

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2090593	(X3) Date Survey Completed 08/23/2023
Name of Provider or Supplier Morehead Pediatrics	Street Address, City, State 130 New Towne Square, Morehead, 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 08/23/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, document and policy review, the laboratory failed to ensure proficiency testing (PT) samples were tested using the laboratory's routine methods for one (1) of three (3) PT events reviewed for 2022. The Findings include: Review of the facility policy, titled "Proficiency Testing", initiated 08/28/2015, revealed "Each sample will be tested as patient samples are performed." During an interview, on 08/23/2023 at 10:30 AM, Testing Personnel (TP) #1 stated a new hematology analyzer was purchased on 08/23/2022 and calibration was completed on that date. During a laboratory tour, on 08/23/2023 at 10:40 AM, observation revealed a Sysmex XN-330 hematology analyzer in the laboratory. Review of the "Performance Summary 2022 Hematology/Coagulation - 3rd Event" document from the American Proficiency Institute, revealed PT samples were tested on the new analyzer on 11/10/2022, prior to performance specifications and approval. Document review revealed the performance specifications for the analyzer were performed on 12/19/2022. During an interview, on 08/23/2023 at 1:05 PM, Testing Personnel (TP) #1 stated the PT was run on the new machine. TP #1 stated the old machine was still being used for patient samples while validating the new analyzer and getting staff trained on the new machine. During an interview, on 08/23/2023 at 1:35 PM, the Lab Director stated she approved the new the Sysmex XN-330 analyzer for patient testing</p>

in January 2023 after all the calibration, validation, and evaluations were completed. The Lab Director stated they ran the PT samples on the new analyzer because they were going to use the new analyzer going forward. The Lab Director further stated, they were still testing patient samples on the old analyzer. The Lab Director acknowledged the laboratory failed to ensure the PT samples were run on the same analyzer used to conduct patient testing.