

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2179948	(X3) Date Survey Completed 06/17/2021
Name of Provider or Supplier Parj Diagnostics Llc	Street Address, City, State 3706 Crondall Lane Suite 100c, Owings Mills, MD	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedures and final report for toxicology testing, the laboratory written procedure did not include procedures for the preparation of the final report and interpretation of test results. Findings: 1. The final report includes an interpretation of the toxicology test results obtained from analysis of patient urine specimens. Depending on the medications the patient is prescribed and the positive and negative reactivity of the drugs analyzed, the final report states whether or not the test results are consistent with prescribed medications. This determination is documented on the final report; 2. The written procedure did not include instructions</p>

to review the list of prescribed medications from the requisition and the test results to make the determination as to whether the results are consistent, and what to do in the event of an unusual situation; and 3. The laboratory did not have a written procedure to describe how the laboratory reports or performs corrective action in the event that the temperature of the patient urine sample is missing, or is too high or low.