

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D1056245	<b>(X3) Date Survey Completed</b> 04/18/2018
<b>Name of Provider or Supplier</b> Associates In Pediatrics	<b>Street Address, City, State</b> 1530 N Randall Rd, Elgin, IL	
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 review of the application for certification (CMS 116), policies and procedures manuals, laboratory personnel report - CLIA (CMS 209), personnel records and interview; the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings: 1. Review of the CMS 116 submitted during the laboratory's survey of April 18, 2018 revealed that the laboratory performed Urinalysis and Hematology procedures. 2. Review of the laboratory's procedures manual revealed that there were no procedures that described the laboratory's process for assessing the competency of the Technical Consultant and Clinical Consultant. However, there were instructions for performing and documenting the training and competency of testing personnel. 3. Review of the CMS 116 revealed that the following information: a. There was 1 person listed as the laboratory director who also fulfilled the positions of Clinical Consultant (CC), Technical Consultant (TC), and Testing Personnel (TP). b. There were 7 additional persons listed as CC. c. There were 25 additional persons listed as TP 4. Review of personnel records revealed that there was no documentation to show the competency assessments for 1 of 1 TC; 7 of 8 CCs and 3 of 26 TP. 5. During survey date 04/16/18, the Clinical Manager confirmed the surveyor's findings.</p>
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures manuals; Laboratory Personnel Report (CMS 209) and personnel records; the laboratory director failed to specify in writing the responsibilities and duties of each consultant and each person engaged in the testing process; and identify which examinations and procedures each individual is authorized to perform, and whether supervision and/or director review is required prior to reporting patient test results. Findings: 1. Review of the laboratory's policies and procedures manuals revealed the laboratory director did not specify which testing personnel performs the microscopic urinalysis procedures. 2. There were a total of 26 testing personnel listed on the CMS 209. 3. Review of personnel records revealed that there was no documentation to show which testing personnel were responsible for performing urinalysis testing for 26 of 26 testing personnel. 4. During survey date 04/16/18, the Clinical Manager confirmed the surveyor's findings.