person.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual record review and interview with the Histology Supervisor, the laboratory did not have written procedures for histology grossing, the use of the cryostat, and the automatic stainer. Findings included: Review of the</p>

procedure manual revealed the laboratory did not have a procedure for histology grossing, use of the cryostat, and the automatic stainer. The laboratory had the manufacturer's manual for the automatic stainer, but it was found wrapped in cellophane. Interview with the Histology Supervisor on July 19, 2018 at 10:15 AM confirmed that the laboratory did not have written procedures for histology grossing, the use of the cryostat, and the automatic stainer.