

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0327580	(X3) Date Survey Completed 12/11/2024
Name of Provider or Supplier Medical And Surgical Associates	Street Address, City, State 1930 Tamarack Rd, Newark, OH	
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 an interview with the Technical Consultant (TC), the laboratory failed to follow a written policy and procedure to assess competency of Testing Personnel (TP) #1 as required in the personnel requirements in subpart M. This deficient practice had the potential to affect one out of two TP in the specialties of Chemistry and Hematology. This deficient practice had the potential to affect 259,027 patients tested in the specialty of Chemistry and 71,100 patients tested in the speciality of Hematology. Findings Include: 1. A review of the laboratory's CMS-209 form, approved and signed by the Lab Director on 12/11/2024, found two individuals listed as TP. 2. A review of the laboratory's "Orientation, Training and Competency" policy and procedure found the following statement: "...After initial competency assessment at the completion of orientation and training, competency assessment will occur at 6 months, 12 months and annually thereafter for testing personnel ..." 3. A review of the laboratory's competency assessment data for TP #1 found the following: TP #1 2023: [none] 2024: 4-23-24 4. The surveyor requested 2023 competency assessment documentation for TP #1 from the TC. An interview with the TC, on 12/11/2024 at 2:43 PM, confirmed that the laboratory failed to follow the competency assessment policy for TP #1 and was unable to provide the requested documentation on the date of the survey.</p>