

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0320394	(X3) Date Survey Completed 04/12/2023
Name of Provider or Supplier Norton Children's Medical Group-Crestwood	Street Address, City, State 6411 Veterans Memorial Parkway, Suite 200, Crestwood, 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 04/12/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure the attestation form for the third proficiency testing event of 2022 was signed for one (1) of seven (7) proficiency tests reviewed as required by Clinical Laboratory Improvement Amendments (CLIA) regulations and laboratory policy. Findings included: Review of the laboratory policy titled, "Proficiency Testing", dated 03/24/2021, revealed "4. All proficiency testing (PT) specimens will be tested within routine workload and analyzed by personnel who routinely test patient samples, using the same primary method systems as for patient samples. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods." Review of the laboratory "American Academy of Family Physicians (AAFP)-PT 2022-C", completed 10/17/022, revealed the attestation form for modules 613, automated differential (auto diff) I, and 662, neonatal bilirubin, were not signed by the Laboratory Director (LD), their designee, or the testing personnel (TP) who performed the analysis of PT samples. During an interview on 04/12/2023 at 10:30</p>

AM, the Technical Consultant (TC) acknowledged the attestation was not signed as required by the LD, their designee, or the TP who performed the analysis of PT samples.