

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0873812	(X3) Date Survey Completed 05/24/2022
Name of Provider or Supplier J D C Pediatrics	Street Address, City, State 25 West Shore Drive, Camp Hill, PA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of peer review record and interview with the office coordinator, the laboratory failed to verify twice a year the accuracy of urine culture for 11 of 11 testing personnel (TP) from 5/24/2020 to 5/24/2022. Findings include: 1. On the day of survey, 05/24/2022 at 09:32 AM, review of the peer review record revealed the laboratory could not provide biannual verification of accuracy performance for 11 of 11 TP (CMS 209 Personnel # 1,2,3,4,5,6,7,8,9,10, and 11) from 5/24/2020 to 5/24/2022. 2. The office coordinator confirmed the above findings on 05/24/2022 at 10:40 AM.</p>
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: Based on observation of the laboratory, lack of temperature record, and interview with</p>

the office coordinator at the time of inspection, the laboratory failed to document and monitor the refrigerator temperature for the storage of Urinalysis and Alere Cholesterol LDX quality controls (QC) from 05/24/2020 to 05/24/2022. Findings include: 1. Observation of the laboratory on 05/24/2022 at 10:15 AM, showed the following QC were stored in refrigerator as per manufacturer's instructions (2-8 degree Celsius). 1 of 1 box of Microbiologic Urine Control Kit LOT#22108103, EXP-4/03/2023 1 of 1 box of Abbott Cholestatic LPX HDL Control LOT#429474, EXP-10/31/2022 2. Laboratory failed to provide temperature record for the refrigerator. 3. Interview with office coordinator confirmed the findings above on 05/24/2022 at 10:40 AM.