

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2061638	(X3) Date Survey Completed 03/03/2020
Name of Provider or Supplier Genemarkers Llc	Street Address, City, State 126 E South Street, Kalamazoo, MI	
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 Laboratory Director (LD), the laboratory failed to follow written polices to access the competency of the Clinical Consultant for 2 (March 2018 to March 2020) of 2 years. Findings include: 1. A record review of the laboratory's established "CLIA Competency Assessment" policy revealed a section stating "CAs (competency assessments) will be performed for all personnel involved with CLIA-certified PGX testing." 2. A review of the laboratory's competency assessments revealed a lack of documentation of the Clinical Consultant competency assessments. 3. An interview on 3/3/2020 at 12:05 with the LD confirmed competency assessments for the Clinical Consultant were not available.</p>