

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2147425	(X3) Date Survey Completed 11/23/2021
Name of Provider or Supplier Arkansas Pediatric Clinic	Street Address, City, State 16115 St Vincent Way, Ste 320, Little Rock, AR	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: . Through a review of temperature logs for 2021, lack of documentation and interviews with staff, it was determined the laboratory failed to document freezer and refrigerator temperatures that are essential for the proper storage of reagents and supplies. Survey findings include: A. A review of the laboratory temperature record revealed that temperatures of the laboratory freezer must be between -70 and -20 degrees Celsius and laboratory refrigerator temperature must be between 2 and 8 degrees Celsius. B. A review of the laboratory temperatures for January- November 2021 (eleven of eleven months) revealed the laboratory failed to document refrigerator and freezer temperatures on four of 25 days of testing in May 2021. Freezer temperature was not documented on May 22nd, 24th, or 25th, and refrigerator temperature was not documented on May 22nd, 24th, or 26th or 27th. C. In an interview on 9/2/2021 at 10:30, the technical consultant confirmed the laboratory failed to document refrigerator and freezer temperatures on days when the laboratory was in operation.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</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.

This STANDARD is not met as evidenced by:

Through a review of quality control documentation, a review of patient test records, and interviews with laboratory staff, it was determined the laboratory failed to perform two levels of bilirubin controls on days of patient testing. Survey findings include: A. During a review of January through November 2021 quality control documentation, it was determined the laboratory failed to document two levels of quality control on two of twenty-six days of patient testing in April 2021 and two of twenty five days of patient testing in May 2021 day of patient testing. Quality control was not documented on April 28, April 29 and May 1, and only one level of quality control was documented on May 28. B. A review of patient test records revealed three patients (# 105792, # 55838, and # 79201) had bilirubin results reported on 4/28/2021, two patients (# 70672 and # 84257) had bilirubin reported on 4/29/2021, two patients (# 84257 and # 70708) had bilirubin reported on 5/1/2021, and one patient (# 91287) had bilirubin reported on 5/28/2021. C. In an interview, at 10:35 on 11/23/2021, the technical consultant (listed as employee #6 on the form CMS-209) confirmed patients were tested on days without two levels of quality control documented.