

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0320482	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Norton Children's Medical Group - Prospect	Street Address, City, State 9217 Us Highway 42, Prospect, 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 07/16/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with 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: Based on policy review, document review, and confirmed in staff interview, the laboratory failed to maintain attestation statements signed by the testing personnel (TP) that performed the testing for 1 of 7 proficiency testing (PT) events reviewed. Findings included: Review of the laboratory's policy titled, "Retention Times for Records and Specimens," revised on 07/19/2023, revealed, "Policy: The following are the minimum required retention times for various records and Specimens." The policy specified, "Proficiency Testing: Two (2) years- records of test handling, preparation, processing, examination, results of reporting, the signed attestation statement and feedback reports." Review of the laboratory PT performance revealed the laboratory participated in the American Proficiency Institute (API) Hematology/Coagulation third event in November 2022 with scores of 100%. Original printouts were available</p>

to document the results of the five PT samples, which were analyzed on 11/28/2022. Review of the "Attestation Statement" for the "2022 Hematology/Coagulation - 3rd [third] Event" revealed, "SIGNATURES REQUIRED- For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." The Attestation Statement reflected the PT testing was electronically submitted on 11/28/2022 and was signed by the Laboratory Director (LD). The LD signature date was not completed, and there were no signatures of the TP who performed the testing or information regarding which TP tested each sample set. During an interview on 07/16/2024 at 9:40 AM, the Technical Consultant (TC) stated the original attestation statement documentation was discarded because staff did not realize the original documentation needed to be kept until November 2024 to satisfy the two-year retention period requirement.