

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2121698	(X3) Date Survey Completed 08/22/2024
Name of Provider or Supplier Norton Children's Medical Group-Preston	Street Address, City, State 7926 Preston Highway, Suite 210, Louisville, KY	
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	A recertification survey was conducted on 08/22/2024. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: 1. Based on review of laboratory policy, American Proficiency Institute testing (PT) events (2023 Hematology Event 1:Chemistry Event 1, 2023 Hematology Event 2: Chemistry Event 2, 2023 Hematology Event 3:Chemistry Event 3, 2024 Hematology Event 1:Chemistry Event 1, 2024 Hematology Event 2:Chemistry Event 2), and confirmed in interview, the laboratory failed to have documentation of attestation forms for 8 of 10 PT events. 2. Review of the laboratory PT events revealed the following: a. 2023 Event 1 - No Chemistry attestation form; No signature of testing personnel for the Hematology attestation. b. 2023 Event 2 - No signature of testing personnel for the Hematology attestation. c. 2023 Event 3 - No attestation forms for Hematology and Chemistry. d. 2024 Event 1 - No attestation form for Hematology. e. 2024 Event 2 - No attestation forms for Hematology and Chemistry. 3. In an interview</p>

on 8/22/2024 at 11:20 AM in the break room, the Technical Consultant (TC) was asked if attestation forms were produced for the PT events. The TC confirmed the attestation results were not produced for the 8 testing events. This confirmed the findings.