

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2087187	<b>(X3) Date Survey Completed</b>  06/04/2018
<b>Name of Provider or Supplier</b>  Smith Winqvist And Associates Md Pa D/B/A	<b>Street Address, City, State</b>  9332 Sr 54 Ste 100 Rm 124, Trinity, FL	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 competency record review, review of the CMS Laboratory Personnel Report form (CMS 209), and interview with the Histotechnologist, the laboratory failed to perform annual competency evaluations for 2 out of 3 Testing Personnel (Testing Personnel B and Testing Personnel C and Histotechnologist C who are the same Testing Personnel) for 2017 and 2018 . Findings included: During record review of the CMS 209, it was found that there was 3 Testing Personnel (Testing Personnel A, B, and C) listed on the form. During competency record review, it was noticed that Testing Personnel B and Testing Personnel C/Histotechnologist C did not have annual competency assessments for 2017 and 2018 . During an interview on June 4, 2018 at 12:00 PM, the Histotechnologist stated that annual competency assessments had not been performed for 2017 and 2018, by the Laboratory Director who is Testing Personnel A and also is the Technical Supervisor, for Testing Personnel B and Testing Personnel C.</p>
<b>D6107</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting</p>

and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with the Histotechnologist, the laboratory failed to have written job descriptions for the Clinical Consultant, Technical Supervisor, and General Supervisor. Findings included: During review of the laboratory procedure manual, it was found that the manual was missing job descriptions for the Clinical Consultant, Technical Supervisor, and General Supervisor. During an interview on 06/04/18 at 12:05 PM, the Histotechnologist confirmed the manual did not contain the job descriptions for the Clinical Consultant, Technical Supervisor, and General Supervisor.