

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0189685	(X3) Date Survey Completed 09/21/2021
Name of Provider or Supplier Integrated Medical Group Pc	Street Address, City, State 8 Oak Grove Road, Pine Grove, PA	
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 review of competency assessment (CA) records and interview with testing personnel (TP), the laboratory failed to establish a complete competency assessment policies and procedures to assess the competency of 1 of 1 testing personnel (TP) for each test methodology performed in the departments of Chemistry, Hematology, and Urinalysis in 2019, 2020, and 2021. Findings Include: 1. On the day of survey, 09/21/2021 at 09:07 a.m., the laboratory could not provide a CA procedure to assess 1 of 1 TP for 2019, 2020, and 2021. 2. The laboratory could not provide CA records for 1 of 1 TP for 2020. 3. The laboratory could not provide separate CA records for each test methodology performed by the TP in hematology, chemistry, and urinalysis for 2019, 2020, and 2021. 4. The TP confirmed the findings above on 09/21/2021 at 11:30 a.m.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the testing personnel (TP), the laboratory failed to establish a maintenance policy to assess the maintenance /function for 3 of 3 traceable thermometers used to monitor the temperature of reagents used on the Beckman Coulter DxH520 hematology analyzer, Roche Cobas Integra 400+, and Roche Cobas e411 chemistry analyzers from 09/21/ 2019 to the day of survey. Findings Include: 1. On the day of survey, 09/21/2021, the surveyor observed 2 of 2 traceable refrigerator thermometers and 1 of 1 traceable room temperature thermometer in use to monitor the temperatures of reagents used on the Beckman Coulter Dix hematology analyzer, Roche Cobas Integra 400+, and Roche Cobas e411 chemistry analyzers. The thermometers were due for maintenance on August 2019. 2. The laboratory could not provide a maintenance policy for the thermometers. 3. TP #1 confirmed the findings above on 09/21/2021 around 09:00 a. m.