

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0314780	(X3) Date Survey Completed 01/22/2025
Name of Provider or Supplier Pediatric & Adolescent Medicine Of East Memphis Pc	Street Address, City, State 1102 Brookfield Road 2nd Fl, Memphis, TN	
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 laboratory observation, a review of the laboratory's procedure manual, a review of testing personnel competency assessment records, and staff interview, the laboratory failed to follow the established testing personnel competency assessment policy when the six required elements were not included in the competency assessments for three of three testing personnel, four of four competency assessments reviewed from 2024 for performance of patient testing for the Complete Blood Count with White Blood Cell Differential (CBC w/Diff) using the Beckman Coulter DxH 500 instrument. The findings include: 1. Laboratory observation on 01/22/25 at 11:45 a.m. revealed the Beckman Coulter DxH 500 (Serial number DB04006) used for patient testing for CBC w/Diff. 2. A review of the laboratory's Quality Assurance Plan under section "VI. Personnel Assessment" revealed that testing personnel evaluations would be performed using direct observation of routine testing, monitoring the recording and reporting of results, review of worksheets, quality control records, proficiency testing records, and preventative maintenance records, direct observation of instrument maintenance and function checks, assessment of test performance through testing of previously analyzed specimens or external proficiency samples and assessment of problem-solving skills. 3. A review of testing personnel competency assessment records revealed the following: Testing person one: The six-month competency assessment performed on 02/09/24 did not include documentation of test performance assessment through previously analyzed samples or external proficiency testing. The annual competency assessment performed on 07/11/24 did not include</p>

direct observation of routine testing, monitoring the recording and reporting of results, review of worksheets, quality control records, proficiency testing records, and preventative maintenance records, direct observation of instrument maintenance and function checks, or assessment of test performance through testing of previously analyzed specimens or external proficiency samples. Testing person two: The annual competency assessment performed on 08/08/24 did not include direct observation of routine testing, monitoring the recording and reporting of results, review of worksheets, quality control records, proficiency testing records, and preventative maintenance records, direct observation of instrument maintenance and function checks, or assessment of test performance through testing of previously analyzed specimens or external proficiency samples. Testing person three: The annual competency assessment performed on 08/08/24 did not include direct observation of routine testing, monitoring the recording and reporting of results, review of worksheets, quality control records, proficiency testing records, and preventative maintenance records, direct observation of instrument maintenance and function checks, or assessment of test performance through testing of previously analyzed specimens or external proficiency samples. 4. The laboratory director confirmed the survey findings during an interview on 01/22/25 at 2:30 p.m.