

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0334668	(X3) Date Survey Completed 06/01/2026
Name of Provider or Supplier Mercy Health - Allen Hospital	Street Address, City, State 200 W Lorain Street, Oberlin, 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 Administrative Director (AD), the Laboratory Manager (LM) and the Coordinator of Quality Assurance and Point of Care Testing (CQAPOCT), the laboratory failed to follow written policies and procedures to assess the competency of three out of three of the Technical Consultants (TC) for the moderate complexity routine chemistry, endocrinology and hematology testing; one out of one Technical Supervisor (TS) and three out of three General Supervisors (GS) for the high complexity hematology testing procedures performed based on the responsibilities of each position. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director via signature and date on 06/01/2026 and provided on the date of the inspection, revealed three qualified and listed individuals to function as TC's for moderate complexity chemistry, endocrinology and hematology testing and one TS and three GS's for the high complexity hematology procedures performed. 2. Review of the laboratory's "Laboratory Staff Training and Competency Assessment" policy and procedure, approved by the Laboratory Director on 01/20/2026 and provided on the date of the inspection revealed the following statement: "J. The performance of...technical supervisors, general supervisors, technical consultants...is assessed annually and documented in Workday." 3. Review of the laboratory's 2024, 2025 and 2026 competency assessment documentation provided on the date of the inspection did not find any competency assessment documentation for TC#1, TC#2, TC#3, TS, GS#1, GS#2 and GS#3 based on the responsibilities of each position assigned by the Laboratory Director. 4. The Inspector requested the laboratory's 2024, 2025 and 2026</p>

TC, TS and GS competency assessment documentation from the AD, LM and CQAPOCT. The LM confirmed the laboratory did not follow the laboratory's policy and procedure to assess the TC's, the TS and GSs based on the responsibilities of the position and did not conduct competency assessments on TC#1, TC#2, TC#3 TS, GS#1, GS#2 and GS#3 in 2024, 2025 and 2026. The AD, LM and CQAPOCT were unable to provide the requested documentation on the date of the inspection. The interview occurred on 06/01/2026 at 10:45 AM. 5. Review of laboratory test records revealed 382,272 patient test results reported between 06/01/2024 and 06/01/2026.