

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0671810	(X3) Date Survey Completed 11/15/2021
Name of Provider or Supplier Uf Health Pediatrics - Millhopper	Street Address, City, State 5528 Nw 43rd Street, Gainesville, FL	
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
D0000	At the time of the announced, on-site recertification survey, UF Health Pediatrics - Millhopper, was found NOT in compliance with the CLIA laboratory requirements of 42 CFR 493.
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review of American Proficiency Institute (API) Hematology proficiency testing results and interview with the laboratory director, the laboratory failed to submit the proficiency testing results in the specified timeframe for the 2nd Hematology Event in 2021, resulting in a score of 0% for all Hematology analytes. Findings included: Review of the API Hematology proficiency testing results showed that the laboratory had obtained a score of 0% "Failure to Participate" for the following analytes: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red cell distribution width (RDW), Neutrophils, Lymphocytes, and Monocytes. Interview on 11/15/21 at 9:30am with the Laboratory Director stated that during the transition to UF Health and change in office staff, the results were not submitted.</p>
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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document annual competency assessment for three of three testing personnel for one of two years reviewed. Findings include: Review of competency assessment documents showed Testing Person A, B, and C had a competency assessment performed in 2019 and 2021. No competency assessment was performed in 2020. During an interview with the Laboratory Director on 11/15/21 at 11:00AM, it was confirmed that personnel competency had not been performed annually.