

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0980676	(X3) Date Survey Completed 02/24/2023
Name of Provider or Supplier Storybook Pediatrics, Pc	Street Address, City, State 130 Enterprise Parkway, McDonough, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 23, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory established a written policy and procedure that ensured positive identification for the patient specimens, but did not follow the policy, which states to have 2 identifier's on the patient's specimen. The Findings include: 1. Lab tour and observation revealed that the laboratory did not have two identifier's on 3 out of 3 patient specimens. 2. Laboratory document policy and procedure review revealed the laboratory established a procedure for the positive identification for the patient's specimen, but did not follow the policy. 3. During an interview with Testing Personnel#4(CMS-209) on February 24, 2023 at 10:45 AM, in the laboratory, confirmed that 3 out of 3 patient's specimen's did not contain 2 identifier's on the patient specimens.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on laboratory review and interview with testing personnel (TP), the laboratory failed to perform and document maintenance on Horriba Micros60 for hematology.

The Findings include: 1. Laboratory document review revealed the monthly maintenance was not performed and documented on Horriba Micros60 for hematology for August 2021. The September 2021 maintenance indicated that the Micros60 was not in use and was documented as such. 2. During an interview with Testing Personnel#4 (CMS-209), on February 24, 2023, at 12:20 PM, confirmed that the monthly maintenance for Horriba Micros60 was not performed for August 2021.