

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1042402	(X3) Date Survey Completed 05/31/2024
Name of Provider or Supplier Night Lite Pediatric Center, Llc	Street Address, City, State 11325 Lake Underhill Rd Ste 103, Orlando, FL	
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	Validation survey was conducted from 4/29/2024 to 5/31/2024. Night Lite Pediatrics LLC clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories.
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to run two levels of controls for 1 out of 4 patients reviewed for complete blood count (CBC), (#3). Findings included: On 4/29/2024 at 10:17 AM, a tour of the lab revealed an instrument called Pochi-100i used for CBC. Review of Quality Control records for Pochi-100i revealed no documents for Quality Control (QC) performed on 11/10 /2023. Review of 4 CBC patient records revealed patient #3 was tested on 11/10/2023 at 6:02 PM for CBC. Review of Quality Control Program effective date 10/01/03 read, "run QC (3 controls) for CBC machine. Document results in CBC daily maintenance log. Initial, stamp, and file the printout for results. Enter control results in Sysmex website for Pochi machine." On 4/29/2024 at 1:34 PM, the Technical Consultant confirmed there was no documentation of Quality Control run for CBC on 11/10/2023.</p>