

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2282811	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Pandora S9, Inc	Street Address, City, State 10234 Alliance Road, Blue Ash, OH	
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 record review and an interview with the Technical Consultant (TC) and Testing Personnel (TP) #1, the laboratory failed to include in their policies and procedures contamination prevention instructions during sample receipt and the transferring of patient specimens from one open container to another open container for patient testing. This deficient practice had the potential to affect 1,975 patients tested under the subspecialties of Bacteriology and Parasitology from 02/15/2024 through 05/22/2024. Findings Include: 1. Direct observation on the day of inspection revealed TP #2 opening individual patient sample packages containing urine and swab</p>

specimens then opening the specimen containers and transferring the specimens to another vial for onsite testing. TP #2 did not change gloves before opening and transferring specimens from another patient. 2. Review of the "Preventx US-SOP-08 Sample Preparation" policies and procedures, signed and dated by the Laboratory Director on 09/03/2023 failed to find instructions for the Bacteriology and Parasitology contamination prevention during sample receipt and open container specimen transfers. 3. The inspector requested policies and procedures which included contamination prevention instructions during sample receipt and open container specimen transfers of urine and swab specimens from the TC and TP #1. The TC confirmed the laboratory did not have a policy and procedure which included instructions for the contamination prevention of sample receipt and open container specimen transfers of urine and swab specimens and was unable to provide the requested documentation on the date of inspection. The interview occurred on 05/22/2024 at 12:10 PM.